# The application of a human factors approach to the evaluation of a novel outpatient parenteral antimicrobial therapy service in Malta.

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# THE APPLICATION OF A HUMAN FACTORS APPROACH TO THE EVALUATION OF A NOVEL OUTPATIENT PARENTERAL ANTIMICROBIAL THERAPY SERVICE IN MALTA

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**PhD** **2020**

# THE APPLICATION OF A HUMAN FACTORS APPROACH TO THE EVALUATION OF A NOVEL OUTPATIENT PARENTERAL ANTIMICROBIAL THERAPY SERVICE IN MALTA

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## *Abstract*

The application of a Human Factors approach to healthcare has been gaining traction ever since its first mention in the early 1960s. The need for this synergistic collaboration stems from the poor safety and quality outcomes which have been plaguing the history of healthcare despite continuous efforts by stakeholders to offer patient-centred care at all costs. In recent years, healthcare practitioners have positively contributed to bridging the gap between clinical practices and systems-based approaches. To this aim, this research project set out to apply a Human Factors approach to the evaluation of a specific niche in healthcare- the newly launched Maltese OPAT service.

Considering the high quality attributed to systematic literature reviews (SLR) in evidence-based medicine, the first phase of this study featured a dual discipline PROSPERO-registered SLR. Data was critically appraised, synthesised and presented to deduce whether Human Factors approaches were amendable to OPAT pathways. Data synthesis using the SEIPS 2.0 model, successfully extracted facilitators and barriers to OPAT services across the globe indicating how systems needed to be redesigned to improve service outcomes. At this point during the research journey, the absence of a singular reference source about OPAT episodes made benchmarking and auditing against international service provisions impractical. Thus the second phase addressed this lacuna by conducting a prospective observational cohort study about OPAT episodes whilst concomitantly compiling a repository (October 2016 to October 2019). Details about the patient cohort and OPAT episodes, completion statuses, OPAT durations and the cost to run the service were inferred. Over the study timeframe, a total of 132 episodes were rendered to 117 patients equating to a total of 3287 hospital bed days saved. Of these only 23 episodes resulted in a readmission thus the overall success rate was of 82.6%. The OPAT duration was significantly influenced by the presenting infection ($p=0.021$), VAD ($p<0.001$) and occurrence of a readmission ($p=0.05$). Despite the importance of these findings, they offered little knowledge about the patients' and professionals' experiences as end users of the service. This reasoning guided the pursuit of identifying facilitators and barriers attributable to the service from the perspective of these end-users. A cross-sectional questionnaire and a focus group session were conducted to gather data from patients and the OPAT team respectively. Quantitative and qualitative analysis were supplemented by

Human Factors strategies namely hierarchical task analysis and SEIPS-based modelling. Following quantitative data analysis, a general positive trend in patient satisfaction scores (satisfaction rate of 95.8%) was recorded thus favouring the service and the high standard it managed to maintain through the years of provision. Thematic analysis supported this finding and advised caution in terms of focusing on the patient's wellbeing, standardisation of practices, availability of resources and the involvement of informal caregivers. Certain themes were also reiterated from the analysis of the focus group discourse whereby the OPAT team also stressed the importance of standardisation of procedures (with specific reference to the referral process and training/education methods) and the team's flexibility and adaptability prior to expanding the service further. SEIPS-based modelling conducted on data collected during the cross-sectional survey and focus group contributed towards the mapping of a systems based model applicable to the local service. Comparisons between the former and the model created during the SLR about global OPAT services, shed light on the requirements for system redesigns of local practices. This doctoral research has contributed both to the practice of OPAT nationally and to the application of systems-based strategies to ensure the betterment of healthcare outcomes. Future work should focus on the use of new methods to gather more data about the local service including more robust pharmacoeconomic studies, an in-depth ethnography study from the perspective of the end-users through fieldwork which could then supplement further Human Factor approaches such as workflow analysis, thus ensuring further triangulation of data. On a larger scale, the findings of this research shed light on the amenability of Human Factors approaches to healthcare practices in general and thus should be applied across the institution beyond the boundaries set by this case study research.

**Keywords:** Human Factors, OPAT, SEIPS, service evaluation, Malta

## *Acknowledgments*

To my husband Daniel,
my baby girl Nathalia
and my family

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Little did I know, back in October 2016, the implications of pursing a doctoral research whilst juggling a full-time and part-time job. Four years of researching, the beginning of my married life and a baby later, I can finally conclude this chapter of my life- thanks to a lot of help from my very own 'complex system'.

I would first like to thank God for inspiring me as well as aiding those around me to offer support when it seemed like there weren't enough cups of coffee that would see me through the end. Secondly, I would like to thank my principal supervisor Dr. Helen Vosper. October 2015 marked not only the start of my master's thesis but also the beginning of a fruitful and collaborative relationship with a great academic, who I can call my friend! Many emails later laden with words of encouragement, foresight and guidance she has managed to get me through the most difficult academic venture I have embarked on and for this I am forever grateful. May she continue to inspire more students in the years to come!

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burdens. Last but not least I would like to show my appreciation to my husband whose unwavering love and support is the reason why today I can proudly say I have completed this project and my beautiful baby girl who has been a blessing - patiently accepting to behave to the best of her ability.

*"Not all of us can do great things, but we can do small things with great love" Mother Theresa*

## *External Outputs*

### Systematic Review Protocol

1. BUGEJA, S.J. et al., 2017. *Protocol. Human factors approaches to evaluating outpatient parenteral antimicrobial therapy services: a systematic review protocol.* York, UK: PROSPERO.

### Full peer reviewed papers

1. BUGEJA, S.J. et al., 2020. Human Factors approaches to evaluating outpatient parenteral antimicrobial therapy services: A systematic review. *Research in Social and Administrative Pharmacy*, 16(5), pp.614-627.

### Conference papers

1. BUGEJA, S.J., STEWART, D. and VOSPER, H. [2020]. Staff team perceptions of the Maltese outpatient parenteral antimicrobial therapy service. In Charles, R. and Golightly, D. (eds.). Contemporary ergonomics and human factors 2020: proceedings of the 2020 Ergonomics and human factors conference (EHF 2020), co-located with the 13th International organisational design and management conference (ODAM 2020), 27-29 April 2020, Stratford-upon-Avon, UK. Birmingham: CIEHF [online]. Available from: https://publications.ergonomics.org.uk/uploads/Staff-team-perceptions-of-the-Maltese-outpatient-parenteral-antimicrobial-therapy-service.pdf

### Conference abstracts

1. BUGEJA, S.J. et al., 2018. A systematic review of Human Factors identified from Outpatient Parenteral Antimicrobial Therapy research using the SEIPS 2.0 model. *2018 British Society for Antimicrobial Chemotherapy National OPAT Conference*. 13-14 December 2018. Birmingham: International Convention Centre

## Pending publications

"Clinical benefit and cost-effectiveness of the Maltese OPAT service" submitted on 31.08.2020 to the journal for Research in Social and Administrative Pharmacy and was accepted with major revisions on the 24.10.2020.

## *Foreword*

The content of this thesis gives credibility to the importance of understanding specific healthcare settings through the application of Human Factors approaches. The healthcare niche chosen for this study was the Maltese Outpatient Parenteral Antimicrobial Therapy (OPAT) Service.

My tertiary education commenced in 2008 when I enrolled for the undergraduate pharmacy course in Malta. Following five years, I successfully graduated with a bachelor in pharmaceutical sciences (2012), a master's in pharmacy degree (2013) and a warrant to practice as a pharmacist. For a brief period, I worked as a community pharmacist on a full-time basis and eventually applied for a hospital pharmacist post with the acute general hospital of Malta, Mater Dei Hospital. As a new graduate, I began to search for an academic path that would enable me to balance my personal and working life whilst residing in Malta. With that intent, I started reading for master's degree in clinical pharmacy practice with Robert Gordon University in January 2014 which was closely followed by my official appointment as a hospital pharmacist in May 2014.

My strategic employment within the dispensary enabled me to conduct my master's thesis on prescription medication errors under the supervision of Dr. Vosper (who gratefully was to become my principal supervisor for my doctoral degree). On completing my masters in 2016, I felt that I could make an innovative contribution to the profession considering my position with the hospital which led me to apply for a doctorate in September 2016.

In October 2016 I was appointed as a member of the Maltese Outpatient Parenteral Antimicrobial Therapy (OPAT) team and immediately discussions commenced on how we can amalgamate both my academic and professional life. Since this breakthrough, the doctoral journey has been every researcher's dream. My position within the team was an important asset when designing the research aims and methodology for this thesis. Moreover, in time it made me realise the importance of my research and the positive influence it may have to enhance the quality of service provision in my country. My interest in the subject and more complex research methods was spearheaded by the impact little amendments had on the service based on my research.

In conclusion, this research journey clearly shows how the academic input of one researcher can influence the running of a healthcare service for years to come and hence the importance to further promote this synergism as a healthcare practitioner and researcher.

## *Abbreviations*

ADR- adverse drug reaction

Bd- twice daily

CASP- Critical Appraisal Skills Programme

CIEHF- Chartered Institute of Ergonomics and Human Factors

CINAHL- Cumulative Index to Nursing and Allied Health Literature

CRD-Centre for reviews and dissemination

CRM- Crew Resource Management

DLN- Discharge Liaison Nurse

FTE- Full-time equivalent

GLM- Generalised linear model

GP- General practitioner

HCP- Healthcare professional

HFE- Human Factors and Ergonomics

HROs- High-reliability organisations

HTA- Hierarchical task analysis

IDSA- Infectious Diseases Society of America

IPA- International journal of psychology

IPAT- Inpatient parenteral antimicrobial therapy

MDH- Mater Dei Hospital

MRSA- Methicillin-resistant Staphylococcus aureus

NPSA- National Patient Safety Agency

NTS- Non-technical skills

OPAT- Outpatient Parenteral Antimicrobial Therapy

PICC- peripherally inserted central catheter

PRISMA-P- Preferred Reporting Items for Systematic review and Meta-Analysis Protocols

QI- Quality improvement

RCT- Randomised Controlled Trial

SEIPS- Systems Engineering Initiative for Patient Safety

SHERPA- System Human Error Reduction and Prediction Approach

SLR- Systematic Literature Review

SOPs- Standard Operating Procedures

Tds- three times daily

VAD- Vascular access device

WHO- World Health Organisation

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## *Glossary*

| | |
|---|---|
| Care process | series of tasks (not necessarily organized linearly) performed by one or several persons using various technologies in a physical and organizational environment |
| Case study research | a strategy for doing research which involves an empirical investigation of a particular contemporary phenomenon within its real life context using multiple sources of evidence |
| Complexity | associated with systems containing large numbers of entities (especially when they are ill-defined and constantly changing) that interact in ways which are not easily understood |
| Crew Resource Management (CRM) | focuses particularly on social skills such as communication, teamworking and cognitive skills such as decision making |
| Functional resonance | the result of variations to everyday performance that aggregate in an unexpected manner in response to daily work conditions (i.e. not predefined) |
| Heuristic evaluation | inspection of usability issues with a user interface |
| Hierarchical task analysis | systems based analysis whereby tasks are decomposed from the overall 'goal' into 'sub goals' which together ensure the performance of the task led by 'plans' |
| High reliability organisations (HROs) | organisations (such as those in the nuclear sector, aviation and defence) that operate in intrinsically dangerous environments yet have only small numbers of adverse events |
| Human Factors (or Ergonomics) | the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimise human well-being and overall system performance |

| | |
|---|---|
| Mixed methods case study design | a type of mixed methods study in which the quantitative and qualitative data collection, results, and integration are used to provide in-depth evidence for a case(s) or develop cases for comparative analysis |
| Multi strategy designs | involve not only combining methods in some way but also using more than one research strategy |
| Non decomposable systems | systems, characterised by the large numbers of both components and component interactions which can rarely be broken down into separate components which can be studied individually, primarily because of these interrelations |
| OPAT team | a clinical team that supervises parenteral antimicrobial therapy in a non-inpatient setting |
| Patient centered Human Factors | the application of HFE or related discipline[s] (e.g., human-computer interaction) to study or improve patients' and other non-professionals' performance of effortful work activities in pursuit of health goals |
| Patient journey | the spatio-temporal distribution of patients' interactions with multiple care settings over time |
| Safety | the level of system performance required to keep the incidence of harm (and risk) as low as reasonably practicable |
| Scholarship of practice | to improve professional practice by using empirical research as the groundwork for developing practice and policy |
| Sociotechnical | characterised by relationships between people and technologies |
| System | a set of inter-related or coupled activities or entities with a joint purpose… it has inputs and outputs which may connect in many-to-many mappings |

# Chapter 1

## Introduction

This chapter introduces the two fields of research that are drawn together in this study namely Human Factors and Outpatient Parenteral Antimicrobial Therapy (OPAT). The research presented in this chapter discusses complexity and safety, situating healthcare (and more specifically, OPAT services) as complex sociotechnical systems which can be best understood using Human Factors systems analysis tools. The specific systems modelling tool- the Systems Engineering Initiative for Patient Safety (SEIPS) is introduced, and the research aims are framed within this context.

## 1.1 Human Factors in healthcare: Background

The International Ergonomics Association defines Human Factors (or Ergonomics) as the science exploring "the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimise human well-being and overall system performance" (IEA, 2000). A common misconception is that Human Factors and Ergonomics (HFE) are different from each other rather than being two interchangeable terms. This is largely a nomenclature issue whereby 'Ergonomics' is the term which has largely been used in Europe (including the United Kingdom) since the 1950s whereas Human Factors tended to be the more commonly used term in North America from 1957. The application of Human Factors to the design of systems is often called Human Factors and Ergonomics (HFE). Within the context of this discipline, a system refers to "a set of inter-related or coupled activities or entities with a joint purpose… it has inputs and outputs which may connect in many-to-many mappings" (Wilson, 2014). 'Sociotechnical' systems are characterised by relationships between people and technologies, something which is often seen in healthcare. In Human Factors terminology, 'complexity' is a feature associated with systems containing large numbers of entities (especially when they are ill-defined and constantly changing) that interact in ways which are not easily understood. This is commonly seen in healthcare, where systems are large and often not consciously designed – rather they tend to evolve organically over a period of years. Through a system analysis approach, HFE offers a better understanding of the complexity of a system, which in turn instructs the redesign of interventions based on human performance and wellbeing (whereby humans are defined as the stakeholders within the system) (Hignett et al., 2015).

HFE does this by drawing on several domains, including psychology, engineering, anatomy, physiology, sociology, biomechanics, anthropometry and design. Such an approach has much to offer healthcare. Firstly, healthcare systems are intrinsically complex and sociotechnical in nature as demonstrated by the dynamic relationship between people, technology and the organisation (social context) they operate in (Vosper et al., 2018a; Neumann et al., 2019; Timmons et al., 2015). Secondly, Human Factors-led designs have the potential to optimise system performance and human wellbeing during both everyday circumstances and unforeseen situations. Such 'informed design' considers both the physical and

cognitive characteristics of the people involved as well as their interactions with the overall work system (Russ et al., 2013). In 2015, Xie and Carayon published a systematic literature review which aimed to investigate the influence of HFE approaches to system redesigns. The identified 23 studies bore witness of the benefits of healthcare system redesign when delivered by suitably qualified and experienced HFE professionals, using validated tools. The studies identified included: a proactive risk assessment identifying barriers associated with the implementation of a computerised physician order entry system in an intensive care unit; heuristic evaluation (i.e. inspection of usability issues with a user interface) of a smart infusion pump; and the use of HFE methodology to guide the design of an electronic hospital referral system, still in use after its introduction in 2017 (Woodward et al., 2020).

In the United Kingdom (UK), the Professional HFE body is the Chartered Institute of Ergonomics and Human Factors (CIEHF). This body, established in 1949, works in partnership with other organisations, including the UK government to promote the application of HFE principles in high-reliability organisations (HROs). HROs are organisations (such as those in the nuclear sector, aviation and defence) that operate in intrinsically dangerous environments yet have only small numbers of adverse events. In recent years, there has been an increasing realisation that healthcare is also intrinsically dangerous. Since the publication of the Institute of Medicine's landmark report "To Err is Human: Building a Safer Health System" report (Kohn et al., 2000) which highlighted the impact of "medical errors" on patient safety, it has become clear that risks are high and adverse outcomes common. It is not easy to calculate accurate figures, but estimates suggest that adverse healthcare outcomes are a leading cause of death in developed nations (Haukland et al., 2019; Sutherland et al., 2020). This has led to an increased interest in healthcare HFE. While some of this interest has been driven by suitably qualified and experienced HFE professionals, the impact has been limited by the conflation between HFE and 'non-technical skills.' This has resulted from transference from the aviation sector of Crew Resource Management (CRM). CRM emerged from the need to shift from training of technical skills required to fly an aircraft to the need to address behavioural safety of pilots. It focuses particularly on social skills such as communication, teamworking and cognitive skills such as decision making. In aviation, CRM was a genuine HFE solution – holistic, system-

wide consideration of a number of incidents in the 1970s revealed that commercial pilots at the time shared similar military backgrounds. In their former role, they were used to operating as single crew and having to make rapid decisions with incomplete information and to take full responsibility for these decisions. These character requirements did not favour communication and teamworking, and a number of accidents (including the incident at Tenerife, where two Boeing 747 aircraft crashed on the runway, resulting in the loss of almost 600 lives) were attributed to poor non-technical skills. Observations that a number of healthcare adverse events had poor non-technical skills as a contributory factor led to the assumption that CRM-type initiatives would be valuable in reducing such events. This has proved to be of benefit in certain circumstances, such as surgical teams (Gaba et al., 2001; Fletcher et al., 2002; Roche, 2016; Flin and Agnew, 2018; Spurgeon et al., 2019). These successes have led to the assumption that CRM training would be of value to all healthcare staff, but this fails to acknowledge the fact that non-technical skills are only one element of a complex work system. Poor communication in a healthcare setting is attributable to an ill-designed system which does not help to support effective communication channels rather than resulting from individual people lacking in communication skills and non-technical skills training is unlikely to address the issue.

The lack of a systems approach has been further exacerbated by the popularity of Quality Improvement (QI) methodology. Despite sharing similar origins i.e. to harness a proactive problem-solving practice, HFE and QI differ in terms of scope and methods (Hignett et al., 2015). Considering QI is often driven by performance based on processes rather than the people undertaking those processes, its methods rarely take on a genuine systems approach. On the other hand, Human Factors is a champion of the systems approach, with its design-led nature, and its focus on productivity and wellbeing outcomes, including safety (Dul el al., 2012; Vosper et al., 2018a). Moreover, QI strategies use methods which eliminate waste (lean) and variance (e.g. six sigma) and improve performance (e.g. business process re-engineering). Meanwhile, HFE methods use task analysis to map cognitive human variance (e.g. hierarchical task analysis featured in Chapter 6), physical human variance (e.g. anthropometry) and product design (e.g. user-centred design). Despite these differences, Human Factors and QI strategies offer

synergies and an integrated approach is considered to have value for patient safety research (Hignett et al., 2015), but this is rarely, seen in practice.

## 1.2 Complexity, emergence and 'normal accident theory'

Healthcare systems are recognised as being highly complex (Long et al., 2018). In systems terms, this reflects the "interrelatedness" of the system's components: the greater the number of components and the higher the number of interactions, the greater the overall complexity. Additionally, healthcare components (entities) are often variable – for example, recruitment issues mean there is heavy utilisation of bank staff. Complex systems, characterised by the large numbers of both components and component interactions like the healthcare setting, can rarely be broken down into separate components which can be studied individually, primarily because of these interrelations. This is referred to in systems terms as being "non-decomposable" (Kannampallil et al., 2011; Underwood and Waterson, 2014). Outcomes resulting from these interrelations are described as *emergent*, i.e. they cannot be predicted by considering the characteristics of the system's individual components. Important healthcare outcomes (including safety and patient satisfaction) are, in fact, emergent outcomes. So also is system failure – recognition of this is reflected in Perrow's 'normal accident theory' which states that, in complex systems, "multiple and unexpected interactions of failure are inevitable" (Perrow, 2011). In systems terms, therefore, 'human error' is not an individual failing, but an emergent outcome, and a high error frequency reflects a poorly designed system. Improving safety and performance thus requires a move away from focussing on outcomes, and instead looking at how the interactions between entities give rise to these outcomes. This awareness has given rise to the development of healthcare system models.

The Swiss cheese model introduced by Reason et al. in 1990 is an example of a sequential accident causation model. The model sought to explain how the alignment of gaps ('holes') within the model's defensive barriers (the 'cheese'), could result in accident occurrences (1990).

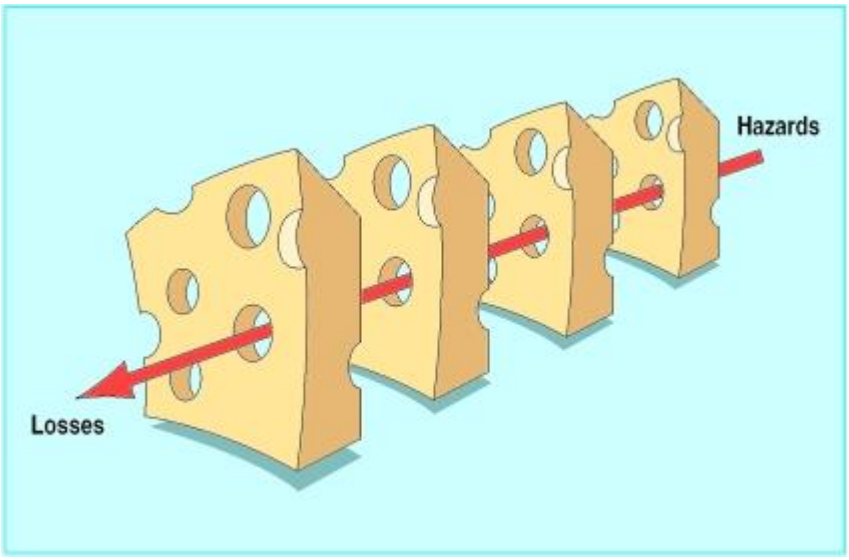


Figure 1.1 The Swiss Cheese Model (Adapted from Reason, 2000)

While popular, the concept is simplistic and better fitted to linear, highly engineered systems, and is thus not well suited to complex systems such as those prevalent in the healthcare industry (Larouzee and La Coze, 2020). Underwood and Watson (2014) also argue that the model falls short in terms of its need for an 'active failure' (unsafe act) to be present for an accident to occur. Furthermore, there is no real consideration of interactions between system entities, and it provides little insight into how the holes 'line up' to allow an accident to happen. Understanding 'holes' and 'cheese' requires the work system to be looked at in a different way, shifting the perspective from 'Safety I' to 'Safety II.'

## 1.3 Safety I and Safety II

In general, safety is often considered to be about "preventing accidents" and usually follows *casuality credo* ideology, meaning erroneous outcomes occur due to an active failure (often on the part of a person within the system) (Hollnagel, 2017) and it assumes two important attributes - that a system is (i) decomposable into its constituent entities and (ii) bimodal (it is either functioning correctly or malfunction). Such an approach is characterised by a retrospective consideration of adverse events, with a view to finding a root cause that can then be addressed in order to prevent future incidents. This is referred to by Hollnagel, a Danish professor specialising on patient safety, as 'Safety I.' In Safety I, the incident

becomes the 'unit of study' and often the investigation is undertaken simplistic tools such as fishbone diagrams, '5-whys' and other QI strategies in which linearity is assumed (McNab et al., 2020). Inevitably, some 'error' will be found, often a violation or other non-compliance of a member of staff which may involve short-sighted initiatives such as re-training or new protocols. This approach generally results in poor outcomes as it fails to recognise that 'error' is in reality an emergent system outcome (Russ et al., 2013; McNab et al., 2020). Safety I also underpins 'blame culture', the outcome of which can be damaging to individual staff who often must deal with disciplinary action (Spurgeon et al., 2019). It can also undermine open reporting culture as staff are reluctant to disclose information which may implicate them (McNab et al., 2020). Perhaps the weakest point of Safety I is that it is retrospective – the harm has already happened.

Safety II takes an alternative perspective, recognising that the vast majority of the time, outcomes are good (or at least acceptable). A more valuable way of looking at things would be to explore every day, 'normal' work (what Hollnagel describes as 'work-as-done') and look for evidence of positive behaviours and try to re-design systems to optimise these (Hollnagel, 2015). One of the flaws of Safety I is an assumption that when the system is functioning normally, people are carrying out 'work-as-imagined' (i.e. that dictated by standard operating procedures etc). Consequently, if an incident investigation reveals that an individual has not followed such procedures, this will often be seen as contributory to the incident. Safety II requires exploration of 'work-as-done' and reveals that people are 'non-compliant' with procedures etc. with high frequency, and it is their ability to adjust work to the daily pressures that allows successful outcomes to be delivered. This is known as 'functional resonance' and without it, successful outcomes are unlikely (Patriarca et al., 2017). However, if staff are having to make constant adaptations to deal with poorly designed systems then poor outcomes are more likely. Understanding Safety II as a concept makes it easier to see the limitations of the Swiss Cheese Model. Having to adapt behaviour to meet the needs of a constantly changing work environment means that both holes and cheese are constantly changing making it very difficult to understand how holes align to produce adverse events. Highly complex healthcare systems require models that can shed light on functional resonance.

## 1.4 Application of HFE models in healthcare – the story so far

In an article published by Carayon and colleagues in 2010, the beneficial value of utilising a Human Factors approach was discussed as a response to adverse events identified in healthcare. They suggested that progress in relation to patient safety was limited and they attributed this to the lack of reliable data on patient safety, resistance from clinicians to participate in safety initiatives and failure to appropriately redesign healthcare systems (Carayon et al., 2010). This failure is likely to be underpinned, at least in part, by the conflation between HFE and 'factors of the human' i.e. person factors attributable to that actor in the system. This has been particularly problematic when reinforced by high profile bodies such as the World Health Organization (WHO), which published its patient safety curriculum, complete with chapters on "what is human factors engineering and why is it important to patient safety?" and "understanding systems and the impact of complexity on patient care" (Carayon et al., 2014; WHO, 2017). While this guidance discussed the need to design healthcare systems with the human actors at its centre (Russ et al., 2013), it lacked clear distinction between the concept of 'factors of the human' and the discipline of Human Factors and did not provide any resources to support systems analysis.

Despite this, through growing research programmes and application of Human Factors in various medical contexts, the discipline is gaining recognition as an instrumental method of redesigning systems and providing safer care (Xie and Carayon, 2015). Unfortunately, implementation has been slow and is happening on a small (and often local) scale (Gurses et al., 2012; Xie and Carayon, 2015). Carayon et al. (2018) identified five challenges which were seen to impede the application of Human Factors and systems engineering including (i) cultural differences between engineers and HCPs (ii) lack of resources and expertise (iii) the organisational environment (iv) fragmentation of care process (v) policy and market issues. The lack of widescale embedding of HFE principles in healthcare means that the learning from even high quality HFE studies is limited - a systems approach needs not only to be applied to investigating the problem, but also to implementing solutions (Carayon et al., 2018). A good example of this is the study by Ward et al. (2010) into methotrexate safety. Methotrexate toxicity resulting from inadvertent overdose has been the subject of a number of patient safety

alerts in the UK. The National Patient Safety Agency (NPSA) reviewed a ten-year period and identified 137 reported incidents, 25 of which were fatal, with a further 26 incidents resulting in serious injury. Even looking at this from a superficial perspective, a number of issues are obvious. Inadvertent overdose occurs when methotrexate is used as a disease modifying drug for the treatment of rheumatoid arthritis. When used in this context, it is prescribed as a weekly dose, which is extremely rare – most medicines are prescribed for daily use. Prescribing errors in relation to the dose frequency are therefore more likely, especially when general practitioners (GPs) are using electronic prescribing software, for which the default dosing frequency is daily. Furthermore, methotrexate has an anti-folate property and is therefore usually prescribed alongside folic acid. Folic acid tablets look remarkably similar to methotrexate (in size and colour). Folic acid is taken daily, and it is not hard to appreciate that the tablets may get mixed up. Interventions have generally been behavioural in nature, exhorting 'checking' and 'taking extra care' from both healthcare practitioner and patient.

The Ward study considered this in much more detail, and took a systems approach, engaging with all stakeholders. Another interesting element of this study was its patient-centred aspect. It must be appreciated that it is impossible to accurately describe a complex sociotechnical system due to its dynamic nature – however deeply it is explored, it is impossible to uncover all of the interactions. The dynamic nature of such systems also means that any study only captures a snapshot in time. Another dimension which has to be considered is that systems are sociotechnical constructs – and they often look very different to each of the system actors. In effect, there is no 'one, true' system. What HFE attempts to do is take a participatory approach to engaging with all stakeholders, capturing multiple perspectives and using these to build a working model of the system that is recognised by all and can be used as a basis for improvement. The way in which the system is framed can have a big impact on findings. For example, the system could be viewed as a 'safe methotrexate prescribing system' or it could be flipped and viewed from the patient perspective as 'my safe methotrexate management system.' This is what the Ward study did, and a combination of workshops and direct observation of patients in their home setting was used to capture their experience in more detail. The study revealed that while prescribing errors did occur, more errors occurred from taking the tablets at home. Most of these

problems could be seen to stem from packaging and labelling issues. Patients with rheumatoid arthritis are likely to be older, will certainly have musculoskeletal impairments, as well as visual and even cognitive deficits. These latter impairments made it difficult for patients to recognise their medication, but the main issue was the packaging of medicines in child-resistant containers. Patients were unable to open these, and often resorted to decanting tablets into other (unlabelled) containers (Ward et al., 2010). While these findings were well-received and published widely (Clarkson et al., 2017), and some changes were implemented, they were certainly not system wide, and fatalities and safety alerts continue.

To better integrate HFE approaches in everyday healthcare scenarios, with a focus on patient safety, Gurses and colleagues (2012) proposed the following five methods: (i) aid healthcare providers to understand the implications of HFE e.g. education programmes, (ii) promote the production of safer products which are HFE-design based, (iii) ensure the availability of HFE practitioners in healthcare institutions, (iv) promote patient safety initiative instructed by HFE approaches and (v) promote collaboration between HFE practitioners and healthcare professionals. These suggestions are in keeping with those described by Carayon et al. (2014) and supplemented by Hignett and colleagues (2015) who called for the application of HFE to the design of safer tools, enhanced collaboration amongst involved parties and the use of HFE tools and knowledge. This current study into Outpatient Parenteral Antimicrobial Therapy (OPAT) seeks to embed this guidance.

## 1.5 System redesign through analysis and evaluation

How might a system re-design be approached? In their systematic review investigating the application of HFE in healthcare, Xie and Carayon (2015) identified successful initiatives in which authors reported improvements in terms of quality of care, such as decreased error rates and reduced task completion time, as well as improvements in patient safety such as lower complication rates and reduced hospital mortality. The synthesis phase of the review suggested that these approaches could be seen to share four phases: analysis, design, implementation and evaluation. The analysis phase involved assessing the current system with its deficiencies and requirements through methods such as direct observation,

interviews with stakeholders and review of archival data. The review highlighted that some studies approached this phase using specific HFE tools such as hierarchical task analysis, workflow analysis and heuristic usability evaluation. The design phase was an iterative process pooling information from stakeholders and instilling HFE design principles to create prototypes which were further assessed using methods such as focus groups. Once all issues were addressed, the successful implementation of the new design would be ensured through effective project management including communication and user training. Another observation was that all successful HFE initiatives used a systems framework as the basis for their research.

## 1.6 Selecting a model for studying OPAT: Systems Engineering Initiative for Patient Safety (SEIPS) Model

### 1.6.1 The origin of the SEIPS model

A patient safety model which can be applied to a complex sociotechnical context is the Systems Engineering Initiative for Patient Safety (SEIPS). This conceptual framework was developed by Carayon and colleagues in 2006, constructed on the Donabedian model (1988) thus categorising quality in terms of structure, process and output (Carayon et al., 2010). The authors developed the Donabedian model's understanding of 'structure' using the work system model designed by Carayon and Smith (2000). This gave rise to five 'factor groups' namely person, task, environment, organisation, tools and technology known collectively as the work system, which exist in a dynamic state of interaction. Meanwhile, the 'outcome' component of the Donabedian model was expanded to go beyond patient outcomes and to also cater for professional and organisational outcomes (Carayon et al., 2010, Spurgeon et al., 2019).

In terms of the 'process' part of the Donabedian model, the SEIPS model conforms to the HFE paradigm developed by Karsh et al. (2006), namely the 'Input-transformation-output' model of healthcare professional performance. The latter explains how human performance (whether physical, cognitive or social) is the 'transformation' that converts system inputs (the interactions between entities) into outputs (either immediate or downstream). The success (or otherwise) of this will depend on the quality of the inputs which are, in essence, the prevailing system conditions. This model also incorporates feedback as a mechanism for instructing

future system redesign and/or to serve as an input for new processes. The linear sequential order observed in the SEIPS model draws heavily on the Donabedian Model as well as the Input-Transformation-Output Model in systems theory which also incorporates constant adaptation through integrated feedback loops.

This model has been designed to meet the specific needs of healthcare and thus is well suited for studying the complexity of the healthcare setting as opposed to other models such as that of the Swiss Cheese developed by Reason. This consideration of everyday work variability and adaptation encourages an in-depth exploration of functional resonance as described by Hollnagel (Hollnagel, 2012; Hollnagel et al., 2014; Neumann et al., 2019). Functional resonance is the result of variations to everyday performance that aggregate in an unexpected manner in response to daily work conditions (i.e. not predefined). This understanding of the variability in work conditions (and the adaptations staff have to make to account for this variability) can un turn shed light on the barriers and facilitators influencing performance.

### 1.6.2 The components of the SEIPS model

The SEIPS model originally described by Carayon et al. (2006) (explained in section 1.6.1) underwent significant modifications by Holden et al. (2013) seven years later. The model was revised to consider improvements in the understanding of healthcare systems. The main difference was the recognition of the patient as an equal stakeholder thus acknowledging their contribution especially in management of chronic conditions. It also captured the idea that there are multiple competing outcomes which are recognised by SEIPS as 'acceptable outcomes' and which vary according to the stakeholder. Figure 1.2 below is a graphical representation of the SEIPS 2.0 model.

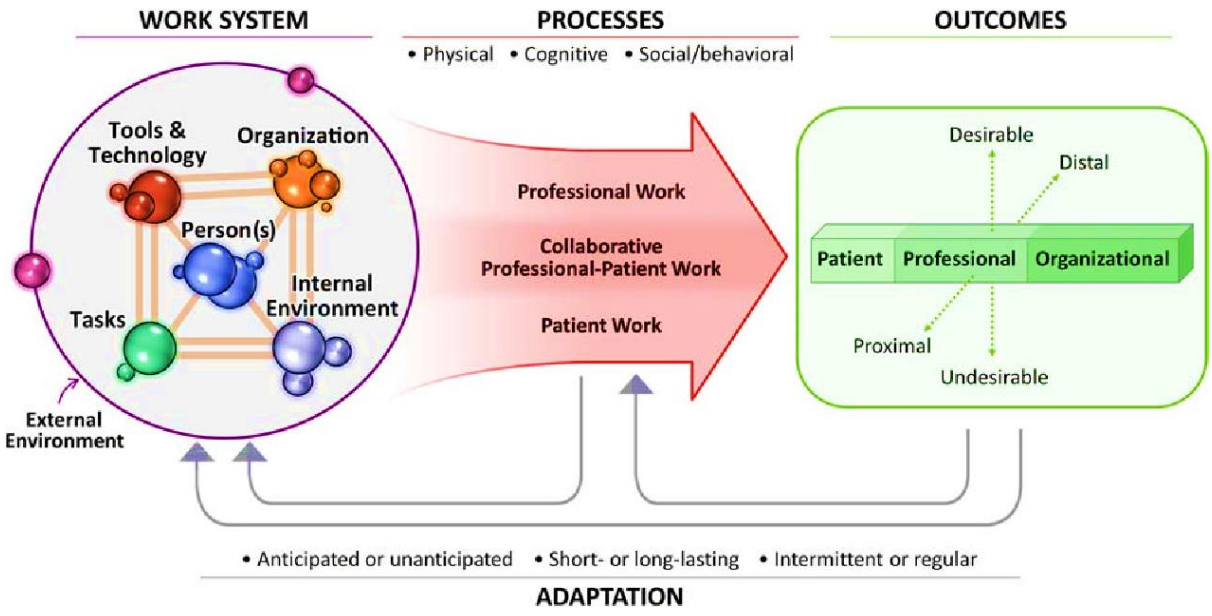


Figure 1.2 The SEIPS 2.0 model

The sociotechnical work system on the left can be further expanded as shown in the table below.

Table 1.1: SEIPS 2.0 model work system elements with descriptive features

| **Work System Element** | **Descriptive Features** |
|---|---|
| **1. Person** | Centre of the work system |
| | Refers to an individual or a group of people – in healthcare, these could be patient/client/family/carer etc. |
| | Attributes and characteristics of persons involved in/directly |
| **2. Tasks** | Characteristics e.g. complexity, ambiguity, sequence etc. |
| **3. Tools and Technologies** | Required to perform task or assist |
| | Characteristics e.g. usability, accessibility, familiarity etc. |
| | Body that organises time, resources etc. |
| **4. Organisation** | Characteristics e.g. work schedules, training, policies etc. |

| | |
|---|---|
| **5. Environment** | Internal: light, temperature, physical space |
| | External: economic, policy outside of organisation, other related systems |

Holden and his research team emphasised the importance of situating 'person' factors relevant to both patients and professionals alike at the core of the work system. In addition, the hierarchy prevalent in the work system was recognised as a means for understanding the influences of multi-level and cross-level interactions. Interactivity between system levels raises the importance of understanding the interactions that occur at interfaces. Karsh et al. (2014) acknowledge the concept of 'nesting' within levels i.e. that each broader (macro) level system has subordinate (micro) level systems nested within it. This concept is referred to as a 'system of systems' by Siemienuich and Sinclair (2014). These 'nested' systems may be underestimated - and at times not even recognised - but it is through their consideration that we can fully understand the potential of Human Factors to reform system design (Holden et al. 2013; Karsh et al. 2006; Carayon et al., 2010). By way of including the external environment (e.g. financial, societal, political influences) as another work system element, one can account for the system in its entirety or as a system fully nested within another system. The clearer this distinction, the greater the possibility of understanding the interactions which have driven the outcomes of both systems. Such clarity supports a more productive system redesign. This consideration is in keeping with one of the challenges described by Carayon et al. (2018) in terms of fragmentation present amongst system entities and interacting systems which in turn impede the broader application of HFE principles.

This is probably one of healthcare's greatest shortcomings. Nowadays, stakeholders have the tendency to report targets and statistics in isolation and measure success in terms of these predefined outcomes. When these outcomes are not achieved, a 'blame' culture ensues and very little is done to investigate the aetiology of the resultant situation. This ideology is very important when one considers certain outcomes to be a result of emergence. Emergence can lead to negative outcomes or also to positive outcomes, when workarounds are discovered

by system actors that compensate for poor design (Hollnagel, 2012; Beerepoot and van de Weerd, 2018; Dunford and Perrigino, 2018; Wilson, 2014).

Carayon et al. (2014) recognised that the system's processes are not separate from the work system but rather embedded within. They defined a care process as encompassing a "series of tasks (not necessarily organized linearly) performed by one or several persons using various technologies in a physical and organizational environment". In terms of the work processes, Holden et al. (2013) discussed the concept of engagement whereby one considers the adaptive nature of persons who are at the centre of the work system. Within this context, a person directly involved in the work activity was considered to be 'engaged' whilst a person indirectly involved was considered to be a co-agent. Three categories where delineated in this regard namely patient work, professional work and collaborative work.

These new additions to the model are important to instruct system redesign as they reflect the dynamic state occurring amongst all the elements of the model and is not exclusive to the outcomes and inputs as explained in the Karsh model (2006). The need was felt to add these concepts to reflect advancements in parallel fields which were benefitting from their inclusion e.g. cognitive systems engineering, resilience engineering etc. (Holden et al., 2013). One shortcoming of many healthcare systems is that they are not actually designed but have evolved over many years. This has posed complications for the retrospective implementation of Human Factors approaches. This highlights the importance of attempting their integration in the early stages of design for new systems. OPAT is a good target for such an approach despite its introduction in healthcare nearly fifty years ago. This is due to the slow rate of expansion meaning that many systems are relatively small and relatively new (or even still in the planning stages).

## 1.7 Global Provision of Outpatient Parenteral Antimicrobial Therapy (OPAT) Service

### 1.7.1 The Origin of the OPAT Service

The OPAT team is defined as "a clinical team that supervises parenteral antimicrobial therapy in a non-inpatient setting" and is generally considered to

provide a wide range of benefits to the patients, professionals and the organisation at large (Durojaiye et al., 2019). OPAT dates to 1974 when Rucker and Harrison published research about the benefits of such a service to a paediatric population diagnosed with chronic bronchopulmonary infection associated with cystic fibrosis. Even at the time, the revolutionary implications of this model of care on patient acceptability with concomitant reduction of complications and hospitalisations were identified. This study, published almost thirty years after the introduction of parenteral administration in healthcare, shed light on the fact that the care setting was not the determining factor in successful treatment. It was the professional's skill set in a setting outside hospital and their knowledge of infectious diseases that were of more relevance (Rucker and Harrison, 1974).

OPAT has its roots in a concept originally devised in France in 1961 entitled 'Hospitalisation à Domicile' (hospital at home) which was set up with the intention of offering services in a patient's residence that were traditionally provided in a hospital setting (Shepperd et al., 2009; Gonçalves-Bradley et al., 2017). In time, the ethos of the service has been modified to accommodate a variety of conditions and patient populations (Chapman et al., 2019). To this aim, OPAT offers patients the opportunity to be discharged earlier or outright avoid an admission without compromising the quality of care received (Chapman, 2013). This diversification has resulted in an organic expansion of the OPAT models of care, each with their own setting, training necessities and involvement of healthcare workers (Norris et al., 2018).

### 1.7.2 The OPAT Models of Care

The evidence of the versatility of the service is present in the models of care utilised to provide the OPAT service globally namely the home model which could involve the assistance of a visiting nurse or complete self-administration (by patient or caregiver), the infusion clinic/centre, and the skilled nursing facility (Norris et al., 2018; Minton et al., 2017). Each model of care brings its own safety concerns in relation to venous access, drug compatibility and emergence of line-related infections which need to be addressed depending on the context (Laupland and Valiquette, 2013).

The infusion centre model offers patients the facility of receiving their treatment at regular intervals at an ambulatory infusion centre. The home model involving the visiting nurse refers to the practice whereby skilled staff administer treatment to their patients' in the latter's residences. The self-administration option of the home model as the name implies accounts for those patients or caregivers who administer their own treatment at home. Lastly, the skilled nursing facility refers to the administration of treatment in a long-term care facility (Laupland and Valiquette, 2013; IDSA E-OPAT, 2016).

The infusion centre model is preferred for short antimicrobial treatment courses lasting a few days but requires a high degree of infrastructure and daily transportation for visits; the visiting nurse model is offered to patients who cannot self-administer or attend the clinic, whilst the self-administration model is suitable for long term or repeated courses but requires patient/caregiver availability, competence and compliance (Bellamy, 2018; Norris et al., 2018; Wee et al., 2019). Despite the disparate nature of the models, the intrinsic principle of avoiding or reducing a hospital stay is common to all. This is largely achieved by selecting patients who are otherwise stable and can be offered a long-term intravenous therapy due to the nature of the infection (Durojaiye et al., 2018).

Through the home model (i.e. visiting nurse and self-administration), patients are given the opportunity to be treated at their residence with theoretically the same quality of care offered in the hospital. Unfortunately, a clear comparison between the inpatient and OPAT setting is not always possible due to variations stemming from the nature of the OPAT team, hospital management and patient (Boese et al., 2019). For this reason, an objective measure of 'quality' is difficult to attain, and assessment tends to be subjective, relating to patient satisfaction. As a result, several tools have been designed to evaluate the impact care has on the patient's everyday life (Norris et al., 2018). It is reassuring to note that the literature supports high patient satisfaction rates irrespective of the OPAT model of care provided (Durojaiye et al., 2019; Twiddy et al., 2018; Berrevoets et al., 2018; Quintens et al., 2020).

By discharging patients onto the service, organisations gain from a reduced bed occupancy and average length of stay, while the risk of nosocomial infection dispersion is also lower (Sriskandarajah et al., 2018; Mansour et al., 2018; Norris

et al., 2018). The service also positively impacts cost incurred by the institution and is deemed as an effective measure to reduce financial burdens (Berrevoets et al., 2018; Psaltikidis et al., 2018) whilst satisfying the global shift towards care in patients' residences (Chapman, 2013; Gonzalez-Ramallo et al., 2017; Bellamy, 2018). For example, Durojaiye and colleagues in 2018 reported a total of approximately 50,000 bed days saved which accounted for 15% of inpatient costs for an infectious disease unit through the provision of OPAT.

### 1.7.3 Global OPAT Research today

An increased academic interest in OPAT patient safety performance indicators including patient selection e.g. introducing new selection criteria (Appa et al., 2020), adverse events e.g. factors which increase susceptibility of an adverse outcome (Keller et al., 2020c), drug events (Hanamunthadu and Breathnach, 2020) and readmissions (Marks et al., 2020, Durojaiye et al., 2019; Keller et al., 2018; Wee et al., 2019) has been noted in recent years. Of mention, two systematic literature reviews were published with the aim of investigating the safety and efficacy outcomes of the service (Mitchell et al., 2017; Sriskandarajah et al., 2019). In the review published by Mitchell et al., this was evaluated by comparing OPAT to the inpatient setting. The team reported higher cure rates and higher vascular access device adverse event rates with similar drug related adverse events, readmissions and mortality rates for those receiving OPAT. In the Sriskandarajah review (2019), safety features of OPAT (provision of antimicrobials) versus a more holistic service Hospital in the Home (provision of antimicrobials with other services) were compared. The review concluded that Hospital in the Home provides a similar safety profile when compared to OPAT in terms of readmission rates, mortality and adverse event rates. Due to the heterogeneity of OPAT services globally, standardisation of quality indicators has been lacking. However, in an attempt to address this problem, a recent study published by Berrevoets et al. (2020), identified 33 quality indicators for OPAT following a systematic review and a RAND-modified delphi method. These focused on the structure of the OPAT team, the necessity of standardised communication channels, policies and documentation procedures and regular monitoring amongst others.

Due to the high number of indications under the care of OPAT teams globally, several guidelines have been published to respond to national OPAT demands in a holistic manner. These include the recently published Infectious Diseases Society of America (IDSA) guidelines (Norris et al., 2018) which are an update from the 2004 guidelines (Tice et al., 2004) as well as the joint British OPAT recommendations (Chapman et al., 2019) which superseded the previous adult (Chapman et al., 2012) and paediatric (Patel et al., 2014) OPAT guidelines.

Guidelines have always substantiated the importance of patient selection criteria in gatekeeping the 'right' patients for the service. With time, these criteria have been challenged to verify whether OPAT could be safely offered to new patient groups e.g. patients who inject drugs (Appa et al., 2020). According to the 2018 IDSA guidelines on OPAT, there is no recommendation that can be provided in terms of people who inject drugs, and these should be tackled on a case-by-case basis (Norris et al., 2018) as was reiterated in the recent British guidelines (Chapman et al. 2019). Despite this, researchers are publishing data about this patient group with satisfactory results and guidance in terms of patient selection and engagement (Appa et al., 2020, Marks et al., 2020). In a study published by O'Callaghan et al. (2019), this cohort presented complications such as high readmission rates, non-attendance and line related infections. Nevertheless, this service did not jeopardise professional safety and did not result in patient deaths. The authors in fact emphasised the need for appropriate patient selection and resources to maintain such outcomes.

A growing body of evidence is being published in terms of administration devices which moves away from the traditional gravity drop sets towards the introduction of new devices e.g. elastomeric pumps which enable the continuous administration of medication (Vourmard et al., 2018). Despite the positive face value benefits of such devices, additional research is being carried out about the stability of the antimicrobial solutions in the pumps (Voumard et al., 2018; Perks et al., 2020). A systematic review published by Perks et al. (2020) concluded that stability data in terms of use in varying temperatures (at room temperature and higher) were insufficient thus inferring that current OPAT services are practicing blindly in this regard. Moreover, the recent IDSA guidelines discuss how the steady increase of antimicrobial agents used within the scope of OPAT practice, has seen an increase in the diversity of administration techniques including gravity and intravenous

push as well as devices e.g. electronic infusion devices and elastomeric pumps. The authors compiled a well-illustrated reference table for practitioners by merging pertinent information about treatment options (including antibacterials, antifungals and antivirals) used in OPAT including daily doses, infusion times, administration device options, the type and frequency of monitoring and types of adverse events (Norris et al., 2018).

OPAT research is also gaining traction from a qualitative angle. Such research is important if one is to understand the patients' and caregivers' experiences as crucial outcomes of the service (Tonna et al., 2019; Saini et al., 2019). Previously, the patient's experience was briefly researched using satisfaction surveys without thorough evaluation (Chapman et al., 2019). Whilst some have opted for a mixed method tool which incorporates both open and closed questions (Hamad et al., 2019), in recent years, researchers have employed qualitative techniques such as focus groups and interviews directed at patients and informal caregivers (Twiddy et al., 2018; Berrevoets et al., 2018; Keller et al., 2020b) as well as healthcare providers (Minton et al., 2017) to gain a better understanding of OPAT outcomes.

A shift towards patient centred care has been reported in the field of healthcare. The fundamental notion is that patients are equally involved in all aspects of their care together with the respective professionals. Despite the perceived optimism, patients' feedback rarely finds its way into making a significant contribution to altering the way healthcare systems operate and in turn influence the patient's experience as concluded in a systematic review by Wong et al. (2020). According to semi structured interviews conducted by Moore et al. (2017), barriers which impeded the implementation of a patient centred approach included (i) time constraints, (ii) pre-existing cultures and mindsets, (iii) the intervention design and (iv) the fragmented unstructured documentation methods. However, they also attributed successful integration of this approach to good leadership, organisational elements and attitudes. Santana and colleagues (2019), using the Donabedian model, classified factors pertinent to this approach according to the three main categories: structure, process and outcome. This study identified educational programs, structured environments and integrated informatics conducive to the application of this model. Communication and integration of care were deemed to be the pertinent processes which gave rise to the approach's outcomes namely access to care and patient reported outcomes.

This shift towards person-centred care is not new to the field of healthcare, and OPAT is no exception. With service models such as those practiced in the home setting i.e. the visiting nurse and more importantly the self-administration model, patients and informal caregivers are at the core of most OPAT tasks (Keller et al., 2019b). This position gives impetus to improve OPAT provision through qualitative research focussing on this stakeholder. In fact, Berrevoets et al. (2018) designed the topic guide for their semi structured focus group sessions based on the 8 Picker principles of patient centred care to better understand home OPAT model by recommending a shift from investigating diseases to understanding patients and informal carers. Wee et al. (2019) investigated health-related quality of life of patients receiving OPAT in an attempt to offer a better patient centred approach to OPAT outcomes. Their study concluded that early termination of OPAT, resuming work commitments whilst receiving care and low risk of complications were associated with perfect health related quality of life.

## 1.8 The importance of a Human Factors approach to OPAT research

Apart from recognising the complexity of healthcare systems, it is important not to underestimate the importance of safety i.e. "the level of system performance required to keep the incidence of harm (and risk) as low as reasonably practicable" (Vosper et al., 2018a) given current healthcare agendas. The OPAT service is no exception.

OPAT cannot be considered as a standalone outpatient service as it strongly relies on seamless transition from the sourcing health institution. OPAT comprises various healthcare transitional boundaries, including the shift of responsibility from the referring medical care team to the OPAT care team, patient discharge from hospital to their residence, hospital follow up appointments etc. Such transitions are vulnerable areas in terms of safety, quality and standard of care. Carayon and her research team specifically pointed out that the discharge of a patient from hospital to their residence is laden with patient safety concerns if the transition is of poor quality (Carayon et al., 2010). Moreover, an important quality indicator pertinent to transitional care is readmission rate which is also one of the most important quality measures of any OPAT service (Radhakrishnan K, 2018;

Berrevoets et al., 2019; Berrevoets et al., 2020). Bearing in mind that OPAT is a complex sociotechnical system forming part of a system of systems, one is to expect a varied pool of stakeholders with multiple patient safety considerations. It is an example of person-centred care and consequently it is well-suited to holistic analysis using a Human Factors approach (Van Melle et al., 2018; Werner et al., 2018; Carayon et al., 2020). This approach gains relevance when one considers the reported readmission rates prevalent in the literature which despite not alarming, possibly reflect the suboptimal patient selection criteria which are constantly undergoing revisions (Chapman et al., 2019; Norris et al., 2018).

An interest in studying the field of OPAT utilising a Human Factors approach has to date been shown by an American researcher. From a commentary published in 2016 about terms and failures of OPAT, Keller and colleagues have published two studies in 2019. One study identified physical hazards present at a patient's residence (e.g. animals, household clutter, extremes in temperature etc.) and the strategies patients took to overcome these barriers. The authors concluded that educational methods must address patient awareness in terms of everyday artefacts at home which could pose a threat to their safety whilst receiving OPAT (Keller et al., 2019a). The other study investigated the patients' and caregivers' ability to perform OPAT related tasks (e.g. administration of medications, caring for the venous catheter device etc.). The authors deduced that education strategies such as 'teach back' methods, visual and verbal instructions and cognitive aids amongst others could contribute to an enhanced skillset (Keller et al., 2019b).

## 1.9 Maltese provision of the OPAT Service

Considering the widely reported benefits of OPAT, a decision was taken by the infectious diseases physicians and the hospital administration to launch the visiting-nurse OPAT home model in the Maltese national hospital, Mater Dei Hospital (MDH). This decision was taken to address the needs of those patients who could not make use of the infusion centre model already in operation at the hospital. Some of these reasons included transport accessibility, patient mobility and work commitments of informal caregivers.

Several standard operating procedures were devised with the intention of regulating the development, implementation and provision of the first national OPAT service. Prior to the launch of the service, the Medical Investigations and Treatment Unit within MDH served as the main infusion centre for patients requiring parenteral antimicrobials. Despite the instantaneous accessibility of trained staff and specific venous access devices, the infusion centre model is recognised as having its own limitations including the inconvenience caused to the patient especially if they live far from the hospital or require more than one dose a day (Bellamy, 2018).

October 2016 marked the launch of a visiting nurse service OPAT model to all adult patients who at that point in time were inpatients at Mater Dei Hospital. This model, in contrast to the infusion centre model enabled patients to receive treatment in the comfort of their home with trained supervision but risked the potentially negative impact on the nurse's time, privacy and safety (Bellamy 2018; Norris et al., 2018). The provision of the service by MDH followed the current trend seen internationally whereby patients continue to be treated by the institution which provides the service (Tice, 2000). The launch of this service aligned with the National Patient Charter of rights and responsibilities which promotes safe patient centred care offered by qualified professionals. The charter covers all those patients receiving care within the Maltese healthcare system (Healthcare Standards Directorate, 2016). To date, the self-administration model of care has not been introduced to the national OPAT service. Currently there isn't the infrastructure to provide the self-administration model in terms of training patients or provide them with the necessary devices (Bellamy, 2018).

As per the guidelines available at the time of Malta's initiation of the OPAT service, the latter was built around the pragmatic guidance offered at the time in terms of service delivery and quality assurance (Tice et al., 2004; Chapman et al., 2012). Evidence of this commitment can be seen in the appointment of the hospital's OPAT team, which is considered as a crucial factor in ensuring a successful OPAT service (Chapman et al., 2012; Chapman et al., 2013; Seaton and Barr, 2013; Gilchrist and Seaton, 2015; Halilovic et al., 2014; Williams et al., 2015; Bellamy, 2018; Mansour et al., 2018; Chapman et al., 2019; Wijnakker et al., 2019; Berrevoets et al., 2020). Despite the fact that some institutions internationally are still striving to standardise the presence of a dedicated team, this is not the

case for the local service (Lane et al., 2014; Williams et al., 2015; Muldoon et al., 2015). According to the fourth recommendation of the OPAT team and service structure in the recent British guidelines, "the OPAT multidisciplinary team should include, as a minimum, a medically qualified clinician, a medically qualified infection specialist, a specialist nurse and a clinical antimicrobial pharmacist" (Chapman et al., 2019) At present the current team is composed of two doctors with a specialisation in infectious diseases and their assigned medical care teams, ten specialised practice nurses and one pharmacist.

Mansour et al. (2018) hypothesised that a designated OPAT team was seen to improve communication channels amongst the healthcare professionals involved which led to reduction in re-admissions. This was also backed up by Williams et al. (2015). Bellamy et al. (2018) emphasised the need for a designated team with a structured framework of responsibilities to avoid overlooking activities related to the service provision. Wijnakker and colleagues (2019) discussed the concept of an expert team as opposed to an individual specialist which is strongly emphasised in OPAT research especially in terms of predischarge infectious disease physician consultation. To this aim, certain studies focused on OPAT services which were led by healthcare professionals other than the infectious disease consultants namely pharmacists (Chung et al., 2016; Howe et al., 2020).

In Malta, this role was entrusted to a multidisciplinary team of healthcare professionals including infectious disease physicians, discharge liaison nurses (DLN) and a designated pharmacist. Figure 1.3 below illustrates the patient's journey from the moment they are considered as potential candidates for the OPAT service.

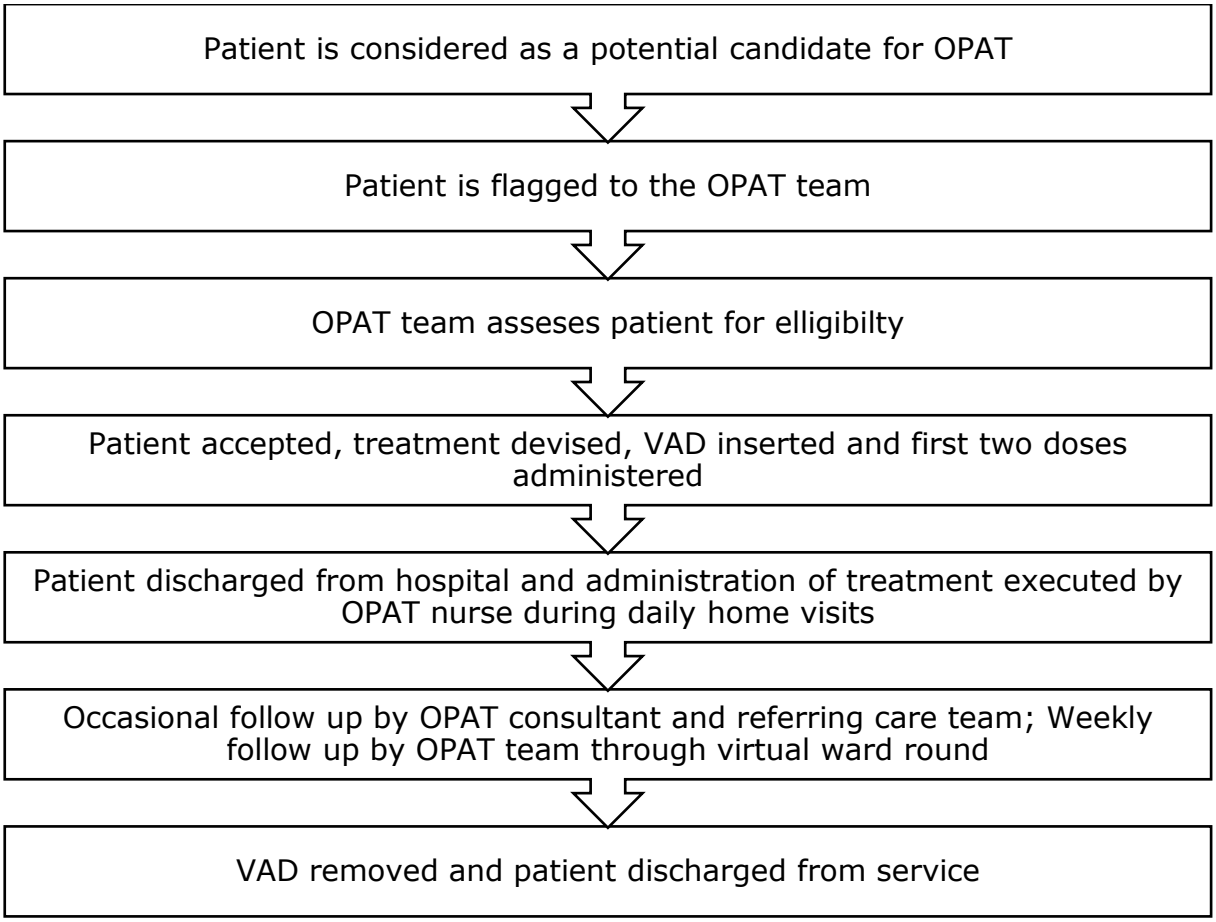


Figure 1.3 Theoretical pathway of the patient's OPAT journey

Despite the apparent simplicity of Figure 1.3, OPAT provision, like other healthcare services, is highly complex. The OPAT service provided in Malta is a strong example of a collaboration between patient and professional. However, one must consider the number of people involved in the patient's care, including all the members of the referring care team, the OPAT team, professionals involved in the insertion of the access device, any informal care givers and, of course, the patient. Considering the various stakeholders involved, it is important that a designated group of individuals oversees the smooth running of each service provision i.e. the OPAT team. The roles and responsibilities of the main three stakeholders within this team are described in Figure 1.4.

**Infectious Diseases Physicians**

1. Receives referrals of potential candidates
2. Reviews and devises an antimicrobial plan with the referring consultant
3. Liaises with OPAT nurses about the flagged patient
4. Prescribes the planned antimicrobial/s prior to discharge
5. Performs a deep vein thrombosis risk assessment and prescribes prophylaxis if necessary
6. Monitors the enrolled patient at outpatient clinics
7. Leads weekly multidisciplinary meetings
8. Communicates with referring consultant, GP and other professionals involved

**Nurses**

1. Verifies patient's suitability prior to discharge
2. Provides the patient and carer with basic education about the service, infection control and daily care of the VAD
3. Attains written consent of acceptance
4. Coordinates the discharge plan with pharmacist
5. Ensures patient has appropriate venous device prior to discharge
6. Ensures patient has an electronic file for daily data inputting
7. Administers intravenous antimicrobials and documents event
8. Manages possible problems that arise in the community setting

**Pharmacist**

1. Periodically reviews all reconstitution and administration documents
2. Reviews patient's drug history for possible interactions
3. Reviews antimicrobial/s treatment prescribed through the service
4. Ensures rational drug use and patient tailored dosing
5. Coordinates supplies of antimicrobials and prophylaxis agents with OPAT nurses
6. Alerts ID physicians and OPAT nurses should there be a shortage of treatment
7. Endorses seamless care from hospital to home environment
8. Coordinates the return of treatment from patients' homes and quarantined accordingly

Figure 1.4: The roles and responsibilities of the Maltese OPAT team

Moreover, the duality of the principal author's role as an academic researcher and the OPAT pharmacist for the local service enabled not only the execution of a Human Factors study, but also the opportunity to implement those findings at a service-wide level – prospects which are rarely available in other studies.

## 1.10 The health system in Malta

According to the European health consumer index for 2018, which ranks the performance of healthcare systems globally, Malta was awarded 27$^{th}$ place out of 35 with 631 points and was positively reported to have adequate accessibility to healthcare when compared to other countries (Times of Malta, 2019). The points are awarded depending on the quality of the healthcare system. Whilst Malta was commended on the level of accessibility, the issue concerning lack of financial subsidy in terms of public services and treatment was brought up (Björnberg, 2016). Provision of healthcare in Malta predominantly resides in the private and public sector but is also provided by the third sector, including religious and voluntary organisations. The public sector extends its health services to all those patients living in Malta who are covered by the Maltese social security legislation as well as patient groups, including minority groups requiring assistance and foreigners who have a valid work permit. Due to the absence of funding sources such as user charges (cost sharing), co-payments and parallel health systems, the public sector is funded by taxes (paid by all economically active workers who earn more than the minimum threshold), government revenues and European Union funding. The annual budget assigned to healthcare is determined by the Ministry of Finance and is subsequently approved by Parliament. Generally, this budget is based on previous expenditures, but it does not limit future amendments which are deemed necessary. In fact, 2016 saw a €52 million increment from the previous year's budget allocation (€466 million). The public sector on occasion has been assisted by the private sector with the aim of reducing waiting lists through the procurement of services. To date, the are no risk-adjusted resource allocation formulas within healthcare since there is no system of regional or local health budgets. On the other hand, funding in the private sector for medicines and services is mainly out-of-pocket and, on some occasions, one could benefit from personal private insurance (Azzopardi Muscat et al., 2017).

Primary care is mainly provided by GPs who are either employees of the public service or work privately. Currently, the medical services of GPs in the private sector are sought out more by the Maltese citizens as opposed to those in the public sector as can be deduced from the number of appointments made (PricewaterhouseCoopers, 2012). This is generally the case since GPs in the private sector are more accessible since they are distributed in pharmacies (over 200) and private clinics over the island rather than working from nine public health centres. Moreover, seeking a private GP can ensure continuity of care by the same professional (Azzopardi-Muscat et al., 2017). Secondary and tertiary care are provided by both the public and private sector in Malta and in Gozo, with the main acute general hospital being MDH.

MDH is located on the island of Malta and offers ambulatory, inpatient, intensive and specialised services. At present, the superintendent of public health is responsible for the quality assurance of public health services, ambulatory and inpatient care as stated by the 2013 Health Act. Pharmaceuticals fall under the responsibility of the Medicines Authority as per the Medicines Act legislation of 2003 (Azzopardi-Muscat et al., 2017).

Various models of macro- and micro-management of services within a dynamic health system are being considered including restructuring of distributing resources, reorganising community frameworks etc. (Department for Policy in Health, 2014). In fact, the notion of decentralisation of services by providing an outpatient service that could be offered to a patient in lieu of inpatient stay has been gaining importance in healthcare administration globally. Such a transition has the potential to ensure reduced pressure on inpatient care, thus propelling patient satisfaction and cost effectiveness of the institution. One method of ensuring the seamless transition from the hospital to the primary care setting is through the involvement of discharge liaison nurses, a project which was launched in Malta in 2014 (Health ministry, 2014). This project positively contributed to one of the major reforms being employed by MDH which was to increase the efficiency of bed occupancy management (Azzopardi-Muscat et al., 2017). Evidence of these initiatives received global recognition with Malta reporting a higher discharge rate when compared to other member states (European commission, 2018).

In fact, Malta's healthcare system is constantly under scrutiny by EU funded projects to determine its level of excellence. One such project is the Transfer of resilient, effective, equitable, accessible, sustainable and comprehensive health services and systems (To-reach) project, financed by the EU Horizon 2020 project. Of note and importance to this study, areas of improvement were highlighted including patient participation in research, patient safety and quality of care, employee well-being and decentralisation of secondary healthcare to primary health care (Tomaselli et al., 2018).

## 1.11 Research aims

The SEIPS 2.0 model was used as the overarching conceptual framework to guide data collection, analysis and interpretation of the system and to set its boundaries. The model was then used again to organise data and build a systems model based on international OPAT services and that rendered locally. These led to recommendations which could instruct system redesign through an iterative process of adaptation. With this in mind, the study was designed to use the SEIPS 2.0 systems framework to:

- To critically appraise, synthesize and present the available evidence relating to adult OPAT services.
- To appraise system outcome measures of the Maltese service including, but not limited to, referral, treatment and clinical outcome details for patients flagged.
- To evaluate the service through the views and perspectives of those healthcare professionals and patients involved through a focus group and cross-sectional survey respectively.

# Chapter 2

## Methodology

This chapter provides an in-depth description of the research philosophy, methodology and methods applied throughout this work. Considering the study aims were deeply rooted in a Human Factors approach, a pragmatic philosophy was considered appropriate. Bearing in mind the relevance of this work to a real life scenario and the cohort under study was bound by 'edges' set by the researcher i.e. the local OPAT service, a convergent mixed methods case study approach was deemed a bespoke methodology. The chapter explains the selected methods and the reasoning behind their use. Detailed descriptions of the measures taken to assure quality for each method and eliminate overall bias are provided. The final section provides a scheme of work for the entire research project.

## 2.1 Practice-based research

The desired outcomes of the system evaluation carried out in this study (as exemplified in the research aims described in Chapter 1) were two-fold: (i) to determine whether the theoretical benefits are being delivered (and to what extent) in this system and (ii) to verify whether this data can be used to identify aspects that contribute strongly to outcomes (as barriers or facilitators) and use these findings to support evidenced-based re-design to optimise system performance and human wellbeing. In keeping with this rationale, this work can be considered as a form of practice-based research. As described by Frayling (1993), practice research can be "*for* practice, where research aims are subservient to practice aims, *through* practice, where the practice serves a research purpose, or *into* practice, such as observing the working processes of others."

Traditionally, academic institutions were the main driving force behind practice progression but in time, their prominence in the research field diminished when compared to that of practitioners and private/ non-academic entities (Panda and Gupta, 2014; Carta et al., 2020). By answering a pre-determined research question which generally evolved from theories or novel research hypotheses, academic institutions strove to solve what academics considered to be the critical practice problems of the time. However, due to the nature of these methods, research was invariably presented in a scientific context which often only depicted significant statistical findings which offered a degree of generalisability. These findings were often difficult for practitioners to understand and even more difficult to apply in practice, limiting their usefulness. A move to practice-based research addressed these issues by taking a different perspective whereby the importance of findings was measured against the impact on practice and the ability to transfer this data to real life scenarios. Furthermore, participants were viewed as partners in the research process who could shed light on the social and culture influences that were inherent to the practice setting (Robson and McCartan, 2016).

Practice-based research is synonymous with the scholarship of practice. The scope of scholarship of practice is "to improve professional practice by using empirical research as the groundwork for developing practice and policy" (Braxton, 2014). This is an approach based on the need (i) to generate knowledge for a requirement

in practice, (ii) to create collaborations with practitioners to explore new academic ventures and (iii) to embark on research which amalgamates knowledge and practice concurrently (Smith and Wilkins, 2018; Lykon-Segosebe, 2017). This is exemplified in one of the feedback loops inherent to Reason and Kimball's (2013) theory-to-practice translation model described in student affairs literature which illustrates the journey from formal theory to practice whilst encompassing the importance of institutional context (i.e. the values and beliefs of the members of an institution) and informal theory (i.e. common sense that allows a person to make associations) shown in Figure 2.1.

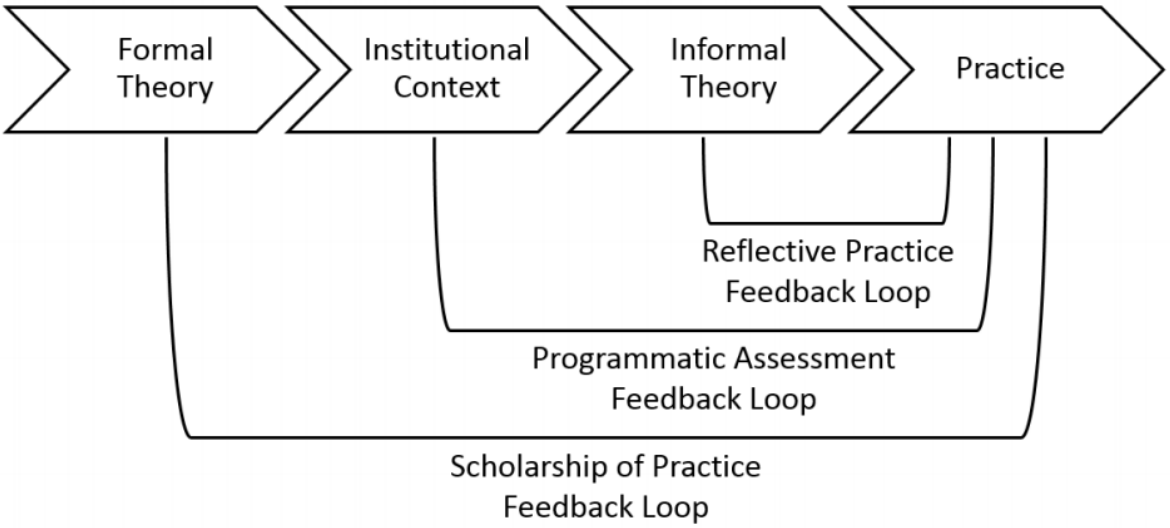


Figure 2.1 Reason and Kimball's theory to practice transition model (2013)

As early as the 1940s, recognition of the divide between academics and practitioners was noticeable possible due to their different audiences, reporting styles, research methods, interests, viewpoints etc. (Battaglio and Scicchitano, 2013). The importance of the application of scholarship to improve disciplinary action was emphasised by Boyer (1990) who published this rationale in his book entitled "Scholarship reconsidered: priorities of the professoriate." Practitioners expressed concerns and scepticism about the relevance of academic influences whilst academics were uncertain whether existing theory was being applied to everyday practices (Lyken-Segosebe, 2017). Various nomenclature has been attributed to this dichotomy namely 'theory-practice gap' in the field of nursing (Scully, 2011), 'rigour-relevance' debate in the field of management (Thorpe et

al., 2011; Panda and Gupta, 2014) to name a few. To address this impasse, the need was felt to amalgamate knowledge generation and use in a single initiative through scholarship of practice which recognises that there is knowledge *in* practice and *for* practice (Forsyth et al., 2005). Battaglio and Scicchitano (2013) reported a number of measures that could help bridge the gap, such as collaboration models and professional interaction through conferences. Certain measures specific to academics were proposed, namely refocusing their attention on matters pressing to society and practitioners, utilising a language style which is easy to comprehend and portraying a clear inference of their findings on practices. This has led to a growing shift away from the perceived dichotomy between practice and research towards a more applied view whereby academics use practice as part of their research.

### 2.1.1 Real world research as an applied form of practice-based research

Real word research refers to those studies which are small in scale in terms of participants or situations and targets issues which within a specific context, have great implications on the cohort in question. This form of research, despite generally having a stringent scope is of great relevance within an applied field. The role of the researcher is to understand what is occurring in a real-life scenario, to implement the necessary changes, to address an issue and to monitor the progress if any. In order to effectively execute this role, one must be in a position of direct involvement or at least possess the necessary skills and knowledge about the given context. The value of this applied research means that practices including policy and decision-making processes are based upon evidence stemming from an informed cohort (Robson and McCartan, 2016).

Conducting a real world study endorses a scientific approach since it leads to the "generation of knowledge that places high regard for empirical data and follows certain norms and practices that develop over time because of their usefulness" (Johnson and Christensen, 2004). The problem-solving capacity of this research resonates in its systematic, sceptic and ethical execution. Through the appropriate description and scrutiny of context specific observations whilst abiding to good ethical research practices, a researcher can ensure social responsibility is being upheld (Robson and McCartan, 2016).

#### 2.1.1.1 Rationale for choosing the real world approach in this study

As per Frayling's definition of practice research, this work is an example of research *into* practice as it is based on the observations of work processes pertinent to the local OPAT service. This is coherent with the scope of real world research, since these observations are taking place in a grounded specific context (OPAT service in Malta) using a systems-based approach. OPAT, which is an applied field of healthcare professional practice can be of benefit to patients receiving antimicrobial treatment in a hospital setting, in terms of their mental and physical health. As a result, hospital workload is reduced, financial burdens are alleviated, and hospital bed occupancy can be better managed. These outcomes are grounded in a specific context, i.e. that of the Maltese healthcare system which is under today's pressures in terms of the physical and human resources it can offer. Moreover, considering the Human Factors research underpinning this study, this approach is befitting as it is context specific and contributes to the discovery of outcomes which influence system redesign thus influencing the lives and practices of those involved.

## 2.2 Research philosophy

Determining the research philosophy is the first step towards establishing one's research framework (Creswell and Creswell, 2017). Research philosophies are essentially a spectrum of perspectives that vary from the idea of 'objective reality' through to the notion that there is no such thing as reality - it's all subjective perception (Saunders et al., 2019). Figure 2.2 below illustrates the research onion described by Saunders which dictates the steps inherent to a research process namely the philosophy, approach, strategy, choice of method, time horizon and techniques and procedures.

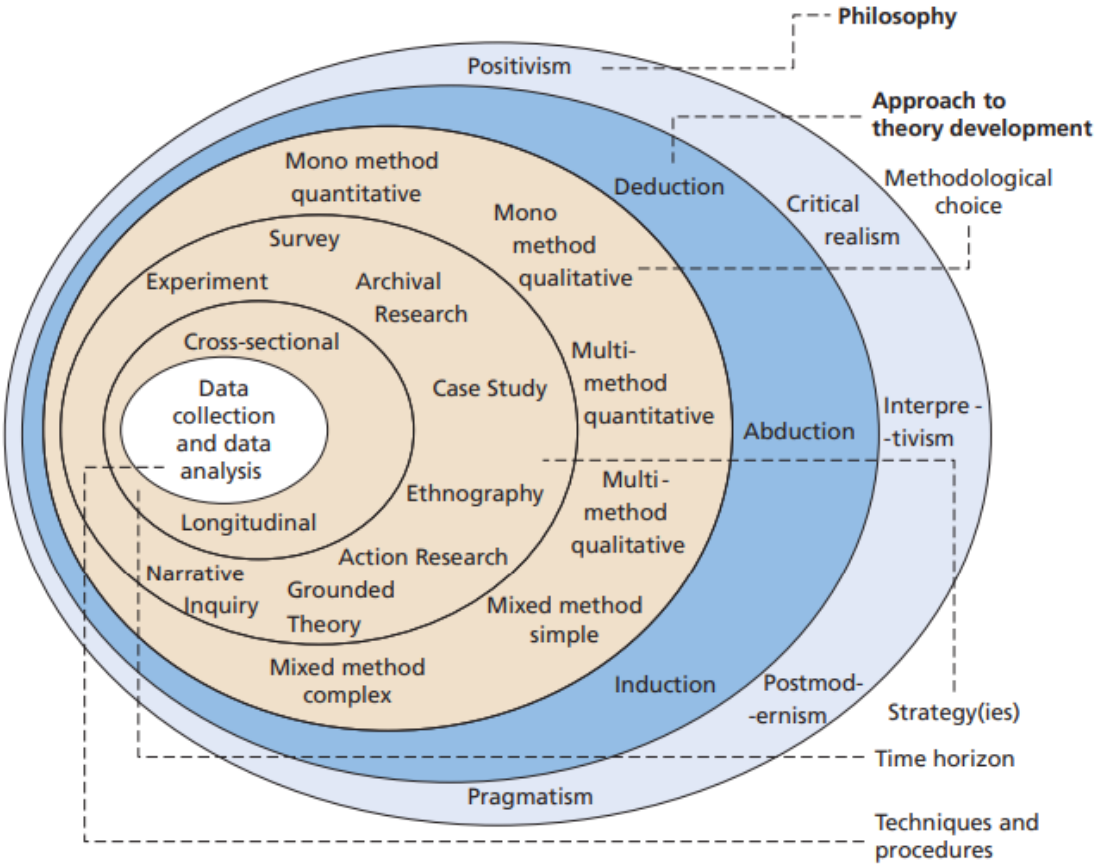


Figure 2.2 Research onion (Saunders et al., 2019)

While these different research philosophies appear very different (certainly in their extreme forms) there is significant overlap and a pragmatic philosophy recognises this. In fact, pragmatism as a philosophy dictates that subjective and objective realities are both extremes, but there are elements of all that hold true which can only be explored by changing the guiding philosophy as appropriate. Considering this research employs a Human Factors approach, which is on the cusp of science and humanities, it inclines towards a pragmatic philosophy and methodology whilst drawing from other philosophies such as the post-positivism and social constructivism as can be seen in Table 2.1. This concept of drawing from a spectrum of philosophy resonated in an article by Harrison et al. (2017) who described post-positivism/realism, pragmatic constructivism and constructivism as being attributable to case study designs (Section 2.3.2.1).

Table 2.1 Philosophies pertinent to this study

| **Philosophy** | **Characteristics** | **Relevance of philosophy to study** |
|---|---|---|
| Post-positivism | • Facts (objective knowledge) cannot be separated from values therefore the researcher and the subjects under research are not two independent components of a study.<br>• Observations made are subject to the researcher's view which is thus imperfect and subject to personal bias. | SEIPS 2.0 model does not dissociate objective knowledge from its value and context and for this reason elements such as internal and external environments are considered when trying to understand a system under study. Secondly, importance is also given to the value of the outcomes of a system as an important source of information which guides a system's adaptation and redesign. This feedback loop ensures that amendments are dynamic and related to the specific context at a certain point in time. |
| Social constructivism | • People's perception of reality is based on how they 'construct' their interpretation of reality in response to the interactions they forge with one another giving rise to a multitude of realities.<br>• Targets individual perceptions rather | The idea of gathering 'multiple realities' from individuals resonates in this study when one considers the cross-sectional surveys used with patients and the focus group used for the OPAT team. Both data collection methods understood that patients and service providers do not exist separately.<br><br>Human Factors approach incorporates theoretical perspectives assuming self, society |

| | | |
|---|---|---|
| | than a collective construct. | and reality which are constructs developed through interaction, relying on communication and language. The interactions between people and their environment within a system influence the resultant service provision. |
| Pragmatism | Section 2.2.1 | Section 2.2.1.1 |

However, it is important to note that Human Factors reflects aspects of the different research philosophies thus making pragmatism an appropriate underlying research philosophy for this work.

### 2.2.1 Pragmatism

Modernism was the first shift seen towards an approach that advocated science as opposed to superstition which was predominant in the middle ages. Through modernism, it was believed that knowledge could be attained by way of reason to gain general 'truths'. This concept was opposed by postmodernists who believed that reality is constructed and thus a real 'truth' does not exist. These constructions which define multiple truths are the result of people's perception and their associated understanding. Such perceptions are influenced by innate, fixed or less fixed factors including genetic, personal experiences and education respectively. The middle ground stance taken by moderate postmodernists lies with the understanding that universal truth does not exist but rather it exists as "specific, local, personal and community forms". This type of research draws onto any research design which will result in the better understanding of a real world problem. For this reason, one can detect elements stemming both from qualitative and quantitative paradigms (Robson and McCartan, 2016).

Pragmatism is in fact characterised by the complimentary and synergistic duality approach using both quantitative and qualitative methodologies (Morgan, 2014). This approach generates different observations, theories and experiences which help in understanding both realistic and constructed views, thus promoting pluralism and rejecting reductionism (Green and Caracelli 1997; Tashakkori and

Teddlie 1998; Creswell and Creswell, 2017; Robson and McCartan, 2016). Pragmatism strongly applies to mixed methods research as it enables the versatility of research between the physical world and the social world (McBride et al. 2019; Meixner and Hathcoat 2019).

However, the pragmatic approach has its shortcomings in terms of the extent to which such research will change society by immediate results, its ability to withstand philosophical disputes and the strength of its use unless explained by the researcher (Johnson and Onwuegbuzie, 2004; Ivankova et al., 2006). Another potential limitation is the researcher's own position in relation to the research especially when qualitative approaches are being utilised (Hignett and Wilson, 2004).

#### 2.2.1.1 Rationale for considering pragmatism as the overarching philosophy of this study

For this study, the pragmatic worldview resonates with an ergonomic approach for a multitude of reasons. Firstly, it endorses pluralism which supports the two disciplines this study is attempting to integrate namely OPAT and Human Factors. This is in keeping with the fact that OPAT is a complex sociotechnical system and would thus benefit from the use of more than one type of research method to resolve the principle research aims.

Secondly, the importance of generating qualitative and quantitative data for Human Factors research was emphasised by Carayon et al. (2015) thus endorsing a pragmatic approach. As described by the International Ergonomics Association (2000; Chapter 1), Human Factors research falls on the "cusp of sciences and humanities" in the centre of the quantitative and qualitative continuum (Hignett and Wilson, 2004). In keeping with this observation, this work dismisses philosophical paradigms in their purist sense i.e. strict positivism and post-positivism and endorses more 'moderate' post-positivistic or post-modernist views.

Lastly, this research was conducted in four phases namely a systematic literature review (Chapter 3), quantitative prospective observational cohort study (Chapter 4), quantitative cross-sectional survey (Chapter 5) and a qualitative focus group session (Chapter 6). Considering the various mixed methodologies and methods taken to answer this work's aims, the pragmatic worldview was bespeaking to this research.

## 2.3 Research methodologies

The philosophical worldview is strongly related to the research design of a study. The research design can be quantitative, qualitative or a mixture of both in the mixed methods design (Creswell and Creswell, 2017). As described in Section 2.2.1, a pragmatic philosophy and methodology best suits this research since it endorses a mixed methods design (Creswell, 2003; Tashakkori and Teddlie, 2003). A mixed methods approach makes use of both quantitative and qualitative methodologies rather than opting for a design that employs only one paradigm, which are explained in further detail in Sections 2.3.1-2.3.3.

### 2.3.1 Quantitative methodologies

Quantitative designs are mainly constructed around a hypotheses and numerical data is gathered to support or refute the hypotheses. Generally, an instrument is designed and validated with the intent of collection such data which is then analysed using statistical methods. The data generated from quantitative designs is numerical in nature and based on for example an observation or performance (Creswell and Creswell, 2017). From the spectrum of quantitative research designs, this study employed survey research and observation research with the aim of gathering the details about the patients' OPAT episodes and their relevant views (Creswell and Creswell, 2017). Other quantitative methodologies were considered for this research but were refused on the basis of their relevance to this research as shown in Table 2.2 below.

Table 2.2 Examples of quantitative methodologies

| **Quantitative methodology** | **Description** | **Rationale for rejection/ utilisation** |
|---|---|---|
| Correlational design | Investigator assesses the degree of association between two or more variables. | Does not apply to this study since predictor variables could be manipulated. |

| | | |
|---|---|---|
| Casual-comparative/ quasi experimental | Investigator assess two groups based on a factor which has occurred. | No comparators present in this study. |
| Survey research | Investigator quantifies trends and perceptions of a population at a point in time (cross-sectional) or over a period of time (longitudinal). | The cross-sectional survey employed in this study (Chapter 5) investigated the views of the patients who had used the service. |

### 2.3.2 Qualitative methodologies

Qualitative methodologies gained appreciation during the mid-1970s and into the 21st century as alternative to previously described quantitative methodologies. This design generates data which can be textual, graphic and/or audio-visual depending on the nature of the observation (Creswell and Creswell, 2017). Of note, these include narrative research, phenomenology, grounded theory, ethnography and case studies. To conduct these approaches, the researcher plays a pivotal role and thus must possess intrapersonal skills to conduct objective research. This can be achieved through good communication skills and by adapting the initial methodology to provide the best interpretation of the context under study. Descriptions of qualitative methodologies can be seen in Table 2.3.

Table 2.3 Examples of qualitative methodologies

| **Qualitative methodologies** | **Description** | **Rationale for rejection/ utilisation** |
|---|---|---|
| Narrative | Summarises renditions given by several participants and is presented in the form of a narrative. | Not applicable to this study. |

| | | |
|---|---|---|
| Phenomenology | Focuses on a phenomenon experienced by all participants. | Applied in this study when investigating the experiences of patients (Chapter 5) and the OPAT team (Chapter 6). |
| Grounded | Through various stages of data collection and analysis, generates a theory (emergent) which is rooted in the participants' perceptions. | Applied in this study since this research is specific to the provision of the OPAT service. |
| Ethnography | Depends on the investigator's observations taken within the natural setting over time. The focus of this type of study are social and cultural realities. | Applied in this study when recording data from the observational study, surveys and focus group session. |
| Case study | Multiple methods are used to explore in depth the 'case' in question. | Section 2.3.2.1 |

This study draws from four of the above forms of qualitative methodologies namely grounded theory, phenomenology, ethnography and case study research, with the greatest influence from the latter.

#### 2.3.2.1 Case study research

Case studies analyse a 'case' which could refer to a person or group of people (e.g. community studies, social group studies) which collaboratively constitute an institution. The 'case' can also be an attribute associated to people e.g. relationships. These types of studies are specific to activity and timing and are conducted over time by using both quantitative and qualitative methods but the

former generally predominates (Creswell and Creswell, 2017). Case study research is defined as "a strategy for doing research which involves an empirical investigation of a particular contemporary phenomenon within its real life context using multiple sources of evidence" (Yin, 2013). This definition dismisses the notion that case study research is a method but rather an approach which conducts research through multiple methods to gain consensus about a case which is context specific. In fact, there are three elements to any case study research namely: it must focus on an individual or group of individuals, be conducted in the natural setting and be robust in detail (Harrison et al., 2017). There are various types of case study designs, five of which are described in Table 2.4 below.

Table 2.4 Types of case study research (Harrison et al., 2017)

| **Types of case study research** | **Description** |
|---|---|
| Explanatory | Explanation of a phenomenon or issue. |
| Exploratory | Identification of tools which would instruct further research. |
| Descriptive | Description of a case in its real world context. |
| Instrumental | The case is a tool. |
| Intrinsic | The case itself is of interest to the researcher. |

In keeping with Yin's explanation, Creswell and Plano Clarke (2018, p. 116) formulated a definition for mixed methods case study design which is "a type of mixed methods study in which the quantitative and qualitative data collection, results, and integration are used to provide in-depth evidence for a case(s) or develop cases for comparative analysis."

It is important to note that case study and mixed methods research (Section 2.3.3) are not separate entities but rather the boundary between them is permeable and fluid allowing each to either support or lead in a research endeavour" (Carolan et al., 2016).

2.3.2.1.1 Rationale for identifying this work as case study research

For this study the case study research design was utilised for a multitude of pertinent reasons. Firstly, in line with the justifications for a pragmatic approach, the aims of this research could only be met by combining both deductive (quantitative) and inductive (qualitative) research. Secondly, such a design will result in a stronger and clearer conclusion based on the converging data and analysis performed throughout the study thus informing theory and practice which is still at its infancy nationally. Thirdly, the concept of using more than one method eliminates risk of being restricted when generating data and thus ensuring generalisability of results which is crucial not only for the service but other services to be developed which will employ a similar model. This design enables the triangulation of data from different methods to understand the same phenomenon which in this case is the OPAT service (Renz et al., 2018).

The overall design was an integrated mixed methods convergent case study design since quantitative data from the service's performance in the repository (Chapter 4) and the experiences of the patients (Chapter 5) were gathered simultaneously with the qualitative data from focus group session with the OPAT team (Chapter 6). The results were then merged together to make inferences.

Deriving data from multiple sources has been commended in the context of healthcare research (Allsop et al., 2013) and more specifically clinical pharmacy (Hadi and Closs, 2016). This reasoning has been attributed to the fact that health services incorporate a variety of complex tasks (Craig and Petticrew, 2013) and can be better understood through a range of methods rather than a descriptive and cross-sectional research alone (Borglin et al., 2012; Borglin et al., 2015; Uprichard and Dawney, 2019). Notwithstanding the complexity of interventions required to make a difference in the field of healthcare, emphasis is also made on the complexity of mixed methods and the need to produce visual renditions of the models to ensure enhanced conceptual understanding (Ivankova et al., 2006) as seen in Table 2.5. Moreover, health systems are recognised to be different from other disciplines, in terms of the involvement of people who are not researchers, the continuous nature of the discipline which cannot be disrupted and the influence of external policies (Summers Holtrop et al., 2019).

Table 2.5 Data collection tools and analysis performed during this study

| **Design** | **Tool** | **Analysis** | **Analysis tools** |
|---|---|---|---|
| Aggregative and configurative (primarily) | Systematic literature review | **Synthesis:** Narrative<br>**HF:** SEIPS-based modelling | SEIPS 2.0 model |
| Quantitative | Prospective observational cohort | **Quantitative:** descriptive, predictor modelling, comparative | IBM® SPSS® |
| | Survey | **Quantitative:** descriptive, hypothesis testing (e.g. normality)<br>**Qualitative:** thematic<br>**HF:** SEIPS-based modelling | IBM® SPSS® NVivo® and SEIPS 2.0 model |
| Qualitative | Focus group | **Qualitative:** thematic<br>**HF:** SEIPS-based modelling | NVivo® and SEIPS 2.0 |

Case study research was chosen as the overarching methodology for this study since this work is bounded i.e. the researcher establishes boundaries around the study, it is reflective of a real-world context (Yin, 2014) and it is unique in relation

to other cases. Table 2.6 provides details of this methodology and the case under study.

Table 2.6 Details of the case study methodology employed in this study

| **MMCSR approach** | **Purpose** | **Mixed methods design** | **Participants/ Case** |
|---|---|---|---|
| Inductive | Descriptive | Convergent | OPAT patients<br>an OPAT team |

### 2.3.3 Mixed methods methodologies

Mixed methods research is defined as "the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e. g. use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration" (Johnson et al., 2007, p123). Mixed methods research attempts to favour methodological pluralism and reject scientific dogmatism embodied in experimental science (Ridde and De Sardan, 2015). However, there is another school of thought that deems mixed methods research to be a combination of more than one paradigm due to the range of underlying ontological principles (Ghiara, 2019). Despite this, mixed methods research can give rise to one or many points of convergence throughout the research process with respect to data collection, analysis and interpretation (Creswell and Plano Clark, 2011).

Schoonenboom and Johnson (2017) identify seven design dimensions which ensure validity of a mixed method research design namely (i) purpose (ii) theoretical drive (iii) timing (iv) point of integration (Table 2.7) (v) typological/ interactive design approaches (vi) planned/emergent design (vii) design complexity. In terms of the third point, the importance of simultaneity is essential when trying to comprehend the three primary models of mixed methods including the convergent parallel, explanatory sequential and exploratory sequential. This implies that sequencing can occur at any phase of the research process including collection and/or analysis (Palinkas et al., 2019). According to the notation

developed by Morse, convergence between components is denoted by a "+" sign whilst sequentially is denoted by "→" sign (1991). Another important consideration in terms of timing is the dependency of components and whether designs are 'component designs' i.e. components are independent of each other or 'integrated designs' being the more complex since components are interdependent (Schoonenboom and Johnson, 2017).

The convergent parallel model defines the method of collection of quantitative and qualitative data simultaneously prior to their integration. The other two models are sequential i.e. the phases follow each other whereby the explanatory method generates quantitative data results which are further explained by qualitative data. On the other hand, an exploratory method would commence with the generation of qualitative data and the results which will set the foundation for the subsequent quantitative phase (McBride et al., 2019).

Another important aspect to consider in mixed methods design is the point of integration of qualitative and quantitative designs. Greene, Caracelli and Graham scheme identifies the purpose behind 'mixing' in mixed methods research (Greene et al., 1989) as can be seen in Table 2.7.

Table 2.7 Rationale for mixing in mixed methods research (Greene et al., 1989)

| **Integration justification** | **Description** |
|---|---|
| Triangulation | The combination of findings from the different methods. |
| Complementarity | The findings of one approach help to explain the findings of the other approach |
| Development | The findings of one method instruct/develop the subsequent method. |
| Initiation | Exposes results from one method by challenging them with results from the other method. |
| Expansion | The utilisation of various methods to increase the robustness of data. |

Moreover, one must be aware of the difference between mixed model and mixed method research whereby 'mixed model' refers to the spectrum of approaches within or across the study whilst 'mixed method' refers to the inclusion of a quantitative and qualitative phase in the study (Johnson and Onwuegbuzie, 2004).

Robson and McCartan (2016) opt for another term to refer to mixed methods design namely 'multi-strategy' since these designs "involve not only combining methods in some way but also using more than one research strategy they are referred to here as multi-strategy designs." The authors continue by describing a methodology which resorts to integration through development as being 'flexible' in design, despite flexible research designs were attributed to studies which mainly collected qualitative data. Considering this conflation, the term multi-strategy design is preferred.

Despite its value, this form of research also comes with its limitations. Firstly, researchers might not have the same aptitudes when conducting both quantitative and qualitative approaches and feel that their strengths lie more in one approach. Secondly, a realistic timeframe is unknown at the start of the study since the research team must execute more than one method. However, as a rule, quantitative methods are shorter in duration. Lastly, the integration of both paradigms is weak, casting doubt on the overall benefit (Bryman, 2004; Bryman, 2006; Palinkas et al., 2019).

## 2.4 Research methods

The research methods are the last part of the research framework which include the collection, analysis and interpretation of data. Quantitative methods make use of instruments which generate data e.g. performance, census etc. which can be statistically analysed and interpreted. On the other hand, qualitative methods make use of open-ended questions in their tools which give rise to data e.g. observational, audio-visual etc. which need to be analysed and interpreted in terms of their themes and patterns. Mixed methods draw on both quantitative and qualitative methods and hence vary in their data collection tools, analysis and inferences (Creswell and Creswell, 2017).

### 2.4.1 Quantitative methods

#### 2.4.1.1 Prospective observational cohort study

The observation technique enables the collection of primary data in an environment which exposes an interaction or phenomenon (Kumar, 2019). Studies such as the one published by Raine et al. (2014) describe how one can go about the collection and analysis of both quantitative and qualitative data during non-participant meetings in a standardised manner.

Participant observation in the healthcare setting, enables the researcher to pragmatically understand process and service deliveries considering the group's interactions which an interview or focus group would not be able to reveal (Hughes et al., 2013). Moreover, the advantage of participant observation over other methods like formal interviews is in terms of the validity and apt interpretation of one's account, which is a key component of ethnography (Hammersley, 2018).

Limitations to observation methods especially participatory observation methods as a means of data collection include the bias of the person - known as 'reactivity' e.g. gender, race etc. which will then influence the subsequent analysis (Hughes et al., 2013; Kumar, 2019). Moreover, observation may instil a lack of trust in the people being observed thus information may be retained and even subjects changed completely (Kumar, 2019). There might be discrepancies in the interpretation derived from one observer compared with another. Finally, the accuracy of the observation depends on the researcher's capability to notice detail and document accordingly and their presence when observing the participants. During an observation it is highly probable that the observer will fail to detect certain cognitive aspects in the absence of proper explanation from the participants, as opposed to a physical observed event (Kawulich et al., 2005). In fact, should an observer opt for note taking s/he might miss out on crucial interactions between the group members. Moreover, participants may modify their behaviour simply because they are being observed. This phenomenon is known as the 'Hawthorne effect' (Kumar, 2019).

When using observation as a qualitative data generation method, the observer may assume four roles namely the complete participant, the participant as observer, observer as participant and complete observer (Table 2.8). Whilst observing, it is important for the observer to take note of task factors, person

factors such as participation and relationships, environmental tasks etc. (Polgar and Thomas 2013)

Table 2.8 Characteristics of the observer roles

| **Observer Roles** | **Characteristics** |
|---|---|
| Complete Participant | • Assume role of participant in studied scenario<br>• Participates without knowledge or consent of other participants<br>• Attempts to minimise difference in behaviour due to presence of observer |
| Participant as observer | • Assume role of participant in studied scenario<br>• Participates with knowledge and consent of other participants |
| Observer as participant | • Does not assume role of participant in studied scenario<br>• Observer interacts with participants |
| Complete observer | • Does not assume role of participant in studied scenario<br>• Does not interact with other participants<br>• Does not disclose intent |

On the other hand, observations with the intent of extracting quantitative data, usually demand a complete observer or observer with participant role with a specific recording guide for the variable observed. The rigidity of the observation guide enables ease when collecting and summarising data but may prove lacking when recording unique or unforeseen events (Polgar and Thomas, 2013).

Generally, the observer makes use of a narrative recording technique in order to generate qualitative data. On the other hand, the observer might opt to gather quantitative data through the design of scales but may be subject to errors including the elevation effect, halo effect or error of central tendency (Kumar, 2019).

#### 2.4.1.1.1 Rationale for using observation techniques to construct an electronic quantitative database for service outcome data entry

In the absence of quantitative data reflecting the success and failures of the local OPAT service when compared to services rendered internationally the need was felt to design a bespoke electronic repository for comparative research through auditing methods. In order to identify the database's parameters, the principal researcher took a qualitative 'observer as participant' role during the preliminary OPAT team meetings to design the content of the electronic database. This step was taken considering other services run globally utilise repositories for auditing purposes (Chapman et al., 2019). Moreover, observation techniques commonly feature in Human Factors approaches and hence compliment the overall research intent.

Secondly, a quantitative approach was taken to compile the content database taking a complete observer approach. From the moment of the patient's enrolment, their demographic characteristics, treatment and referring care team details were inputted. Over time, other observations including the occurrence and rationale for a readmission and the termination date of the OPAT episode were noted down. This quantitative approach enabled future analysis of the data gathered including statistical correlation, predictive modelling and numerical testing.

### 2.4.1.2 Cross-sectional survey

The design of a study can be based on the number of times a participant is contacted including once in a cross-sectional design, twice in a before-and-after study and multiple times in a longitudinal study (Kumar, 2019). The design of a cross-sectional study is defined by the data collection of a cohort at a specific point in time as opposed to longitudinal studies which enables the observance of a trend over a period due to multiple data collections. Due to the singular collection point this design proves to be cheap and relatively easy for the researcher to conduct. However, it should be borne in mind that such a design will only generate information about association and not causation (Sedgwick, 2014).

During the conduction of a survey by telephone, the combination of audio-recordings and note-taking, is seen as a positive measure to eliminate any unclear

data recorded by the researcher. This approach does not eliminate the disadvantages associated with audio recording e.g. reduced disclosure and intrusion. Neither does it exclude limitations associated with response sheets e.g. researcher's bias in recording and the adaptability of the sheet to cater for unforeseen responses (Polgar and Thomas, 2013).

#### 2.4.1.2.1 Rationale for use of a cross-sectional survey in this study

In this study, a cross sectional survey was conducted by telephone utilising a structured survey. The tool contained both open-ended and closed-ended questions with the aim of enriching the quantitative data being gathered. This guided approach was deemed more appropriate to obtain information in an equal manner from all respondents. Data collection took place by telephone rather than using postal or self-administered methods. This method ensured a level of anonymity and privacy which are limitations to other collection methods rejected in this study e.g. video recording.

### 2.4.2 Qualitative methods

#### 2.4.2.1 Focus Group

The concept behind a focus group is to have a discussion in a face-to-face environment amongst a group of approximately ten people with the assistance of a facilitator. Whilst appreciating that there is a level of bias that may arise from such discussions, the level of participant interaction is paramount and essentially the key methodological advantage (Nyumba et al., 2018). Focus groups enable collective data collection in one session thus deemed more fruitful than individualised meetings, encourage contribution of views, discourage discrimination and overcome literacy issues (Polgar and Thomas, 2013; Green, 2013; Kumar, 2019).

On the other hand, focus group may not always facilitate a group discussion and rather reduce a participant's will to express their view. Despite this, the same repression can be part of the overall social construction generated in the session.

Moreover, there is an ethical limitation in this method in the sense that certain confidentiality is lacking amongst members of the group and it is up to the discretion of the members to conform to respect. A means to overcome such a shortcoming, is for the facilitator to introduce ground rules on confidentiality from the start and continue to honour them throughout the session (Plummer, 2017a).

Focus groups are deemed to be an appropriate method in healthcare research in terms of the setting within which one is asked to voice their opinions considering health topics as this is common practice in everyday communications amongst individuals, media etc. Moreover, it offers a supportive setting in which one might feel more comfortable to talk and prompted to discuss topics due to other participants' accounts. (Green, 2013; Kumar, 2019).

The advantage of having a group of participants with homogenous experiences provides an environment which is conducive of further conversation and discussion. It is important to note that such discussions and conversations are not encouraged to reach a form of consensus (as opposed to e.g. Delphi technique) but rather a wide range of experiences (Plummer, 2017b).

#### 2.4.2.1.1 Rationale for the use of a focus group in this study

In this study, a focus group method was used to extract the experiences of the healthcare professionals involved in running the OPAT service i.e. the OPAT team. Their views were deemed as important as that of the patients since the SEIPS 2.0 model gives equal weighting to the outcomes of both patients and professionals which will in turn redesign the work system through adaptive measures. Moreover, considering that the participants were involved in the early stages of the service delivery and committed to designing recommendations to ameliorate their work conditions, a focus group method was considered appropriate.

The disadvantage of lack of integration amongst participants was deemed negligible since the participants collaborate daily together when running the service thus the need to establish a group dynamic was not necessary. On the contrary, such a session offered a platform for the service providers to discuss various facets of the service, an exercise which was last conducted prior to the launch of the service in October 2016.

Moreover, this study opted to use two separate methods to obtain patients' and healthcare professionals' views, the surveys and focus group respectively. The reason behind this was firstly to avoid patients coming to the hospital and thus defeating the purpose behind the outpatient environment which the OPAT service strives to maintain. Secondly, the healthcare professionals called to take part in the focus group never had the opportunity to collectively discuss facilitators and barriers influencing the service since its launch. Thus, the presence of a patient might have influenced responses both in terms of the content expressed and direction away from administrative, logistic issues which are dealt by the staff on a day to day basis.

### 2.4.3 Systematic Literature Review

A systematic literature review aims to answer a research questions whilst exhausting all possible sources in accordance with a predefined set of criteria. According to the hierarchy of evidence for reviews published by Djulbegovic and Guyatt (2017), higher levels of evidence carry higher methodological weight thus enabling evidence-based recommendations to be graded. Level I is evidence derived from a systematic review of all pertinent randomised controlled trials (RCT). In order to avoid omitting published evidence which can be used to inform clinical guidelines, the Grades of Recommendation Assessment, Development, and Evaluation (GRADE) system was developed as shown in Figure 2.3.

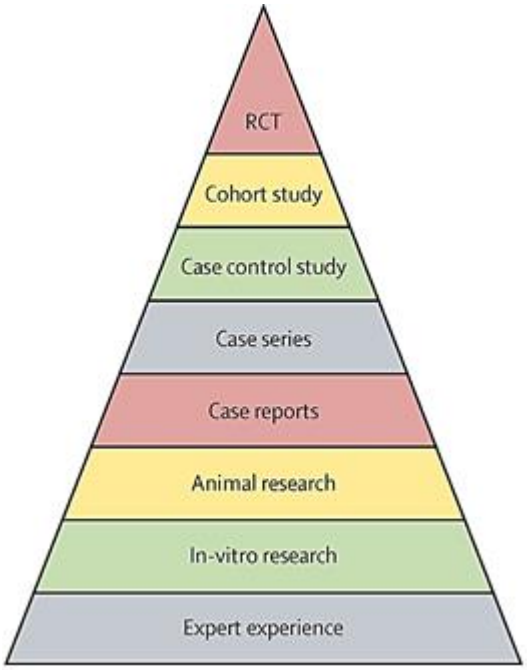


Figure 2.3 Grades of Recommendation Assessment, Development, and Evaluation (Adapted from Djulbegovic and Guyatt, 2017)

Despite the levels appearing to favour quantitative research, there is increasing awareness in healthcare that qualitative research is also important in understanding health conditions and interventions and informing policy (Jones et al., 2013)

When conducting a systematic review, the initial step is to consider a research question and check it is amenable to the PICO method. This method ensures that the main parameters are taken into consideration including the population (p), intervention of interest (i), comparator (c) and outcome of interest (o). Figure 2.4 depicts the process.

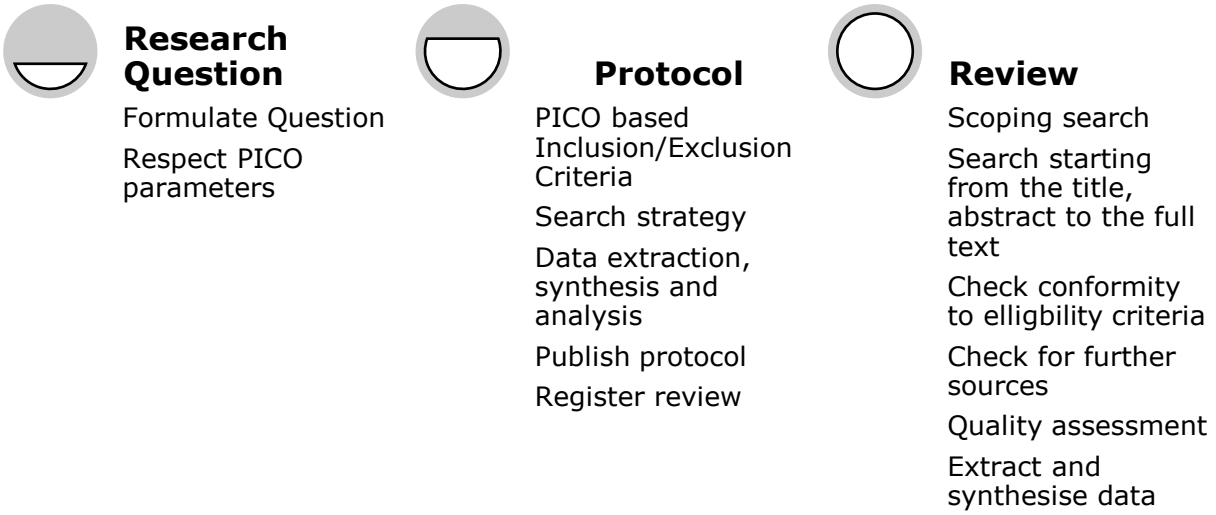


Figure 2.4 Overview of Systematic Literature Review Process (Adapted from Cullum and Dumville, 2015)

Data synthesis in systematic reviews can be either classified as aggregative (i.e. to test predefined concepts using predefined methods) or configurative (i.e. the interpretation of information to generate new concepts). The form of synthesis depends on the type of review being carried out. For example, in the case of a meta-analysis, a quantitative stance is taken to aggregate findings from the selected studies (Gough et al., 2012). Other reviews which employ a mixed method approach in a systematic review combine both quantitative and qualitative approaches.

#### 2.4.3.1 Rationale for the use of systematic literature review in this study

Commencing the study with a systematic review was considered appropriate since it coincided with the rollout of the OPAT service in Malta. Whilst acknowledging that OPAT services are likely to be setting-specific (since they are influenced by their own work systems and external environments), this exercise aided in gathering information about the 'best' global practices which could potentially be implemented locally. This was done using a narrative synthesis to summarise the findings of multiple studies in a textual format. In addition, carrying out a further level of meta-analysis, using SEIPS 2.0 as a framework to support data extraction and synthesis allowed the research team to validate the model for use in later

stages of the study. For this reason, this review used both aggregative and configurative approaches.

Since its introduction in the 1970s (Rucker and Harrison, 1974), OPAT has diversified to cater for a broad spectrum of cases including various patient groups, different infective conditions using various antimicrobial agents in a variety of settings (Smismans et al., 2018). Variances in practices have made it difficult to standardise and measure service outcomes and hence conduct meaningful auditing exercises (Chapman et al., 2019). This disjointed method of reporting outcomes was highlighted in a systematic review published by Sriskandarajah et al. (2017). The authors struggled to identify common outcome measures for all the studies and thus the number of indicators had to be broadened including the cure rate, readmission rate, adverse events, mortality, unplanned telephone calls and unscheduled staff outreaches. This lack of clarity in reporting is exacerbated by the fact that research teams also opted for different scales to measure the same outcomes including adverse events and readmission rates thus making comparisons impractical. It can be concluded that outcome measures hold true for the population under study in a specific setting and thus lack in transferability and generalisability. This is a limitation affecting OPAT research globally, making it difficult for service providers to benchmark their service against others. One suggestion for resolving these issues is the compilation of national databases to harmonise the data being collected (Chapman et al., 2019). However, considering the complexity of OPAT, it is only in theory that databases offer a 'one size fits all' solution for data collection.

This challenge is recognised in the recent UK OPAT guidelines published by Chapman and colleagues (2019). Previous categorisation distinguished between patient infection (cure/improved/failure) and OPAT specific (success/partial success/ intermediate/failure) outcomes. However, when registering patients in the national British repository, it was noticeable that providers were finding it difficult to assign outcome terms to individual patient episodes. For example, a deceased patient was considered a 'failure' both in relation to infection and OPAT specific outcomes. Arguably, this cannot hold true for a patient using the service for palliation or suppression purposes. To address cases like these, the new guidelines proposed a shift towards patient specific treatment aims, although this has yet filtered into practice, and clarity is still lacking in OPAT literature. Given

that global understanding of OPAT outcomes is weak, and that such outcomes arise as a result of OPAT system interactions, using a Human Factors framework to support data extraction and synthesis was considered useful.

Given that Human Factors approaches are rare in healthcare generally, the initial scoping search did not generate content formally defined as Human Factors. The content was therefore analysed based on the premise that the papers represented SEIPS 2.0 was chosen as the model (Holden et al., 2013), allowing the research team to also explore the suitability of the tool for investigating the Maltese OPAT context.

### 2.4.4 Human Factors and Ergonomics based methods

#### 2.4.4.1 Hierarchical task analysis (HTA)

Hierarchical task analysis (HTA) was first developed in the 1960s (Annett and Duncan, 1967) to address limitations inherent to the analysis of complex non-repetitive cognitive laden tasks synonymous to the steel and petrochemical industries (Annett, 2003). HTA was proposed as a means of assessing human activity when propelled by a 'purpose' within the context of an organisation or system (Shepherd, 2000). In fact, HTA draws from systems thinking whereby systems have purposes whilst tasks have goals, but both are influenced by systemic factors derived from a hierarchy of subsystems (Shepard, 2000). Annett also remarked the influence the concept of goal driven feedback loops has on HTA, which identifies the 'operation' as the unit of analysis (Annett, 2003). HTA sets itself apart from other forms of task analysis since it aims to (i) understand the link between work activity and safety in tasks and (ii) develop an empirical understanding of teamwork (Naweed et al., 2018). In HTA, tasks are decomposed from the overall 'goal' into 'sub goals' which together ensure the performance of the task led by 'plans' (Shepherd, 2000). HTA thus differs from other task analysis techniques including cognitive task analysis (where the focus is on the cognitive aspect of the task, or goal directed task analysis, which focuses on the situation awareness requirements necessary to complete a task (Naweed et al., 2018). In time the use of HTA has shifted to cover a variety of research fields including healthcare as exemplified by its application to medicine management and surgery (Hignett et al., 2019).

#### 2.4.4.1.1 Rationale for using HTA in this study

It was evident from the thematic analysis and SEIPS-based modelling performed in Chapters 5 and 6, that recurrent barriers to service success were inherent to the suboptimal referral processes, which lacked standardisation. Aspects such as communication, selection of the 'right' patient, delivery of information, screening for nosocomial infections, discharge procedures (amongst others) were occasionally performed or completely forgone to the detriment of the patient's quality of care. This lack of standardisation was further complicated by the numerous medical and surgical care teams who could refer the patient as well as the dynamic roles taken up by the members of the OPAT team whereby for example an OPAT nurse could be responsible for the pre-assessment check on one day, and the outreach administrations on another. For these reasons, it was felt necessary to perform a hierarchical task analysis based on the tasks reported by the OPAT team in relation to the referral process i.e. commencing from the moment the patient is identified by the referring care team to their transition to the home environment.

### 2.4.4.2 SEIPS-based modelling

#### 2.4.4.2.1 Rationale for using SEIPS-based modelling in this study

At face value, OPAT services are considered to be a safe and effective solution to providing care to clinically stable patients who are diagnosed with an infectious disease. Despite this, since its inception in the early 1970s, there are still reports of readmissions and other adverse events despite the continuous advancements in technology and patient inclusion criteria in this field. This wavering reassurance in OPAT practices reinforced the need to use a new approach to address safety and quality in OPAT. Considering the breakthroughs being observed in patient safety using a systems approach (Carayon et al., 2020), the SEIPS model was bespoke to understanding the underlying factors resulting in such adverse outcomes. Despite the lack of literature which directly addresses Human Factors and systems thinking, the content of studies published in the field of OPAT was considered to represent the work-as-reported by the practitioners and not necessarily the work-as-done (Hollnagel, 2015). The second version of the SEIPS model was selected

for this research since it was the most recent modification of the model available at the time of this work's initiation (October 2016). Data extracted from the systematic review (Chapter 3), the cross-sectional survey (Chapter 5) and the focus group session (Chapter 6) were categorised according to the components of the SEIPS model namely the work system, processes and outcomes. The model generated from the systematic review served as a baseline (reflective of OPAT services rendered internationally) for comparison with the model based on the local service provision (Chapters 5 and 6). Discrepancies between the two models which reflected solutions to the current local barriers, supplemented strategies derived from this research to inform system redesigns for the Maltese service (Chapter 7).

## 2.5 Sampling

In quantitative research, sampling is divided into two categories namely non-probability and probability sampling, whereby the latter uses random methods of selecting participants (i.e. participants an equal chance of being selected) thus reducing bias and increases the likelihood of generalisability. Examples of non-probability sampling techniques include convenience, quota and purposive whilst probability sampling techniques include simple random, stratified random, cluster and systematic designs (Fisher and Fetney, 2016; Palinkas et al., 2019). In quantitative research it is important that samples are chosen randomly, and a power calculation is carried out to make sure it is representative of the population (Onwuegbuzie and Collins, 2017). This does not apply for qualitative research.

Sampling strategies used in qualitative research are termed non-probabilistic since randomisation is not used. Purposive sampling is the mainstay technique to demonstrate specific cases or issues to achieve saturation i.e. no new information is identified in the data analysis stage and thus collection may be terminated (Faulkner and Trotter, 2017; Palinkas et al., 2015). This type of sampling also includes quota sampling and maximum variation sampling. Apart from purposive sampling, there are three other sampling strategies that can be used when performing qualitative research namely convenience, theoretical and snowball

sampling (Fisher and Fetney, 2016). Description of all sampling strategies mentioned above is provided in Table 2.9.

Table 2.9 Sampling strategies used in quantitative and qualitative research

| **Examples of sampling strategies used in quantitative research** | |
|---|---|
| Random sampling | Equal chance of a participant in a population of being selected and is directly linked to the external validity (i.e. generalisability) of the study. |
| Stratified random sampling | Participants are placed in homogenous groups then randomly selected from each. |
| Cluster sampling | Groups of people rather than individuals are selected based on simple or stratified random sampling. |
| Systematic sampling | Participants are selected at a fixed interval. |
| **Examples of sampling strategies used in qualitative research** | |
| Convenience sampling | Selection based on participant's availability in terms of access and location. |
| Purposive | Selection based on relevance to predefined research aims and questions.<br>Quota: researcher decides the number of participants and the element of interest. |

| | |
|---|---|
| | Maximum variation: researcher ensures that the entire spectrum is represented by the cohort. |
| Snowball | The participants lead the researcher to more participants for the study. |
| Theoretical | Selection starts from a homogenous group and is then propagated to a heterogenous group. |

In this study, a multilevel selection of participants was considered since the people recruited for the focus group i.e. the OPAT team (Chapter 6) did not correspond to the patient group recruited and analysed in the other phases (Chapter 4 and 5). However, these participants corresponded to the populations they represented and thus no sampling strategies were required.

## 2.6 Quality

Mixed methods design encompasses both quantitative and qualitative techniques therefore quality must be ensured throughout with observance to the standards expected from both research paradigms. On one side, quantitative research techniques must consider rigour i.e. internal validity, reliability, generalisability and sampling strategies (Table 2.10).

Table 2.10 Quantitative quality measures of rigour

| **Quality Measure** | **Categories and Descriptions** |
|---|---|
| Validity | Face: first glance indicates outcome measure is relevant. |
| | Content: outcome measure includes content which is relevant. |
| | Construct: outcome measure ties in with previous studies. |
| | Criterion: outcome measure is in line with a recognised standard measure. |
| Reliability | Test-retest: repetition after a short period of time renders same result. |
| | Internal: consistency within a tool. |

With respect to qualitative data, one refers to the term trustworthiness which is composed of four main factors namely dependability, credibility, transferability and confirmability (Hadi and Closs, 2016; Plummer, 2017b) as seen in Table 2.11.

Table 2.11 Qualitative quality measures of trustworthiness

| **Quality Criteria** | **Description** |
|---|---|
| Dependability | Ability for another research group to repeat the study. |
| Credibility | To which length the results capture the reality. |
| Transferability | Ability to generalise results from the study to another study of similar context. |
| Confirmability | Confirm that the results stem from the study rather than the researcher's bias. |

Research validity and credibility have been shown to be more pronounced when multiple forms of data are derived from different methods (Lewith and Little, 2013).

### 2.6.1 Quality of the systematic literature review (Chapter 3)

The evaluation of the quality of the systematic literature review is not optimal. However, certain measures were enforced to ensure quality including:

1. Assessing their methodological quality: since the quality of the review was highly dependent on the studies included, their assessment was of utmost importance.
2. Following the PRISMA statement: this guided tool aided the reporting of the systematic literature review.
3. Registration of the protocol in PROSPERO®: registration ensured that the review was novel and of high quality.

### 2.6.2 Quality of the prospective observational cohort study (Chapter 4)

1. Face/content and internal validity: a panel of experts from different professional backgrounds in healthcare were asked to assess the tool in terms of its face, content, construct and predictive validity (Polgar and Thomas, 2013).
2. Reliability and feasibility test: a pilot test was carried out to ensure that the database's criteria captured data which was present in all case notes (handwritten/electronic) about enrolled patients.

### 2.6.3 Quality of the cross-sectional survey (Chapter 5)

In this study, the validity of the tool was ensured through:

1. Face and content validity: a panel of experts from different professional backgrounds in healthcare were asked to assess the tool in terms of its face, content, construct and predictive validity (Polgar and Thomas, 2013).

2. Reliability: a test-retest process was applied to ensure the tool generated similar results after a short period of time. The findings were correlated not only for the same participant (intra-observer reliability) but also between participants (inter-rater reliability) in both English and Maltese (Polgar and Thomas, 2013; Calnan, 2013)
3. Dependability and credibility: auditability through the clarity of one's procedure ensured that other research teams could repeat the design (Polgar and Thomas, 2013).
4. Confirmability: the design resulted in triangulation and confirmation of the results thus reducing researcher bias (Renz et al., 2018; Forero et al., 2018).
5. Credibility: a pilot study was performed prior to starting the study to ensure the results generated are true.

### 2.6.4 Quality of the focus group method

In this study, the trustworthiness of the focus group was ensured through (Plummer, 2017b):

1. Dependability and transferability: documentation based on the methods used enabling other research teams to reproduce the study phase.
2. Credibility: the utilisation of a piloted and validated topic guide which was designed based on findings in the literature.
3. Confirmability: disclosure of researcher background was important to identify possible areas of bias.

## 2.7 Bias

The importance to identify and address elements of bias is paramount when ensuring the legitimacy of the effects of an intervention. Some bias is related to specific studies e.g. randomised controlled trials might be subject to selection,

performance and/or researcher/participant bias (Lewith and Little, 2013; Smith and Noble, 2014). For example, the utilisation of the ROBIS tool is good practice to eliminate and/or identify all sources of bias in a systematic review (Whitting et al., 2016).

In social science research, it is difficult to detach the researcher from the subject in terms of design, practice and inferences. The level of bias is acceptable when strategies are put in place to eliminate subjectivity e.g. reflexivity i.e. reflecting on one's subjectivity to ensure high quality research without influencing the given scenario (Moon et al., 2019) as shown in Table 2.12.

Table 2.12 Bias inherent to different stages of the research process

| **Phase of the study** | **Type of Bias** | **Explanation** |
|---|---|---|
| Design e.g. sampling | Selection bias | Randomisation of participants is hindered (Rouslton and Shelton, 2015); sampling frame does not cover the population; applicable if a sample of the population cannot be contacted or refuse to participate (Kumar, 2019); snowballing can introduce bias since the participants are not randomly chosen (Onwuegbuzie and Collins, 2017), selection of article in a systematic literature review (Patel et al., 2019). |
| Researcher characteristics | Investigator bias | When the researcher influences the scenario or participants involved (Rouslton and Shelton, 2015); when a view is endorsed by the moderator (Plummer, 2017a). |
| | Detection bias | When researcher is selecting the relevant articles for a systematic review (Patel et al., 2019). |
| Participants' attitudes | Reactive bias | The Hawthorne effect i.e. change in behaviour of a person because s/he is being observed (Kumar, 2019). |

| | | |
|---|---|---|
| | Recall bias | Patients' opinion of an outcome is influenced by an occurrence happening at the same time (Pannucci and Wilkins, 2010) (Althubaiti, 2016). |
| Research process | Response bias | A flaw in an instrument hinders data collection; Ambiguous, leading or double-barrelled questions (Kumar, 2019). |
| Data analysis and interpretation | Confirmation bias | Researcher's opinion influences the data gathered to aid prove a hypothesis (Rouslton and Shelton, 2015). |

Throughout this study, strategies were put in place to minimise the potential bias at each phase of the research process as described in Table 2.13.

Table 2.13 Strategies used to minimise bias in the various phases of the study

| **Types of Bias** | **Strategies to minimise bias** |
|---|---|
| Design | • Sampling: the entire population of enrolled patients and OPAT team were used in the study phases thus eliminating selection bias.<br>• Response: for the cross-sectional survey study, participants were phoned three times on different occasions and at different times of the day to ensure maximal response rate; for the focus group, a date and time suitable to all participants was scheduled to ensure maximal attendance. |
| Researcher characteristics | • Despite the principal researcher's professional involvement with the other members of the OPAT team, bias during the focus group session was minimised through the use of a topic guide and the presence of an assistant moderator. |
| Participants' attitudes | • The dichotomous design of the survey for the cross-sectional survey minimised reporting bias by the principal researcher when reporting participant answers. |

| | |
|---|---|
| | • Patients older than 80 years of age were excluded from the cross-sectional survey to avoid recall bias and this was confirmed during the pilot study. |
| Research process | • All the tools used in the study including the survey for the cross-sectional survey and the topic guide for the focus group were piloted, translated and validated by a panel of independent experts. |
| Data collection, analysis and interpretation | • Two reviewers were used during the extraction, synthesis and quality evaluation processes of the systematic literature review to minimise bias.<br>• The ROBIS tool was used to ensure negligible bias in the review.<br>• Field notes and audio recordings were taken during the telephone calls and focus group session to avoid memory bias; attention bias was eliminated during the focus group session by using a topic guide.<br>• Triangulation ensured that bias from one method e.g. survey is minimised by the use of another method e.g. focus group. |

## 2.8 Visual representation of this study's research phases

Figure 2.5 illustrates the worldviews and methods used for each phase of the research.

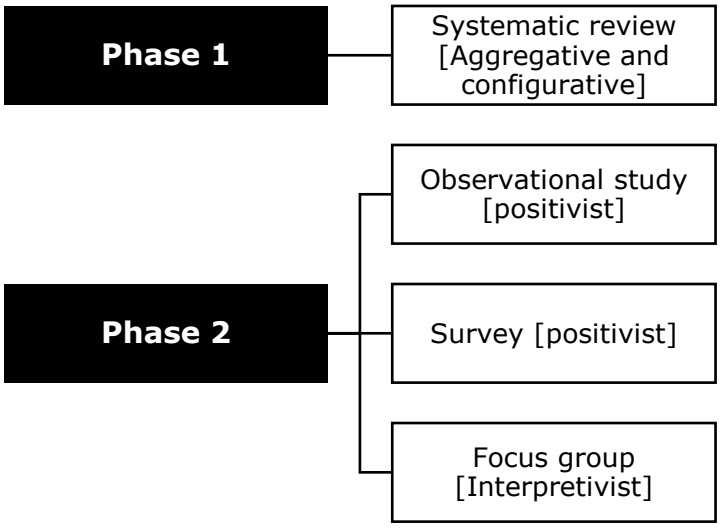


Figure 2.5 Visual representation of research approaches in this study

## Chapter 3

## Systematic literature review

This chapter provides an in-depth description of the steps taken to conduct a PROPSERO-registered systematic literature review. The aim of the review was to verify the amenability of a Human Factors tool namely the SEIPS 2.0 model to global OPAT services. The categorisation of data considered as 'work-as-reported' according to the components of the SEIPS model enabled the identification of barriers and facilitators which influenced service delivery. This model would then serve as a baseline to which the local systems model could be compared.

## 3.1 Introduction

### 3.1.1 Systematic Review

Systematic reviews are notable for having a detailed plan and search strategy decided upon *a priori*, with the aim of reducing the inherent bias, capturing all the relevant literature and to appraising its quality before synthesising the data. This robust approach means that systematic reviews are stand-alone pieces of research but can become even more valuable if subjected to further analysis for example, meta-analysis of statistical data. For this reason, systematic reviews are the foundation of evidence-based healthcare (Munn et al., 2018). Systematic reviews are built on three pertinent phases namely (Xiao and Watson, 2019):

1. Planning the review: identifying and framing the problem, designing a review protocol and validating it.
2. Conducting the review: searching the literature, applying the inclusion/exclusion criteria, appraising the quality and extracting, analysing and synthesising the data.
3. Reporting the review: reporting the results.

In this study we have considered the published documents to be (in Human Factors terms) 'work-as-reported'. We have used this as a basis for generating research data using the SEIPS 2.0 model as a systems analysis framework.

### 3.1.2 Rationale

An initial scoping search indicated an almost complete absence of literature concerning a consideration of Human Factors relating to OPAT service delivery. For this reason, this part of the study set out to identify gaps in the literature which would eventually shape the later stages of this research project.

### 3.1.3 Study aims and research questions

The aims of this review were (i) to critically appraise, synthesise and present the available evidence relating to adult OPAT services (ii) to explore if the OPAT service is amenable to analysis using the SEIPS 2.0 framework.

To execute the above aims, this phase sought to answer the following research questions namely:

1. Which predominant elements characterise adult OPAT services?
2. What is the methodological quality of the literature in relation to adult OPAT services?
3. Can Human Factors be extracted from literature reporting OPAT services using the SEIPS model?
4. What are the benefits of and barriers to OPAT provision?

## 3.2 Method

### 3.2.1 Protocol

In April 2017, preliminary meetings were carried out with the supervisory team to discuss which research questions the review was designed to answer using a pre-set PICO model and inclusion/exclusion criteria. During this phase, a systematic literature review protocol was drawn up using the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) checklist (Moher et al., 2015). Further guidance was attained from the Centre for Reviews and Dissemination (CRD)(2009) guidance on systematic reviews and the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, 2011). On completion, the protocol was submitted to Prospero® and official registration was granted on the 17th July 2017 (CRD42017071901) (Bugeja et al., 2017)(Appendix 3.1).

### 3.2.2 Inclusion and Exclusion Criteria

3.2.2.1 Population

Patients, carers and healthcare professionals (HCPs) e.g. doctors, nurses, pharmacists, social workers etc. involved at any stage of the service delivery were

included. Any studies solely relevant to paediatric population (under the age of 18 years) as the patient cohort were not included since such a service is not available locally.

#### 3.2.2.2 Types of Interventions

All studies which reported the development, implementation and/or evaluation of an OPAT service were included. Studies which were not described from a Human Factors point of view or referred to Human Factors were also included.

#### 3.2.2.3 Type of Comparators

There were no comparators in this systematic literature review since all OPAT models of care were taken into consideration.

#### 3.2.2.4 Outcomes

Studies which researched any outcome measure of the OPAT service during the design, implementation, and delivery phases were included.

#### 3.2.2.5 Study Design

Study design was not used as an exclusion criterion. Peer-reviewed primary research studies, systematic reviews, meta-analysis and studies applying quantitative, qualitative or mixed methods were included. Only abstracts, letters and grey literature were not included.

#### 3.2.2.6 Language

Only literature written in the English language was considered.

3.2.2.7 Capture Dates

The capture dates were set from January 2000 to June 2019 with the aim of capturing research which describes the discipline of Human Factors in the context of patient safety literature. Prior to this capture timeframe, Human Factors research mainly focused on patient handing, musculoskeletal disorders etc.

### 3.2.3 Search Strategy, screening and selection

To determine the search string which would be most appropriate for this review, a scoping search of MEDLINE (U.S. National Library of Medicine, 2017), and Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO Publishing, 2017) was carried out using the following keywords. Keywords were identified from MeSH headings, titles, abstracts, keyword sections and references to formulate the final search string as shown in Table 3.1.

Table 3.1 Search terms utilised to generate the final search string

| **Core term** | **Sub-terms** |
|---|---|
| **Human Factors** | 1.1 human factor* |
| | 1.2 ergonomic* |
| | 1.3 task analysis |
| | 1.4 system* analysis |
| | 1.5 patient safety |
| | 1.6 1.1 OR 1.2 OR 1.3 OR 1.4 OR 1.5 |
| **Antibiotics** | 2.1 anti-biotic* |

| | |
|---|---|
| | 2.2 antibiotic* |
| | 2.3 anti-bacterial* |
| | 2.4 antibacterial* |
| | 2.5 anti-microbial* |
| | 2.6 antimicrobial* |
| | 2.7 anti-infective* |
| | 2.8 2.1 OR 2.2 OR 2.3 OR 2.4 OR 2.5 OR 2.6 OR 2.7 |
| **OPAT setting** | 3.1 ambulatory |
| | 3.2 home |
| | 3.3 outpatient |
| | 3.4 out-patient |
| | 3.5 3.1 OR 3.2 OR 3.3 OR 3.4 |
| **Administration** | 4.1 intravenous |
| | 4.2 parenteral |
| | 4.3 4.1 OR 4.2 |
| **Final search** | 1.6 AND 2.8 AND 3.5 AND 4.3 |

The final search string was the following "1.6 AND 2.8 AND 3.5 AND 4.3." The search string was applied to four databases including MEDLINE (U.S. National Library of Medicine, 2017), CINAHL (EBSCO Publishing, 2017), International Pharmaceutical Abstracts (IPA) (EBSCO Publishing, 2017) and PsychINFO (APA, 2017). Titles and abstracts were evaluated against the set criteria by two independent reviewers. Any inconsistencies amongst the two reviewers were resolved by consensus. Reference lists were looked through to pick up further studies which were worth considering. Full text reviews were carried out as the final step in the selection process.

### 3.2.4 Data extraction

A data collection tool was constructed based on recommendations and guidance material on critical appraisal tools provided by the Joanna Briggs Institute (2017), CRD (2009), Cochrane Public Health Group (Higgins and Green, 2011) and the Cochrane guidance (Stovold et al., 2014).

The tool was designed to extract components of the study in terms of publication, participants, interventions and outcomes of the study as shown in the Table 3.2 and Appendix 3.2.

Table 3.2 Data extraction tool

| **Category** | **Details** |
|---|---|
| **Publication details** | Principal Author |
| | Year |
| | Publication type e.g. article, book |
| | Type of study e.g. randomised control, control before and after, interrupted time series, other |
| | Aim(s) |
| **Participation Details** | Number of participants |
| | Age |
| | Sampling strategy employed |
| | Final sample is representative of the population being studied |
| | Disease state |
| | Recruitment procedure |
| | Inclusion/Exclusion criteria utilized |
| **Intervention Details** | Focus |
| | Type of OPAT |
| | Duration |

| | |
|---|---|
| | Setting/Country |
| | Providers |
| **Outcome Details** | Outcomes/Results |
| | Details of statistical analysis |
| | Specific mention of Human Factors |

Moreover, the tool integrated the extraction of the SEIPS 2.0 model components i.e. work system, processes and outcomes for the OPAT context. To this aim two additional fields were added to the data extraction tool: one for Human Factors attributable to HCPs and the other for patients. When studies did not mention Human Factors directly (which was generally the case), data extraction was solely dependent on the subjective opinion of all reviewers. An example of the extracted data is shown in Figure 3.1. In the event of a disagreement, discussions were carried out to reach consensus.

| **Principal Author** | Perez-lopez J | Suleyman G | Al alawi | Hernandez |
|---|---|---|---|---|
| **Human factors related to healthcare professional** | **Task:** the need for a stringent patient selection by health professionals; **Person:** knowledgable about home based treamtent; **Task:** individual assessment to include clinical examination and testing was reported | **Task:** careful selection and close monitoring of patients by the ID physician | **Organisation:** Drop in readmissions were seen once the OPAT clinic started operating as well as well as a reduction in bed days for the hospital thus clearing space for new admissions and reducing cost burdens | **Task:** patient selection criteria used in this study although biased ensures the success of the service, **Organisation:** no formal guidance exists for this patient cohort thus this study's findings are an indication that healthcare systems can benefit from a formal OPAT selection criteria (98% of courses completed) |

Figure 3.1 Example of Human Factors data extraction using SEIPS model

### 3.2.5 Quality assessment

A quality assessment tool was designed based on the guidance provided by the Critical Appraisal Skills Programme (CASP) tools (Stovold et al., 2014), as well as an article by Young and Solomon (2009). The objectives, design, recruitment, data collection, ethics, results, bias, and Human Factors aspects of all studies were assessed for methodological quality during the process of data extraction. The studies were then reviewed by two independent reviewers and any discrepancies resolved through discussion. Reviewers rated each question using 'yes', 'no', unclear', 'not applicable' and 'partial' as options. The tool consisted of the questions presented in Table 3.3 and Appendix 3.3.

Table 3.3 Methodological quality assessment tool

| **Quality assessment questions** |
|---|
| 1. Was there a clear statement of the aims/ objectives of the research? |
| 2. Was the research design appropriate to address the aims of the research? |
| 3. Was the recruitment strategy appropriately described? |
| 4. Were the data collected in a way that addressed the research issues? |
| 5. Were participant characteristics described in detail? |
| 6. Have ethical issues been taken into consideration? |
| 7. Is there a clear statement of findings? |
| 8. Did the authors mention facets of the service which can be considered as Human Factors? |
| 9. Were failures of the service mentioned? |
| 10. Did the authors declare that there were no conflicts of interest or bias? |

### 3.2.6 Data synthesis

A narrative synthesis was employed for this review due to the heterogeneous nature of the study designs included. Initially, the OPAT service system entities were categorised according to the SEIPS 2.0 work system model.

The factors pertaining to each work system entity potentially can interact with one or more factors from other elements when work processes are undertaken. This complex network of interactions underpins the system outcomes. Despite the absence of any direct mention of Human Factors (or related term), studies were considered to represent 'work-as-reported' and data was extracted based on the subjective opinion of the researchers in identifying system factors and likely interactions.

Factors could frequently be assigned to more than one entity. As with any complex system, OPAT factors were frequently assigned to more than one category. For example, the work system component 'person' could refer to the patient receiving the service. In this case, one 'person factor' would be the relationship between a patient's disease state and the suitability of the treatment selected.

Similarly, the choice of antibiotic was considered to relate to 'task' (selecting the antibiotic), 'person' (having the skills and knowledge required to make this choice) and 'tools and technology' (the antibiotic itself) factors. Another example was the enforcement of standardised criteria which could be considered as an 'organisational', 'person', 'tool' and 'internal environment' factor due to local need to enforce policies, patient eligibility in relation to these criteria and whether or not the patient's residence meets the requirements as described in the criteria respectively. Having assigned factors in this way, interactions were identified and tabulated. The strategy for data synthesis is shown in Figure 3.2. The principal researcher and another reviewer with an expertise in Human Factors carried out the synthesis. Any inconsistencies amongst the two reviewers were resolved by consensus.

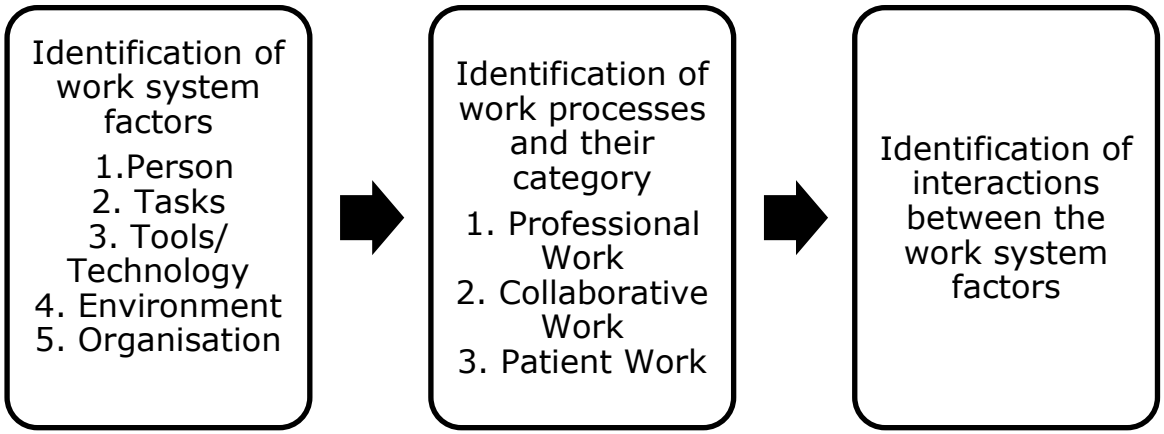


Figure 3.2 Data synthesis strategy

## 3.3 Results

### 3.3.1 Search results

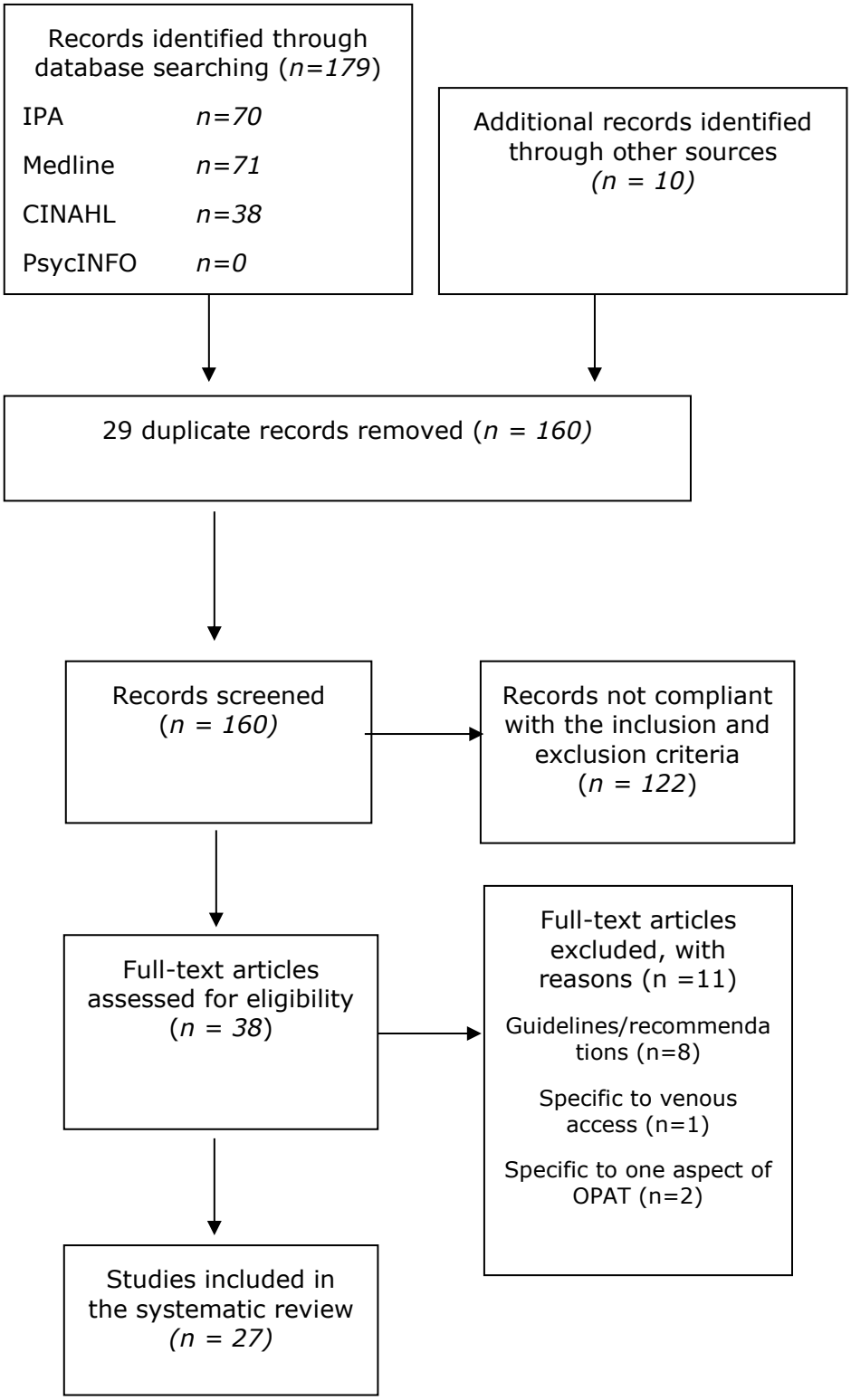


Figure 3.3 Prisma chart portraying the search process

### 3.3.2 Study characteristics

#### 3.3.2.1 Study Selection

As shown in Figure 3.3, out of a total of 189 publications, 179 articles were identified from the four main database searchers whilst the other 10 publications were identified from the reference lists of these publications. From the 189 publications, 29 were duplicates whilst 122 articles were not in compliance with the pre-set criteria. The remaining 38 articles were assessed but 11 full texts were removed based on relevance. This process was fulfilled to completion leaving a total of 27 studies for critical appraisal and extraction. References for the included and excluded studies can be found in Appendices 3.4 and 3.5.

#### 3.3.2.2 Study Publication Dates and Designs

The final studies spanned over an eighteen-year timeframe, with the first study published in 2001 (Bernard et al., 2001) and the last in 2019 (Keller et al., 2019a, Keller et al., 2019b). Notwithstanding that most popular study design was the retrospective cohort study, other authors used a controlled quasi experiment (Keller et al., 2013), consensus statement (Gilchrist et al., 2008), prospective investigation (Gardiol et al., 2016; Perez-Lopez et al., 2008; Goodfellow et al., 2002) or retrospective cross-sectional design (Suleyman et al., 2017; Al Alawi et al., 2015; Muldoon et al., 2015; Lane et al., 2014). Most research teams used patient files, case notes and electronic databases as their main sources of data except for two studies which used a survey (Muldoon et al., 2015; Lane et al., 2014).

#### 3.3.2.3 Study sampling

Purposive sampling was the most prevalent sampling strategy used in the publications except for two studies which opted for an opportunistic sampling strategy (Muldoon et al., 2015; Lane et al., 2014). The size of the cohort under

study was determined by factors instated by the authors. For example, the patient's age (Perez-Lopez et al., 2008; Cox et al., 2007), patient's residence (Hernandez et al., 2016) or disease state (Al Alawi et al., 2015; Seaton et al., 2011; Htin et al., 2013). These measures resulted in varying cohort numbers irrespective of the timeframe used. For example, despite sharing a common timeframe (n=9 years), Htin et al. (2013) recruited 68 patients whilst Barr et al. (2012) recruited 2233 patients.

On the other hand, more than half of the studies (n=16) researched the provision of the OPAT service to a heterogeneous cohort suffering from various disease states (Keller et al., 2013; Perez-Lopez et al., 2008; Suleyman et al., 2017; Hernandez et al., 2016; Muldoon et al., 2015; Williams et al., 2015; Cox et al., 2007; Al Ansari et al., 2013; Lane et al., 2014; Barr et al., 2012; Goodfellow et al., 2002; Esposito et al., 2004; Miron-Rubio et al., 2016; Hitchcock et al., 2009; Gardiol et al., 2016; Durojaiye et al., 2018).

#### 3.3.2.4 Study setting

Settings varied in terms of the country where the study took place, the study timeframe and the delivery mode that was selected for the service. One study took place in Australia (Htin et al., 2013), eight in the United States of America (Suleyman et al., 2017; Keller et al., 2013; Cox et al., 2007; Hernandez et al., 2016; Esposito et al., 2004; Williams et al., 2015; Keller et al., 2019a; Keller et al., 2019b), one in Canada (Goodfellow et al., 2002), two in East Asia (Al Alawi et al., 2015; Al Ansari et al., 2013) and 13 in Europe (Perez-Lopez et al., 2008; Gilchrist et al., 2008; Miron-rubio et al., 2016; Duncan et al., 2013; Barr et al., 2012; Mackintosh et al., 2011; Esposito et al., 2004; Seaton et al., 2011; Hitchcock et al., 2009; Twiddy et al., 2018; Gardiol et al., 2016; Berrevoets et al., 2018; Durojaiye et al., 2018).

The OPAT model evaluated in each article varied from a standalone model as opposed to more than one model concomitantly (Hitchcock et al., 2009; Bernard et al., 2001; Mackintosh et al., 2011; Esposito et al., 2004; Lane et al., 2014; Muldoon et al., 2015; Keller et al., 2013). Single model studies focused on either the home nurse assisted model (Htin et al., 2013; Perez-Lopez et al., 2008; Cox

et al., 2007; Hernandez et al., 2016; Barr et al., 2012; Miron-Rubio et al., 2016; Goodfellow et al., 2002; Gilchrist et al., 2008; Keller et al., 2019a; Keller et al., 2019b; Berrevoets et al.; 2018), or the infusion centre model (Suleyman et al., 2017; Al Alawi et al., 2015; Al Ansari et al., 2013) or the home self-administration method (Williams et al., 2015). Whilst the classification of the OPAT model was based on the reviewers' opinion if not reported by the authors, extraction was impacted by the lack of information about which model was investigated and the potential lack of distinction between the two home models i.e. self-administration and visiting-nurse model. Table 3.4 portrays the extracted study characteristics described in Sections 3.3.2.2 to 3.3.2.4.

Table 3.4 Study characteristics of the selected articles

| | |
|---|---|
| **Publication Date** | Oldest study: Bernard et al. (2001)<br><br>Most recent: Two studies published by Keller and colleagues in 2019 (Keller et al., 2019a; Keller et al., 2019b) |
| **Study Design** | Most studies used a retrospective cohort design except for:<br><br>Controlled quasi experimental evaluation: Keller et al. (2013)<br><br>Expert panel: Gilchrist et al. (2008) produced a consensus statement which was used to map and identify risks associated with OPAT service delivery.<br><br>Prospective Investigative Design: used by Perez-Lopez et al. (2008), Gardiol et al. (2016) and Goodfellow et al. (2002)<br><br>Retrospective cross-sectional design: Suleyman et al. (2017), Al Alawi et al. (2015), Muldoon et al. (2015) and Lane et al. (2014) |
| **Population demographic** | Opportunistic sampling: Muldoon et al. (2015) and Lane et al. (2014)<br><br>Purposive sampling: employed for all other studies. |
| **Data Collection** | Retrospective retrieval of data by using:<br>Survey: Muldoon et al. (2015) and Lane et al. (2014) |

| | |
|---|---|
| | Patient files, case notes and/or accessing an electronic database: used for all other studies |
| **Patient Cohorts** | Specific patient cohort: the homeless (Hernandez et al., 2016), elderly (Perez-Lopez et al., 2008; Cox et al., 2007)<br><br>Specific disease conditions: skin and soft tissue infections (Seaton et al., 2011; Al Alawi et al., 2015), bone and joint infections (Bernard et al., 2001; Mackintosh et al., 2011) or infective endocarditis (Duncan et al., 2013; Htin et al., 2013).<br><br>Broad disease conditions: remaining 16 studies |
| **Study timeframe** | A short time frame: 2 months (Gilchrist et al., 2008), 1 month (Lane et al., 2014)<br><br>A long-time frame: 9 years (Htin et al., 2013; Barr et al., 2012),12 years (Duncan et al., 2013) |
| **Study setting** | Australia (Htin et al., 2013),<br><br>USA (Keller et al., 2019a; Keller et al., 2019b; Suleyman et al., 2017; Keller et al., 2013; Hernandez et al., 2016; Cox et al., 2007; Williams et al., 2015; Esposito et al., 2004)<br><br>Canada (Goodfellow et al., 2002)<br><br>Europe (Twiddy et al., 2018; Gardiol et al., 2016; Berrevoets et al., 2018; Durojaiye et al., 2018; Gilchrist et al., 2008; Perez-Lopez et al., 2008; Barr et al., 2012; Seaton et al., 2011; Mackintosh et al., 2011; Duncan et al., 2013; Esposito et al., 2004; Miron-rubio et al., 2016; Hitchcock et al., 2009) |

| | |
|---|---|
| | East Asia (Al Alawi et al., 2015; Al Ansari et al., 2013) |
| **OPAT model** | Home-visiting professional (Htin et al., 2013; Perez-Lopez et al., 2008; Hernandez et al., 2016; Cox et al., 2007; Barr et al., 2012; Goodfellow et al., 2002; Miron-rubio et al., 2016; Gilchrist et al., 2008; Berrevoets et al., 2018; Durojaiye et al., 2018; Keller et al., 2019a)<br><br>Infusion centre model (Suleyman et al., 2017; Al Alawi et al., 2015; Al Ansari et al., 2013)<br><br>Multiple modes of delivery (Bernard et al., 2001; Keller et al., 2013; Muldoon et al., 2015; Lane et al., 2014; Mackintosh et al., 2011; Esposito et al., 2004; Hitchcock et al., 2009; Twiddy et al., 2018; Gardiol et al., 2016<br><br>Self-administration: Williams et al., 2015; Esposito et al., 2004 |
| **Sample Size** | Small samples: 43 patients (Hernandez et al., 2016), 82 patients (Goodfellow et al., 2002), 77 patients (Duncan et al., 2013)<br><br>Large samples: 4005 patients (Miron-rubio et al., 2016), 963 patients (Seaton et al., 2011) |

### 3.3.3 Methodological quality assessment

As can be seen in Figure 3.4, a positive general trend was gathered from the ratings given by the reviewers ('Yes' (Y), 'No' (N), 'Unclear' (U), 'Not Applicable' (N/A) or 'Partial' (P)) thus indicating a high level of quality. Of note, consensus was reached amongst the three reviewers. The question relating to the identification of system aspects that could be classified from a Human Factors point of view attained the highest positive score (27/27, 100%). This was followed by the question about the clarity of the findings with 26 out of 27 positive responses (96%) and with 25 out of 27 positive responses, the description of participant characteristics, appropriate data collection and clear statement of findings in relation to aims ranked the third. The 'not applicable' option was utilised once for a study when assessed about its recruitment strategy. For the other questions which received fewer positive assessments, there was a high proportion of partial rankings especially in terms of research design, declaration of conflicts and bias. In conclusion, the quality was deemed to be high. Results of the reviewers' assessments are described Table 3.5 below.

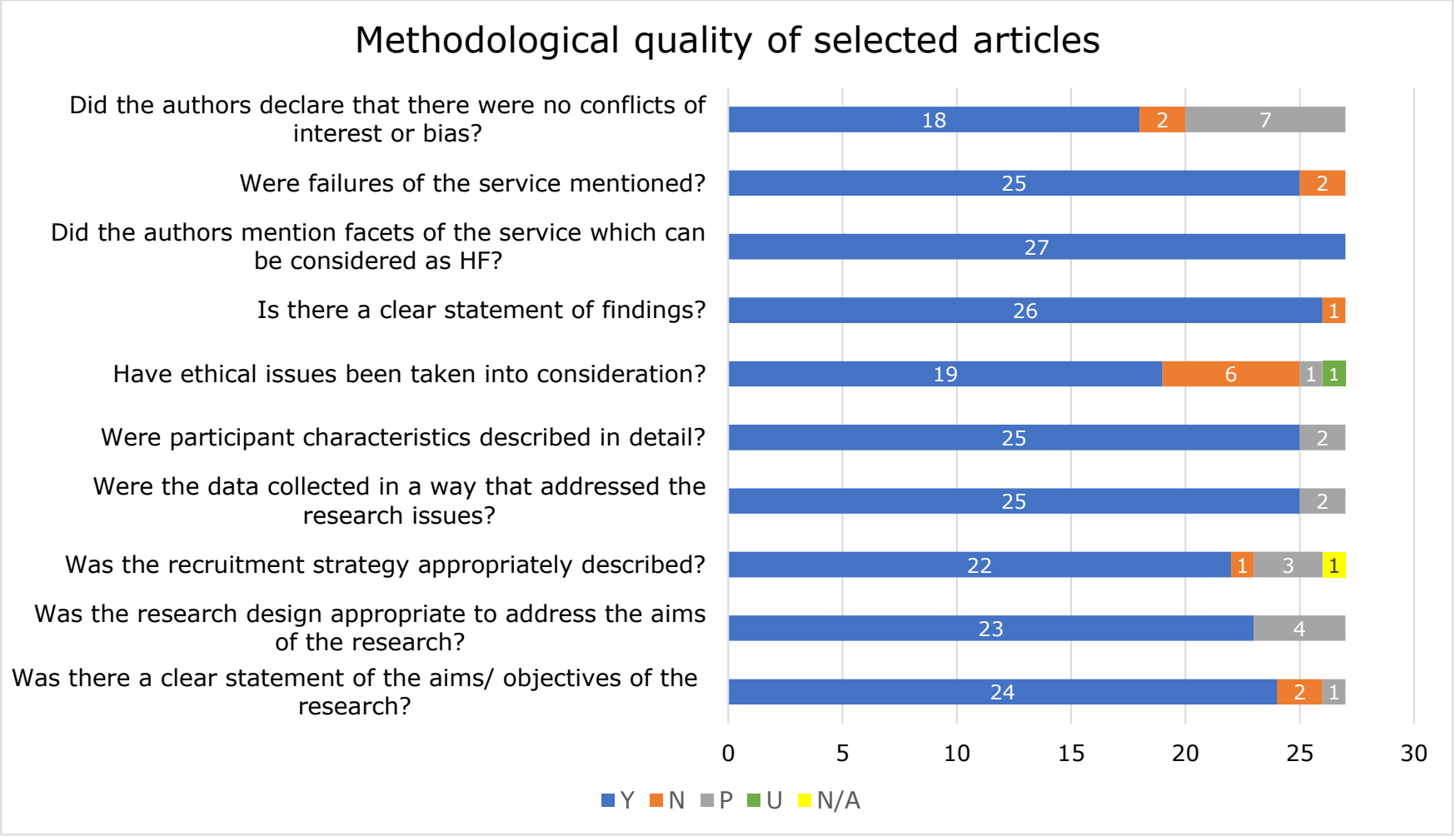


Figure 3.4 Stacked bar chart of the methodological quality

Table 3.5 The results of the final methodological assessments for the studies

| **Quality assessment criteria** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** | **25** | **26** | **27** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [Yes/No/Partial/Unclear/N/A] | Htin et al., 2013 | Keller et al., | Perez-Lopez et | Suleyman et al., | Al Alawi et al., | Hernandez et | Muldoon et al., | Williams et al., | Cox et al., 2007 | Al Ansari et al., | Lane et al., | Barr et al., 2012 | Goodfellow et | Duncan et al., | Esposito et al., | Mackintosh et | Miron-Rubio et | Bernard et al., | Gilchrist et al., | Seaton et al., | Hitcock et al., | Twiddy et al., | Gardiol et al., | Keller et al., | Keller et al., | Berrevoets et | Durojaiye et al., |
| Was there a clear statement of the aims/ objectives of the research? | Y | Y | Y | Y | Y | Y | Y | N | Y | Y | Y | Y | Y | Y | P | Y | Y | Y | Y | Y | N | Y | Y | Y | Y | Y | Y |
| Was the research design appropriate to address the aims of the research? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | P | P | Y | Y | P | Y | Y | P | Y | Y | Y | Y | Y | Y |
| Was the recruitment strategy appropriately described? | Y | Y | Y | Y | Y | Y | Y | N/A | Y | Y | Y | Y | Y | Y | N | Y | Y | Y | P | Y | Y | p | P | Y | Y | Y | Y |
| Were the data collected in a way that addressed the research issues? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | P | Y | Y | Y | Y | Y | p | Y | Y | Y | Y | Y | Y |
| Were participant characteristics described in detail? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | P | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | P | Y | Y | Y | Y |
| Have ethical issues been taken into consideration? | Y | Y | N | Y | Y | Y | U | Y | Y | N | N | Y | Y | Y | N | Y | Y | N | Y | P | N | Y | Y | Y | Y | Y | Y |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Is there a clear statement of findings? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | Y | Y | Y | Y | Y | Y |
| Did the authors mention facets of the service which can be considered as HF? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Were failures of the service mentioned? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Did the authors declare that there were no conflicts of interest or bias? | N | Y | Y | Y | P | P | Y | Y | P | P | Y | Y | P | Y | Y | Y | Y | N | P | Y | P | Y | Y | Y | Y | Y | Y |

### 3.3.4 Data extraction and synthesis

The following sections describe the components pertinent to the SEIPS 2.0 model including the work system and its entities (3.3.4.1), the processes (3.3.4.2) and the outcomes (3.3.4.3).

3.3.4.1 Work System

Table 3.6 The work system factors characterised according to the SEIPS 2.0 model

| **System Element** | **Factors** |
|---|---|
| **Tools and Technology** | Eligibility criteria specific to the ear, nose and throat department (Al Alawi et al., 2015). |
| | Choice of drug based on profile/clinical condition/penicillin resistance (Al Alawi et al., 2015) e.g. Ceftriaxone. |
| | Consideration of various routes of administration (Al Alawi et al., 2015). |
| | Improved medical devices and technologies (Barr et al., 2012; Williams et al., 2015) elastomeric pumps (Gardiol et al., 2016; Miron-rubio et al., 2016). |
| | Adaptability of the service allows more intravenous medicines to be administered (Barr et al., 2012). |

| | |
|---|---|
| | New treatment options allow more conditions to be treated (Barr et al., 2012). |
| | Patient/carer capability to self-administer (Gardiol et al., 2016) increases range of drugs and frequencies (Miron-rubio et al., 2016). |
| **Tasks** | Written instructions to go to the emergency department if adverse event occurs (Al Ansari et al., 2013). |
| | Availability of eligibility criteria (Al Alawi et al., 2015) and patient selection (Al Alawi et al., 2015; Htin et al., 2013; Perez-Lopez et al., 2008; Suleyman et al., 2017; Lane et al., 2014). |
| | Assistance by family/carer with medication administration (Perez-Lopez et al., 2008); travelling to avoid delays in administration (Keller et al., 2019a); understanding information (Berrevoets et al., 2018). |
| | Monitoring (Bernard et al., 2001) daily (Al Alawi et al., 2015) by the infectious diseases' physician (Gilchrist et al., 2008) of the patients' clinical assessment and laboratory parameters (Muldoon et al., 2015; Lane et al., 2014; Barr et al, 2012; Williams et al., 2015; Al Ansari et al., 2013). |
| | Complexity categorisation depending if they are short or long treatments (Al Ansari et al., 2013). |
| | Patient follow up (Gilchrist et al., 2008; Muldoon et al., 2015; Twiddy et al., 2018; Mackintosh et al., 2011). |
| | Treatment selection with respect to cost, efficacy, frequency of administration, comorbidities etc. (Williams et al., 2015). |

| | |
|---|---|
| | Education for patients/carers for performing infusions, importance of sterility (Htin et al., 2013; Cox et al., 2007; Twiddy et al., 2018). |
| | Patients/carer capability in performing infusions, importance of sterility (Cox et al., 2007) daily activities with an indwelling line (Keller et al., 2019a). |
| | Travelling to appointments (Twiddy et al., 2018). |
| **Person** | Eligibility e.g. Comorbidities (diabetes mellitus, hypertension, obesity, chronic obstructive pulmonary disease, asthma) (Al Alawi et al., 2015) cardiac, renal (Duncan et al., 2013). |
| | Eligibility based on specific clinical guidelines (Al Alawi et al., 2015; Al Ansari et al., 2013) |
| | Eligibility e.g. Inability to swallow (Al Alawi et al., 2015). |
| | Willingness to deal with multiple conditions (Al Alawi et al., 2015; Al Ansari et al., 2013); willingness to accept service if provided with more information about treatment given (Twiddy et al., 2018). |
| | Knowledge, skills and ability to perform before the patient is discharged on the service (Keller et al., 2013; Perez-Lopez et al., 2008; Twiddy et al., 2018). |
| | Patient's age (Perez-Lopez et al., 2008). |
| | Patient willingness to be offered service (Esposito et al., 2004; Berrevoets et al., 2018; Gardiol et al., 2016), hesitation to leave inpatient setting (Goodfellow et al., 2002; Twiddy et al., 2018). |

| | |
|---|---|
| | Emotional impact of having an indwelling device (Twiddy et al., 2018; Berrevoets et al., 2018). |
| **Organisation** | Referrals from medical, surgical and emergency departments (Miron-rubio et al., 2016; Al Ansari et al., 2013); avoidance of delayed transition from hospital to residence (Berrevoets et al., 2018). |
| | Multidisciplinary OPAT team with the necessary training and skills (Al Ansari et al., 2013; Lane et al., 2014; Seaton et al., 2011; Duncan et al., 2013; Durojaiye et al.,2018) . |
| | Education for referring institutions to avoid their refusing eligible patients (Hitchcock et al., 2009). |
| | Provision of formal guidelines (Hernandez et al., 2016). |
| | Channels of communication (Lane et al., 2014) involving infectious diseases specialists (Muldoon et al., 2015; Berrevoets et al., 2018) electronic databases (Williams et al., 2015). |
| | Role of the OPAT director to decide which measure to use to monitor measure outcomes (Muldoon et al., 2015). |
| | Move towards community-based model to decrease bed occupancy (Gardiol et al., 2016). |
| | Involvement of infectious disease physicians prior to discharge (Lane et al., 2014). |
| | Lack of a reporting system for errors (Lane et al., 2014), lack of an in-house database (Durojaiye et al., 2018). |
| | Other medical services e.g. diabetes control, wound management, nutritional support (Mackintosh et al., 2011). |

| | |
|---|---|
| | Flexibility of provider avoids limiting patients' daily activities (Berrevoets et al., 2018; Durojaiye et al., 2018). |
| **External environment** | Guidelines e.g. centres for disease control and prevention guidelines (Al Alawi et al., 2015). |
| | Referral from private entity to maintain treatment (Al Alawi et al., 2015), referral from a GP (Al Ansari et al., 2013). |
| **Internal environment** | OPAT Clinic (Al Alawi et al., 2015). |
| | Geographical distribution of patients (Lane et al., 2014). |
| | Influence of this on administration times (Hitchcock et al., 2009) |
| | Versatility of the service allows more intravenous medicines to be administered (Barr et al., 2012). |
| | Patient or carer model versus infusion model (Esposito et al., 2004). |
| | Home environment that guarantees personal safety (Twiddy et al., 2018) and that of the access device (Keller et al., 2019a). |
| | Hospital environment supporting transmission of *Clostridium difficile* and MRSA (Twiddy et al., 2018). |
| | Avoidance of extreme temperatures, dirt, pets and measures to declutter residence (Keller et al., 2019a). |

Table 3.7 below demonstrates the most common interactions between the work system components.

Table 3.7 Key interactions occurring between work system factors

| **Work System Factors** | **Factor Descriptors** | **Key interactions** |
|---|---|---|
| Tools/tech Factors- T1, T2 | **T1** Design and efficiency of medical devices and technologies used to administer treatment | Tas4, P2, P3, EE2 |
| | **T2** Accessibility of medical devices and technologies to perform laboratory testing from blood samples | Tas2, Tas3, P3 |
| Tasks Factors- Tas1, Tas2, Tas3, Tas4 | **Tas1** The need to ensure that patients are selected in line with international OPAT guidelines | P1, P3, EE1, O1, P2, O2, IE1 |
| | **Tas2** The requirement to ensure regular patient laboratory monitoring and clinical evaluation | Tas3, P2 |
| | **Tas3** The importance of carrying out regular patient follow-up and re-evaluation by healthcare professionals to assess patient's prognosis | P2, O2, IE1, P3, O3 |

| | | |
|---|---|---|
| | **Tas4** The need to educate patient/carer about the service and their involvement with the professionals offering the service | P2, P3, O2 |
| Person(s) Factors- P1, P2, P3 | **P1** Patient eligibility due to comorbidities such as diabetes mellitus, hypertension, obesity, chronic obstructive pulmonary disease, asthma, cardiac, renal | |
| | **P2** Healthcare professionals' knowledge, skills and ability to provide OPAT service | O2, O3, IE, EE2 |
| | **P3** Patient willingness to be offered service and leave inpatient setting | |
| Organisation Factors- O1, O2, O3 | **O1** The organisational need to ensure patients are discharged from hospital onto the OPAT service | O2, P1, O3 |
| | **O2** Setup and maintenance of an appropriately trained and skilled multidisciplinary OPAT team | EE1 |
| | **O3** Existence of standard channels of communication | |

| | | |
|---|---|---|
| | between healthcare professionals to ensure seamless care | |
| External Factors- EE1 | **EE1** Referral from private institution to maintain treatment e.g. GP clinic | |
| | **EE2** Geographical distribution of patients influences administration times | |
| Internal Factors- IE1 | **IE1** Physical environment depends on the model of care (i.e. infusion centre, patient residence etc.) | |

3.3.4.2 Processes

Patient selection and the tasks required to assess the eligibility of the patient was the first process. These tasks included but were not limited to the assessment of the patient in terms of comorbidities, absent illicit use of drug intravenously etc. Another pertinent process was the referral from one medical entity for example a medical care team, GP etc. to a person or compliment of people responsible for the running of the service for example a formal OPAT team, a specialised OPAT nurse, an infectious disease physician etc. This was followed by the pre-discharge process which encompassed the writing up of a treatment and monitoring plan.

The following process was related to the service delivery including administration of treatment, laboratory monitoring and clinical monitoring by the responsible professionals entrusted with this process. The last process is dynamic and cyclical in nature and is only terminated once the patient is discharged from the service. It is of note that these processes vary in terms of the model of care employed. For example, a visiting nurse model must ensure that the suitability of the home environment is factored in the patient selection process, however the level of dexterity and administration skills is quite irrelevant since a professional would be taking care of that task. The model of care as can be seen impacts the ratio of patient, professional and collaborative processes. The main processes as gathered from the 27 studies are illustrated in Figure 3.5 below.

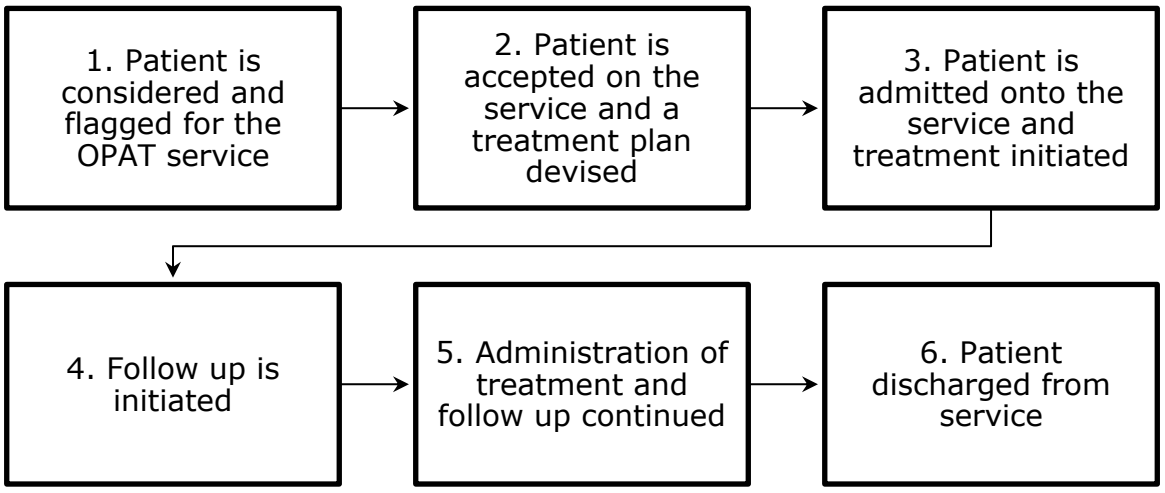


Figure 3.5 The main phases involved in rendering an OPAT service

The following tables (Table 3.8 to 3.10) shed light on the professional work, patient work and the collaboration between the two in terms of their physical, cognitive and social/behavioural processes as described by Karsh et al. (2006), Carayon et al. (2006) and Holden et al. (2013).

1. Professional Work

Table 3.8 The 'professional work' processes as characterised by the SEIPS 2.0 model for each phase of the OPAT service

| **Service Phase** | **Physical** | **Cognitive** | **Social** |
|---|---|---|---|
| **Patient is considered and flagged for the OPAT service** | Assessment of OPAT workload to evaluate whether the team can take on another patient (Durojaiye et al., 2018) | Selection of the patient according to the institution's eligibility criteria (Seaton et al., 2011; Htin et al., 2013; Suleyman et al., 2017; Barr et al., 2012) | Communication with all stakeholders involved in rendering the service (Muldoon et al., 2015; Williams et al., 2015; Berrevoets et al., 2018); Motivating professionals to cure more complex disease states (Barr et al., 2012) |
| **Patient is accepted on the service and a treatment plan devised** | Treating homeless patients e.g. using a respite shelter (Hernandez et al., 2016) | Teaching patients how to administer using aseptic techniques (Barr et al., 2012; Miron-rubio et al., 2016; Keller et | Decreasing the use of inappropriate therapy (Muldoon et al., 2015; Lane et al., 2014; Suleyman et al., |

| | | | |
|---|---|---|---|
| | | al., 2019a; Keller et al., 2019b); Awareness of new pharmaceutical formulas which allow new administrations (Perez-Lopez et al., 2008) | 2017; Williams et al., 2015); Liaising with all stakeholders to successfully discharge patient onto the service (Muldoon et al., 2015; Williams et al., 2015) |
| **Patient is admitted onto the service and treatment initiated** | Administration of treatment; Use of different administration techniques (Esposito et al., 2004; Miron-rubio et al., 2016) | Improvement of transitional care processes e.g. reducing the errors that occur during antimicrobial prescribing (Keller et al., 2013) | Provide support to patients and caregivers (Berrevoets et al., 2018) |
| **Follow up is initiated** | Requesting and charting of laboratory tests (Bernard et al., 2001; Lane et al., 2014) | Monitoring and inferences from laboratory tests (Bernard et al., 2001; Lane et al., 2014; Keller et al., 2019b; Durojaiye et al., 2018) | Culture of regular monitoring set up to prevent adverse events (Twiddy et al., 2018) |
| **Administration of treatment and follow up is continued** | Drawing of blood samples to be sent to the laboratory for | Addressing patterns of previous unsuccessful patient groups to | Empowering patients (Barr et al., 2012; Miron-rubio et al., 2016); Working |

| | | | |
|---|---|---|---|
| | testing (Keller et al., 2019b) | pre-empt future readmissions (Duncan et al., 2013) | towards lowering readmission rates through better follow up measures (Keller et al., 2013; Al Alawi et al., 2015; Durojaiye et al., 2018) |
| **Patient is discharged from the service** | Removal of vascular access device (Keller et al., 2019b) | | Planning of the service to generate higher success rates and fewer readmissions (Muldoon et al., 2015; Seaton et al., 2011; Htin et al., 2013; Suleyman et al., 2017; Barr et al., 2012; Gardiol et al., 2016); Achieving professional satisfaction (Esposito et al., 2004) |

2. Collaborative Work

Table 3.9 The 'collaborative work' processes as characterised by the SEIPS 2.0 model for each phase of the OPAT service

| Service Phase | Physical | Cognitive | Social |
|---|---|---|---|
| **Patient is considered and flagged for the OPAT service** | Assessment of skill set and dissemination of roles and responsibilities (Keller et al., 2019b) | Knowing which factors cause poor outcomes e.g. older age, methicillin-resistant Staphylococcus aureus infection and diabetic foot infection (Mackintosh et al., 2011) | |
| **Patient is accepted on the service and a treatment plan devised** | Taking consent prior to toxic treatment (Muldoon et al., 2015) | Deciding which administration techniques to use depending on discussions between professionals and patients (Mackintosh et al., 2011); training vascular access device management (Keller et al., 2019b) | Recognition that an appropriate OPAT structure can establish a treatment plan with patient (Durojaiye et al., 2018) |
| **Patient is admitted onto the service and** | Delivery of medications by | Monitoring of patient technique | Establishing and maintaining communication |

| | | | |
|---|---|---|---|
| **treatment initiated** | courier (Keller et al., 2019b) | by team (Keller et al., 2019b) | channels between OPAT team members and patients (Gilchrist et al., 2008; Hitchcock et al., 2009; Keller et al., 2019b; Twiddy et al., 2018) |
| **Follow up is initiated** | Devising a schedule for withdrawal of blood samples and testing (Keller et al., 2019b) | | |
| **Administration of treatment and follow up is continued** | Ensuring patients attend hospital appointments (Muldoon et al., 2015); Reporting of adverse events (Lane et al., 2014) | Awareness of sterility procedures during administrations (Keller et al., 2019b) | Ensuring patients are taking care of vascular access device and coping with daily life activities (Berrevoets et al., 2018) |
| **Patient is discharged from the service** | Removal of venous access device (Keller et al., 2019b) | | |

3. Patient Work

Table 3.10 The 'patient work' processes as characterised by the SEIPS 2.0 model for each phase of the OPAT service

| Service Phase | Physical | Cognitive | Social |
|---|---|---|---|
| **Patient is considered and flagged for the OPAT service** | Assessment of patient comorbidities in managing at home (Twiddy et al., 2018) | Reducing the onset of delirium and worsening social function especially in older patients (Perez-Lopez et al., 2008); considering self-administration option based on patient skill set (Twiddy et al., 2018; Gardiol et al., 2016); learning about the service prior to discharge (Keller et al., 2019b) | Consideration of the impact of home visits on the patient's freedom (Berrevoets et al., 2018) |
| **Patient is accepted on the service and a treatment plan devised** | Ensuring adherence to prescribed therapy especially in intravenous drug abusers (Williams et al., 2015) | Recognising that offering the option of being treated at home may help in terms of patient responsiveness and morale (Hernandez et al., 2016; Cox et al., 2007) | Maintaining a home environment including supporting maintenance of familiar dietary habits, continuous family support and the ability to move about |

| | | | |
|---|---|---|---|
| | | | (Perez-Lopez et al., 2008) |
| **Patient is admitted onto the service and treatment initiated** | Asking for the assistance of family members with administration techniques and devices (Cox et al., 2007); ensuring patients are aware how to tackle home hazards (Keller et al., 2019a) | Improving psychological distress and social functioning, due to emotional problems (Goodfellow et al., 2002; Al Alawi et al., 2015) wellbeing (Al Ansari et al., 2013; Williams et al., 2015) | Empowering a culture that promotes more admissions onto the OPAT service (Al Alawi et al., 2015; Hitchcock et al., 2009) |
| **Follow up is initiated** | Ensuring that patients do not fail to show up at follow up appointments (Williams et al., 2015); ensuring travel arrangements are done for any appointments (Twiddy et al., 2018) | | |
| **Administration of treatment and follow up is continued** | Seeking urgent care services especially a geriatric cohort (Cox et al., | Ensuring the patients are correctly administering medications for | Maintaining a normal daily routine (Barr et al., 2012; Esposito et al., |

| | | | |
|---|---|---|---|
| | 2007); ensuring the vascular device is not misused (Williams et al., 2015); calling the infectious diseases pharmacist or physicians with questions especially older patients (Cox et al., 2007); ensuring the vascular device is kept safe from home hazards (Keller et al., 2019a) | the given amount of time (Keller et al., 2019b) | 2004); factoring in the support required from relatives Berrevoets et al., 2018); avoiding harm whilst performing activities of daily living (Keller et al., 2019b) |
| **Patient is discharged from the service** | | | Maintaining a normal daily routine (Barr et al., 2012; Esposito et al., 2004) |

3.3.4.3 Outcomes

As expected, the studies published researched a particular aspect of the OPAT service including its safety and efficacy (Bernard et al., 2001; Al Alawi et al., 2015; Htin et al., 2013; Muldoon et al., 2015; Gardiol et al., 2016; Suleyman et al., 2017; Keller et al., 2019a; Keller et al., 2019b), readmission rates (Keller et al.,

2013), care processes (Cox et al., 2007; Hitchcock et al., 2009; Miron-Rubio et al., 2016; Keller et al., 2013; Lane et al., 2014), quality of life (Goodfellow et al., 2002; Berrevoets et al., 2018), patient satisfaction (Al Alawi et al., 2015; Al Ansari et al., 2013), cost effectiveness (Bernard et al., 2001; Al Alawi et al., 2015; Al Ansari et al., 2013; Hernandez et al., 2016), treatment completion rates (Hernandez et al., 2016), service failures (Gilchrist et al., 2008; Mackintosh et al., 2011; Seaton et al., 2011; Duncan et al., 2013) and the service's provision (Esposito et al., 2004; Barr et al., 2012; Williams et al., 2015; Durojaiye et al., 2018). Table 3.11 describes the outcomes derived from the OPAT services mentioned in the studies.

Table 3.11 Extracted outcomes from the selected articles using the SEIPS 2.0 model

| **Outcomes** |
| --- |
| **Patient** |
| • Satisfaction (Al Alawi et al., 2015; Al Ansari et al., 2013; Esposito et al., 2004); reduced psychological distress (Perez-Lopez et al., 2008); Inability to perform duties due to physical and emotional problems (Goodfellow et al., 2002; Twiddy et al., 2018); delivery at home achieved (Bernard et al., 2001; Keller et al., 2019b) Clinical outcome measures e.g. Throat soreness, fever, number of visits (Al Alawi et al., 2015; Al Ansari et al., 2013)<br>• Clinical efficacy e.g. Safety, rates of compliance, readmission (Al Alawi et al., 2015) Lost to follow up as course not completed (Al Alawi et al., 2015); patient relocated (Suleyman et al., 2017); cost (Suleyman et al., 2017); severity of the infection (Cox et al., 2007)<br>• Infection relapses (Keller et al., 2013); Severity of infection e.g. MRSA leads to failure irrelevant to the length of treatment, age or diagnosis (Mackintosh et al., 2011)<br>• Antimicrobial related ADRs (Keller et al., 2013; Williams et al., 2015; Duncan et al., 2013; Seaton et al., 2011); leading to switch or readmission (Duncan et al., 2013) |

- Comorbidities which influence readmission rates (Perez-Lopez et al., 2008; Cox et al., 2007; Seaton et al., 2011) e.g. parenteral nutrition (Cox et al., 2007); acceptance rates (Twiddy et al., 2018)
- Catheter related concerns e.g. misplaced line, occlusion (Hernandez et al., 2016; Cox et al., 2007), handling (Keller et al., 2019a; Keller et al., 2019b)
- Concerns raised about a patient missing an appointment (Hernandez et al., 2016), travel (Twiddy et al., 2018)
- Recognition of device handling problems especially in order population (Cox et al., 2007) and that self-administration increases risk of failure (Miron-rubio et al., 2016)
- Improved quality of life and social functioning (Bernard et al., 2001; Goodfellow et al., 2002; Berrevoets et al., 2018); because of patient involvement in decision making process (Berrevoets et al., 2018)

**Professional**

- Detection of antimicrobial prescribing errors (Keller et al., 2013)
- Notification that a laboratory test has taken place helps the OPAT team ensure regular follow up is taking place (Keller et al., 2013)
- Device complications (Williams et al., 2015)
- Physician satisfaction ensures continuity of service (Esposito et al., 2004)
- Switching antibiotic or to oral therapy to avoid failure (Seaton et al., 2011; Hitchcock et al., 2009)
- Growing experience in appropriate antimicrobial choices reduces the duration of treatment (Seaton et al., 2011)

**Organisational**

- Cure rates; Deaths (Muldoon et al., 2015; Lane et al., 2014; Durojaiye et al., 2018)
- Saved bed days, cost cuts (Al Alawi et al., 2015; Gardiol et al., 2016); hospital capacity (Williams et al., 2015); positive mental change (Goodfellow et al., 2002)
- Reduced readmissions (Al Alawi et al., 2015; Keller et al., 2013); emergency department visits (Muldoon et al., 2015; Miron-rubio et al., 2016)

- Cost cuts compared to inpatient stays (Al Alawi et al., 2015)Process map defining the roles of all those individuals involved in service delivery (Keller et al., 2013)
- Scrutiny of OPAT model effectiveness as determined by outcomes (Bernard et al., 2001; Hernandez et al., 2016)
- Recognition that early monitoring can increase awareness of clinical deterioration and pre-empt readmissions (Bernard et al., 2001; Lane et al., 2014)
- Information about healthcare associated infections (Barr et al., 2012; Berrevoets et al., 2018) e.g. related to the devices (Barr et al., 2012)
- Recognition of the importance of additional care services e.g. diabetes control (Mackintosh et al., 2011)
- Reduced nosocomial infections (Miron-rubio et al., 2016; Hitchcock et al., 2009) transmission of MRSA, C*lostridium difficle* associated diarrhoea (Hitchcock et al., 2009; Twiddy et al., 2018)
- Increased quality of communication between stakeholders (Gilchrist et al., 2008) assisted with the setup of an OPAT structure (Durojaiye et al., 2018)

Due to the heterogeneity of aims and methods, it was not possible to compare results across all the studies and hence why a meta-analysis could not be employed. As per the reviewers' subjective opinion, outcomes which reported a service's cure or improvement rates were deemed as successes whilst readmissions, deaths and complications were categorised as failures. When data wasn't explicitly reported by the authors but there was sufficient quantitative data to deduce a value, this was calculated by the reviewers. Table 3.12 below reports some outcomes identified across the studies.

Table 3.12 Success and failure rates which were reported in the selected studies

| **Main author** | **Success** | | **Failures** | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | **Readmission** | | **Death** | **Complications** | | |
| | | | | | | **Complication (most common)** | | **Reason** |
| Htin et al., 2013 | 64/68 (94%) | | 3/68 (4%) | | 0 | 1/68 (1.4%) | | Line infection |
| Perez-Lopez et al., 2008 | 83/90(92%) (>70years) | | 20/90 (22%) (>70years) | 13/55(23%) (<70years) | 0% | 14/90(15%) (>70years) | 9/55(16%) (<70years) | Phlebitis, rash, post antibiotic diarrhoea |
| Suleyman et al., 2017 | 120/122(99%) | | 2/122(2%) | | 0% | 16/122(13%); 3/102(3%) | | Adverse drug event; line complications |
| Hernandez et al., 2016 | 33/43(77%) | | 8/43(18.6%) | | 0% | 7/43(16%) | | Social concerns |
| Williams et al., 2015 | NR | NR | 67/1115 antibiotics (6%) (data from 957 | 3/342 antibiotics (1%) (data from 229 | 0% | 134/1115 antibiotics (12%); 279/1115 | 19/342 antibiotics (6%); 14/342 | Drug related event; venous access complications |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | patients) (Period 1) | patients) (Period 2) | | antibiotics (25%)(data from 957 patients)( (Period 1) | antibiotics (4%) (data from 229 patients (Period 2) | |
| Barr et al., 2012 | 2063/2233 OPAT episodes (92.4%) | | 262/2233 OPAT episodes (11.7%) | | 8/2233 OPAT episodes (0.4%) | 219/2233 OPAT episodes (9.8%) | | Adverse drug event |
| Duncan et al., 2013 | 55/80 episodes (68.7%) | | 21/80 episodes (26.3%) | | 2/80 episodes (2.5%) | 7/80 episodes (8.7%); 3/80 episodes (4.1%) | | Adverse drug event, other line complication |
| Miron-Rubio et al., 2016 | 4018/4416 episodes (91%) | | 328/4416 episodes (7.4%) | | 58/4416 episodes (1.3%) | 241/4416 episodes (5.4%) | | Catheter complications |
| Seaton et al., 2011 | 83/9963 episodes (87.1%) | | 58/963 episodes (6%) | | NR | 68/963 episodes (7%) | | Complication of infection process, |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | significant adverse event |
| Hitchcock et al., 2009 | 278/303 episodes (91.7%) | 23/303 courses (7.6%) | NR | 2/303 episodes (0.7%) | Adverse drug event |
| Gardiol et al., 2016 | 168/179 episodes (94%) | 24/179 episodes (12%) | 0% | 10/179 episodes (5.5%) | Adverse drug event |
| Durojaiye et al., 2018 | 3357/3812 episodes (88.1%) | 265/3812 episodes (7%) | 2/3812 episodes (0.1%) | 265/3812 episodes (7%) | Adverse events, line related complications |

## 3.4 Discussion

Despite a general absence of 'Human Factors' reporting, the review provided valuable information about the global OPAT offering through an extraction and synthesis process using the SEIPS 2.0 model. The only mention of the Human Factors discipline was in two articles published by Keller et al. (2019b) which looked at patient/caregiver task analysis and the impact of the home environment on OPAT tasks (2019a). Although the authors refer to the use of the SEIPS model, the analysis was not carried out to completion. On the contrary, this work describes the service using articles of high methodological quality through the SEIPS 2.0 model and the service lends itself well to this specific tool.

During data extraction, it was noticeable that authors reported different outcomes. Hence there wasn't a 'standard outcome set' which in turn made comparison between different settings challenging. Having said that, recurrent outcome themes emerged from the published work namely user satisfaction (including patient and staff satisfaction), clinical outcome measures (including service success, failure, safety ADRs, prescribing errors, monitoring, reduced nosocomial infections etc.) and non-care related outcomes (including bed days saved, reduced expenditure etc.).

### 3.4.1 Outcomes

From the studies identified, satisfaction was one of the most cited patient outcomes and it was seen to influence e.g. their psychological state (Perez-Lopez et al., 2008) or their ability to perform OPAT related tasks (Goodfellow et al., 2002; Twiddy et al., 2018). Authors such as Al Ansari et al. (2013) and Al Alawi et al. (2015) described the impact of high patient satisfaction on service adaptation as was substantiated by good clinical outcomes e.g. absence of clinical deterioration. Physician satisfaction was also an important psychometric outcome as it drove the continuity of the service and the maintenance of various OPAT models of care (Esposito et al., 2004).

Patient satisfaction was also influenced in part by the patients' comorbidities which in turn led to their subjective decision to consent to receiving the service (Twiddy et al., 2018). This person factor was also seen to influence outcomes related to readmissions (Perez-Lopez et al., 2008; Cox et al., 2007; Seaton et al., 2011). The latter were compounded by antimicrobial related adverse events (Keller et al., 2013; Williams et al., 2015; Duncan et al., 2013; Seaton et al., 2013) as well as infection relapses (Keller et al., 2013) which were aggravated by the severity of the infection (Mackintosh et al., 2011). Negative patient outcomes revolved around the lack of adherence to follow ups e.g. due to travel complications (Twiddy et al., 2018), patient relocation (Suleyman et al., 2017), incomplete treatment course (Al Alawi et al., 2015) and financial expenses (Suleyman et al., 2017). On the other hand, the patients' involvement in the decision-making process (Berrevoets et al., 2018) was seen to positively contribute to their quality of life and social functioning (Bernard et al., 2001; Berrervoets et al., 2018; Goodfellow et al., 2002).

Regular follow-up was identified as an important professional outcome which could be standardised through technological aids e.g. laboratory test notifications (Keller et al., 2013). This professional outcome ensured the success of organisational outcomes related to recognising early clinical deterioration in patients which would otherwise result in a readmission (Al Alawi et al., 2015; Keller et al., 2013). This was crucial in light of institutional outcome targets including cure rates (Muldoon et al., 2015; Lane et al., 2014; Durojaiye et al., 2018), cost cuts (Al Alawi et al., 2015; Gardiol et al., 2016), hospital capacity (Williams et al., 2015), reduced emergency department visits (Muldoon et al., 2015; Miuron-rubio et al., 2016) and a reduction in nosocomial infections (Miron-rubio et al., 2016; Hitchcock et al., 2009).

Keller et al. (2013) identified a process map outlining the roles of the service providers to ensure successful organisational outcomes. A proposed approach focused on strengthening professional outcomes which focused on the OPAT team's skillset including their ability: to alter treatment agents and routes (Seaton et al., 2011; Hitchcock et al., 2009), to address device complications (Williams et al., 2015) and to detect prescribing errors (Keller et al., 2013). Addressing the team's competence within the context of an established framework (Durojaiye et

al., 2018) which supported good communication practices (Gilchrist et al., 2008) was conducive to positive organisational outcomes.

A few processes were identified as being particularly important to generating positive outcomes probably the most important of these was selecting the right patient, facilitating communication and administering treatment for professional, collaborative and patient work respectively.

### 3.4.2 Processes

#### 3.4.2.1 Processes which involved professional work

The decision process governing the patient selection task was the most important cognitive process carried out by professionals in an OPAT service. In fact, three out of six processes reported by Gilchrist et al. (2008) specifically focused on this aspect including the patient's eligibility, acceptance and assessment. Based on the patient's mobility and ability to administer one's medications, a cognitive process was triggered whereby a professional had to decide the most suitable OPAT model. This cognitive process based on knowledge, forethought and problem solving ability was reflected in their care to avoid certain patient cohorts which led to high success rates with few adverse events (Seaton et al., 2011; Htin et al., 2013; Suleyman et al., 2017; Barr et al., 2012).

The most obvious physical process carried out by the involved professionals was the administration of antimicrobial agents. The ability of professionals to reach their patients in various physical environments depending on the model of delivery (Hernandez et al., 2016; Esposito et al., 2004) (physical process) whilst having the knowledge to administer through various VADs e.g. PICC (Esposito et al., 2004; Miron-Rubio et al., 2016) has enhanced the culture of service provision (behavioural). In a scenario where a patient is difficult to reach daily (physical process), the ability of the professional to teach the patient self-administering techniques (cognitive process) can empower patients to start managing their own condition (social/behavioural process) (Barr et al., 2012; Miron-Rubio et al., 2016).

Requesting and charting laboratory monitoring of patients was an important physical process as it aided professionals in making an informed decision about the management of their patients (cognitive process) (Bernard et al., 2001; Lane et al., 2014; Keller et al., 2019a; Durojaiye et al., 2018). This in turn drove a social/behavioural process which ensured that a systematic method of laboratory tracking was enforced (Muldoon et al.,2015) and absolute accessibility emphasised (Williams et al., 2015). Moreover, it assisted OPAT directors in monitoring readmission rates (Muldoon et al., 2015; Williams et al., 2015; Gardiol et al., 2016) and endorsing clinical governance of OPAT (Barr et al., 2012).

#### 3.4.2.2 Processes which involved collaborative work

The availability of a telephone OPAT helpline encouraged the physical process of communication to answer any queries (patients) and monitor the patients (professionals) (Htin et al., 2013; Berrevoets et al., 2018; Twiddy et al., 2018; Keller et al., 2019a). This in turn motivated the cognitive process that ensured the original decision made between the two stakeholders was still valid. Furthermore, professionals undertook the cognitive process of weighing patient factors such as age and type of presenting infections. This process promoted the social/behavioural culture of communication for better overall outcomes (Gilchrist et al., 2008; Hitchcock et al., 2009; Keller et al., 2019a).

Other physical processes involved the professionals' visits to patient residences and patients' visits to the hospital or centre offering the service (Muldoon et al., 2015), taking patient consent prior to prescribing toxic treatment (Muldoon et al., 2015), the reporting of adverse events (Lane et al., 2014), withdrawal of the VAD (Keller et al., 2019a) and the maintenance of an organised residence for home administrations (Berrevoets et al., 2018).

#### 3.4.2.3 Process which involved patient work

As with the professional group, the physical process of administering treatment was brought up in the context of patient processes executing self-administration with or without the assistance of family members or carers (Cox et al., 2007; Gardiol et al., 2016). Patients were taught the necessary skills to perform

administration in their home environment (Esposito et al., 2004; Barr et al., 2012; Gardiol et al., 2016; Twiddy et al., 2018) (cognitive process) which in turn promoted a positive social culture favouring OPAT admissions (Al Alawi et al., 2015; Hitchcock et al., 2009).

Certain physical processes were attributed to a specific cohort e.g. geriatric patients who seemed to present at urgent care or phone OPAT team members for assistance more frequently (Cox et al., 2007). This in turn drove the cognitive process which reduced functional worsening (Perez-Lopez et al., 2008) and encouraged the social process of accepting admission to the service based on family support, comfort in their home environment etc. (Perez-Lopez et al., 2008). Another cohort of concern were the intravenous drug abusers, who didn't attend follow ups and misused intravenous devices which made them non-adherent to therapy leading to failed OPAT courses (Williams et al., 2015).

### 3.4.3 Work system Factors

The selection of the 'right' patient was a central theme for most articles. Positive service outcomes were attributed to the enforcement and standardisation of patient selection criteria within institutions (Htin et al., 2013; Perez-Lopez et al., 2008; Suleyman et al., 2017; Hernandez et al., 2016; Lane et al., 2014) who *a priori* excluded patients who were clinically unstable (Perez-Lopez et al., 2008; Al Alawi et al., 2015; Hitchcock et al., 2009), drug abusers (Hitchcock et al., 2009), had a history of psychiatric disorders (Perez-Lopez et al., 2008), absent informal caregiver support (Perez-Lopez et al., 2008) and lack of communication and transport accessibility (Perez-Lopez et al., 2008; Al Alawi et al., 2015; Hitchcock et al., 2009).

The importance of selection standardisation was emphasised in a study by Gilchrist et al. (2008) who attributed numerous system shortcomings to this task factor when mapping the OPAT service. However, patient factors such as comorbidities, were seen to aggravate the frequency of complications (Al Alawi et al., 2015; Duncan et al., 2013). This was reported in various studies as being the reason for lack of clinical stability, late discharges and treatment failures (Perez-Lopez et al., 2008; Seaton et al., 2011; Duncan et al., 2013). Moreover, the patient's

willingness to consent to the service and return back to their residence (Goodfellow et al., 2002; Twiddy et al., 2018) was another person factor which determined the success of patient selection (Esposito et al., 2004; Berrevoets et al., 2018; Gardiol et al., 2016). This was further compounded by the HCP's knowledge and skills which directly influenced their ability to undertake a thorough assessment prior to patient enrolment (Keller et al., 2013; Perez-Lopez et al., 2008; Twiddy et al., 2018).

Patient eligibility was also subject to OPAT model-specific internal environmental factors. In the case of OPAT, this refers to the physical environment where the service was rendered e.g. an OPAT clinic (Gardiol et al., 2016) or the patients' residences (Twiddy et al., 2018; Keller et al., 2019a). Opting for a home model of care requires patient education about keeping a safe environment e.g. regulation of temperature, humidity, clutter etc. as this may have an impact on the integrity of the VAD's dressing (Keller et al., 2019b). Patient selection was also influenced at a meso-level by the organisational factor of promoting patient discharges onto OPAT and at a macro-level by external environmental factors such as the referral of a patient from a private institution (Al Ansari et al., 2013).

Once the patient was selected, risks to the OPAT referral process could be mitigated by imparting hierarchical responsibility and assigning a designated multidisciplinary team (Keller et al., 2013; Gilchrist et al. 2008; Al Alawi et al., 2015; Lane et al., 2014; Williams et al., 2015; Durojaiye et al., 2018). The team must demonstrate person factors such as knowledge and a wide and diverse skillset (Al Ansari et al., 2013; Lane et al., 2014; Seaton et al., 2011; Duncan et al., 2013; Durojaiye et al.,2018) which make them competent to perform OPAT related tasks even if compounded by environmental factors such as the geographical distribution of patients (Lane et al., 2014; Hitchcock et al., 2009). The multidisciplinary approach was not the same in all settings, with some services opting for a physician/s, nurse/s and pharmacist/s structure (Keller et al., 2013; Williams et al., 2015; Barr et al., 2012; Goodfellow et al., 2002; Hitchcock et al., 2009; Mackintosh et al., 2011) and others opting for just physician/s and nurse/s (Bernard et al., 2001; Miron-Rubio et al., 2016; Lane et al., 2014; Hernandez et al., 2016; Suleyman et al., 2017; Perez-Lopez et al., 2008; Htin et al., 2013). Other professionals were reported to participate in the patient's OPAT care, including the family physician (Al Alawi et al., 2015; Al Ansari et al., 2013), nursing

manager (Cox et al., 2007), community nursing staff (Goodfellow et al., 2002) and clinical microbiologist (Hitchcock et al., 2009).

The success of the patient's transition of care was seen to be dependent on patient specific factors such as age (Perez-Lopez et al., 2008) which can jeopardise a successful OPAT referral. These issues are further influenced by the existence of standard channels of communication amongst HCPs. Gilchrist et al. (2008) described three main channels including that between (i) patient and service providers, (ii) providers and internal/external colleagues and (iii) the providers amongst themselves. The authors attributed 57% of system failures to communication issues which further endorses the need for their rectification and standardisation. HCP attributable person factors such as their knowledge and capabilities, were seen to influence the existence and maintenance of standard communication channels (Lane et al., 2014) including those involving infectious diseases specialists (Muldoon et al., 2015; Berrevoets et al., 2018) or those making use of electronic databases (Williams et al., 2015).

The establishment of communication channels was crucial for task factors related to service delivery including the importance of patient follow-up and reassessment (Barr et al., 2012; Keller et al., 2013; Miron-rubio et al., 2016; Williams et al., 2015; Gilchrist et al., 2008; Muldoon et al., 2015; Twiddy et al., 2018; Mackintosh et al., 2011). Numerous studies hinted at the need for a standardised evidence-based framework that would encompass all the factors and processes pertaining to follow ups, monitoring and obligatory consultations (Muldoon et al., 2015; Hernandez et al., 2016; Seaton et al., 2011; Williams et al., 2015). Lane et al. (2014) emphasised the need for standardised monitoring procedures within an institution to prevent making overdue interventions. Person factors such as the patient's willingness to be offered the service (Esposito et al., 2004; Berrevoets et al., 2018; Gardiol et al., 2016) and the competence of the OPAT team (Al Alawi et al., 2015; Al Ansari et al., 2013) were identified as key elements which influenced the success of this. Moreover, it was emphasised that their competence and knowledge must be applied within the context of a designated multidisciplinary team which can perform follow-ups irrespective of the model-specific internal environment (Esposito et al., 2004).

The need for regular follow-ups was strongly associated with another task factor that of assessing the patient through regular laboratory monitoring (Muldoon et al., 2015; Lane et al., 2014; Barr et al., 2012; Bernard et al., 2001; Gilchrist et al., 2008). These task factors would not be possible without the influence of tools and technology factors which ensured the accessibility of medical devices and technologies to perform laboratory testing (Barr et al., 2012; Williams et al., 2015). Laboratory testing of blood samples was considered crucial to ensure the reliability of these task factors (Williams et al., 2015) especially when carried out within the context of a home-assisted or self-administration model (Bernard et al., 2001).

Aside from diagnostic equipment, the need was felt to invest in novel drug delivery technologies e.g. elastomeric electronic infusion pumps especially when patients and carers were performing the administrations (Miron-rubio et al., 2016, Gardiol et al., 2016). The availability of user-friendly designs was seen to improve person factors e.g. the confidence of patients and caregivers to administer treatment (Cox et al., 2007; Keller et al. 2019a) whilst the availability of more efficient devices assisted HCPs' outreaches, even if the patients resided in a wider geographical distribution (Lane et al., 2014). These considerations together with the task factor involving the need to educate patients and caregivers about administration techniques, was detrimental to safeguard the end-user, especially within the context of a self-administration model (Htin et al., 2013; Cox et al., 2007; Twiddy et al., 2018). It is important to note that the application of the SEIPS 2.0 model identified the design of technological devices apart from training (which is the common go to strategy) and patient-specific liabilities e.g. geriatric group (Cox et al., 2007), as being conducive to the achievement of successful administration outcomes.

### 3.4.4 Strengths and Weaknesses

The strength of this review in confirming the amenability of the OPAT service to the SEIPS 2.0 model, was further substantiated when an absence of Human Factors reporting was noted during the initial scoping search. This lacuna in the literature, emphasised the importance of a Human Factors approach to the

extraction and synthesis of data extracted from the 27 studies in terms of performance details reported about each service provision.

This review successfully executed the synthesis of work system elements, processes and outcomes irrespective of the patient cohort, model of delivery, setting, research timeframe etc. This success further attests to the capability of the SEIPS 2.0 model to serve as a generic conceptual framework to study a heterogenous sample of publications about the same service. The result enables researchers to identify factors which act as facilitators or barriers to the success of a service as reported by the authors.

Through this review, it is evident that there is a strong requirement in terms of education and training not only to provide the service but to instil standardisation as governed by international guidelines. This highly reported requirement indicates that a Human Factors approach can positively influence this system, which at present is proving to be not well designed.

The systematic review is limited by the exclusion criteria set at the start of the review including capture dates, patient cohorts and publication language. Despite this, the quality was maintained throughout the progress of the review through abidance to the ROBIS tool. Moreover, the factors identified in the synthesis phase are strongly dependant on the timeframe employed in each study. This is an important consideration in the context of the SEIPS 2.0 model which caters for both proximal and distal patient, professional and organisational outcomes. Lastly, due to the heterogenous study designs, aims and methodologies, the extraction and weighting of interactions was subjective. Despite these limitations, the review successfully fulfilled the aim of the review which was to evaluate the amenability of the OPAT service to the SEIPS 2.0 model.

## 3.5 Conclusion

The systematic review identifies numerous factors which are inherent to OPAT systems worldwide but are generally overlooked due to reporting styles or lack of knowledge in the field of Human Factors. Despite the identification of potential facilitators to service success e.g. the need to select the right patient for the

specific service context, barriers to service delivery were persistent through the studies and not necessarily tackled to identify their causation or impact. Albeit the robustness of this review, more research must be carried out to uncover more factors attributed to the OPAT models of care by using new sources of information e.g. patients' experiences as end users of the service and important elements in the SEIPS 2.0 model in terms of system adaptation.

### 3.6 Reflection

The findings of the systematic literature review guided the next phases of this research. The abundance of outcome performance indicators including the frequency of enrolments, readmissions, adverse events etc. informed the first stage of this research which led to the compilation of the national repository. The systematic review identified the need for databases, reporting mechanisms and a need to standardise reporting styles in this regard as evidenced by Table 3.12. The multiple reported outcomes were integrated into the repository to improve the prospects of future comparisons between the local service and those rendered internationally (Chapter 4).

Moreover, due to the successful attempt to verify the amenability of the SEIPS 2.0 model to OPAT, it was possible to identify barriers as well as facilitators to the provision of OPAT internationally. This model in turn would serve as a reference model to which the local service could be compared. During the SEIPS-based modelling it was evident that factors were derived from the perspective of the patient as well as the organisation- an end-user view which locally has never been gathered. For this reason, the subsequent phases were to collect the perspectives of both the patients who used the service and the HCPs rendering the service.

Considering the lack of standardisation in measuring and reporting patient satisfaction in the literature, this study attempted to address this limitation by designing, validating and delivering a cross-sectional questionnaire (Chapter 5). The findings gathered by way of this tool, together with data compiled in the electronic repository (Chapter 4) were further substantiated by the opinions of the OPAT team during a focus group session. This was deemed crucial since OPAT and healthcare research at large have the tendency to report performance outcome

data to gauge service success and the views of the involved HCPs are often overlooked or minimal (Chapter 6). These two chapters i.e. Chapter 5 and 6 substantiate the SEIPS model framework governing this research project to efficiently perform system redesign of the local service.

## Chapter 4

## Prospective observational cohort study

This chapter provides a detailed account of the prospective observational cohort study based on the visiting nurse home OPAT model performed from the perspective of the organisation. This chapter describes the creation and validation of the electronic repository which served as a data collection tool for patient characteristics and measurable outcomes, over a three-year period. Within, the chapter offers descriptive analysis of the data (Section 4.3.1), as well as other statistical analysis including (i) hypothesis testing with respect to the observed and forecasted duration for an OPAT episode (Section 4.3.3.4) (ii) tests for normality (Section 4.3.3.3) and ensuing comparative tests (Sections 4.3.3.5) (iii) comparative tests for categorical variables (Section 4.3.1.7) and (iv) the design of a generalised linear model (GLM) based on significant variables deduced in Section 4.3.3.5 (Section 4.3.3.6.1). Moreover, an activity-based costing exercise is conducted and explained in depth to provide a financial breakdown of the running cost of the service (Section 4.3.4).

The patient population was of 117, 15 of whom used the service twice, for a total of 132 episodes. Ceftriaxone was the most common single agent used (n=52, 34.9%), whilst a total of 17 (11.4%) antimicrobial courses out of the total 132 courses saw the concomitant use of two antimicrobials during the same patient episode. The most frequent combination was that of teicoplanin and ertapenem (9 courses, 52.9%). A total of 23 episodes (17.4%) resulted in a readmission, thus the success rate of the service equated to 82.6% since no deaths attributed to service delivery were recorded. A difference of 6 days was reported between the median of the forecasted duration (median=22) and the observed duration (median=28) for an OPAT episode. The presenting infection (p=0.021), occurrence of a readmission (p=0.05) and venous access device (VAD)(p=<0.001) were found to significantly contribute to the duration of an OPAT episode and were used to design a GLM to predict the duration of future OPAT episodes. A total of 3,287 days of hospital stay were avoided in the cohort. Considering the self-reported durations OPAT team members took to perform OPAT tasks, extrapolated to a three year

period and with consideration to annual salaries for the year 2019, the mean running weekly cost of the service was €455.47. In conclusion, the OPAT service proved to be a safe and cost-effective alternative to promote patient-centred care without hospitalisation.

## 4.1 Introduction

### 4.1.1 Importance of auditing the OPAT service

According to the first recommendation on outcome monitoring and clinical governance in the recent British OPAT guidelines, a repository containing data on OPAT patients should be recorded prospectively for service improvement and quality assurance (Chapman et al., 2019). In an article by Durojaiye and his colleagues, the British Society for Antimicrobial Chemotherapy guidelines promote the presence of a repository to assess the OPAT service over time. This repository can take the form of a local or national database with the latter offering the added advantage of comparing one's service with others (Durojaiye et al., 2019). Auditing in the context of OPAT can take the form of assessing the service's clinical benefit (Durojaiye et al., 2019; Mitchell et al., 2017; Quintens et al., 2020), the cost-effectiveness (Gonzalez-Ramallo et al., 2017; Mansour et al., 2018; Psaltikidis et al., 2017) and patient satisfaction (Durojaiye et al., 2018; Twiddy et al., 2018; Berrevoets et al., 2018). Moreover, according to the fifth recommendation on outcome monitoring and clinical governance, the guidelines state the service should be reviewed annually to make sure it is adhering to national standards (Chapman et al., 2019).

### 4.1.2 Rationale for conducting a prospective observational cohort study

In the absence of previously reported data related to characteristics and outcomes of patients enrolled on the service, the need was felt to construct a national repository whose content could accommodate the compilation of data for each OPAT episode despite the heterogenous nature of the cohort. Since the principal researcher was notified about a patient from the outset, the former was in a

position to prospectively collect preliminary data e.g. patient demographics, referring care team information, presence of MRSA carriage etc. and follow the patient throughout service provision and record e.g. the occurrence of a readmission, the date when the service was terminated etc.

### 4.1.3 Study aims and research questions

The aim of this phase of the study was to appraise system outcome measures of the service, including (but not limited to) referral, treatment and outcome details for patients flagged. Moreover, this phase aimed to evaluate the cost required to run the service.

To achieve these aims, the following research questions were designed:

1. What were the characteristic features of the patient cohort and of the OPAT episodes?

2. What was the outcome of OPAT episodes in terms of improvements, readmissions or deaths?

3. What trends were evident in the OPAT episode durations?

4. What was the running cost to render the service?

## 4.2 Method

### 4.2.1 Inclusion and exclusion Criteria

All patients enrolled into the local home visiting nurse OPAT service between October 2016 and October 2019 were included in this study with no exclusions.

### 4.2.2 Study design

Demographic, clinical and OPAT outcome data were extracted from the hospital information system and handwritten patient files and compiled in the repository.

Other data e.g. the termination date of an episode was communicated directly by the OPAT team members to the principal researcher.

### 4.2.3 The Content of the Database

A series of meetings were held with the other members of the OPAT team to reach consensus about the design of the repository. Salient points were noted and documented. Fields which were deemed of major importance included patient demographics, treatment details, vascular access device (VAD) details, the number of outreaches per day and details of a readmission. From these notes, measurable parameters were extracted and shortlisted depending on their probability of being recorded for each patient episode. Since the running cost of the service was specific to staff self-reported task durations rather than to the individual OPAT episodes, this data was stored in an electronic location separate from the OPAT database.

### 4.2.4 The Data Collection Tool Variables

The scope behind the creation of the electronic database was to serve as a repository for the prospective data collection for each OPAT patient episode. To substantiate the extraction of the measurable parameters from the field notes (Section 4.2.3), a literature search of other OPAT services was carried out to deduce which parameters were most frequently reported and which (even if absent) were considered by the authors to be worth recording. Moreover, reference was made to the local OPAT standard operating procedures (SOPs) from the institution's intranet, to ensure inclusion of any remaining parameters deemed to be important for this study (Appendix 4.1). Table 4.1 provides a detailed overview of the database's fields together with the rationale for their inclusion.

Table 4.1 Electronic database fields with rationale for inclusion

| **Electronic database fields** | **Rationale for inclusion** |
|---|---|

| | |
|---|---|
| Patient code | Pseudonymising the patient's details in line with good ethical practice. |
| Patient's age | Included to obtain demographic data about the cohort. |
| Gender | |
| OPAT completion outcome | Option to report the occurrence of a readmission, the reason behind the readmission and the patient's death. |
| The choice of VAD | The four options included (i) a peripherally inserted central catheter (PICC), (ii) an implantable venous access system (IV cannula) or (iii) one of a peripherally inserted intravenous cannula i.e. Venflon® or midline. |
| Clinical governance during referral process | Details of the referring care team and patient location (i.e. ward). |
| Responsible OPAT doctor | Included to gauge their experience in taking responsibility of the patient and other OPAT duties including attendance to virtual ward rounds, communication with the OPAT team and liaison with the referring care team about the patients' progress. |
| Entry of the number of visits carried out by OPAT nurses per day and the number of times the patient made use of the service i.e. OPAT episodes | Crucial to monitor the workload incurred mainly by the OPAT nurses to complete all antimicrobial courses. |
| Forecasted duration provided by the OPAT doctor | Duration was based on multiple factors including the patient's presenting |

| | |
|---|---|
| | infection, additional co-morbidities, previous treatment in ward etc. |
| Date the patient was flagged and the first and last OPAT visit dates carried out at the patient's residence | Such dates were crucial to deduce the number of episodes occurring per year in chronological order (flagging date) and the range in days between the first and last OPAT visit to calculate the actual duration of the service. This range was synonymous with the number of hospital bed days saved (considering presenting infection and medical team are the same). |
| Equivalent hospitalisation cost | Following the pilot study (Section 4.2.6), it was deduced that patients were all discharged from a general ward. For this reason, according to the subsidiary legislation S.L.35.28, the cost of an inpatient stay taking place in a general ward amounted to €256.23. Hospitalisation cost was calculated by multiplying the actual observed OPAT duration by this fee. |
| Patient's presenting infection, prescribed treatment and the organism(s) cultured. | To verify whether the treatment prescribed was appropriate with respect to the presenting infection and the organism(s) cultured. |
| MRSA nasal swab screening result | Included since local infection control guidelines state, "if the CVC [central venous catheter] insertion is planned several days in advance, an MRSA nasal swab should be taken as soon as |

| | |
|---|---|
| | the decision to insert the line is made" (Infection control committee, 2012). |

### 4.2.5 Construction of the tool

The tool was constructed using the spreadsheet program Microsoft Excel® considering the ease of data inputting, the integrated functions allowing simple arithmetical calculations and the facility to import this data in statistic programs. Specific equations were integrated into the spreadsheet including the subtraction of the first and last visit date to determine the duration of the OPAT service as well as the calculation for the cost of a hospital stay (described in Table 4.1). The document was kept on the main researcher's computer to safeguard the contents of the study as per good ethical practice. The final design and content was reviewed by the OPAT team members. The database was only accessible to the principal researcher and was used for the purpose of this research project.

### 4.2.6 Pilot testing

A pilot study was carried out to ensure the data collection tool lends itself to the collection of the specified parameters and to instruct any modifications if parameters were proving to be impractical to record. A total of ten OPAT episodes were included for the pilot study. The only difficulty encountered during this study was to report the infective organism(s) reported by the laboratory findings. Six out of the ten episodes resulted in different sampled mediums (i.e. blood, sputum etc.) or in one case, a culture and sensitivity test was not carried out. For this reason, this field was removed from the database.

### 4.2.7 Analysis

Patient demographics and OPAT episode characteristics

The statistical software IBM® SPSS version 25 was utilised for the statistical analysis of this study. Descriptive statistics were carried out on patient demographics (including age and gender), the equivalent cost of hospitalisation and OPAT episode details namely referring consultant, VAD, presenting infection

and antimicrobial regimen. Considering OPAT episodes varied even for the same patient, if a patient was enrolled more than once into the service, this episode would be recorded separately from the first and labelled with a new code.

Pearson's Chi square testing was carried out between categorical variables to investigate whether certain variables significantly influenced a patient's likelihood of a service failure i.e. readmission or death.

OPAT completion status

The completion status of the episode based on whether the patient improved, was readmitted or passed away during the service was analysed descriptively. For the purpose of this study, if a patient was not readmitted, they would continue benefitting from the service until the OPAT doctors deemed their improvement to be sufficient to allow the service to be terminated. For this reason, the success rate was considered to be represented by the percentage of improved episodes reported.

OPAT duration

Descriptive analysis was carried out on the number and duration of OPAT episodes occurring every year during the study timeframe. The primary measurable outcome for this part of the study was the observed duration of OPAT episodes. The Kolmogorov–Smirnov test was used to test the normality of the observed duration. The data were not found to be normally distributed and therefore non-parametric tests were carried out on the data recorded in the database. These data were compared to the forecasted duration of OPAT episodes established by the OPAT consultant at the start of the OPAT episode using the Wilcoxon signed ranks test. This test was used to determine if the discrepancy between the forecasted and observed duration and a p-value of less than the 0.05 criterion was statistically significant.

The Kruskal-Wallis test was then used to investigate the influence of measured categorical parameters on the observed duration of OPAT episodes. Considering more than one categorical parameter was deemed to be significant in relation to

the observed duration when using this test, a generalised linear model (GLM) was applied to evaluate which variable had the greatest significant influence on this parameter. The model was formulated to predict the observed duration of a future episode based on the three categorical factors which turned out to be significant namely the presenting infection, the vascular access device and readmission occurrence.

The GLM is a bespoke method for assessing the collective influence of significant predictors on a dependant variable which does not satisfy the normality assumption. Based on the three significant variables described above, the GLM offers the service provider the opportunity to predict any future OPAT episode. This is of significant value when resource allocation considerations are made prior to the patient's enrolment. Since the observed duration was not normally distributed and instead demonstrated a right skewed distribution, a gamma distribution with a reciprocal link function was used. In order to cater for the subcategories pertaining to the three variables (namely presenting infection, VAD and readmission status), a dummy coding was incorporated. For the purpose of this model, presenting infections were represented by the capital letter "I", the VAD was represented by the capital letter "V" and the readmission status was represented by the capital letter "R". Since the model included all the subcategories of the three variables, a value of 1 was attributed to that subcategory reflected in the OPAT episode e.g. the specific type of presenting infection whilst a value of 0 was allocated if it was not the case. If all variables generate the value 0, the duration is based on the intercept of the regression. From the three variables required for this model, the presenting infection is disclosed when the patient is referred and a decision about the appropriate VAD is taken shortly afterwards. Although it is uncertain whether a patient's episode will be terminated prematurely due to a readmission, one can use the model to forecast both scenarios i.e. whether a readmission did or didn't occur.

Costs required for service delivery

In the absence of a formal breakdown of costs incurred by the hospital to offer inpatient parenteral antimicrobial therapy (IPAT), the first preferred cost analysis exercise using the daily cost of a general ward bed stay was dismissed. Instead an activity-based costing exercise was carried out to deduce the running cost of the

service. This evaluation was based on staff's partial salary allocations and any incurred fees to execute OPAT related tasks. Since the OPAT team carry out other functions apart from OPAT duties, their 'partial' salaries were calculated using full-time equivalents (FTE) calculated for the doctors, nurses, pharmacist and clerk based on the self-reported time they allocated to perform their duties. First the mean of task completion durations was calculated over a period of one month. Subsequently, the FTE was calculated by dividing the total scheduled hours for an employee by the total of hours for a full-time work week (i.e. 40hours). The following equation was used to calculate FTE:

FTE= total number of hours to perform all tasks/40hours

If the employee gave a time range for a specific task, the minimum and maximum FTEs were calculated. The cost incurred by the institution to employ the team to run the service was calculated by multiplying the FTE by the mean salary of the respective profession. The salary brackets were based on the grades of the team at the time and the corresponding annual pay for 2019, excluding allowances. Setting up costs were not included in the evaluation since certain administrative resources were already made available to the team (including office space, pagers, landlines, storage space etc) or were not pertinent for an activity to take place.

## 4.3 Results

A total of 132 episodes were recorded using the visiting nurse OPAT model during the timeframe. Of these, 117 patients had a single episode whilst 15 patients had two episodes. The second episode was up to the discretion of the OPAT team. For some patients this took place after a few weeks or months whilst for others, this occurred after a readmission (which terminated the first episode). Considering the differences between repeat episodes (e.g. choice of antimicrobial agent), for the purpose of analysis, data were presented per episode rather than per patient.

### 4.3.1 Study outcome: patient demographics and OPAT episode characteristics

4.3.1.1 Patient demographics

From a total of 117 enrolled patients, 76 patients were male (65%) and 41 patients were females (35%). The youngest patient was 16 years old whilst the oldest was 92 years old. The mean age of the cohort was 61.3 years and the standard deviation was 14.9.

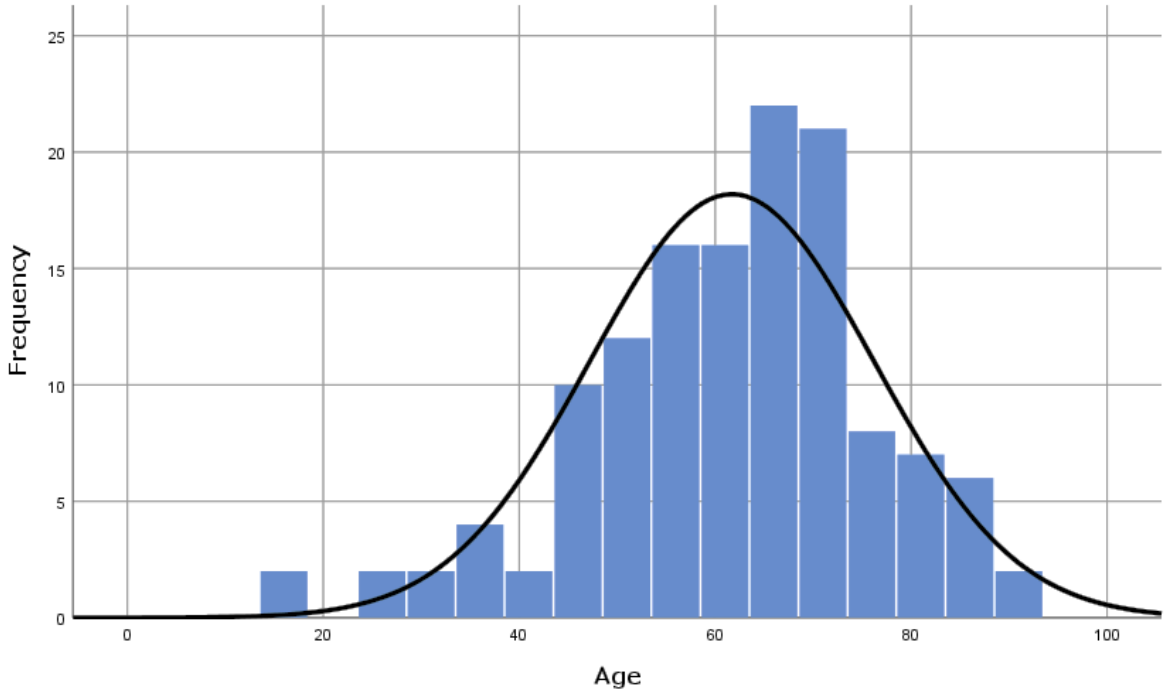


Figure 4.1 Histogram illustrating age groups of patient cohort

4.3.1.2 OPAT episode referral characteristics

The 132 episodes were characterised by the following referrals namely: 29 referrals from a surgical ward (22%), 27 referrals from the infectious diseases ward (20.5%), 22 referrals from medical wards (16.7%), 21 referrals from orthopaedic wards (15.9%), nine referrals from cardiac wards (6.8%) eight referrals from urology wards and another eight referrals from the diabetic foot ward (6.1%), five referrals from the ENT ward (3.8%), two referrals from accident and emergency department (1.5%) and another referral from an oncology ward (0.8%).

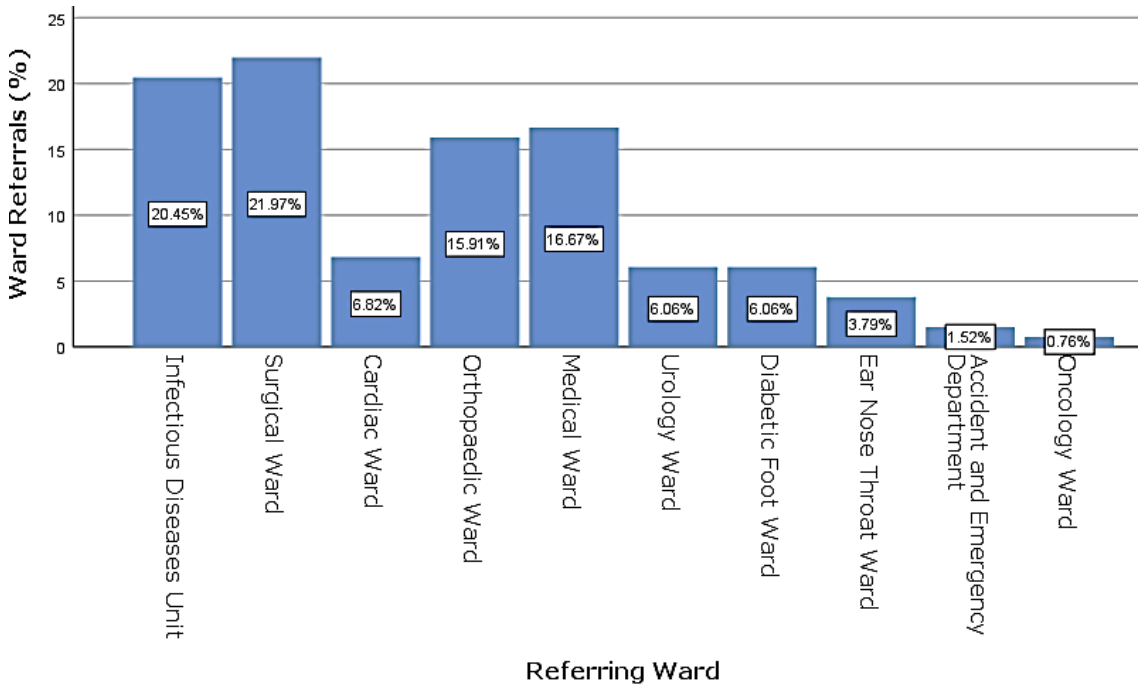


Figure 4.2 Bar chart of the percentage ward referrals to OPAT infectious diseases consultants

Considering that patient's ward location might not necessarily reflect the speciality of the referring care team due to limitations of hospital bed management, data were gathered about the referring consultant. The OPAT infectious diseases consultants flagged and discharged 35 patients- the largest proportion of patients (26.5%) onto the service. Other referrals were received from medical consultants (28 episodes, 21.2%), vascular surgeon consultants (25 episodes, 18.9%), orthopaedic consultants (20 episodes, 15.2%), surgical consultants (9 episodes, 6.8%), cardiac consultants (5 episodes, 3.8%), ENT consultants (4 episodes, 3%), urology consultants (3 episodes, 2.3%) and oncology consultants (3 episodes, 2.3%). No referrals were received from emergency department consultants.

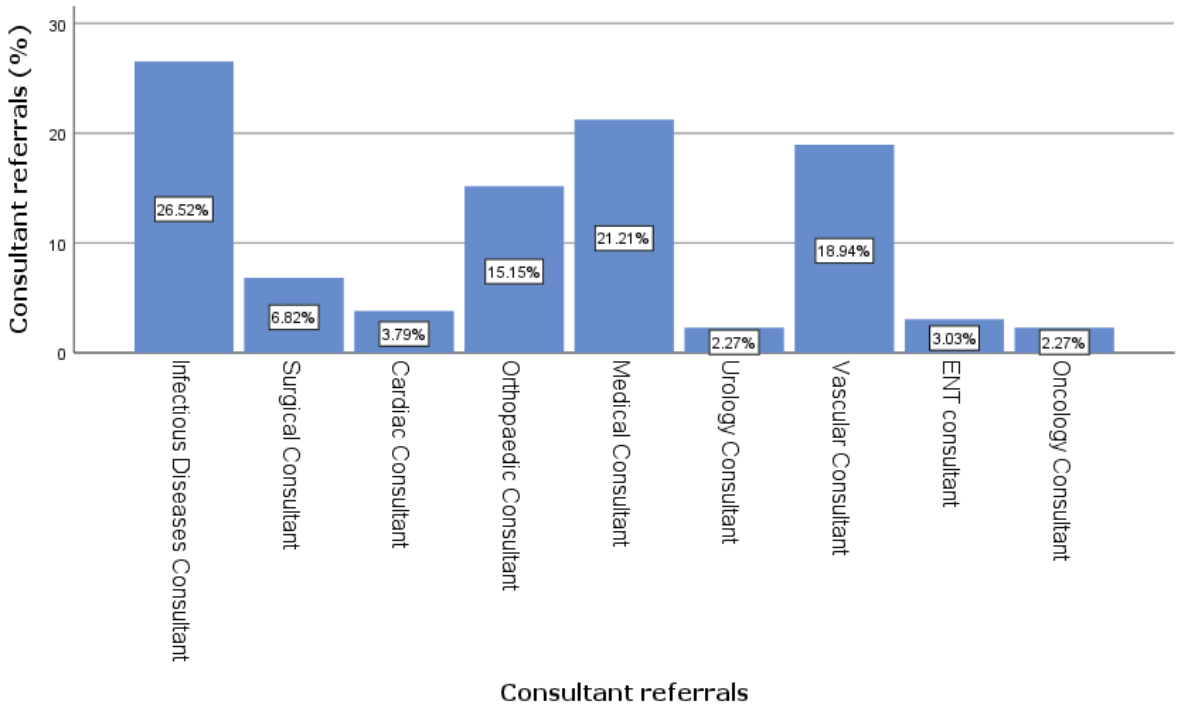


Figure 4.3 Percentage referrals by referring consultant to OPAT infectious diseases consultants

#### 4.3.1.3 OPAT Infectious disease physician

The head of the OPAT service had the greatest number of patients (n=94) under his care (71.2%) The other two infectious disease consultants took care of the remaining approximately 25% of patients with one physician being responsible for 27 patients (20.5%) and the other of 11 patients (8.3%).

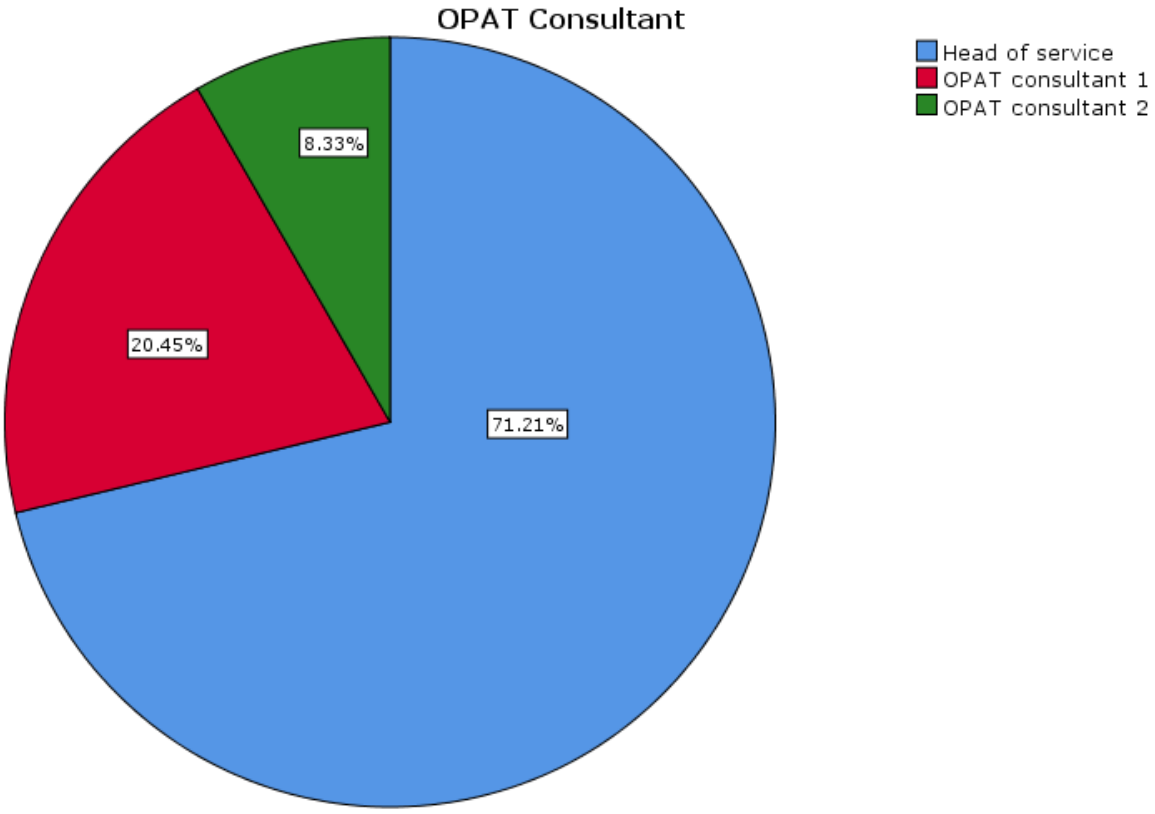


Figure 4.4 Pie chart illustrating the proportion of episodes as per the responsible OPAT consultant

#### 4.3.1.4 Choice of VAD and antimicrobial treatment used

Most episodes were characterised by the insertion of a PICC (n=112, 84.8%). The other episodes required the insertion of peripherally inserted intravenous catheters, three midlines (2.3%) and 10 intravenous cannulas (7.6%). Seven episodes were characterised by the insertion of an implantable venous access system (5.3%).

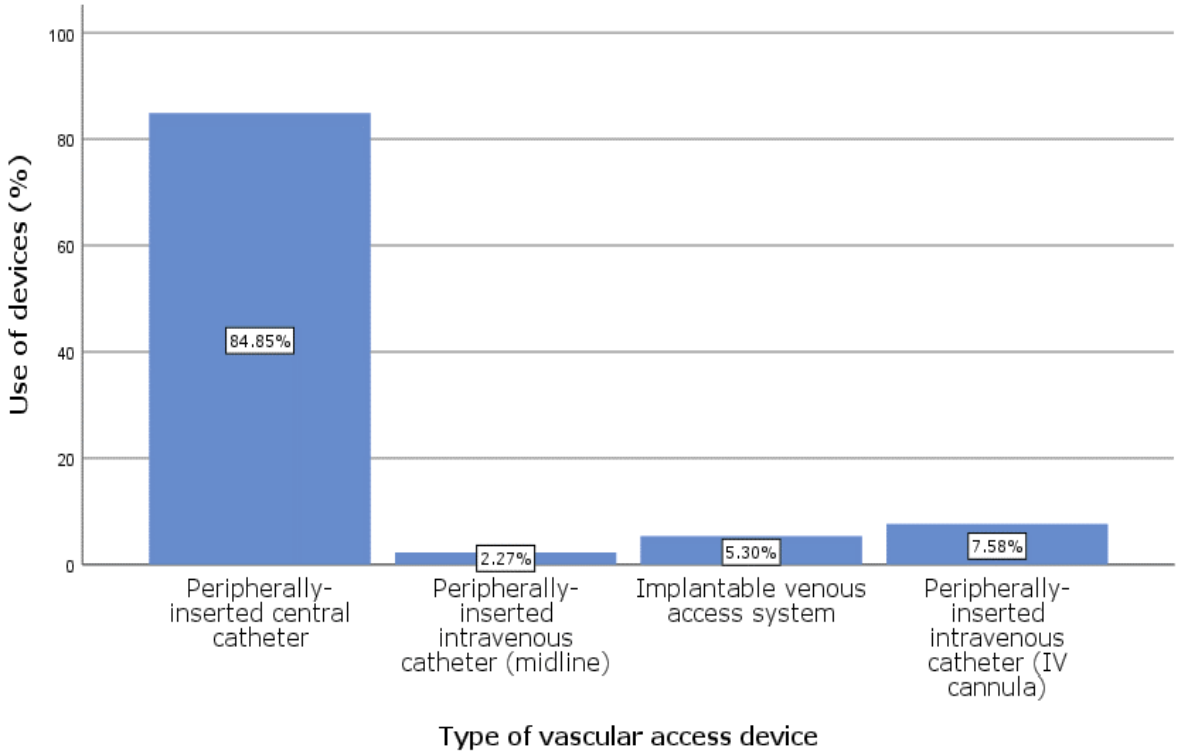


Figure 4.5 Percentage of VAD used on patients

The most predominantly used antimicrobial as a single agent was ceftriaxone with a total of 52 courses making use of this drug (34.9%). Following ceftriaxone, ertapenem was used for 38 courses (25.5%), teicoplanin in 21 courses (14.1%), ceftazidime in 19 courses (12.8%), tigecycline in eight courses (5.4%), meropenem in six courses (4%), colistimethate in three courses (2%) and piperacillin/tazobactam in two courses (1.3%). A total of 149 antimicrobial agents were used.

Only 17 (11.4%) antimicrobial courses out of the total 132 courses saw the concomitant use of two antimicrobials during the same patient episode. The most frequent combination was that of teicoplanin and ertapenem (9 courses, 52.9%). This combination was followed by four courses of ceftriaxone and teicoplanin (23.5%), two courses of colistimethate and meropenem (11.8%), a course of ceftriaxone and tigecycline (5.9%) and another course of ceftazidime and colistimethate (5.9%).

4.3.1.5 MRSA carriage and presenting infections prevalence

Only 6 patients (4.5%) tested positive for MRSA following screening using a nasal swab. Only one of these patients was readmitted during OPAT provision.

The presenting infections were divided into seven categories as can be seen in the bar graph below.

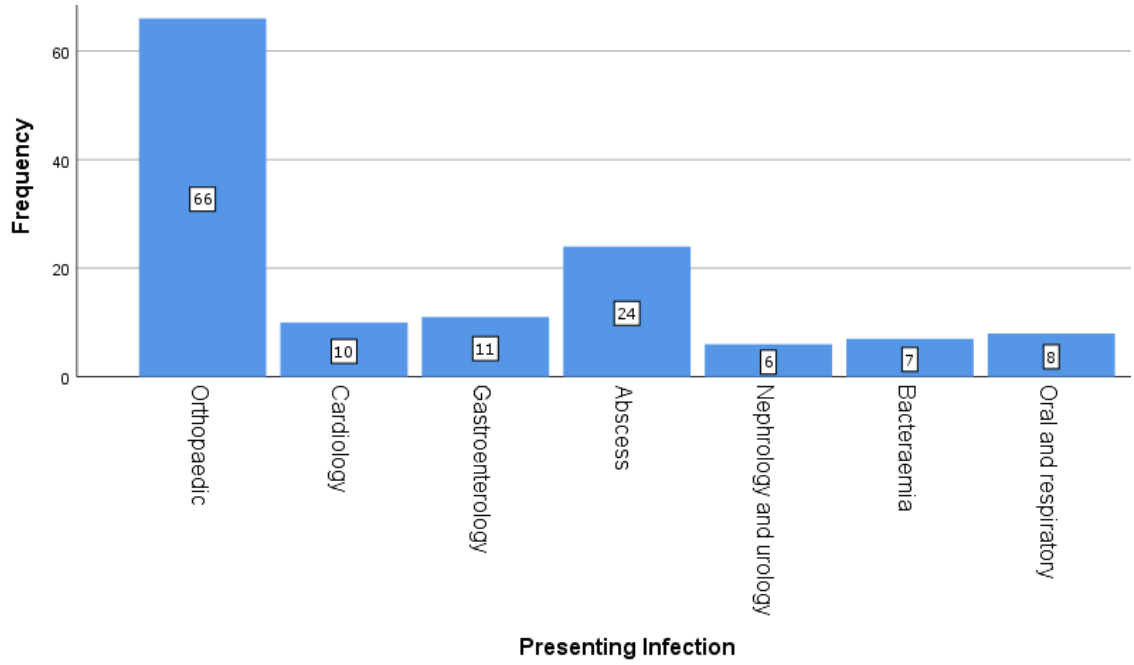


Figure 4.6 Presenting infections treated through the provision of the OPAT service

Half of the presenting infections fell under the orthopaedic category which grouped cases such as osteomyelitis, fractures, prosthetic joint infections etc. (n=66, 50%). The other half were characterised by the following presenting infections: 24 episodes treated abscesses in various sites including liver, brain, skin and spine (18.2%), 10 episodes were grouped under the cardiology speciality and included infections such as infective endocarditis (7.6%), 11 episodes were grouped under gastroenterology and included infections such as intra-abdominal infections and sclerosing cholangitis (8.3%), eight episodes were grouped under the

oral/respiratory category and included infections such as osteonecrosis of the jaw, bronchiectasis, oral actinomycosis etc (6.1%), seven episodes treated bacteraemia (5.3%) and another six episodes were grouped under the nephrology/urology category for infections such as urinary tract infection, pyelonephritis etc. (4.5%).

#### 4.3.1.6 Cost of a hospital stay

Based on the assumption that the duration of inpatient parenteral antimicrobial therapy (IPAT) is equivalent to the observed duration of the OPAT episodes, the cost for what would have been an inpatient stay was calculated. The total mean cost (based on the observed OPAT episode durations) amounted to approximately €39,600. The highest mean cost was attributed to orthopaedic related infections (€7234.0), followed by oral and respiratory (€7046.3), nephrology and urology cases (€6790.1) and abscesses (€6651.3).Table 4.2 shows that despite the greatest expenditure is attributed to orthopaedic cases, episodes treating abscesses had a greater financial impact with a minimum cost of €1793.6 as opposed to €512.5.

Table 4.2 Cost of hospitalisation according to the presenting infection

| | N | Mean (€) | Std. Deviation | Minimum (€) | Maximum (€) |
|---|---|---|---|---|---|
| Orthopaedic | 66 | 7234.0 | 4364.5 | 512.5 | 27672.8 |
| Cardiology | 10 | 4560.9 | 2024.1 | 512.5 | 7430.7 |
| Gastroenterology | 11 | 5008.1 | 4268.2 | 1281.2 | 14605.1 |
| Abscess | 24 | 6651.3 | 3691.9 | 1793.6 | 15630.0 |
| Nephrology and urology | 6 | 6790.1 | 5858.1 | 768.7 | 13836.4 |
| Bacteraemia | 7 | 2306.1 | 1087.1 | 1281.2 | 4612.1 |
| Oral and respiratory | 8 | 7046.3 | 7218.8 | 1793.6 | 23573.2 |

4.3.1.7 Comparison of categorical variables using the Pearson's Chi Squared test

The Pearson's Chi-squared test was used to assess the association between two categorical variables. The null hypothesis specified that there was no association between the two categorical variables and was accepted if the p-value exceeded the 0.05 level of significance. The alternative hypothesis specified that there was a significant association between the two categorical variables and was accepted if the p-value was less than the 0.05 level of significance.

Only the comparison between patient death and type of VAD resulted in a significant result. There was one patient (n=1) who died whilst receiving OPAT while the remaining 131 patients did not. Moreover, there were many patients who

had a PICC inserted (n=112). The p-value of chi square (p=<0.001) was less than the 0.05 level of significance and indicated that there is an association between the two variables. In other words, the prevalence death is specific to the type of vascular access device. However, this result has to be interpreted in its context i.e. only one patient passed away during the study timeframe.

On the other hand, the comparison between the presenting infection and readmissions (p=0.876), the prevalence of death and MRSA carriage (p=0.827), and the prevalence of death and presenting infection (p=0.086) did not result in a statistically significant result thus indicating that the variables weren't specific to each other. More details of the Pearson's chi squared results can be found in Appendix 4.3.

### 4.3.2 Study outcome: OPAT completion status

A total of 23 episodes were interrupted by a readmission (17.4%) whilst the other 109 episodes (82.6%) were seen to completion, giving a success rate of 82.6%. Of these 23 prematurely terminated episodes, 20 (87.0%) were unplanned whilst three (13.0%) were electives. As expected, a high proportion of these episodes were characterised by the utilisation of a PICC line as the VAD (n=18). The unplanned readmissions were mainly due to worsening symptoms of the presenting infection being treated by OPAT including phlebitis, fever, diarrhoea, lethargy etc. (6, 30.0%). The second reason was due to worsening of the patient's comorbidities (3 episodes, 15.0%%). Other factors included erythema of the infected site (3 episodes, 15.0%), atrial fibrillation (2 episodes, 10.0%), deep vein thrombosis (2 episodes, 10.0%), anaemia (1 episodes, 5.0%), death (1 episodes, 5.0%), switch to oral therapy (1 episode, 5%) and social circumstances (1 episode, 5.0%). Of these 20 unplanned cases, the majority of the patients were receiving care for an orthopaedic infection (n=12, 60%) followed by another three who were diagnosed with an abscess (n=3, 15%), two who had a heart infection (n=2, 10%), one who had nephrology related infection, one who had an oral and respiratory system related infection (n=1, 5%) and one patient who passed away due to oncology related complications (n=1, 5%).

### 4.3.3 Study outcome: OPAT duration

#### 4.3.3.1 Observed OPAT duration

A steady increase was seen in the number of episodes recorded every year of OPAT provision. During the first year (beginning of October 2016-2017) 29 episodes were recorded (total of 736 days), during the second year (beginning of October 2017-2018) 47 episodes were recorded (total of 1306 days) whilst in the third year (beginning of October 2018-2019) 55 episodes were recorded (total of 1245 days). The total recorded observed days was that of 3,287 days. During the three-year period only 15 patients (12.8%) had two OPAT episodes.

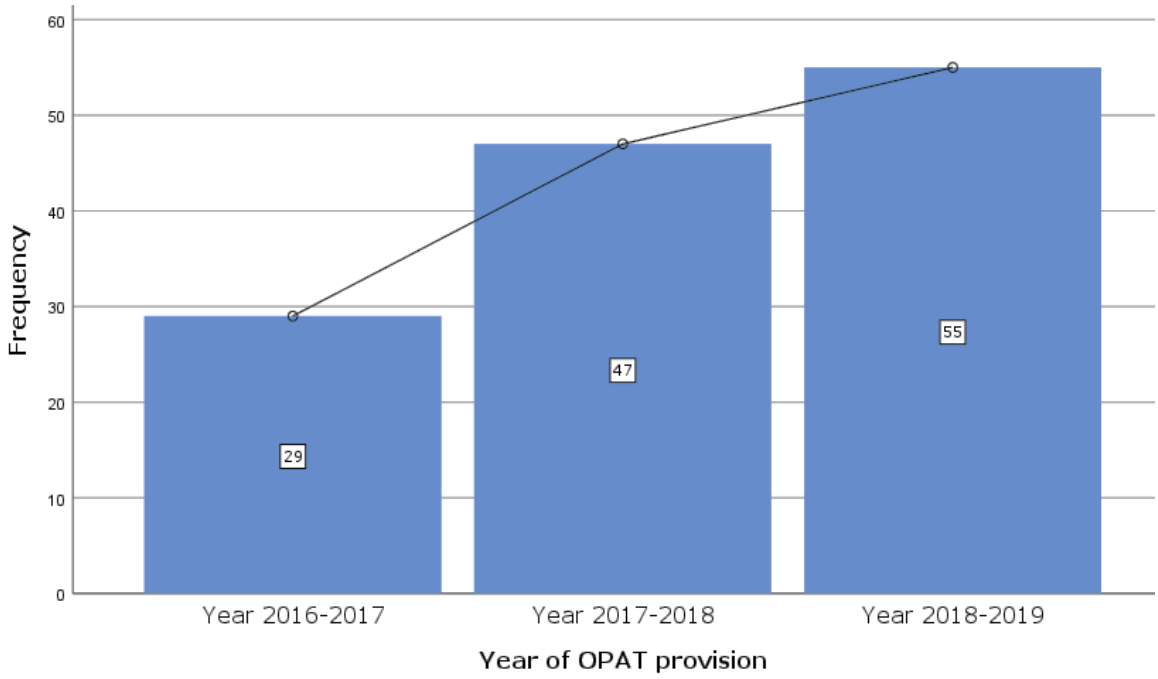


Figure 4.7 Bar chart illustrating the number of episodes recorded per year

The longest observed duration was that of 108 days and only occurred for one patient (0.8%).

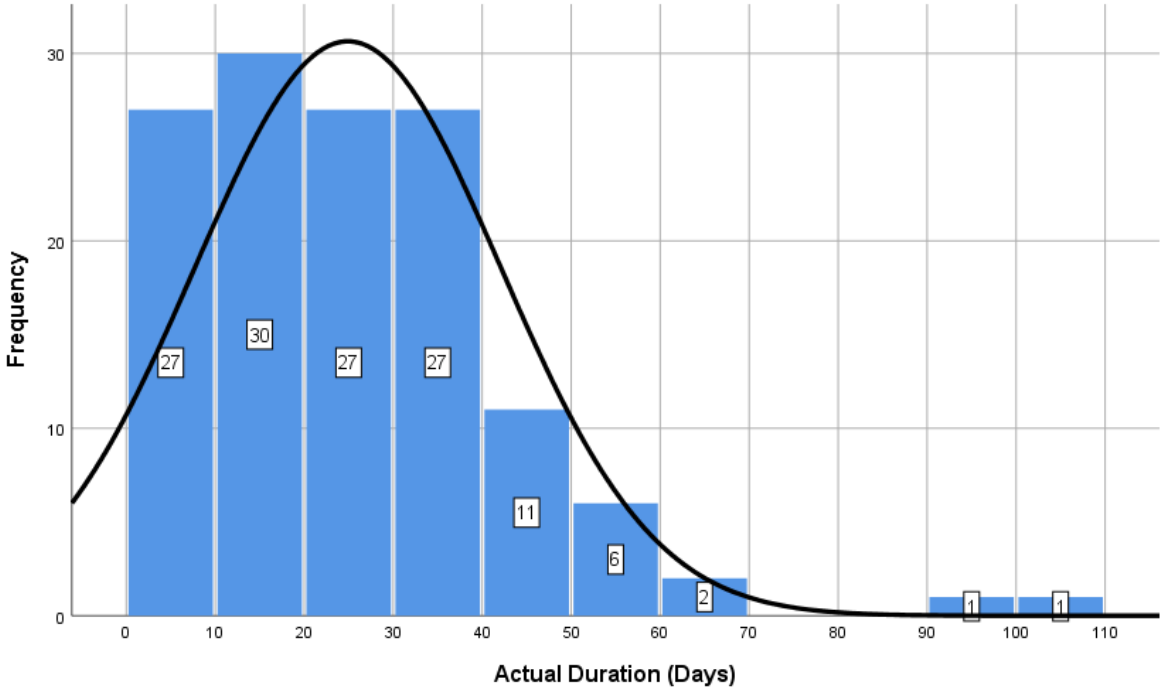


Figure 4.8 Histogram of the frequency of the observed durations of OPAT provision

There were certain patient and OPAT episode characteristics that contributed to the length of the OPAT episode. Longer durations were seen when patients had a PICC line as the VAD of choice (median=25 days, IQR=13-36). Subsequently, implantable venous access systems (median=18 days, IQR=10-23.5), peripherally inserted intravenous cannula midlines (median=8 days, IQR=7.5-8) and Venflon® (median=6.5 days, IQR=5-7.75) ensued in duration. Moreover, episodes which could follow their nature course (median=24 days, IQR=7-25.5) and were not terminated prematurely by a readmission (median=11 days, IQR=7-25.5) were longer in duration. Lastly, longer durations were seen for those patients receiving care for orthopaedic infections (median=29 days, IQR=15-37.5), abscesses (median=21.5 days, IQR=13-39.25), nephrology infections (median=21.5 days, IQR=8.25-46.75), oral and respiratory cases (median=21 days, IQR=7.75-29.5) and cardiology infections (median=19 days, IQR=13.25-23.5). OPAT care for patients diagnosed with gastroenterology infections (median=13 days, IQR=7-25) and bacteraemias (median=8 days, IQR=7-9) rendered shorter episodes.

#### 4.3.3.2 Forecasted and Expected Duration of therapy

The OPAT infectious diseases consultants were asked to give a forecast duration prior to discharging the patient on OPAT. From Table 4.3 below one can notice a discrepancy between the median and interquartile ranges of the forecasted duration (median=22; IQR=10.75-42) and the observed duration (median=28, IQR=14-42).

Table 4.3 Frequencies for the forecasted and observed durations

| | Forecasted Duration (days) | Actual Duration (days) |
|---|---|---|
| Median | 28.00 | 22.00 |
| Mode | 42 | 7 |
| Std. Deviation | 20.139 | 17.182 |
| Range | 177 | 106 |
| Minimum | 5 | 2 |
| Maximum | 182 | 108 |
| Sum | 3943 | 3287 |

#### 4.3.3.3 Test for Normality

The Kolmogorov-Smirnov test is used to check the underlying distribution of a continuous covariate. The p-value in this test indicates the normality of the distribution. If the p-value is 1, then the underlying distribution is perfectly normal. This normality assumption becomes less evident as the p-value gets closer to 0. In this case, the normality of the actual observed duration of OPAT service provision was tested, with the null hypothesis specifies that data has a normal

distribution. On the other hand, the alternative hypothesis specifies that the data has a non-normal distribution.

For the observed duration, the p-value is 0.007 and was significantly smaller than the 0.05 level of significance. Therefore, the Kolmogorov-Smirnov test indicated that the observed duration did not follow a normal distribution. In conclusion, since the data was not normally distributed, only non-parametric tests could be used to analyse the collection tool's content (Table 4.4).

Table 4.4 Test for normality using the One-Sample Kolmogorov-Smirnov Test on the actual observed durations

| | | Observed Duration |
|---|---|---|
| N | | 132 |
| Normal Parameters | Mean | 24.90 |
| | Std. Deviation | 17.182 |
| Asymp. Sig. (2-tailed) | | 0.007 |

4.3.3.4 Comparison of the forecasted and observed durations using the Wilcoxon signed ranks test

For this study, the forecasted duration was the number of days the responsible OPAT infectious disease consultant thought the patient required the service prior to discharge. For the actual observed duration, the number of days were calculated by finding the range between the first and last nurse assisted visit at the patient's residence.

The Wilcoxon signed ranks test was used to test whether the medians of two related populations differed significantly when these populations did not have a normal distribution. In this case, the test was used to compare the mean estimated service duration with the mean observed duration for 132 patient episodes. The null hypothesis specified that forecasted and observed durations were comparable and was accepted if the p-value exceeded the 0.05 level of significance. The

alternate hypothesis specified that the forecasted and observed durations varied significantly and was accepted if the p-value was less that the 0.05 criterion.

The observed mean duration (24.90 days) was approximately 5 days less than the forecasted mean duration (29.87 days) This difference was significant since p-value (<0.001) was less than 0.05 level of significance hence we can generalise that patients stay on the OPAT service for a significantly shorter period than predicted (Table 4.5).

Table 4.5 Comparison of durations using the Wilcoxon signed ranks test

| | Forecasted Duration – Actual Duration |
|---|---|
| Z | -4.102b |
| Asymp. Sig. (2-tailed) | <0.001 |

On average, the service reduced the forecasted duration of the participants by approximately 5 days. Since the p-value was less than the level of significance, this implies that this reduction was not attributed to chance.

#### 4.3.3.5 Influence of the categorical variables on the observed duration

The Kruskal-Wallis test is a non-parametric test which compares means of a continuous variable in two or more independent groups. This test was used to compare the mean observed duration on OPAT provision between the different categorical variables.

The null hypothesis specified that the mean observed duration vary marginally between the different presenting infections and is accepted if the p-value exceeds the 0.05 level of significance. The alternate hypothesis specified that the mean observed durations vary significantly between the presenting infections and is accepted if p-value is less than 0.05 criterion.

Following univariate analysis (Table 4.6), only three variables were considered to have a statistically significant impact on the observed OPAT duration including the type of VAD ($p<0.001$), the presenting infection ($p=0.021$) and the readmission rate ($p=0.005$). When the Kruskal-Wallis test was applied, all three variables resulted in a p-value smaller than the 0.05 level of significance thus, the null hypothesis was rejected.

On the other hand, the number of visits ($p=0.915$), patient gender ($p=0.693$), patient death ($p=0.345$), number of drugs ($p=0.217$) and MRSA carriage ($p=0.315$) gave p-values which exceeded the 0.05 level of significance. Therefore, the null hypothesis was accepted. This lack of significance was partly attributed to the fact that the sample size of episodes characterised by more than one visit was rather small, only one patient died and only a few patients tested positive for MRSA carriage. Detailed outputs of the Kruskal-Wallis test can be found in Appendix 4.2.

Table 4.6 Comparison of categorical variable on the observed duration using the Kruskal-Wallis test.

| **Categorical variable** | **K-W test** | **p-value** |
|---|---|---|
| Presenting infection | 14.868 | 0.021 |
| Readmission | 7.874 | 0.05 |
| Number of visits | 0.012 | 0.915 |
| Gender | 0.156 | 0.693 |
| Death | 0.894 | 0.345 |
| VAD | 20.36 | <0.001 |
| MRSA | 1.011 | 0.315 |

#### 4.3.3.6 Generalised linear model (GLM)

##### 4.3.3.6.1 The GLM for this study

The GLM identifies all three predictors as significant when analysed collectively since all of them yielded a p-value smaller than the 0.05 level of significance as shown in Table 4.7.

Table 4.7 The p-values for the three significant variables

| | Wald Chi-Square | df | p-value |
|---|---|---|---|
| (Intercept) | 52.221 | 1 | 0.000 |
| Indication | 14.098 | 6 | 0.029 |
| Readmission | 4.904 | 1 | 0.027 |
| Vascular Access Device | 15.540 | 3 | 0.001 |

However, the VAD was the best predictor of actual duration since it has the lowest p-value. This was followed by the patient readmission and the presenting infection. By using the GLM results as shown in Table 4.7, a predictor model could be devised based on the three significant variables to predict future patient episodes (Table 4.8).

Table 4.8 Generalised linear model results

| Parameter | B | Std. Error | Hypothesis Test | | |
|---|---|---|---|---|---|
| | | | Wald Chi-Square | df | P-value |
| Intercept | 0.086 | 0.0203 | 18.050 | 1 | 0.000 |
| Indication=Orthopaedic ($I_1$) | 0.009 | 0.0072 | 1.482 | 1 | 0.224 |
| Indication=Cardiology ($I_2$) | 0.028 | 0.0124 | 4.995 | 1 | 0.025 |
| Indication=Gastroenterology ($I_3$) | 0.017 | 0.0111 | 2.381 | 1 | 0.123 |
| Indication=Abscess ($I_4$) | 0.012 | 0.0082 | 2.014 | 1 | 0.156 |
| Indication=Nephrology and Urology ($I_5$) | 0.003 | 0.0112 | 0.081 | 1 | 0.776 |
| Indication=Bacteraemia ($I_6$) | 0.078 | 0.0257 | 9.098 | 1 | 0.003 |
| Indication=Oral and Respiratory ($I_7$) | 0 | . | . | . | . |

| | | | | | |
|---|---|---|---|---|---|
| Readmission=Yes ($R_1$) | 0.015 | 0.0069 | 4.904 | 1 | 0.027 |
| Readmission=No ($R_2$) | 0 | . | . | . | . |
| Vascular Access Device=PICC ($V_1$) | -0.062 | 0.0195 | 10.238 | 1 | 0.001 |
| Vascular Access Device=Midline ($V_2$) | 0.037 | 0.0490 | 0.557 | 1 | 0.456 |
| Vascular Access Device=Portacath ($V_3$) | -0.052 | 0.0227 | 5.224 | 1 | 0.022 |
| Vascular Access Device=IV cannula ($V_4$) | 0 | . | . | . | . |
| (Scale) | 0.355 | 0.0414 | | | |

As demonstrated in Table 4.8, the subcategories for oral and respiratory cases (parent category: Indication; $I_1$-$I_7$), occurrence of a readmission (parent category: Readmissions; $R_1$ and $R_2$) and type of implantable venous access systems (parent category: VAD; $V_1$-$V_4$) gave a value of 0 indicating they were not required to determine the duration of an episode and were thus removed. Moreover, the intercept for this regression analysis was of 0.086 as shown in Table 4.8. For these reasons, and the fact that the exponential function gamma was chosen with a reciprocal link function, the GLM string is the following:

$1/duration=0.086+0.009I_1+0.028I_2+0.017I_3+0.012I_4+0.003I_5+0.078I_6+0.015R_1 -0.062V_1+0.037V_2-0.052V_3$

4.3.3.6.2 A worked example of a hypothetical episode using the GLM

For example, it is possible to predict the actual duration of an episode which involved treating a patient for an abscess, who was readmitted and administered antimicrobials through a midline by applying the predictor model string shown above.

1/duration= 0.086+0.012+0.015+0.037

1/duration= 0.15

Actual duration= 6.7days

### 4.3.4 Study outcome, costs required for service delivery from the perspectives of the organisation using an activity-based approach

4.3.4.1 Cost of OPAT nursing duties

One member from each professional discipline (i.e. medical, nursing, pharmaceutical and clerical) gave a list of duties they performed within the remit of the OPAT service and the time they took to perform them. The nurse divided

their duties into three categories namely treatment outreach (defined as the tasks involved in the administration of the antimicrobial(s) in the patient residence), referrals (grouping the tasks prior to the enrolment of the patient including education, getting consent etc.) and virtual ward rounds (i.e. participation in the team's weekly discussion about the patients' progression/deterioration). For each task, the nurse reported taking approximately one hour for an outreach, one hour a week for the virtual ward round and between 30 to 45 minutes for a referral. Considering that the study ran for a total of three years (i.e. 156 weeks) one could deduce that 156 hours were dedicated to attendance in virtual ward rounds. Moreover, since the service registered a total of 132 episodes, between 66 to 99 hours were dedicated to referrals (duration range multiplied by 132 episodes). The treatment outreach duration for each episode was calculated by multiplying the observed OPAT duration (the number of days from the first to last visit) by the number of daily visits for that episode to give the total number of visits. Since each outreach was estimated to last one hour, the value obtained reflected the treatment outreach duration. This calculation was performed for each of the 132 episodes. A total of 4,026 hours were dedicated to nursing OPAT duties. Thus, one can infer that since nurses were employed for a 40-hour week, the minimum FTE was 0.68 and the maximum was 0.69.

Most of the OPAT nurses earned a basic pay scale 9 i.e. between € 21,252.00 and €23,936. An average was taken i.e. €22,594 and divided by 52 weeks to generate the average salary per week to employ a nurse i.e. €434.50. Therefore, the salary required for OPAT nursing tasks ranged from €295.79 and €298.09 as shown in Table 4.9.

Table 4.9 Breakdown of tasks and salary calculation for nurse related OPAT tasks

| **OPAT member of staff** | **Task description** | **Minimum** | **Maximum** |
|---|---|---|---|
| Nurse | Treatment outreach | 4026 hours | 4026 hours |
| | Referrals | 66 hours | 99 hours |
| | Virtual ward rounds | 156 hours | 156 hours |
| | Total (over 3 years) | 4248 hours | 4281 hours |
| | Full time equivalent (FTE) | 0.68 | 0.69 |
| | Mean nurse salary/week | €434.50 | |
| | Salary of nurse for OPAT tasks | €295.79 | €298.09 |

4.3.4.2 Cost of OPAT medical duties

The medical representative also attributed one hour a week for the virtual ward round and between 30 to 45 minutes for a referral. Considering that the study ran for a total of three years (i.e. 156 weeks) one could deduce that 156 hours were dedicated to attendance in virtual ward rounds. Moreover, since the service registered a total of 132 episodes, between 66 to 99 hours were dedicated to referrals (duration range multiplied by 132 episodes). Lastly, since a total of 117 patients were enrolled on the service and each outpatient visit took approximately 15 minutes, 30 hours were allocated to this task over the three-year timeframe. Therefore, the minimum and maximum total hours dedicated to OPAT by the medical team equated to 252 hours and 285 hours respectively. Using the FTE equation above, the minimum FTE was 0.04 whilst the maximum FTE was 0.05.

The basic pay for a consultant is €35,251 per annum whilst the basic pay of a resident specialist is of €27,538, with a resultant mean of €29,459 per year (i.e.

€566.52 per week). Therefore, the salary required for OPAT medical tasks ranged from €22.88 and €25.87 as shown in Table 4.10 below.

Table 4.10 Breakdown of tasks and salary calculation for doctor related OPAT tasks

| **OPAT member of staff** | **Task description** | **Minimum** | **Maximum** |
|---|---|---|---|
| Doctor | Outpatient visit | 30 hours | 30 hours |
| | Referrals | 66 hours | 99 hours |
| | Virtual ward rounds | 156 hours | 156 hours |
| | Total (over 3 years) | 252 hours | 285 hours |
| | FTE | 0.04 | 0.05 |
| | Mean doctor salary/week | €566.52 | |
| | Salary of doctor for OPAT tasks | €22.88 | €25.87 |

4.3.4.3 Cost of OPAT pharmaceutical duties

The pharmacy representative also attributed one hour a week for the virtual ward round and between 30 to 45 minutes for a referral. Considering that the study ran for a total of three years (i.e. 156 weeks) one could deduce that 156 hours were dedicated to attendance in virtual ward rounds. Moreover, since the service registered a total of 132 episodes, between 66 to 99 hours were dedicated to referrals (duration range multiplied by 132 episodes). Lastly, in view of a total of 132 episodes, the task of treatment preparation took approximately 20 minutes each time thus 44 hours were allocated to this task over the three-year timeframe. Therefore, the minimum and maximum total hours dedicated to OPAT by the pharmacy team equated to 266 hours and 299 hours respectively. Using the FTE equation above, the minimum FTE was 0.04 whilst the maximum FTE was 0.05.

The OPAT pharmacist earned an average basic pay (scale 7) of €26,618. This was divided by 52 weeks to generate the average salary per week to employ a

pharmacist i.e. €511.88. Therefore, the salary required for OPAT pharmacist's tasks ranged from €21.82 and €24.53 as shown in Table 4.11 below.

Table 4.11 Breakdown of tasks and salary calculation for pharmacist related OPAT tasks

| **OPAT member of staff** | **Task description** | **Minimum** | **Maximum** |
|---|---|---|---|
| Pharmacist | Treatment preparation | 44 hours | 44 hours |
| | Referrals | 66 hours | 99 hours |
| | Virtual ward rounds | 156 hours | 156 hours |
| | Total (over 3 years) | 266 hours | 299 hours |
| | FTE | 0.04 | 0.05 |
| | Mean pharmacist salary/ week | €511.88 | |
| | Salary of nurse for OPAT tasks | €21.82 | €24.53 |

4.3.4.4 Cost of clerical support staff

The clerical representative declared that the only task performed in relation to OPAT was the collection and storage of treatment, which took approximately 30 minutes. Therefore, the total hours dedicated to OPAT by the clerical support staff equated to 66 hours over the three year timeframe. Using the FTE equation above, the FTE for clerical work was of 0.01.

Based on the minimum national wage, the clerk earns a total €761.97 per month, i.e. a mean of €190.49 per week. Therefore, the salary required for clerical support staff equated to €2.01 as shown in Table 4.12.

Table 4.12 Breakdown of tasks and salary calculation for clerical related OPAT tasks

| **OPAT member of staff** | **Task description** | **Minimum** | **Maximum** |
|---|---|---|---|
| Clerk | Treatment collection | 66 hours | As minimum |
| | Total (over 3 years) | 66 hours | |
| | FTE | 0.01 | |
| | Mean clerk salary/ week | €190.49 | |
| | Salary of clerk for OPAT tasks | €2.01 | |

4.3.4.5 Other costs

Considering the fuel consumption and the car rental were required to perform the activity related to outreaches, their fees which amounted to €4200 and €12,800 respectively, were included in the calculation. Table 4.13 depicts the final values for the generation of the average monthly and weekly expenditure to run the service.

Table 4.13 Breakdown of expenses required to run the OPAT service

| **OPAT expenses** | **Minimum** | **Maximum** |
|---|---|---|
| Nurse salary | €295.79 | €298.09 |
| Doctor salary | €22.88 | €25.87 |
| Pharmacist salary | €21.82 | €24.53 |
| Clerk salary | €2.01 | As minimum |
| Fuel consumption | €26.92 | As minimum |
| Car rental | €82.05 | As minimum |
| Total weekly expenditure | €451.47 | €459.47 |
| Total daily expenditure | €64.50 | €65.64 |
| Average weekly expenditure | €455.47 | |

## 4.4. Discussion

### 4.4.1 Findings

The national OPAT service managed to save 3287 hospitalisation days over the three-year period. This achievement is due to the service provision of 132 episodes to a total of 117 patients. From these episodes, only 23 episodes (17%) resulted in the patient's readmission to hospital thus the success rate was of 82.6%. Moreover, using an activity-based approach, the various expenses contributing to the financial requirements of the service were identified. It was deduced that a mean of €455.47 was required per week to run the service from the organisation's perspective.

These findings reflect positively on the momentum gained by the service locally. In the recently published UK guidelines on OPAT, paramount importance was given to service audits and evaluation. In fact, the guidelines state that "data on readmissions, death during OPAT, adverse drug reactions, vascular access complications and healthcare-associated infections, e.g. *Clostridioides difficile* associated diarrhoea and *Staphylococcus aureus* bacteraemia, should also be recorded". Moreover, importance to "data on OPAT patients should be recorded prospectively for service improvement and quality assurance including auditing and benchmarking. A local database would facilitate this process" was also given in the outcomes monitoring section (Chapman et al., 2019).

Over the three years of the study, the service demonstrated its ability to adapt. This versatility was seen in the treatment and resolution of a large variety of presenting infections which were grouped into 7 different categories namely: orthopaedic, cardiology, gastroenterology, nephrology and urology, oral and respiratory, abscesses and bacteraemias. The most commonly treated infections pertained to the orthopaedic category with a total of 66 episodes which represented half of the infections treated during this timeframe. This is an important finding when one considers MDH is an acute general teaching hospital which does not show preferential treatment towards a particular speciality in terms of resource allocation. Considering the significant impact, the presenting infection had on the mean observed duration, one can infer that the service's resources

(staff workload, material etc.) were not equally distributed in treating various patients. The concept of offering OPAT to treat a multitude of presenting infections is well reported in the literature (Keller et al., 2018; Durojaiye et al., 2018; Saini et al., 2019; Hatcher et al., 2019; Briquet et al., 2019). Despite this broad service provision, the lack of resources in terms of human resources influenced the maximum capacity of the service and the launch of the self-administration model as will be discussed in other phases of this thesis.

Another result which reflected the service's versatility was the range of patient ages with the youngest being 16 years old and oldest 92 years old. The consideration here is that patients of different ages lead different lifestyles and conduct different daily activities (Twiddy et al., 2018; Berrevoets et al., 2018). In the morning, a 20-year-old might be preparing to attend a lecture at university, a 40-year-old might be preparing for work and an 80-year-old might be preparing to attend a service at their local church. The coordination between the OPAT team members and the patients made it possible to adjust the timeframes of the visits to accommodate both parties irrespective of the duration of the service provision.

Lastly, another adaptation was made by the members of the OPAT team especially the nurses when a new antimicrobial was introduced for use on the service. When the service was launched in October 2016, only three antimicrobials were considered, namely ceftriaxone, ertapenem and ceftazidime. Over the years, this number increased and, by the end of October 2019, a total of 8 antimicrobials were available to patients enrolled on the service including teicoplanin, tigecycline, meropenem, colistimethate and piperacillin/tazobactam. With assistance from the OPAT pharmacist, the team were immediately trained in the reconstitution of each newly introduced drug to ensure patients weren't delayed treatment. Since the OPAT service is an extension of the services offered by the hospital, the OPAT doctors were at liberty to introduce new agents and practice evidence-based prescribing due to the lack of financial burdens imposed on the patients (as all expenses are covered by the government). Ceftriaxone remained the most frequently prescribed drug during the three-year timeframe with a total of 52 episodes as was the case with other published studies (Minton et al., 2017; Yang et al., 2017; Durojaiye et al., 2018; Hatcher et al., 2019; Briquet et al., 2019).

The level of adaptation was stretched even further when the OPAT consultants started to prescribe combinations of antimicrobial drugs (Tan et al., 2017; Norris et al., 2018). The first case was seen in March 2017, when an elderly woman required the combination of teicoplanin and ertapenem for the treatment of an infected kidney ablation site and urinoma. With time, a total of 17 episodes were characterised by concomitant prescribing of antimicrobials with the teicoplanin and ertapenem combination being the most frequently prescribed (9 episodes).

Apart from the service's versatility, another important element of any service provision is its success in delivering desirable outcomes. This success was portrayed in multiple ways. Firstly, there was a steady increase in the number of episodes over the years (first year=29, second year=47, third year=55) which indicated that the service reputation appealed to other consultants to refer their patients. Secondly, there were fifteen patients who made use of the service twice which although implying that the presenting infection required further treatment, also meant that the service provision was deemed satisfactory by the referring consultant and the patient to warrant reutilisation. This sheds light on the referring team's satisfaction and trust in the OPAT team and service delivery following their previous episode. In conjunction with recording the referring consultant, the study also captured the patient's location when flagged. Despite the assumption that these should correspond in terms of speciality, this was not always the case due to lack of bed availability, dual consultant coverage and inappropriate bed management. Therefore, to correctly deduce the level of awareness and familiarity of ward staff and referring consultant based on the frequency of discharges and referrals respectively, these elements were recorded separately. As can be seen from the results attained, the patient's ward location and the speciality of the referring consultant did not correspond for any category. For example, despite recording 29 episodes from surgical wards, only 9 surgical consultants referred their patients to the service. This discrepancy sheds light on the fact that one cannot assume that surgical consultants are versed in terms of OPAT referrals and discharges based on the number of discharges from surgical wards. This is an important element which will be discussed in other phases of this study.

Thirdly, the high success rate of the service as expressed by the resolution of the presenting infection. During this timeframe, only 23 episodes resulted in a

readmission whilst the other 109 episodes were seen to completion. The lead factor for readmissions were worsening patient symptoms including fever, lethargy and diarrhoea. One can thus infer that the success rate of the service was of 82.6% and the readmissions rate was 17.4% which is at par with the success rates of other OPAT services globally (Durojaiye et al., 2018; Bellamy, 2018; Norris et al. 2018). In a systematic review compiled by Sriskandarajah et al. (2018), OPAT success rates were higher than 80%, readmission rates ranged between 1% and 14.3% whilst mortality rates ranged between 0 and 1.4%.

Moreover, out of the 6 patients who were carriers for MRSA, only one patient who screened positive was readmitted. This was due to atrial fibrillation (and thus unrelated to the presence of MRSA infection). However, the importance of screening and decolonisation cannot be dismissed, especially considering its implications on the duration of treatment (McKinnon et al., 2011). When interpreting the success rate, it is important to note that a distinction between 'improvement' and 'cure' was not made as it is a subjective nomenclature based on the presenting infection or the patient's overall condition. Therefore, the term 'improvement' was used as a means of deducing the service's success. Lastly, only one person died during the provision of the service which was due to a sudden worsening of his terminal condition and not a shortcoming of the service. A very low, fatality rate also compares with that seen in other published data (Sriskandarajah et al., 2018).

The primary outcome of interest related to this phase of the study was the actual observed duration the patient was under the care of the OPAT team. This duration was essential as it had both a social and financial impact. The longer the duration of treatment, the greater the impact on the patients' quality of life, the staff's workload and the financial burden incurred by the institution. Thus, the importance of appropriate culture and sensitivity results prior to discharge to ensure the right antimicrobials are selected for the patient and for a justified duration was essential. The presenting infection ($p=0.021$), occurrence of a readmission ($p=0.005$) and VAD ($p<0.001$) significantly influenced the actual observed duration of service provision. From these variables it was also possible to devise a GLM to be able to predict future episodes for enrolled patients based these three factors. This model continues to ascertain that better predictions of the forecasted duration can be

made by OPAT consultants at the time of the patient's referral irrespective if the outcome is negative (i.e. occurrence of a readmission). This model gains relevance when one considers the statistically significant discrepancy highlighted between the forecasted and observed durations ($p<0.01$). Maintaining such standards is crucial when one considers that such requirements constantly feature in the latest OPAT guidelines (Norris et al., 2018; Chapman et al., 2019). In fact, the total observed duration was of 3,287 days whilst the forecasted duration was of 3,943 days.

From the results section above it was concluded that the VAD was the factor that most significantly influenced the actual observed duration of the OPAT delivery. The most frequently utilised device, for a total of 112 episodes (112/132, 84.8%) was the PICC line, as it enabled longer durations of treatment. This finding correlates with the published literature (Vila et al. 2016; Keller et al. 2018; Norris et al. 2018; Briquet et al. 2019). In fact, the longest OPAT episode was that of 108 days which required the insertion of a PICC line (to treat a gentleman diagnosed with a prosthetic joint infection following knee surgery) using Ceftriaxone for a multidrug resistant *Staphylococcus epidermidis*. The shortest episodes spanned a total of two days and were all terminated due to a readmission, one was due to a social concern whilst the other two experienced worsening of symptoms. In these three cases, two had a PICC line whilst the other patient had an intravenous cannula.

Another important result generated from this phase was the ability to deduce the weekly running cost of the service. Locally, there is an absence of robust hospital fees which give a breakdown of costs incurred when the patient is treated at hospital. An activity-based approach therefore had to be taken. The subsidiary legal notice on Maltese healthcare fees (S.L.35.28) stipulated the daily cost of hospitalisation based on the patient's location- a general bed stay €256.23, high dependency €489.17 and intensive care €931.75 (S.L.35.28, 2007). Moreover, the members of staff forming part of the OPAT team are responsible for carrying out other duties for the institution e.g. OPAT nurses perform discharge liaison duties, OPAT doctors are responsible for the care of inpatients diagnosed with infectious diseases etc. Having to fulfil multiple tasks within an institution is a well-recognised situation however the current British guidelines state that "all OPAT

team members should have identified time for OPAT in their job plans" (Chapman et al., 2019). For this reason, full-time equivalent units were calculated for OPAT team members and utilised to deduce their weekly salaries in terms of OPAT activities. This approach was mentioned in a personal communication reported in these same guidelines (Chapman et al., 2019) and was utilised in a study by Wai et al. (2000).

Since the OPAT service is an extension of services offered by the institution, the hospital's perspective was analysed in this study, as is generally reported in the literature (Psaltikidis et al., 2017). Moreover, since both IPAT and OPAT are offered by the same hospital, the cost of resources e.g. antimicrobial agents, VAD, dressing etc, VAD insertions and setting up costs were deemed irrelevant for the scope of the analysis since they would have been incurred irrespective of the model of care chosen. The calculated daily cost to run the service ranged from €64.50 to €65.64 which is comparable to the results attained by Boese et al. (2019).

### 4.4.2 Strengths and Weaknesses

This study is the first attempt to compile a local database about the visiting nurse OPAT model since its inception in October 2016. Despite being created and used for the purpose of this study, the template for this database can be emulated and integrated in routine practices by the local OPAT service. The data gathered over the three-year time frame started to shape the local repository which would be invaluable for future audits and service evaluations. In clearly defining the outcome measures in terms of duration, episode completion and the cost-effectiveness of the service, the local service could be benchmarked against global OPAT provisions. The study also gave insight into some of the facilitators (e.g. the significant influence of variables on OPAT episode durations including presenting infection, VAD and readmission occurrence) and barriers (evidenced by the reason behind a readmission e.g. worsening of symptoms) in relation to OPAT success which were important to instruct subsequent phases of this thesis. Finally, the success rate observed in this study was also in part due to elements which were collected in this study and warrant further research including the evidence based prescribing of antimicrobials (confirmed by cross referencing with culture and sensitivity results when available), 100% attendance of OPAT nurses for administration visits and documentation of readmission episodes.

Despite these strengths, the study was hindered in terms of the economic evaluation due to the lack of an appropriate breakdown of hospital costs stipulated in the subsidiary legal notice on Maltese healthcare fees (S.L.35.28). Apart from the fact that this legislation was published in 2007, a breakdown of these figures identifying the separate cost allocations is not available e.g. staff salaries, treatment and equipment, meals, main utilities etc. which made the comparison between IPAT and OPAT inconclusive. Moreover, in the absence of culture and sensitivity requests OPAT doctors had to decide on a treatment regimen based on clinical presentation and other parameters thus influencing the appropriateness of the choice of treatment and the forecasted duration given. In addition, considering the heterogenous cohort treated through the provision of this service, presenting infection categories were assigned by the principal researcher. A different categorisation strategy could have resulted in different results when the Kruskal-Wallis test was applied thus varying the significance of categorical variables. Lastly, the activity-based costing exercise was based on the durations disclosed by the members of the team to perform OPAT tasks which is subjective and does not cater for the variability between different members of staff.

## 4.5 Conclusion

This phase of the study demonstrated that the OPAT service offered locally is of clinical benefit to a heterogenous group of patients receiving intravenous care for stable infectious diseases. Such conclusions are based on the high success rate, low readmission rates, the number of bed days saved and the cost-effectiveness of the service.

## Chapter 5

## Perspectives of the Enrolled Patients

This chapter describes a quantitative approach towards understanding the experiences conveyed by patients previously enrolled on the OPAT service using a cross-sectional questionnaire. An overview of the construction of the tool and its administration will be provided together with in depth description of the quantitative and qualitative analysis carried out based on the dichotomous scale and open text responses respectively. Moreover, in compliance with the other phases of this thesis, the conceptual SEIPS 2.0 model was utilised to categorise and report the patients' discourse.

A telephone questionnaire was conducted to gather the experiences of patients who were enrolled by the OPAT team during the timeframe starting October 2016 and ending October 2019. The dichotomous scale utilised in the questionnaire enabled the collection of quantitative data which was then interpreted as a service score based on the patients' responses. It was evident that patients were extremely content with the service since approximately half of the patients (n=45/96) gave a score of 19 points or higher (out of a possible 21 points). The questionnaire also permitted the collection of qualitative data based on the patients' experiences. Overall, the cohort was extremely satisfied with the service with some even opting not to comment further as they felt that they wouldn't change anything about how it was being delivered.

The patient's responses to the open ended questions enabled the design of a SEIPS model which reflected the work system elements, processes and outcomes of the preadmission, provision and cessation stages. Thematic analysis emphasised the importance of patients' wellbeing and the factors which acted as barriers or facilitators to patient-centred care. The need for procedure standardisation was discussed and its success was attributed in part to the availability of resources including human, technological and medical resources. The last fundamental aspect was the role of the informal caregiver with respect to ensuring the smooth running of the patient's OPAT episode.

## 5.1 Introduction

### 5.1.1 Importance of patient satisfaction to inform system redesign

According to a systematic review published by Xie and Carayon (2015), questionnaires ranked amongst the most frequently utilised data collection tools in HFE guided healthcare system re-design. The authors identified studies which used this tool within the re-design process to both identify system shortcomings as well as to assess the impact of HFE guided re-design following intervention. Carayon et al. (2015), also identified questionnaires as HFE tools which can be used with the SEIPS framework to unravel the relationship between healthcare work systems and their processes and outcomes such as quality and safety. Patient satisfaction is one such outcome of the OPAT service work system.

The importance of collecting patient satisfaction to inform service development is becoming increasingly recognised in the literature, and indeed recommendations about the collection of qualitative data are now included in the most up-to-date OPAT guidelines (Chapman et al., 2019). However, currently there is a paucity of literature in this area (Twiddy et al., 2018; Berrevoets et al., 2018; Mansour et al., 2019). Patient satisfaction is subjective, and a standardised definition and method of measurement is therefore difficult to achieve. However, there is value in gathering patient satisfaction feedback as one source of data that can be used to inform interventions that seek to improve the quality outcomes for patients, as the end users. Al-abri and Al-bulushi (2014) reported that standardised questionnaires (whether disseminated by hand or by telephone), were the most common assessment tool used to gauge patient satisfaction in the field of healthcare. Despite their common use, the authors identified only 29 studies which then used assessment of patient satisfaction as the measure for informing quality improvement strategies and enforced the need to address this gap.

### 5.1.2 Rationale for use of methodology

Currently there is no procedure in place to collect, analyse and store patient feedback once they are discharged from the OPAT service in Malta. This was recognised as a shortcoming of the service as patient experience is a valuable

outcome measure which should be considered alongside the patient's clinical picture. This led to the design of a cross-sectional questionnaire.

The survey methodology was chosen as opposed to purely qualitative methodologies since an important element of this phase was to derive a quantifiable score that could reflect patients' satisfaction. This outcome would in turn make it possible to compare the local service to those rendered internationally as well as allowing comparisons between different patient intakes for the local service. This performance outcome could also be used to gauge not only the overall patient experience but also patient satisfaction with respect to specific aspect of the service (as was carried out in this phase). Moreover, as recognised in Chapter 4, each OPAT episode was a unique experience for patients across a spectrum of age groups, treatment options, infectious conditions etc., therefore methods such as focus group sessions which develop a social construct would not have been relevant for this phase. On the other hand, a purely quantitative methodology would have successfully generated a quantifiable patient satisfaction score but would have lacked the individual reflections for each item which offered further insight to the service's facilitators and barriers.

Moreover, the collection of a broader range of data types is more useful in building the system model for OPAT. In fact, the inability to probe patients further in this methodology (more characteristically seen in a qualitative methodology) made it possible to establish a systems model based solely on the items presented in the validated questionnaire.

### 5.1.3 Study aims and research questions

The aim of this part of the study was to evaluate the experiences of patients previously enrolled on the service using a cross-sectional questionnaire and SEIPS based modelling.

To fulfil this aim, the following research questions were devised:

1. Were patients satisfied with each stage (pre-admission, delivery, cessation) of the service they received?

2. Do patients consider the quality of the service conducive to future admissions to the service on a personal level and for other patients?
3. Which elements of the service did patients identify as crucial to a good experience?
4. Which barriers to service success did the patients identify from their experiences?
5. How does the stakeholder perspective add to a systems understanding of the OPAT service?

## 5.2 Method

### 5.2.1 Inclusion Criteria

Patients who received OPAT between October 2016 and October 2019 were included even if the service was prematurely stopped due to a readmission.

### 5.2.2 Exclusion Criteria

Patients who could not be contacted since they (i) no longer resided in Malta, (ii) had no valid contact number or (iii) had died at the point of data collection were not included. Moreover, episodes characterised by service provisions of less than 3 days were excluded from the study due to the questionable robustness of the data which is not reflective of the visiting nurse home model. In fact, in general, patients falling under this category were called in for an outpatient visit and their daily dose was given following the appointment. The pilot study (Section 5.2.4.4) picked up on the fact that patients over the age of eighty were unable to recollect details of service provision and were thus excluded from the study. Due to a certain level of cognitive impairment predominant in this age group, details about OPAT episodes were very difficult to report resulting in patients being unable to recall the service or confusing it with other medical services or instilling a sense of anxiety when receiving a call related to the hospital.

### 5.2.3 Recruitment

To ensure good ethical practice, Figure 5.1 illustrates the procedures taken to recruit patients.

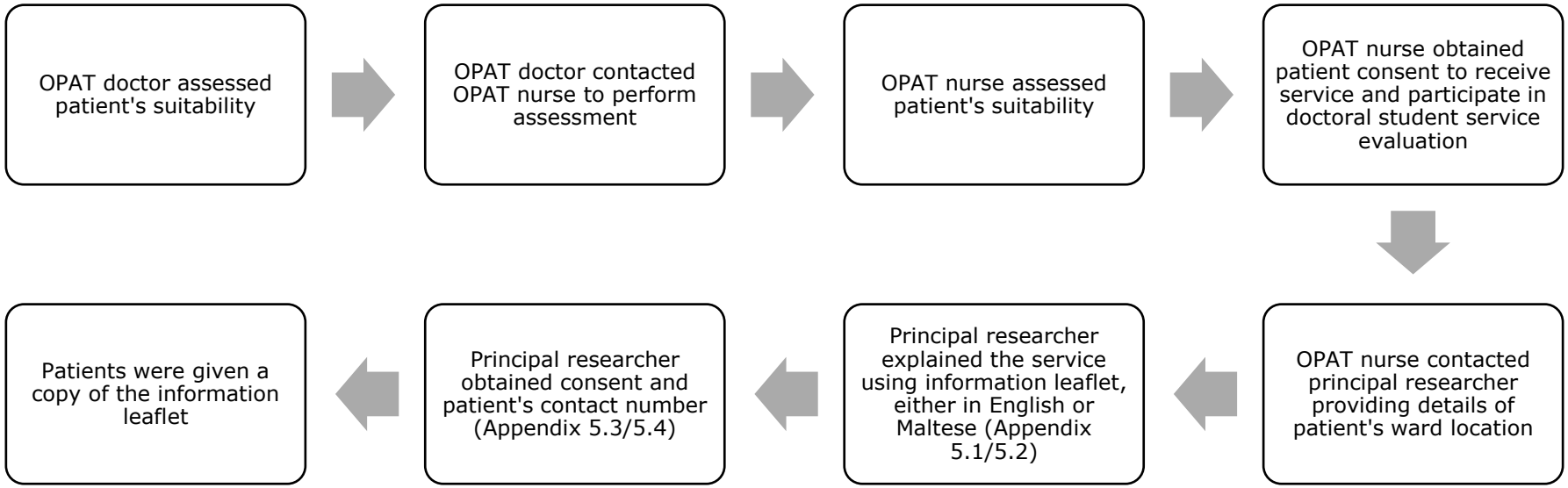


Figure 5.1 Patient recruitment procedure for cross-sectional questionnaire

No sampling strategies were employed for this phase of the study resulting in the inclusion of 117 patients in total.

### 5.2.4 Design, translation and validation of the questionnaire

#### 5.2.4.1 Content

A meeting was organised between the lead OPAT physician (Head of Service) and the principal researcher before the service was launched, to agree on the content of the questionnaire, as the intention was for the local service to also use the questionnaire as an auditing tool. From the outset, the absence of a formal standardised procedure to collect patient feedback was regarded as a limitation of the local service's rollout, and it was acknowledged that the patient experience was essential for gauging success. The Head of Service pointed out areas which may be of interest to the local setting including visiting-nurse punctuality, HCPs assessment of the patient's residence, the importance of clear explanations at hospital and at home, the importance and usability of the OPAT booklet, the patient's willingness to reuse the service and the availability of medications. Minutes of the meeting were taken by the principal researcher for future reference. Additional suggestions for questionnaire content were drawn from the literature including OPAT guidelines (Tice et al., 2004; Chapman et al., 2012) and research studies evaluating OPAT patient satisfaction using questionnaires (Al Alawi et al., 2015; Al Ansari et al.,2013; Seaton et al., 2011)

#### 5.2.4.2 Design

The SEIPS model was used as the conceptual framework for the development of the data collection tool, which was designed to facilitate the collection of data which would shed light on outcomes emerging from system interactions. The questionnaire was divided into three main sections namely the pre-admission phase (i.e. the hospital stay), the service provision (the patient's residence) and

the cessation of the service. The first two sections equally contained nine questions with a 'yes/if no explain' response scale and one open ended question. The last section encompassed three questions with a 'yes/if no explain' dichotomous /qualitative response scale.

Furthermore, to ensure patients clearly read and understood the scope of the question, some questions were reverse coded and scored. One such example is the question addressing the patient's uncertainties prior to their transition onto the service (pre-admission section). If the patient didn't have any residual queries, the patient would have answered in the negative. This answer would have reflected on a positive characteristic of OPAT team i.e. their diligence in coordinating the dissemination of information at ward level.

#### 5.2.4.3 Translation

In order to cater for the patients' written language capabilities, the questionnaire was translated from English to Maltese by a professional translator. The principal researcher verified the translated document for accuracy of content. The Maltese translation was then back translated to English by an independent translator who was not responsible for the initial English to Maltese translation to avoid construct and item bias. The two versions were further compared to ensure semantic and experiential equivalence (Tsang et al., 2017).

#### 5.2.4.4 Validation and pilot testing

As per the methodology used by Tsang et al. (2017) to ensure face (the perceived ability to measure a concept) and content validity (the actual ability to holistically measure a concept), the questionnaire was emailed to a panel of experts comprising of thirteen HCPs of which ten were nurses, one was a doctor and three were pharmacists. Panellists were randomly selected from the hospital's employee list and were given one week to provide feedback on the two versions of the patient satisfaction questionnaire. The comments of the panel are described in Table 5.1.

Table 5.1 Feedback from panel of experts

| |
|---|
| **1. Hospital pharmacists [24.11.17]** |
| • Advised to check the effective capture of the subject through questions asked and common errors like double-barrelled, confusing, and leading questions.<br>• Recommended the use of a calling facility rather than helpline (Section B question 6).<br>• Suggested a clarification about which appointments the patient was scheduled for (Section B question 7).<br>• Asked to increase the number of questions relating to delays and timing at the patient's residence (Section B question 1).<br>• Queried the use of the dichotomous yes/no data retrieval as opposed to Likert scales and open-ended questions to attain quantitative and qualitative data. |
| **2. Hospital doctor [26.11.17]** |
| • Advised to add a question which asks participants if they preferred to remain in hospital and why? (Section C question 1). |
| **3. Ten Nurses [21.12.17]** |
| • Suggested to change the term "booklet" to "information booklet" (Section A question 7).<br>• Asked to rephrase the question "Did the nurses always arrive on time?". Three nurses asked for its removal whilst another two nurses pointed out that it is subjective to traffic/parking. (Section B question 1). |

The questionnaire was piloted with twelve patients to ensure the statements were clear to the respondents and the length was appropriate. Six participants

participated using the English version whilst the other six participants participated using the Maltese version. The pilot test took place in February 2019. This pilot study was considered to be internal in nature since the data was retained seeing as no amendments were required to the questionnaire's content; however, changes were made to the exclusion criteria. During one test, an elderly female patient over the age of eighty was not able to recall the details about the service and her sister had to aid her to complete the questionnaire. Similar situations were recorded with patients aged between late 70s and early 80s. For this reason, a decision was taken to amend the exclusion criteria to exclude those patients over the age of eighty for this part of the study (Section 5.2.2). For those patients who used the service more than once, the feedback session was conducted following the completion of their second episode so that they could comment on both instances.

### 5.2.5 Questionnaire Session

#### 5.2.5.1 Preparation for the Questionnaire

Since the patient's participant code (on the consent form- Appendix 5.3/5.4) was common throughout the study, their corresponding record in the system outcomes database (Chapter 4) was reviewed to take note of any episode details which could aid with contextualising the patient's responses. An electronic spreadsheet using Microsoft Excel® and a word processor document using Microsoft Word® were created to gather the patient's close and open ended responses respectively. These were saved on the principal researcher's personal computer in accordance with good ethical practice.

#### 5.2.5.2 Conducting the sessions

To incur minimal interruption to the patients' daily activities - a fundamental aim of the home OPAT model of care - the questionnaire was delivered through a

telephone call by the principal researcher. The first attempt to contact the patient was made in the morning between a defined time window (9am to noon) on a weekday. In the eventuality that the patient did not answer the call, other attempts were made in the afternoon between (4pm and 6pm) on a different weekday or on an alternative contact number if provided by the patient. The telephone call was put on speakerphone in a location which ensured that only the principal researcher could hear the patients' responses to ensure confidentiality. Two audio recording devices which were set up at locations to ensure the call was recorded. One of the recorders was used as a backup in the event of a recording failure with one of the devices. Calls took place over a time period spanning March to October 2019.

Telephone sessions began with an introduction and explanation about the scope of the call, in line with the contents of the patient information leaflet (Appendix 5.1/5.2) and consent form (Appendix 5.3/5.4). If the patient had difficulty in recalling the service, it was explained in lay terms together with some details of the patient's personal experience, including the condition why the service was started and the timeframe when it was rendered.

The patient was asked each question chronologically in their language of preference (Appendix 5.5/5.6) and given ample time to respond. If the patient decided to answer beyond the "yes/if no explain" criterion, the data was recorded and evaluated at a later stage for relevance. If the patient's response was relevant to another question, the answer was recorded in relation to the respective question to avoid duplication.

### 5.2.6 Reliability Testing

A data set generated from the pilot study was used to carry out tests of reliability to ensure the overall consistency of a measure. A high reliability in this context refers to the ability of a tool to produce similar results are standard conditions. IBM SPSS 25® was used to measure internal consistency reliability i.e. consistency of results across items in a tool using Cronbach's alpha and Guttman Split half. Cronbach's Alpha is equal to the average measure intraclass correlation for consistency. In Guttman Split-Half reliability, items are assumed to measure the same construct and are divided into two sets. For both tests, values greater than

0.9 indicate excellent reliability, values between 0.8 and 0.9 imply good reliability, values between 0.7 and 0.8 indicate acceptable reliability, values between 0.5 and 0.7 indicate questionable reliability and values less than 0.5 imply unacceptable reliability.

Various inter-rater and intra-rater reliability tests were carried out on the results generated from twelve patients. The following comparisons were carried out using Cohen's Kappa test since the evaluation scale was nominal i.e. yes or no responses. The strength of the reliability tests was endorsed by the various Kappa tests carried out namely before and after (with a two-week interval) for the same patient both in Maltese and in English (intra-rater) and between different patients in both languages (inter-rater). For the purpose of the Kappa test, Kappa values of greater than 0.75 indicate excellent agreement beyond chance, values in the range 0.4 to 0.75 indicate fair to good and values below 0.4 indicate poor agreement.

### 5.2.7 Data Analysis

#### 5.2.7.1 Quantitative Analysis

Two sets of data were identified for analysis, the patients' responses using the dichotomous scale (yes/no) which generated quantitative data and the patient responses to negative aspects and the open-ended questions. The quantitative data was further divided into two data sets and analysed using IBM SPSS Statistics 25®. The first set comprised the dichotomous (yes/no) responses to each question about the service namely questions 1 to 9 in sections A and B and the 3 questions in section C. Prior to analysis, the data had to be modified to change the data from yes/no answers to scores. This was conducted in two ways. Firstly 'yes' responses were assigned a score of one point indicating the service was favourable in this aspect. On the other hand, 'no' responses were not assigned a score (i.e. n=0) indicating that the service was lacking in this aspect.

The second modification was necessary as a result of the intent of certain questions which despite giving a positive response in fact reflected a shortcoming of the

service. For example, for question 8 in Section A which referred to the presence of any unanswered questions prior to discharge, if the patient gave a positive answer, it would reflect a shortcoming of the service rather than a successful aspect. The inverse scoring system was applied to those questions which shared a similar design to the one mentioned above namely Section B questions 2, 6 and 8 as well as Section C question 1.

Once all the amendments were affected, the summation of each patients' responses was carried out. This result shed light on the patient's experience and perception of the service in a quantitative manner. Considering the questionnaire was composed of 21 questions that required a dichotomous scale answer, the maximum score that could be attained for a patient episode was of 21 points.

The second set focused on the patients' scores for every questionnaire item to determine whether the aspect of the service was a success or failure. Since a total of 96 people answered the questionnaire, and thus each patient could give each question a score of 1 or 0, then the maximum score that could be assigned to each item of the questionnaire was of 96 points i.e. each patient provided a positive response for the item in questionnaire. Data was analysed using descriptive statistics to determine frequencies and functions of central tendency including the mean, median, mode and ranges.

In terms of statistical analysis, the Kolmogorov-Smirnoff test for normality was applied to the total scores attained for each patient episode (i.e. from a total of 21 points). Since the result was smaller than the 0.05 criterion, non-parametric tests were carried out for this phase of the study. In fact, the Mann-Whitney test was used to identify the influence of the patients' age and gender on the total score achieved. Hypothesis testing was used to determine (i) whether both male and female patients had a similar OPAT experience (null hypothesis) or whether one group had a better experience in comparison (alternate hypothesis) and whether (ii) patients of different ages (younger or older than 50 years of age) had a similar OPAT experience (null hypothesis) or whether one group had a better experience in comparison (alternate hypothesis). A cut off value of 50 years of age was used to reflect the mean age of the participant group. These hypothesis tests were carried out to verify whether specific patient groups had a similar experience when receiving the OPAT service.

#### 5.2.7.2 Qualitative analysis

Considering participants were given the opportunity to express their views in either English or Maltese analysis, procedures were adapted from a study by Lora et al. (2017) which also involved analysis of bilingual discourse. The recording of each call was transcribed *ad verbatim* in both languages for those instances when the patients provided a qualitative response. It is important to note that qualitative data was not gathered from all the patients and some opted for the dichotomous scale without further comments. These accounted for a total of 47 episodes.

For those sections in Maltese, the discourse was then translated to English by a professional translator. The content was checked for accuracy by the principal researcher. To ensure validity, the translated discourse was then back translated by another professional translator, not involved in the previous Maltese to English translation. The data was then pseudonymised and managed using the qualitative data management software NVivo® version 12. Data was pseudonymised as follows: the participant identification number recorded in the patient's consent form was used to categorise the participant's discourse thus ensuring confidentiality and lack of identification. Secondly, any reference to specific patients and/or HCPs were anonymised to safeguard their confidentiality.

Qualitative data analysis was then carried out using open coding and subsequently axial coding once relationships were established. A second reviewer was asked to carry out the same qualitative analysis. Any variances in codes between the two reviewers were discussed, negotiated and amended in NVivo® v12 as shown in Figure 5.2. The codes were inferred to create themes and subthemes, based on the frequency of codes and their relevance to the research question.

"Thankfully I am quite literate since at one point during my transfer to the OPAT team I was approached by an English-speaking doctor and we didn't understand each other much. Probably an elderly person would have had it much worse" (73-year-old male)

"My daughter used to translate or explain when I couldn't understand something handed by one of the members of staff" (58-year-old female)

"It's best if you speak to my sister because I don't know what you need" (84-year-old female)

"It was problematic when foreign doctors explained something in English and we usually used to ask someone to explain the same thing in Maltese (84-year-old female)

"I wasn't expecting to have open heart surgery and in the interim I had managed to sell my house. As a foreigner now without a residence I was warned by the hospital that my next admission to the service would be against a charge" (54-year-old male)

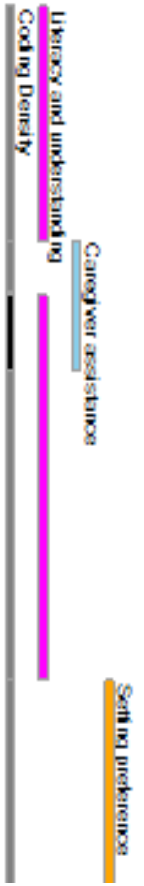


Figure 5.2 Example of axial coding carried out in Nvivo® v12

5.2.7.3. SEIPS based modelling

To align with the aims of the project, SEIPS-based modelling was used to categorise the patient's discourse derived from the questionnaire and build a systems model specific to this phase.

## 5.3 Results

### 5.3.1 Reliability

The Cronbach's Alpha and Guttman Split-Half coefficient test were applied on the results of the twelve participants. The results generated of 0.973 (Cronbach) and 0.977 (Guttman) were greater than the 0.9 criterion thus indicating excellent reliability.

Table 5.2 Cronbach's Alpha and Guttman test to assess internal consistency of the questionnaire

| | | | |
|---|---|---|---|
| **Cronbach's Alpha** | Part 1 | Value | 0.973 |
| | | N of Items | 6 |
| | Part 2 | Value | 0.954 |
| | | N of Items | 6 |
| **Guttman Split-Half Coefficient** | | | 0.977 |

5.3.1.1 Intra-rater reliability for the English version of the questionnaire

The following is an example of the application of the Kappa test to evaluate the intra-rater reliability for a patient who underwent the questionnaire twice in English, with a two-week interval, can be seen in Table 5.3.

Table 5.3 Kappa test to assess intra-rater reliability for same patient using the English version of the questionnaire

| | | Value | Asymptotic Standard Error | Approximate T | Approximate Significance |
|---|---|---|---|---|---|
| Measure of Agreement | Kappa | 0.889 | 0.108 | 4.099 | 0.000 |
| N of Valid Cases | | 21 | | | |

The p-value (<0.001) was less than the 0.05 criterion and indicates that the Kappa value (0.889) was significantly different from zero, indicating excellent intra-rater reliability.

5.3.1.2 Intra-rater reliability for the Maltese version of the questionnaire

The following is an example of the application of the Kappa test to evaluate the intra-rater reliability for a patient who underwent the questionnaire twice in Maltese with a two-week interval, can be seen in Table 5.4.

Table 5.4 Kappa test to assess intra-rate reliability for same patient using the Maltese version of the questionnaire

| | | Value | Asymptotic Standard Error | Approximate T | Approximate Significance |
|---|---|---|---|---|---|
| Measure of Agreement | Kappa | 0.769 | 0.151 | 3.623 | 0.000 |
| N of Valid Cases | | 21 | | | |

The p-value (<0.001) was less than the 0.05 criterion and indicates that the Kappa value (0.769) was significantly different from zero, indicating excellent intra-rater reliability.

5.3.1.3 Inter-rater reliability for the English version of the questionnaire

The following is an example of the application of the Kappa test to evaluate the inter-rater reliability for two patients who underwent the questionnaire in English can be seen in Table 5.5.

Table 5.5 Kappa test to assess inter-rate reliability for same patient using the English version of the questionnaire

| | | Value | Asymptotic Standard Error | Approximate T | Approximate Significance |
|---|---|---|---|---|---|
| Measure of Agreement | Kappa | 0.767 | 0.156 | 3.513 | 0.000 |
| N of Valid Cases | | 21 | | | |

The p-value (<0.001) was less than the 0.05 criterion and indicates that the Kappa value (0.767) was significantly different from zero, indicating excellent inter-rater reliability.

5.3.1.4 Inter-rater reliability for the Maltese version of the questionnaire

The following is an example of the application of the Kappa test to evaluate the inter-rater reliability for two patients who underwent the questionnaire in Maltese can be seen in Table 5.6.

Table 5.6 Kappa test to assess inter-rate reliability for same patient using the Maltese version of the questionnaire

| | | Value | Asymptotic Standard Error | Approximate T | Approximate Significance |
|---|---|---|---|---|---|
| Measure of Agreement | Kappa | 1.000 | 0.000 | 4.583 | 0.000 |
| N of Valid Cases | | 21 | | | |

The p-value (<0.001) was less than the 0.05 criterion and indicates that the Kappa value (1.0) was significantly different from zero, indicating excellent inter-rater reliability.

5.3.1.5 Inter-rater reliability for different versions of the questionnaire

The following is an example of the application of the Kappa test to evaluate the inter-rater reliability for two patients who underwent the questionnaire in different languages can be seen in Table 5.7.

Table 5.7 Kappa test to assess inter-rate reliability for patients using different versions of the questionnaire

| | | Value | Asymptotic Standard Error | Approximate T | Approximate Significance |
|---|---|---|---|---|---|
| Measure of Agreement | Kappa | 0.889 | 0.108 | 4.099 | 0.000 |
| N of Valid Cases | | 21 | | | |

The p-value (<0.001) was less than the 0.05 criterion and indicates that the Kappa value (0.889) was significantly different from zero, indicating excellent inter-rater reliability.

### 5.3.2 Patient demographics

A total of 96 patients successfully completed the feedback questionnaire, from a potential 117 participants (response rate=82.1%). Twenty-one patients were excluded since they either: passed away (n=8), or they were older than 80 years of age (n=6) or the antimicrobial course was shorter than 3 days (n=1), or they left the country (n=3) or they provided an incorrect/illegible contact number (n=3). Of the 96 patients included in the study, a total of 68.8% were males (n=66) whilst the other 31.2% were females (n=30). The mean age was of 59.06 years of whom, 20 patients were younger than 50 years of age, 51 patients were older than 60 years of age whilst the remainder fell under the 50 to 60-year age group as shown in Figure 5.3.

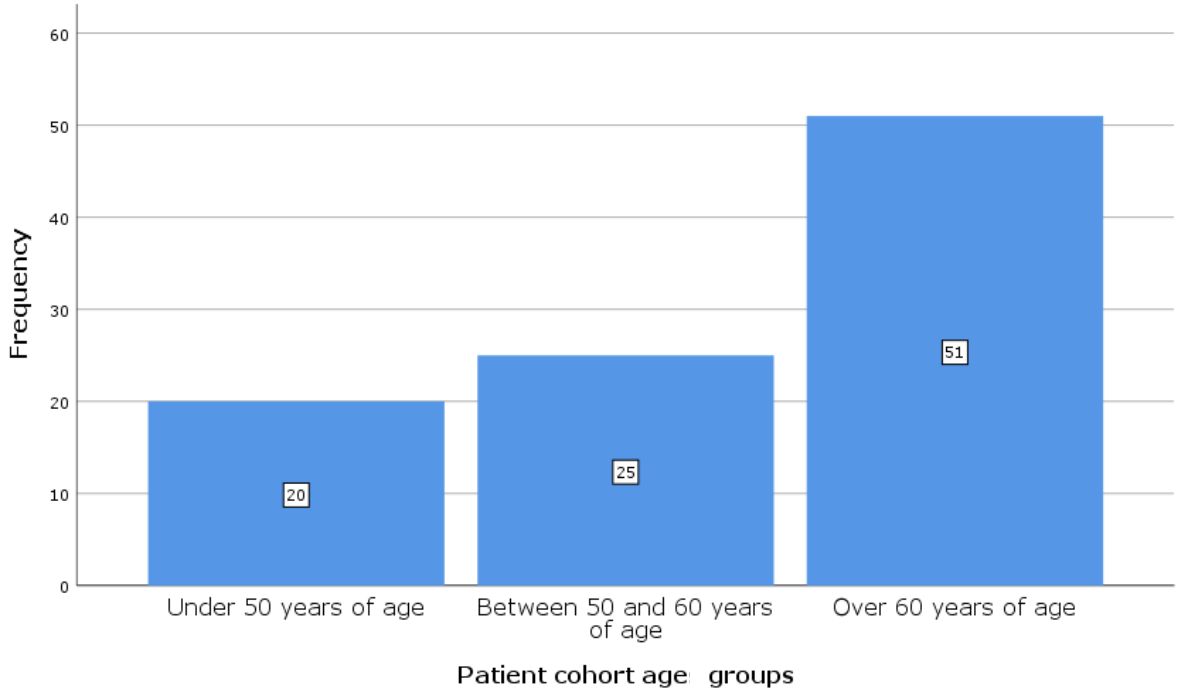


Figure 5.3 Bar graph illustrating the frequencies of the different patient age groups

### 5.3.3 Patient experiences based on rating scores

Based on the positive and negative responses provided by the patients, the lowest score (n=15 points) was attained four times (4.17%), the median score was attained 38 times (39.58%) whilst the maximum score (i.e. 21 points) was attained seven times (7.29%) as shown in Figure 5.4.

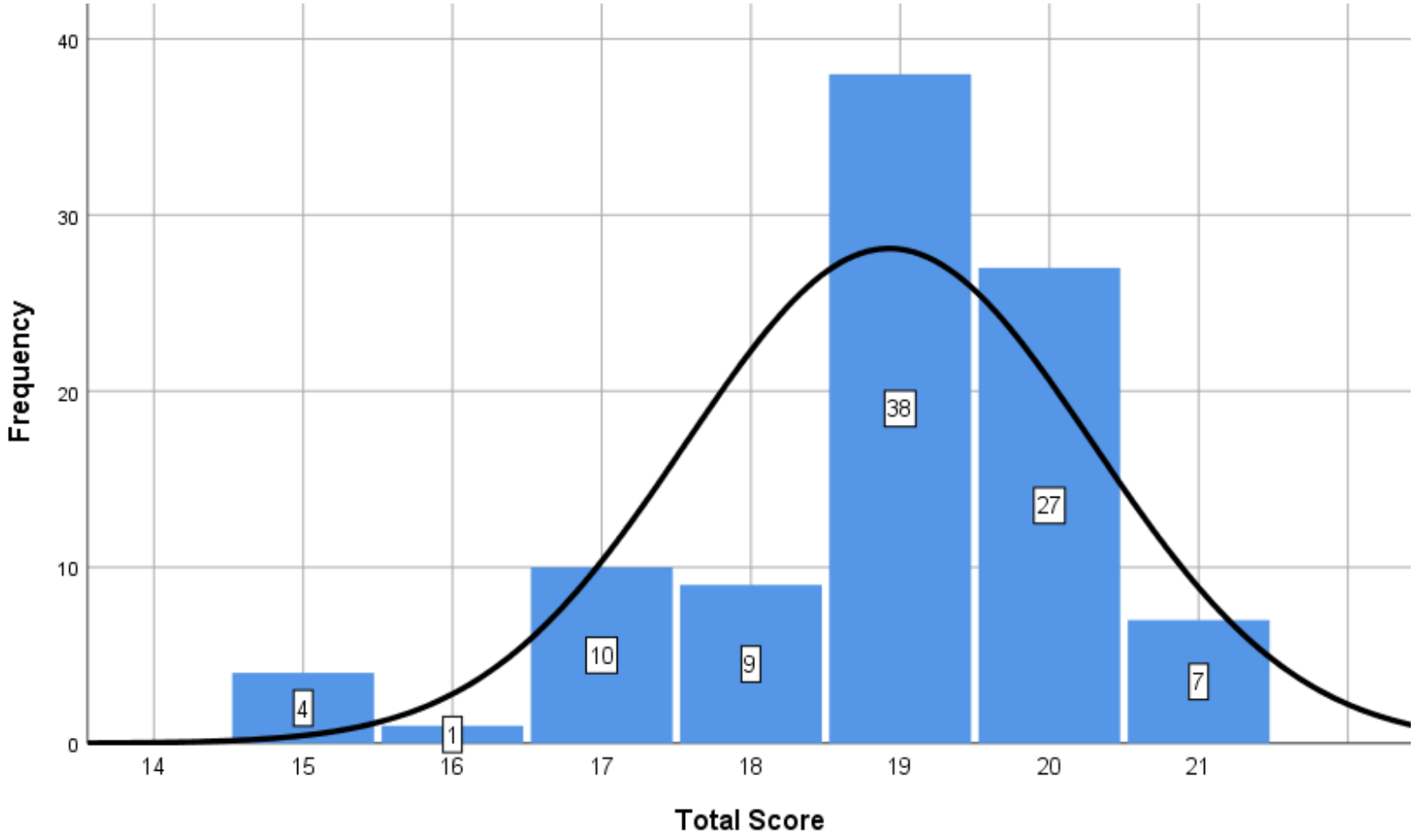


Figure 5.4 Bar chart of service scores based on patient responses

Based on the responses, the mean score was of 18.93 points with a standard deviation of 1.363, an interquartile range of 2 (lower quartile of 18.25 and upper quartile of 20) and a median of 19 points as can be seen in Figure 5.5. The other markings on Figure 5.5 represent the outlier scores.

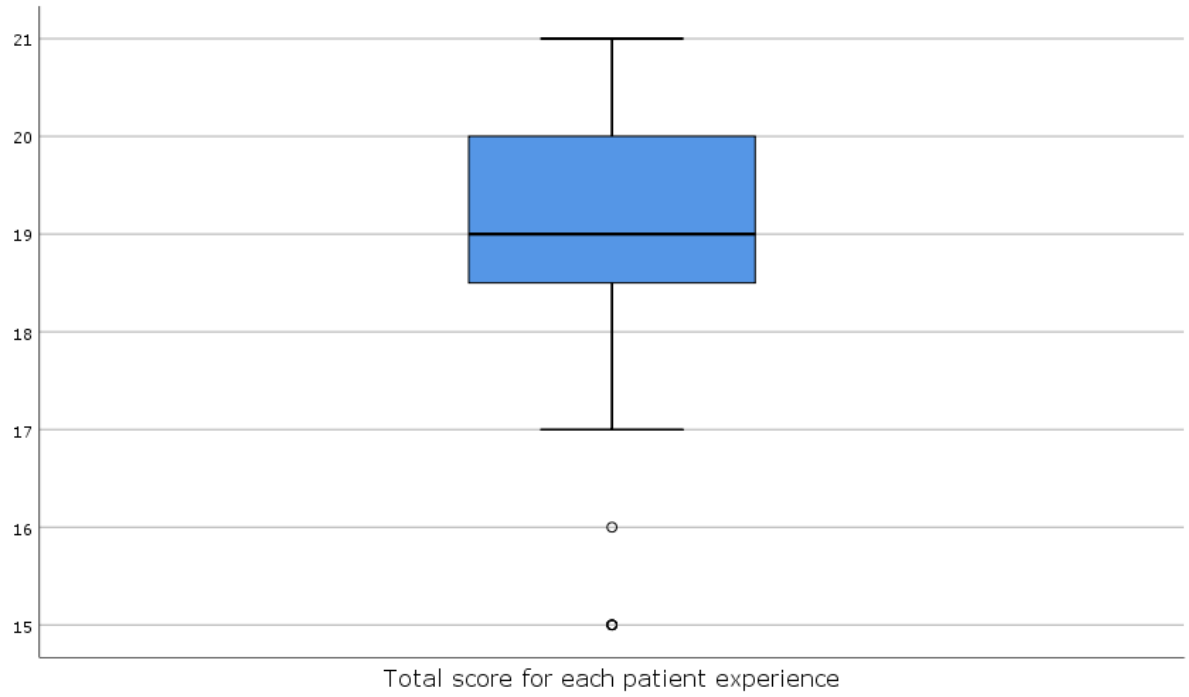


Figure 5.5 Box plot showing the lower quartile, median and upper quartile for the service scores

### 5.3.4 Service rating scores for preadmission stage

Table 5.8 illustrate the sum of the frequencies attained for the first section of the questionnaire which focused on aspects of the pre-admission phase. As evidenced from the sum of frequencies, the timely manner of the team's explanation, the use of layman terms and the ability to reassure the patients received maximum points i.e. a total score of 96 points. A lower score was recorded in terms of adequacy of contact information, the user-friendliness of the information booklet and the avoidance of unanswered questions (n=91). The item attaining the lowest score was related to the patients' awareness about future complications (n=76).

Table 5.8 Sum of frequencies for the preadmission section of the questionnaire

| **Preadmission to the Service** | |
|---|---|
| 1. Were you given enough time to ask questions to the OPAT nurses? Yes/if No, explain | 96 |
| 2. Were you given enough time to ask questions to the OPAT doctors? Yes/if No, explain | 96 |
| 3. Was the service explained in simple layman terms by the OPAT doctors? Yes/if No, explain | 96 |
| 4. Was the service explained in simple layman terms by the OPAT nurses? Yes/if No, explain | 96 |
| 5. Were you aware of any complications that may arise? Yes/if No, explain | 76 |
| 6. Were you given adequate information where to call should you be in difficulty? Yes/if No, explain | 91 |
| 7. Was the OPAT information booklet provided easy to follow? Yes/if No, explain | 91 |
| 8. Did you have any questions that were left unanswered? Yes/if No, explain | 91 |
| 9. Did all the healthcare professionals involved do their best to keep you from worrying? Yes/if No, explain | 96 |

### 5.3.5 Service rating scores for service provision stage

Within this section, only two aspects of the service provision attained full scores based on the patients' responses. With a total of 96 points, the questions related to the OPAT nurses' level of respect towards the patients' residence and their commitment to explain each task they were performing, scored the highest. A slight decrease in the total score was seen when patients were asked if they received adequate follow-up from the OPAT doctors (n=95) and if they were aware of any medication shortages during the provision of the service (n=94). These results were closely followed by questions about the impact different nurses had on the service provision (n=81) and the attainment of information about one's progress (n=78). The other two questions pertaining to this section attained a total of 77 points and 65 points for the coordination with other medical appointments and the need to make use of the helpline respectively. The lowest scoring item in

this section, with a total score of 26 points, concerned the task of informing patients about foreseen delays. These results are illustrated in Table 5.9.

Table 5.9 Sum of frequencies for the service provision section of the questionnaire

| **Service Provision** | |
|---|---|
| 1. Were you informed about foreseen delays in the nurses' arrival time? Yes/if No, explain | 26 |
| 2. Were you affected by the fact that various nurses were providing the service? Yes/if No, explain | 81 |
| 3. Were the nurses respectful of your residence and personal belongings? Yes/if No, explain | 96 |
| 4. Did the nurses explain what they are doing whilst they are administering the medication, changing dressings and taking vital sign parameters? Yes/if No, explain | 96 |
| 5. Did the nurse/doctor keep you informed of your progress? Yes/if No, explain | 78 |
| 6. Did you ever need to phone the discharge liaison nurses? Yes/if No, explain | 65 |
| 7. If you had any other medical appointments, were adjustments made to accommodate you? Yes/if No, explain | 77 |
| 8. Were you made aware of any problems regarding stock levels? Yes/if No, explain | 94 |
| 9. Do you feel that you were adequately followed up by the doctors running the OPAT service? Yes/if No, explain | 95 |

### 5.3.6 Service rating scores for service cessation stage

The three questions pertaining to section C of the questionnaire attained high scores. The questions relating to the patients' overall satisfaction and the inclination to re-enrol in the service got a total of 95 points whilst the patients' preference of care setting scored a total of 90 points as shown in Table 5.10.

Table 5.10 Sum of frequencies for the cessation section of the questionnaire

| **Following cessation** | |
|---|---|
| 1. Would you have preferred to remain as an inpatient? Yes/if No, explain | 90 |
| 2. Were you pleased with the overall running of the service? Yes/if No, explain | 95 |
| 3. Would you consider benefitting from the service again should the need arise? Yes/if No, explain | 95 |

### 5.3.7 Test for normality

The Kolmogorov-Smirnov test was used to check the underlying distribution of a continuous covariate i.e. the total scores for each item of the questionnaire. The p-value in this test indicates the normality of the distribution. If the p-value is 1, then the underlying distribution is perfectly normal. This normality assumption becomes less evident as the p-value gets closer to 0. In this case, the normality of the service scores based on the patients' responses was tested, with the null hypothesis specifies that data has a normal distribution. On the other hand, the alternative hypothesis specifies that the data does not have a normal distribution.

For the total scores, the p-value was less than 0.001 and was significantly lower than the 0.05 level of significance as can be seen in Table 5.11. Therefore, the Kolmogorov-Smirnov test indicated that the scores did not follow a normal distribution. In conclusion, since the data was not normally distributed, only non-parametric tests could be used to analyse the collection tool's content.

Table 5.11 Test for normality using Kolmogorov-Smirnov test

| | Kolmogorov-Smirnov | | | Shapiro-Wilk | | |
|---|---|---|---|---|---|---|
| | Statistic | df | Sig. | Statistic | df | Sig. |
| Service scores | 0.275 | 95 | 0.000 | 0.858 | 95 | 0.000 |

### 5.3.8 Influence of the patient's gender on the total score

Non-parametric tests are used when the measurements are rating or ranking scores or when the measurements do not satisfy the normality condition. Thus, for the purpose of the comparison in this phase, the Mann Whitney test was used.

The Mann-Whitney test was used to determine whether two independent samples came from identical populations. It was used to test the null hypothesis that two population medians are equal where the dependant variable was continuous and not normally distributed. In this instance, the Mann Whitney test was used to determine whether both male and female patients had a similar OPAT experience (null hypothesis) or whether one group had a better experience in comparison (alternate hypothesis).

Table 5.12 Comparison of patient gender on total score using Mann-Whitney test

| | N | Mann-Whitney | p-value |
|---|---|---|---|
| Male | 66 | 916 | 0.541 |
| Female | 30 | | |

The null hypothesis was accepted since the p-value (0.541) exceeded the level of significance as shown in Table 5.12. Therefore, it was concluded that there is no significant difference between the median scores for male or female participants, which implies that there isn't enough evidence that one group, had a better OPAT experience than the other.

### 5.3.9 Influence of the patient's age on the total score

In this instance, the Mann Whitney test was used to determine whether patients of different ages (younger or older than 50 years of age) had a similar OPAT experience (null hypothesis) or whether one group had a better experience in comparison (alternate hypothesis).

Table 5.13 Comparison of patient age on total score using Mann-Whitney test

| | Ages | N | Mann-Whitney | p-value |
|---|---|---|---|---|
| Total Score | Under 50 years | 20 | 684.500 | 0.476 |
| | Over 50 years | 76 | | |

The null hypothesis was accepted since the p-value (0.476) exceeded the level of significance as shown in Table 5.13. Therefore, it was concluded that there is no significant difference between the median scores for participants of different ages, which implies that there isn't enough evidence that one group, had a better OPAT experience than the other.

### 5.3.10 Axial coding for participants' discourse

The following tables (Table 5.14-5.16) illustrate the axial coding and participants' quotes extracted from the telephone call questionnaire. Of note, three consecutive dots (i.e. …) indicate that there was transcribed discourse which was not considered relevant for the required code. The text in square brackets refers to discourse which was not said but was added by the researcher for completeness and better understanding of the intended context. Tables 5.14-5.16 provide a few examples of quotes reflective of the codes attributed to patients' discourse. The remaining examples can be found in Appendix 5.7.

5.3.10.1 Qualitative data of patient experiences during preadmission stage

Table 5.14 Participants' quotes for extracted codes pertaining to the preadmission stage

| **Axial code** | Participants' discourse |
|---|---|
| **Literacy/understanding** | "A Maltese version of the booklet would have helped both my husband and I to understand the service as we do not know much English" (40-year-old female). |
| **Caregiver assistance** | "My daughter used to translate or explain when I couldn't understand something handed by one of the members of staff" (58-year-old female). |
| **Preference of setting: Home** | "I had to be moved to another ward to make way for another patient who was considered more critical than I was…. this was very uncomfortable for me as being in hospital is already unpleasant let alone needing to settle down in a new location with new patients again" (66-year-old female). |
| **Preference of setting: Hospital** | "I wasn't expecting to have open heart surgery and in the interim I had managed to sell my house. As a foreigner now without a residence I was warned by the hospital that my next admission to the service would be against a charge" (54-year-old male). |
| **Treatment options** | "…it was more convenient to receive less administrations of the medicine during the day…wish I started using the service before" (66-year-old female). |
| **Delayed discharge** | "If I was sent home earlier, I probably wouldn't have to be moved to another ward whilst at hospital" (66-year-old female). |

| | |
|---|---|
| **Delayed flagging** | "A quicker referral would have helped me leave the ward earlier which would have been a blessing considering the difficult patient who was located near me" (64-year-old male). |
| **Timeslot/ Service capacity** | "I was told that I had to wait in hospital because there weren't any places when I was originally flagged… so I would suggest employing more people so that new places can be made available" (64-year-old male). |
| **Clear referral information** | "I wish the orthopaedic doctor gave me a better explanation about why I was going to be cared for by new doctors and nurses and why I needed a device inserted" (49-year-old male). |

#### 5.3.10.2 Qualitative data of patient experiences during the service provision stage

Table 5.15 Participants' quotes for extracted codes pertaining to the service provision stage

| **Axial Code** | Participants' discourse |
|---|---|
| **Concern about VAD** | "…it's the device that truly kept me preoccupied until the very end" (60-year-old male). |
| **Patient reassurance** | "the team really managed to change my mentality and accept the changes I was undergoing at home" (61-year-old male). |
| **Informal caregiver support** | "during one of the home visits I was unsure how to answer the nurse's questions, so she decided to phone my younger sister who managed to give her the answers she was looking for" (58-year-old female). |

| | |
|---|---|
| **Wellbeing associated with home environment** | "my family members immediately noticed that my morale improved once I started living at home again "(70-year-old male). |
| **Continuity of daily activities** | "the fact that the nurses came home was perfect for my situation since I was barely mobile and couldn't drive and more importantly, I have a new-born baby. This service was a life saver to my family, you just cannot understand how much!" (38-year-old female). |
| **Continuity of work commitments** | "I had to make changes at work to start later so that the nurse could give me my dose early in the morning…they were very accommodating and almost always on time" (61-year-old male). |
| **Preference of OPAT nurse** | "this is an extra request as the service was of a very high standard, but I preferred one particular nurse over the rest and would have preferred to be cared for by him" (61-year-old male). |
| **Regular follow up** | "one nurse managed to pick up the first signs of what they later explained could have been a thrombosis …she seemed preoccupied about the slight reddening and reduced mobility I had in my arm and immediately contacted the medical team" (66-year-old female). |
| **Lack of travelling** | "after the operation I could barely move so I cannot imagine what it would have been like if the nurses didn't travel themselves…probably my husband would have needed to take time off work to help out and it was enough that I had to stop temporarily from work to recover" (38 year old female). |

| | |
|---|---|
| **Flexibility of nursing visits** | "they used to take the blood samples on Saturday I was told on purpose so that when they have their weekly meetings, they can have a proper discussion about my health…I thought that was very organised on their part" (74 year old female). |
| | "I couldn't believe that not only did I get the opportunity to leave hospital and go home but when I told them that I'd be travelling abroad for health reasons, they gave my daughter who is an anaesthetist a detailed handover of my clinical situation, the medications and devices that she required to continue treatment whilst we were abroad and contact numbers should she need anything" (49 year old male). |
| **OPAT team resources: helpline** | "I was extremely grateful that the helpline was in place since on one occasion I wanted to speak to one of the nurses about a new symptom and I couldn't get hold of my usual general practitioner" (70-year-old female). |
| **OPAT resources: PICC dressing** | "I would stress more on the availability of bigger 'sock' sizes for one's PICC line…in my case I had to use a plastic bag when having a shower" (73-year-old female). |
| **OPAT resources: Medications** | "I sent my husband to get my medications from home but thankfully the item was back in stock when I was discharged back home onto the service" (43-year-old female). |
| **Hospital Human Resources: conducting PICC insertions** | "I received false hope that I was going home since the person doing the PICC lines at that time was on leave and I had to wait an extra four days before I actually got it done and could go home" (63 year old male). |

| | |
|---|---|
| **Punctuality of nursing visits** | "maybe they do not need to introduce a new procedure whereby they call the patient before visiting but at least they can shorten the time frame at home for example to one hour rather than three hours" (48-year-old male). |
| **Adverse events on patient morale** | "looking back, I would have preferred to stay in hospital because the infection got worse whilst I was at home and was a huge hassle to go back to hospital" (61-year-old female). |

5.3.10.2 Qualitative data of patient experiences during the service cessation

Table 5.15 Participants' quotes for extracted codes pertaining to the service provision stage

| **Axial Code** | Participants' discourse |
|---|---|
| **VAD removal** | "When it came to the removal of the PICC line I was extremely concerned but then the nurse decided to tell a joke and before I knew thing was out" (63-year-old male). |
| **OPAT team recruitment** | "I would suggest employing more staff to help the OPAT team with their outreaches to patient homes…. maybe in this way they aren't influenced when the workload starts to increase" (52-year-old male). |
| **Marketing and awareness** | "I think some more promotion would definitely do the service justice since most members of staff I came across seemed to be unaware of the service" (54-year-old female). |

### 5.3.11 The SEIPS model

A SEIPS model was further built on by categorising the patients' responses to the items in the questionnaire. It is important to note, that some patients opted not to substantiate their quantitative response (i.e. yes or no) with an experience or view which accounted for 47 episodes in total. Thus, the model reflects the views of those patients who answered the open ended questions of the telephone call questionnaire. The findings are tabulated in Table 5.16.

Table 5.16 The SEIPS model

| **Work system** |
|---|
| **Person factors** |
| Patients' level of literacy |
| Patients' preference of care setting (hospital versus residence) |
| Patients' concern about their VAD |
| Patients' improved quality of life due to continuation of daily activities e.g. work |
| Patients' preference towards the same nurse conducting the administrations |
| Patients' preference towards punctual nursing visits |
| **Task factors** |
| The need to be assisted by an informal caregiver |
| The need to be reassured about one's VAD, side effects etc. |
| The need be followed up by the OPAT team |
| The need to coordinate with the OPAT team in case administration visits coincided with hospital appointments |
| **Tool/technology factors** |
| Availability of patient information booklets in both English and Maltese |
| Availability of an information booklet which is user-friendly |

| |
|---|
| Availability of antimicrobials which require less frequent administrations<br><br>Availability of the OPAT helpline<br><br>Availability of antimicrobials to cover the patient for the forecasted duration |
| **Internal environment factors** |
| Inaccessibility of one's residence to receive care e.g. patient is a foreigner<br><br>Improved wellbeing associated with patient's residence as opposed to hospital environment |
| **Organisational factors** |
| Lack of proper hospital bed management resulting in patient relocations<br><br>The use of the helpline as a communication channel between patients and the OPAT team |
| **Processes** |
| VAD insertion<br><br>Administration of treatment in the home setting |
| **Outcomes** |
| **Patient outcomes** |
| Earlier flagging of patients results in quicker referral and provision of OPAT<br><br>Patients' morale is negatively affected when readmitted for the same cause<br><br>Patients' morale is negatively affected when an adverse event is caused by the VAD<br><br>Effective collaboration between patient and OPAT team can reduce serious implication of adverse event |
| **Professional outcomes** |
| Better collaborative communication possible if hospital staff are fluent in both Maltese and English |

| |
|---|
| Dissemination of clear information about the referral process from referring care team to OPAT team could result in a quicker enrolment and/or create more time for ensuring patient understanding |
| **Organisational outcomes** |
| Increasing the service's maximum capacity would result in more patient enrolments<br><br>Enrolling new patients on the service could disrupt the established visiting times set for other patients<br><br>Better marketing and awareness strategies across the institution could result in more referrals and thus shorter hospital stays |

## 5.4 Discussion

### 5.4.1 Patient satisfaction scores

The data collection tool offered invaluable data about the patients' experiences whilst receiving the local OPAT service. The lack of information about end-user satisfaction and feedback about OPAT services has been well reported and it was only until recently that studies were taking a more empathic approach towards OPAT outcomes (Minton et al., 2017; Twiddy et al., 2018; Berrevoets et al., 2018). This recommendation is reflected in the new UK guidelines on OPAT provision which states that "regular surveys of patient experience should be undertaken in key patient groups" (Chapman et al., 2019).

As evidenced from the range of total overall scores in this study, one can deduce that OPAT episodes were a subjective and a unique experience for each patient with 92 patients (n=92/96, 95.8%) scoring more than 75% of the total attainable score (n=21). This result echoes patient satisfaction rates documented in the literature which are generally greater than 80% (Durojaiye et al., 2018; Wee et al., 2019; Saillen et al., 2017). In fact, more than half of the cohort studied by Wee et al. (2019) (n= 941/1081, 87%) preferred OPAT over the inpatient setting and 98% (n=144/147) of the cohort studied by Durojaiye et al. (2018) would opt

for this model of care. This was reflected in the local scenario whereby, the patients' willingness to reuse the service was comparable to the Durojaiye study (n=95/96, 99%).

It is of note that despite rating the service with the same overall score (whether low i.e. reflecting a poor service and vice versa) the patients' characteristics were not consistent in terms of age, duration of OPAT and neither were their responses with respect to the questionnaire item which reflected an aspect of the service. This finding supports the study by Minton et al., (2017) who did not attribute the patient's satisfaction to be treated in a specific setting to age, length of infection, OPAT model of care or frequency of infections. This finding thus demonstrates that each patient experience is different and therefore it is important that individual assessment is conducted.

### 5.4.2 Key themes

The need for organisations to adopt an HFE strategy should not come as a surprise considering the contribution of this field to improving healthcare setting since the early 1960s. An organic shift occurring in tandem was evident both in healthcare and HFE research. Healthcare progressed from a biomedical approach to a systems approach and simultaneously HFE progressed from physical and cognitive considerations to a sociotechnical scenario (Valdez and Holden, 2016). These shifts endorse the application of HFE strategies to the study of the OPAT service- a complex sociotechnical system. Thus, the thematic analysis carried out was substantiated by SEIPS-based modelling to identify facilitators and barriers to service success. These findings are discussed in the themes below.

#### Theme 1: Patient wellbeing

- OPAT team's proactivity and ability to mitigate distress

The concept of patient wellbeing resonated throughout the patient's journey. From the moment the patient was considered eligible for OPAT, person factors such as anxiety, lack of confidence and concern influenced the patient's need for reassurance by the OPAT team. The hands on approach taken by the OPAT team to mitigate feelings of distress was seen not only during the enrolment stage but also during service provision- in their ability to take timely action when problems

arose. This was reflected for example in the manner OPAT nurses managed patients who displayed irregular signs and symptoms and how this information was then communicated to the rest of the OPAT team. This immediate action was seen to improve patient outcomes and avoid a detrimental impact on the patients' morale. The patients also commended the team's attitude when dealing with patient's concerns e.g. how the team tackled patient fears about removing the VAD- "When it came to the removal of the PICC line I was extremely concerned but then the nurse decided to tell a joke and before I knew thing was out" (63-year-old male).

A study published by Twiddy et al. (2018) also referred to the nurses' skill set in dealing with patients' distress and how this impacted the overall smooth running of the service. The authors attributed emotional support, respecting patient autonomy and good communication as key skills to provide patient-centred care. In this study, emotional support and good communication were also identified by patients of this cohort. These parallel findings thus inform the type of skill set OPAT teams should adopt as it is championed in different work settings. Unfortunately, communication falls short as described by Spugeron et al. (2019), using the systematic human error reduction and prediction approach (SHERPA). Four errors related to communication were identified namely (i) information not communicated (ii) wrong information communicated (iii) information communication not complete and (iv) information communication unclear. The SHERPA approach endorsed a systems-based thinking by understanding the influence of performance shaping factors on human error. Without addressing these errors linked to communication, the OPAT team could not effectively reassure patients or be proactive when liaising with other professionals.

- Preference of care setting

Moreover, these person factors were also compounded by environmental and organisational factors which ultimately shaped personal preference for a particular care setting i.e. home or hospital. Patients highlighted several limitations pertinent to the hospital setting, including ward changes driven by lack of proper bed management and the hospital reaching maximal occupancy in certain wards. This reality was voiced in a paper by Noonan et al., (2019) who recognised the impact of bed management on the overall patient's hospital stay by delegating the limited

hospital resources in a timely manner. The authors noted that length of stays could be altered by addressing admission and discharge phases and technology played a pivotal role in enhancing communication in these complex scenarios. These measures were compounded by competing interests such as isolation requirements, admitting patients to the appropriate ward, same sex ward regulations etc. Another shortcoming was the fear of contracting an infection whilst being in hospital. This concern was reported by other patient cohorts in OPAT studies which assessed patient perspectives (Minton et al., 2017; Twiddy et al., 2018). Twiddy et al. attributed media coverage about drug resistant organisms such as MRSA to be the cause of patients' concern and advised the need for education to provide a realistic outlook about the risk of contracting such infections.

On the other hand, patients whose residence was inaccessible for service provision e.g. a foreigner not in possession of a residence in Malta had to remain in hospital. In spite of this, the local trend was inclined towards the home setting as reiterated in other single centre OPAT studies (Chapman et al., 2009; Hitchcock et al., 2009; Kieran et al., 2009; Mackenzie et al., 2014).

More recently, the application of HFE to healthcare institutions has shifted towards extra-institutional settings which reflect current cultural trends occurring in healthcare including promoting earlier discharges, increasing patient involvement and increasing fragmentation of care (Valdez and Holden, 2016)- drivers which are also predominant and inherent to OPAT services. Valdez and Holden (2016) shed light on the need for HFE strategies to look beyond healthcare institutions and focus system designs on home and community settings whilst bearing in mind the social, physical and organisational environments.

- Patient's level of understanding

The patient's level of understanding influenced their chances of experiencing a successful OPAT episode (Berrevoets et al., 2019; Chapman et al., 2019). This observation sheds light on the importance of this person factor to determine the eligibility of the 'right' patient to be selected for the service. Locally patient specific selection criteria were deemed important to avoid negatively effecting a patient's morale when managing the VAD at home or being sent back to hospital due to an

adverse event. This shortcoming was also identified in a recent study by Briquet et al. (2020) who disseminated a patient questionnaire to identify satisfaction rates and problems in the delivery of the OPAT program. The cohort attributed a reduction in patient satisfaction to the lack of information (N=218, 4%) and coordination (N=218, 8%) amongst other barriers. Thus, to address this impasse, a two-pronged approach can be integrated in local practices. First, the referral process must incorporate education and training strategies to ensure that information is not only conveyed in a timely manner but understood by the patient using various resources (as explained in theme 3 below). Secondly, the hospital staff must be fluent in both national languages as a means to ensure better collaborative communication and thus reducing the need for the informal care giver's intervention. Wynn et al. (2020) use the term 'health literacy' to refer to the patient's level of understanding of a health related issue. The authors proposed Human Factors initiatives aimed at addressing a spectrum of health literacy capabilities in the form of patient education materials (which are readable, relevant and user-friendly) and patient specific technologies.

- Quality of life at home

Another person factor that contributed to the patients' wellbeing was their improved quality of life at home due to the continuation of daily activities. The cohort pointed out that possibly a shorter visiting timeframe, calling prior to visiting or avoiding altering the visit timeframe when new patients were enrolled could reduce the impact on one's daily activities. Taking lifestyle adjustments into account and ensuring their documentation was reported by Chapman et al. (2019) as a possible strategy for pre-empting potential OPAT failures. Despite this, various studies identified that coping at home and performing domestic tasks wasn't as easy especially due to general health issues, the impact of the infection, treatment side effects and the position of the VAD (Twiddy et al., 2018; Minton et al., 2017). Although complications of this nature were not picked up in this study (possibly since patients were not prompted by the questionnaire items), these findings shed light on the need to perform further research on patients' coping mechanisms at home and how the model needs to be altered to see to their individualistic needs, as seen in patient-centred care.

Patient-centred care looks beyond the dignity of the patient in terms of his/her beliefs, culture, opinion etc. and ensures equality in healthcare with a focus on empowerment and sustainability of treatment (Di Sarsina and Tassinari, 2015). This sustainability can be guaranteed in part through established organisational and educational frameworks which endorse a collaboration between clinician and patient (Dell Olio et al., 2019). The concept of addressing primarily the needs of the patient to improve outcomes is befitting of an HFE approach. Holden and Valdez (2018) defined patient-centred Human Factors (patient ergonomics) as "the application of HFE or related discipline[s] (e.g., human-computer interaction) to study or improve patients' and other non-professionals' performance of effortful work activities in pursuit of health goals." This definition in terms of the local service was applicable to the collaborative informal caregiver/patient-professional work that takes place on a daily basis. As exemplified by one of the patients- "I couldn't believe that not only did I get the opportunity to leave hospital and go home but when I told them that I'd be travelling abroad for health reasons, they gave my daughter who is an anaesthetist a detailed handover of my clinical situation, the medications and devices that she required to continue treatment whilst we were abroad and contact numbers should she need anything" (49 year old male).

- Travelling logistics

Moreover, the avoidance of having to travel to and from the hospital daily (possibly more than once in patients who were on a twice daily dosing regimen) was a major advantage of the service in terms of the patient's quality of life. The patients explained how the visiting nurse model circumvented the need for patients to make use of public transport, depend on other family members and compromise their own health by going out of the house due to e.g. mobility issues, respiratory conditions etc. which is a view shared in other studies (Minton et al., 2017; Twiddy et al. 2018). Despite the availability of public transport to and from most localities on the island to the hospital, patients shared their concern about the impact such travelling could have had on their family members especially those who were frailer than them. The inconvenience related to public transport was reported in patient interviews about foreign OPAT services, especially for geriatric patients who possibly had to travel alone. The cohort suggested short-term parking bays as well as decentralising administration services to GP health centres (Twiddy et al.,

2018). Despite the visiting nurse model circumvents the need to travel to hospital for administration visits it does not eliminate transportation required for outpatient clinic visits. This was brought up by Hamad et al.,(2020) who identified lack of transportation (60%, n=12/20) as the main barrier for absenteeism related to follow up visits.

- Patient confidence through education

The establishment of a good relationship between the patient and the OPAT team coupled with informative education strategies was seen to positively contribute towards the patient's confidence to accept the service as reiterated in other OPAT services rendered abroad (Berrevoets et al., 2018). This consideration was highlighted in this study, whereby not all patients were aware of the complications that could arise during service provision, despite these being mentioned in the service information leaflet. As with this study, Minton et al. (2017) recognised that most patient gave positive feedback about the well written information they received however this was not the case for oral communications since it was subjective on the rapport formed between professional and patient. Despite this, the authors commended the level of communication present in a home visiting nurse OPAT model (as opposed to other models e.g. self-administration) due to the daily nursing visits which offered an opportunity for patients to voice their concerns.

- Preference in OPAT nurse conducting administrations

Another person factor which strengthened this collaborative relationship was the patient's lack of preference in terms of which OPAT nurse performed the daily visits. In this study, approximately 85% of the cohort (n=81/96, 84.4%) were not affected by the continuous turnover amongst the ten OPAT nurses (a consequence of their work rosters) thus indicating that a standard level of care was being provided by all. On the other hand, some patients formed a better relationship with a specific nurse however a negative response (of the dichotomous scale) was not attributable to a short coming related to the other nurses as inferred from their responses to the relevant open ended question. Thus locally, despite the lack of continuity, being cared for a team of nurses did not impinge on the patients perception of care quality delivered which reflected positively on the team's competence. This was evidenced not only by the high patient satisfaction rates

recorded in this phase but the fact that only 23 episodes out of a total of 132 episodes were interrupted by a readmission (17.4%) none of which were terminated by a readmission due to complications related to the collaborative work between the patient and the visiting nurse (Chapter 4). This is in keeping with results reported by Minton et al. (2017), who claimed that patients were content as long as the replacement nurses performing administration visits were adequately briefed and possessed OPAT related skills.

**Theme 2: Standardisation of OPAT procedures**

- Patient follow-up

The importance of patient follow-up (e.g. an outpatient appointment, virtual ward round) to pick up early clinical deterioration is emphasised in all the major OPAT guidelines (Chapman et al., 2019; Norris et al., 2018) and is widely reported in OPAT literature. By proactively identifying a regression in the patient's condition, the team can make timely amendments to their care (e.g. order new treatment) which might in turn avoid readmitting the patient (Palms and Jacob, 2020; Saini et al., 2019; Marks et al., 2020, Steffens et al., 2019; Hamad et al., 2020). From the questionnaire's results, it was evident that despite a few patients feeling that they weren't adequately informed about their progress (n=18/96, 18.8%), this could not be said about follow ups conducted by the OPAT doctors (n=95/96, 98.95%) with most expressing a lack of concern since they felt in good health and received positive feedback during their outpatient appointments. Minton et al. (2017), also identified that at times patients felt they weren't properly followed up and this was attributed to their lack of awareness about the conduction of weekly virtual ward rounds. This finding sheds light on the need to assess the local perception about virtual ward rounds and the patients' awareness in this regard.

- Service logistics

Another important attribute of the OPAT team was their flexibility which in turn ensured the overall co-ordination of all the patient's healthcare related activities. This was evidenced by how the OPAT team rescheduled administration visits when the latter coincided with hospital visits thus ensuring the feasibility of treatment courses. This was accomplished through prior communication and logistical

arrangements that enabled the administration of treatment at hospital or at a different time, thus reducing the impact on one's daily activities or clinical prognosis. This finding was reported by Berrevoets et al. (2018) as well as Minton et al. (2017) who recognised that the patient's quality of life was positively impacted by the team's flexibility in adjusting visiting hours. This level of flexibility was not always possible in a study reported by Hamad et al. (2020), whereby patients claimed they had to delay the time they allocated for administering their treatment due to a doctor's appointment.

In this study, patients praised the OPAT nurses' coordination and diligence in following up patients for example through the weekly collection of blood samples in time for results to be made available during a virtual ward round. Informing the patient of when a blood withdrawal was going to be performed was seen as a positive strategy to mitigate concerns related to ensuring regular monitoring of the patient's overall condition (Keller et al., 2020b). This approach was commended by other researchers who concluded that each service must devise its own laboratory monitoring in terms of content and frequency since it was dependent on the type of infection, patient clinical status etc. (Berrevoets et al., 2020) as described in international IDSA guideline (Norris et al., 2018). This level of coordination as a barrier to safe OPAT care resonated in other recent studies (Briquet et al., 2020; Hamad et al., 2020).

- Nursing administration visits

The aspect of service provision which required most attention was the punctuality of administration visits conducted by the OPAT nurses. As deduced in this study, only 27% of the cohort (n=26/96) were informed about any foreseen delays which was expected seeing as to date this is not standard practice. To this effect, most patients replied that the nurses' arrival time still fell within the allocated timeframe set for daily visits thus no inconvenience was imparted. The opinion of the Maltese patients varies from that reported by Twiddy et al. (2018), whose cohort reported feeling restricted and limited in their homes due to daily administration visits and identified it as a shortcoming of the visiting nurse model. Minton et al. (2017) also described person factors such as frustration but also anxiety as patients feared that they didn't hear the nurse visit. Locally, despite certain elements being identified as beyond the control of the team (e.g. country's infrastructure, rush

hour traffic etc.), patients recommended addressing organisational outcomes such as the enrolment of new patients which led to disruptions in the punctuality of visits.

- Handovers and referral process

The importance of transition of care embodied in the referral process was also highlighted in a study by Berrevoets et al. (2018) who attributed the lack of a responsible person and collaborations to the demise of the quality of transitional care. Using semi-structured interviews and focus group session, Minton et al. (2017) emphasised the importance of communication that occurred amongst members of the OPAT team when giving handovers and briefing their colleagues.

Spugeron et al. (2019), using a systems-based approach assessed communication during verbal handovers and explained the impact of errors in terms of their likelihood and severity using a 5 x 5 matrix scoring scheme to determine the risk score. Apart from being able to mitigate a communication shortcoming, Reedy et al. (2017) identified teamwork and leadership as core Human Factors skills which guide clinical working groups. To this aim, the authors designed and validated a 12 point instrument to measure healthcare professionals self-efficacy in terms of Human Factors skills. The generalisability of this tool across various healthcare professionals and its application when gauging the benefits of an intervention were reported. Other core factors identified and eventually integrated in this tool were situational awareness, decision-making and care (i.e. for self, colleagues and/or patients). It is noticeable that even these factors were picked up from the Maltese patients' responses when describing the team's proactiveness to handle a situation (Theme 1) thus the importance of these skills cannot be stressed enough.

The occurrence of readmissions, adverse events and dissatisfied end users has been attributed to dismal transitional processes occurring in healthcare settings. Werner et al., (2019) using a systems approach determined four main performance shaping factors namely (i) investment in the complex multifaced transition process (ii) availability of resources at discharge (iii) continuation of prehospitalisation needs (iv) assurance that transition work demands does not exceed capacity leading to work overload. Acher et al. (2015) used the SEIPS model to identify factors which influenced the transition process. From their systems approach, the authors attributed poor patient and caregiver

understanding, insufficient educational material and processes as well as inadequate preparation for home care. These factors were all identified in the local study's referral process-when transiting the patient onto the service. This thus emphasises the need to address this quality compromising stage of care.

- Training and education strategies when informing patients

Training and education strategies were seen as a means to circumvent feelings of anxiety at a later stage in the patient's journey. Hazards related to the lack of/erroneous information at the preadmission stage were highlighted by Keller and colleagues (2020b). Using a goal directed task analysis, they were able to identify shortcomings in the task of teaching patients about OPAT related tasks including rushed instructions, misleading information, different instructions from different HCPs etc. The authors looked at the structure of OPAT training and remarked that apart from standardisation, visual aids and teach back methods were imperative to resolve the lack of/erroneous instructions given to patients prior to commencing the service. In this study, the only form of training was supplemented by an information booklet which was already criticised in this cohort in terms of the language used (i.e. English as opposed to both national languages). In addition, various participants reiterated emotions of fear and anxiety when prompted by the open ended questions and only 75% of patients were aware of the complications that can arise as a result of the service. These results shed light on a redesign of training strategies currently in place.

Moreover, recommendations were made to take a patient-centred approach and tailor OPAT training programmes to address the barriers to the patient's safety and their resolutions e.g. a patient with impaired mobility (Keller et al., 2020a). Considering the wide range of conditions covered by the service and flexibility demonstrated by the OPAT team, the local service was no exception to patient friendly measures "after the operation I could barely move so I cannot imagine what it would have been like if the nurses didn't travel themselves".

- Documentation procedures

The cohort in the Minton study (2017) felt that the need to provide detailed information about each administration visit was imperative to ensure traceability, especially when faced with a team of professionals performing the visits. Apart from confidence in the service as a whole, the cohort studied by Quintens et al.

(2020) felt that patients lost confidence in the care professionals if they in turn were not well informed due to the lack of detailed reporting present in handovers. Berrevoets et al. (2020) identified the documentation of response to antimicrobial treatment and details of an adverse event as important quality indicators for a home based OPAT model of care. Locally patients supported the use of marketing and awareness campaigns across the institution which would in turn result in earlier flagging of patients. Both strategies were seen as solutions to increase the service's maximum capacity and reduce hospital stays.

**Theme 3: Availability of resources**

- Information leaflet

The availability of a user-friendly service information leaflet was praised amongst patients. However, the need to offer the content of the leaflet in both national languages and not just in English was recognised. The impact of a patient's limited English fluency in terms of understanding was reiterated by Wynn et al. (2020) who reported more challenges for patients to receive patient-centred care when proficiency in the language used was lacking.

Other research teams attributed the lack of patient understanding to the generic nature of the written forms of communication thus requiring concomitant education and training by the OPAT team (Twiddy et al., 2018; Berrevoets et al., 2018).

- Service helpline

The availability of the helpline reassured patients by making the OPAT team more accessible, especially when their GP couldn't be reached or was not involved in their OPAT care (Keller et al., 2020). When utilised, the helpline fulfilled an organisational function of providing a communication channel for patient concerns, including discussions about worrying symptoms, unavailability for administration visits etc. The importance of setting up a means of communication resonated in various studies who recognised lack of patient confidence and knowledge to be the result of poor communication (Minton et al.,2017; Twiddy et al., 2018). The presence of such a channel with the aim of disseminating information, advice and review was deemed a necessity for an OPAT service in the recently published UK guidelines (Chapman et al., 2019). Furthermore, the availability of such a channel

through technology is consistent with the recommendation published in the recent UK guidelines about the use of telemedicine to improve service structure (Chapman et al., 2019). Within the context of an OPAT service which offers a home self-administration model of care, communication by telephone is imperative to remotely assess complications related to the patient, administrations set and/or the residence (Keller et al., 2020). Although it is not standard practice for the local OPAT team to make use of telemedicine, the incorporation of the helpline made it possible to support patients whilst they were receiving care at home.

In addition, this phase of the study could instruct future enhancements to the service which attempt to integrate telemedicine initiatives e.g. conducting service evaluations by telephone. It is positive to note, that despite the fact the methodology of this study was formalised in 2016, it is in line with recommendations published three years after (Chapman et al., 2019). This inference, especially within the context of the Human Factors project lends itself to a variety of HFE strategies which assess user satisfaction with respect to telemedicine initiatives as described by Buck, (2009) who identified nine Human Factors in this regard including communication procedures. This communication process is gaining momentum in remote health services as an opportunity for healthcare professionals (in a clinical setting) and patients (in their homes) to share and transfer information (Almathami et al., 2020). Thus, the need to apply HFE strategies is still relevant today. Carayon et al. (2018) proposed that further research must be performed in identifying the added benefit of applying HFE strategies to home care especially with respect to devices and information technology which promote patient self-care and communication.

- Treatment options

The availability of long acting antimicrobial drug classes was seen to influence person factors such as the patient's morale, their preference towards the home setting and their quality of life due to multiple daily visits. The availability of such agents made it possible for patients to make both personal and work-related commitments, which was deemed an important measure of the patient's health-related quality of life as emphasised by Wee et al. (2019), with approximately half of the cohort returning to work whilst receiving OPAT (n=278/547, 50.8%) thus enabling patients' productivity by reducing the need for absenteeism benefits. This

was further compounded by stock availability issues. Most of the time, the hospital was well stocked to ensure continuity of the treatment courses thus patients were not made aware of any shortages or these were circumvented before the patient was due for another collection of medications as evidenced by the high score attained (n=94/96, 97.9%).

- Human Resources

Human resources were also identified as important contributors to the success of the service including staff to perform VAD insertions and OPAT team members. Recruitment of staff was deemed to be a solution to increasing the service's maximum capacity, discharging patients before and stabilising visiting timeframes. Staff recruitment was also deemed a viable solution in other OPAT services (Minton et al., 2017). Apart from focusing on formal education training programs, Hignett et al. (2015) identified the benefits of providing integrated training initiatives rooted in Human Factors and Ergonomics as well as Quality Improvement strategies towards practitioners, which was reiterated by Catchpole et al. (2020) as a means for developing a new role and bridging the gap between Human Factors experts and clinicians when redesigning patient care. The need to offer undergraduate curricula which embed HFE principles has been noted in the literature (Backhouse and Malik, 2019). Vosper et al. (2018), go a step further and propose a 12 item framework towards integrating these principles not only at tertiary level but also during postgraduate training and healthcare improvement programs. This holds true especially when the knowledge and understanding of the implications of HFE strategies are usually unknown to healthcare professionals (Pickup et al., 2018). Xie et al. (2019), propose how an HFE toolkit, recruitment of HFE professionals and training of healthcare professionals in HFE can address the aid the application of HFE to healthcare.

The patients attributed their positive experiences to the highly specialised and dedicated OPAT team assigned to the provision of this service. In fact, the appointment of a designated team has been reported as one of the most important quality indicators in OPAT care. Despite this, Hamad et al. (2019), following the dissemination of a questionnaire to members of the Emerging Infections Network, concluded that only 36% (n=182) of respondents had a formal OPAT program. Muldoon et al. (2015), attributed systematic laboratory monitoring, adherence to

clinic visits and communication between providers to the presence of a coordinating OPAT team. Moreover, the involvement of the infectious disease consultants during the preliminary phases of patient selection for OPAT also contributed to safer OPAT care (Shah et al. 2019).

In Malta, one of the infectious disease consultants was appointed as the Head of Service, thus instilling the requirement of their involvement in the patient journey. At face value this is extremely important when one considers the negative implications seen e.g. inadequate prescribing (Friedman et al., 2020) and hospital admissions (Shah et al., 2019) when infectious disease consultations were not part of the OPAT framework. Moreover, the nurses recruited to perform OPAT nursing tasks i.e. the discharge liaison nurses (described in Chapter 1) were already trained in the coordination of hospital discharge services. However, prior to the launch of the service, the nursing staff attended a training program in the UK provided by an OPAT centre based in Birmingham. Lastly, the timely recruitment of a hospital pharmacist with an academic clinical background was deemed appropriate to bridge the gap between the requirements at ward level and the resources required from the hospital dispensary.

**Theme 4: Informal caregiver support**

The collaborative relationship between patient and informal caregivers (generally family or friends) was crucial to assure the success of tasks pertinent to both the preadmission and delivery stages of the service. During the preadmission stage, these mainly focused on making sure patients understood the information imparted by the OPAT team about the service and what it entailed. In this study, specific patient characteristics e.g. age were not attributed to the patient's dependency on their caregivers. One patient identified her limited fluency in English (as opposed to Maltese) to have caused the need for her daughter's (informal caregiver) intervention- "my daughter used to translate or explain when I couldn't understand something handed by one of the members of staff" (58-year-old female). This was remarked by Berrevoets et al. (2018), who reported that patients stressed the importance of having relatives present for information sessions or communications with HCPs. Locally, the importance of their contribution at home was seen in the management of the patients' daily activities and communication with the OPAT team.

In addition to these tasks, Keller and colleagues (2020), through a goal directed task analysis identified other tasks due to the additional provision of the self-administration model under study including learning OPAT related skills, receiving supplies and administering treatment. Other tasks identified in the Keller study could also be applied to the Maltese context since patient care took place at home including maintenance of VAD whilst performing daily activities (e.g. bathing and dressing) and monitoring their clinical status. Minton et al. (2017) found that caregivers were instrumental in terms of offering support at home especially if the patient had problems in terms of general health, mobility, family circumstances etc. These findings were not discussed by the Maltese patients, possibly since they were not prompted by the questionnaire items, but definitely warrants further research based on the local setting. As evidenced from the Keller study and the local study, factors acting as facilitators and barriers are specific to the model of OPAT care provided. This resonated in a study by Katz et al. (2017) who used an HFE approach to address antimicrobial stewardship in long term care facilities, one of the OPAT models of care currently not offered locally. The authors endorsed the incorporation of education strategies and tools which aid review of antimicrobial use and the involvement of infectious disease consultants.

Valdez and Holden (2016) recognised that HFE approaches have to differ from those generally applied in healthcare institutions when dealing with home environments. In one's residence, one cannot forgo the influence domestic daily activities have on healthcare activities and assistance from informal caregivers (which are not usually paid to perform certain tasks). In fact, the authors shed light on the need including the patients and caregivers' needs and preferences as the focus on their design whilst accepting there are challenges when performing fieldwork including ethical and legal implications and safety issues for the researchers.

### 5.4.3 Strengths and limitations

This phase of the study offered the patients a platform to describe their experiences of the local OPAT service. Considering the principal researcher conducted and reported the patients' responses, the robustness of data collection was not limited by the patients' literacy or lack of understanding. Moreover, the

response design assigned to each questionnaire item (i.e. yes/if no, explain?) enabled the inference of patients' quantitative responses through their own explanations rather than the researcher having to make assumptions about the resulting data. The limitation of this tool is the time measurement of exposure and outcome, since it is difficult to derive causal relationships from cross-sectional analysis. Another limitation is that not all patients provided further comments or explanations about improvements to the service thus impacting slightly the robustness of the data collection in this regard. Lastly, since the study's population was limited by the recent launch of the service, the generalisability of the results may be questioned thus making extrapolation to a larger population inaccurate.

## 5.5 Conclusion

From the quantitative and qualitative data collected, patient feedback favoured a high standard of service provision. Patients overall were pleased with the service they received to the extent that should the need arise; they were willing to make use of the service again. The open text responses helped to substantiate inferences derived from the quantitative data. The four themes derived from the patients' discourse namely the patients' wellbeing, standardisation of OPAT procedures, availability of resources and informal care giver assistance shed light on two important key findings. The first is the importance of the referral process in terms of its standardisation and organisational support through resources which in turn can ensure discharges occur in a timely manner and all appropriate information is conveyed to the patient and amongst care teams. Secondly, the need for education and training strategies (for both patients and informal caregivers) is paramount to prepare them as active agents of the patient-centred care the local OPAT service is striving to offer. In conclusion, the findings of this phase further reiterates that patient feedback is a very important outcome measure for any OPAT service provision globally.

## Chapter 6

### Perspectives of the service providers

This chapter provides a detailed account of the perspectives of the OPAT team about the local service. This qualitative data was collected using the focus group technique followed by thematic analysis of the output. The general sentiment expressed by the members of the OPAT team was positive. When discussing elements of the micro and mesolevel system in which they operate, the team appeared highly satisfied with the current procedures adopted, and the professional/patient relationships formed. However, this did not appear to hold true for interactions with the macrolevel system. This was most notable in respect of interactions between the OPAT team and doctors within the institution at large, especially with respect to the referral process. The team was concerned about the inconsistent approaches adopted by various care teams particularly in relation to patient referral which impacted directly on the standard processes carried out by the OPAT team. It is increasingly clear that selecting the 'right' patients for discharge onto OPAT is imperative to ensure successful outcomes. This is much more than a clinical decision: the patient's home environment and personal factors (such as availability of caregiver support) are critical. Referrals that circumvent the standard process were considered to impact negatively on the team's ability to make these decisions. The service providers considered training and education to be crucial to resolving this impasse. Moreover, the cohort felt that the expansion of the service was occurring in a timely and gradual manner which did not compromise the quality of the service. While there was a strong desire to expand the service further, in view of the current resources available, it was recognised that there are significant barriers to be overcome prior to this move.

## 6.1 Introduction

### 6.1.1 The focus group technique

Focus groups can be used as a stand-alone method or in conjunction with other methods for triangulation, as seen in this study, but they are particularly useful for offering a preliminary insight into under-explored topics irrespective of their complexity. Gammie et al. (2017) considered the following elements to be critical to this method: the size of the group, the duration of the session, the selection of participants and the scope of the session. The authors suggest that a purposively and opportunistically selected small group of participants could, over the span of approximately one to two hours, provide sufficient data that will significantly contribute to the research question if appropriately guided. These elements were reiterated by Robson and McCartan (2016) who recognised that these sessions can vary in their degree of structure and flexibility, depending on the intent of the researcher and the level of participation respectively. From the perspective of case study research, the focus group technique can offer a platform for the discussion of facilitators and barriers related to events, something which is particularly critical in this context, where a successful patient journey is largely event driven.

### 6.1.2 The rationale for using this method

Such a technique is also highly appropriate for a Human Factors approach whereby interaction between participants is theoretically a key feature, driven by the snowballing effect that occurs when discussion takes place collectively. It thus follows that outputs from focus groups are not merely a collection of individual opinions, but a social construction. This fits within the overarching aim of this thesis, which is to build a working model of the OPAT service, which is recognisable to all the system actors, a shared understanding which can be used as a basis for evidence-informed service improvement. It is also true to the sociotechnical systems research principle that entities cannot be studied separately but must be considered within the system they naturally occur in, by mimicking the social context in which members of the OPAT team operate (Holden et al., 2013). Indeed, Holden et al. (2020) recognised the increasing importance of the focus group

method as a mainstay of studying and improving "patient work" in terms of understanding phenomena and intervention design.

The focus group technique was considered appropriate for capturing the perspectives of the OPAT team as opposed to other tools such as the nominal group technique, since the scope of the session was not to gain a group consensus, but rather to explore holistically the perceptions of the service providers. Although to date the service has been considered a success by the patients (Chapter 5) it was deemed important to extract outlier views which might shed light on factors contributing to any service shortcomings. One must not exclude the influence of existing hierarchies between participants of an already established group as is the case with the OPAT team (Robson and McCartan, 2016). This is especially important as the OPAT team is composed of different HCPs namely doctors, nurses and pharmacists which furthermore vary in rank within the same profession. Such hierarchies are recognised and accounted for within Human Factors frameworks such as SEIPS 2.0, where they are represented as interactions between work system elements (Holden et al., 2013).

To date, service auditing and benchmarking has not been carried out by the members of the OPAT team contrary to the recommendations made in relation to outcome monitoring and clinical governance in the recent British guidelines (Chapman et al., 2019). Currently, the Maltese service adopts weekly virtual ward rounds which are used for discussing patients' clinical status which is confirmed as good practice in the British Guidelines and recognised by others (Berrevoets et al., 2020) as providing an effective communication channel for OPAT team members. Inevitably, informal discussions about the service itself take place during these virtual ward rounds, but the concept of formal service evaluation meetings does not yet exist. However, with increasing pressures from the organisation to expand the service further, discussions about a road map for the national service have been initiated by the members of the OPAT team. Apart from gaining access to new premises, the team envisage a service which can accommodate more types of infectious diseases by using new antimicrobial agents and regimens through new procurement and logistical arrangements. In the absence of a formal procedure, 'self-auditing' using a systems framework to collect performance data (such as that gained from audits, inspection reports, adverse event reporting etc.) is therefore likely to be valuable.

### 6.1.3 Study aim and research questions

The aim of this part of the study was to capture the views and perspectives of the service providers using a focus group method.

To achieve this aim, the research questions developed for this phase were:

1. What are the thoughts of the healthcare professionals (HCPs) running the OPAT service?
2. How did HCPs respond to feedback on service users' perception of the service?
3. What are the HCPs' perceptions of facilitators and barriers influencing service provision outcomes?
4. What are their views about future expansion of the service?
5. How does the stakeholder perspective add to a systems understanding of the OPAT service?

## 6.2 Method

### 6.2.1 Inclusion criteria

All those HCPs involved in the development, implementation and provision of the service (i.e. the members of the OPAT team) were asked to participate in the study.

### 6.2.2 Recruitment

A recruitment letter (Appendix 6.1) was sent to those members of staff eligible to participate in this part of the study through the hospital's appointment requisition system. In this manner the principal researcher could confirm electronically whether the participants were willing to attend the group session whilst also distributing a copy of the letter coupled with the details of the session.

To ensure maximum attendance, the lead OPAT nurse and the lead service physician were contacted to find a common date convenient for most members. This step was taken considering the OPAT nurses work on a roster basis and the OPAT physicians must cover outpatient clinics and ward rounds in addition to their OPAT responsibilities. One day prior to the session, each member was contacted on their pager by the principal researcher to ensure their attendance.

### 6.2.3 Development, content and validation of the topic guide

In the absence of a published topic guide evaluating OPAT from the perspective of the OPAT team, a literature review was carried out to identify research focusing on facilitators and barriers of OPAT services globally. These included articles which:

1. documented predictors of service success/failure to e.g. readmission rates (Means et al., 2016; Huang et al., 2018), patient selection criteria (Chapman et al., 2012; Norris et al., 2018; Schmidt et al., 2017) and antimicrobial treatment options (Barton, 2018; Smismans et al., 2018)
2. reported guidelines and recommendations relating to OPAT such as those published in the UK (Chapman et al., 2012) and in the USA (Norris et al., 2018)
3. outlined the pros and cons of various OPAT models of care (Bellamy, 2018; Norris et al., 2018)

To portray a realistic reflection of the service's external environment, reference was also made to the institution's standard operating procedures (SOPs). Questions focusing on the presence of defined patient selection criteria and referral process as well as MRSA screening prior to VAD insertion were derived from this source. The content of the topic guide was also influenced by preliminary results reported in the system outcomes electronic database (Chapter 4) and the patients' responses to the survey (Chapter 5). Table 6.1 captures the various sources used to design the topic guide questions.

Table 6.1 Influence of literature, SOPs and preliminary results from previous phases on development of the topic guide

| **Question in topic guide** | **Rationale for question inclusion** |
|---|---|
| Were you expecting less/more patients to be flagged for the service? | Common result reported in OPAT literature (Bauer et al., 2016; Miron-rubio et al., 2016; Suleyman et al., 2017; Durojaiye et al., 2018; Sriskandarajah et al., 2018). Moreover, it can be compared to the number of patients registered in the electronic database (Chapter 4). |
| Were you happy with the way referral processes took place? | In response to the first two preadmission questions (in the patient survey) "Were you given enough time to ask questions to the members of the OPAT nurses (q1) and doctors (q2)", some patients said that despite having enough time, they were immediately discharged on the same day they were told about the service, which did not allow them enough time to reflect on further queries. |
| Do you think referrals could be improved? | Promotes further discussion about the previous question. |
| Do you think more patients could have been referred but were declined due to the service's limitations? If yes, what were the limitations? | In response to "Do you think something should change during this step [preadmission] of service provision?" (patient survey) some patients were upset that they were kept on the service's waiting list because the service's maximum capacity had been reached. |
| Are you content with the number of antibiotics available for use within the service? Do you think this number should increase? | The system outcomes database showed an increase in the number of antimicrobials introduced on the service, and also an increase in the number of combination regimens used. |

| | |
|---|---|
| Once daily dosing was set as the standard regimen to be practiced for all patients. Should this be increased, what opportunities/limitations do you envisage? | In response to "Were you informed about foreseen delays in the nurses' arrival time? Yes/if No, explain" (service provision question 1), patients explained that they were informed that some delays were due to the enrolment of new patients who needed more than one administration per day. Moreover, the database showed an increase in antimicrobial regimens than required more than once daily administration. |
| MRSA screening was deemed as one of the prerequisites prior to discharging a patient. Was this always carried out? If no, why? | MRSA carriage was deemed to contribute to the prolongation of OPAT (Nguyen, 2010, Seaton et al., 2011) Moreover, the service's SOP requires MRSA decolonisation in the presence of a positive nasal swab result with chlorhexidine wash and mupirocin nasal cream. Screening is a prerequisite for PICC line insertions carried out at the institution enforced by the infection control unit (Infection control committee, 2012). |
| A general practitioner in the community was another prerequisite prior to discharging a patient. Did they collaborate? Did they hinder or complicate a patient's prognosis? | The requirement of a GP's details was required to ensure seamless patient care during the time interval between one nursing visit and the next (despite the continuous availability of the accident and emergency department. |
| Considering the number of readmitted cases, did you expect such a result? Could an intervention prior to discharge/at home by the team avoid a readmission from happening? | Based on the number of readmitted cases reported in the system outcomes database. Moreover, the readmission rate is a common statistic published in OPAT literature (e.g. Durojaiye et al., 2018). |
| Did you encounter any complications which were related to the patient's eligibility criteria e.g. residence, social situation, co-morbidities which | OPAT guidelines strongly emphasise appropriate patient selection to ensure optimal performance outcomes (Chapman et al., 2012; |

| | |
|---|---|
| prior to discharge were not considered to be problematic? | Norris et al. 2019; Wee et al., 2019). |
| Would you like to comment on any other aspect of the service not previously tackled in the questions above? | This question was included to ensure the flexibility of the technique despite the high degree of structure inherent to the topic guide. |
| In your opinion, which is the greatest strength of the service? | These questions were included to promote discussion on facilitators and barriers and to verify whether there was consensus or debate amongst participants. |
| In your opinion, which is the greatest limitation of the service? | |

The scope of the guide was to help the OPAT team engage in discussions about the facilitators and barriers of the service based on their personal experiences. Table 6.2 outlines the scope of discussion anticipated by the principal researcher.

Table 6.2 Topic guide questions and underlying principle

| **Topic guide question** | **Underlying principle** |
|---|---|
| Were you expecting less/more patients to be flagged for the service? | Referral process: determine whether there are barriers impeding this process including flagging from care teams, the service's maximum capacity, channels of communication etc. |
| Were you happy with the way referral processes took place? | |
| Do you think referrals could be improved? | |
| Do you think more patients could have been referred but were declined due to the service's limitations? If yes, what were the limitations? | |
| Are you content with the number of antibiotics available for use within the service? Do you think this number should increase? | Pharmaceutical resources: increasing the availability of antimicrobials agents would imply the ability to treat a wider variety of presenting infection |

| | |
|---|---|
| Once daily dosing was set as the standard regimen to be practiced for all patients. Should this be increased, what opportunities/limitations do you envisage? | and the possibility of using drugs that require more dosing on the nurses' workload. |
| MRSA screening was deemed as one of the prerequisites prior to discharging a patient. Was this always carried out? If no, why? | MRSA screening: verify whether referred patients for VAD insertions were being screened and then provided with decolonisation treatment following a positive result. |
| A general practitioner in the community was another prerequisite prior to discharging a patient. Did they collaborate? Did they hinder or complicate a patient's prognosis? | General practitioner: in combination with the OPAT team virtual ward rounds, outpatient appointments and daily nurse visit, the involvement of the GP should ensure seamless care. |
| Considering the number of readmitted cases, did you expect such a result? Could an intervention prior to discharge/at home by the team avoid a readmission from happening? | Readmission rates: in the absence of standardised outcome measures, readmission can be viewed as a measure of service failure (if the episode is directly related to a complication arising from OPAT). |
| Did you encounter any complications which were related to the patient's eligibility criteria e.g. residence, social situation, co-morbidities which prior to discharge were not considered to be problematic? | Patient selection: stringent eligibility criteria is strongly emphasised in OPAT guidelines (Chapman et al., 2019; Norris et al., 2019) to ensure improved OPAT outcomes and avoidance of readmissions. |
| Would you like to comment on any other aspect of the service not previously tackled in the questions above? | Generic question to ensure each participant had the opportunity to share his/her view. |
| In your opinion, which is the greatest strength of the service? | Encourage discussion of facilitators and barriers which might not have been prompted by the guide. |
| In your opinion, which is the greatest limitation of the service? | |

A total of thirteen questions were developed and validated by a panel of experts during a pilot focus group session. The panel was made up of two doctors one from a medical and one from a surgical background respectively, two medical ward

nurses and two hospital pharmacists- all of whom were not involved in the service's development and implementation. Table 6.3 illustrates the amendments made to the topic guide.

Table 6.3 Modification to the topic guide by panel of experts

| **Nature of Modification** | **Recommendation** | **Implementation** |
|---|---|---|
| **Additions** | Insert a question relating to the number of medications available on the service (pharmacist 1) | Question 5: Are you content with the number of antibiotics available for use within the service? Do you think this number should increase?<br>Question 6: Once daily dosing was set as the standard regimen to be practiced for all patients. Should this be increased, what opportunities/limitations do you envisage? |
| | Ask the participants about the involvement of the general practitioner to ensure seamless transitions of care (medical doctor) | Question 8: A general practitioner in the community was another prerequisite prior to discharging a patient. Did they collaborate? Did they hinder or complicate a patient's prognosis? |
| | Add a question about MRSA screening (surgical doctor) | Question 7: MRSA screening was deemed as one of the prerequisites prior to discharging a patient. Was this always carried out? If no, why? |

| | | |
|---|---|---|
| **Deletions** | None | |
| **Modifications** | Add examples of patient eligibility criteria (ward nurse) | Question 10: Did you encounter any complications which were related to the patient's eligibility criteria e.g. residence, social situation, co-morbidities which prior to discharge were not considered to be problematic? |

### 6.2.4 Agenda of the focus group

The focus group session was structured as follows: a brief explanation about the overarching study was given prior to explaining the scope of the exercise, its regulations and the use of the topic guide. The principal researcher who posed as the moderator, facilitated the discussion using the topic guide. The moderator ensured that each question was discussed at length and all participants were given the opportunity to express their opinion. When prompted with question 11 "Would you like to comment on any other aspect of the service not previously tackled in the questions above?" the participants expressed the need to discuss the expansion of the service. Considering the importance of data generated through the flexibility of this technique, this request was accepted by the moderator.

### 6.2.5 Focus Group Session

The session was conducted in the office used by the OPAT team for meetings and virtual ward rounds as it is was deemed the most accessible room for all participants during working hours. The moderator was assisted by another pharmacist (with no involvement with the OPAT service) as the note-taker. The latter was entrusted with the role of taking notes of what was discussed and monitoring the two audio recording devices which were set up at locations that ensured everyone was being recorded. One of the recorders was used as a backup

in the event of a recording failure with one of the devices. The focus group took place in February 2019 and lasted one hour seven minutes.

Initially each member of the OPAT team was provided with the consent form (Appendix 6.2) and the topic guide (Appendix 6.3). Each participant was asked to read the consent form to ensure they were aware of the implications and rights of their participation and sign it. Moreover, they were asked to complete the participant demographics section and were given a few minutes to familiarise themselves with the topic guide questions prior to commencement. The discussion followed the agenda described in Section 6.2.4. The topic guide sheets bearing the demographic data completed by the participants was collected at the end of the session. Following cessation of the session, all recording devices and notes were collected and protected for purposes of confidentiality and anonymity.

### 6.2.7 Data Analysis

Considering participants were not prohibited from sharing their views in Maltese, analysis procedures were adapted from a study by Lora and colleagues (2017) who also analysed bilingual discourse from their focus group sessions. The recording was transcribed *ad verbatim* in both languages. For those sections in Maltese, the discourse was then translated to English by a professional translator. The content was checked for accuracy by the principal researcher. To ensure validity, the discourse that underwent translation was then back translated by another professional translator (not involved in the previous Maltese to English translation). The data was then pseudonymised and managed using the qualitative data management software NVivo® version 12. Data was pseudonymised as follows: the participant identification number recorded in the healthcare professional consent form was used to categorise the participant's discourse, thus ensuring confidentiality and lack of identification. Secondly, any references to specific patients and/or HCPs were anonymised to safeguard their confidentiality. Other data collected by the note-taker were taken into consideration and used to double check the transcribed text. The text was reread several times to ensure data immersion.

Qualitative data analysis was then carried out using open coding and subsequently axial coding once relationships were established. A second reviewer was asked to

carry out the same qualitative analysis. Any variances in codes between the two reviewers were discussed, negotiated and amended in NVivo® v12 as shown in Figure 6.1. The codes were inferred to create themes and subthemes. The frequency of codes and their relevance to the research question influenced the generation of themes.

HCP05: on an average manpower we are four nurses and a charge nurse

HCP06: yes, our request was for another workmate working full time and if the daily administrations are increased, if there is the demand for dailies another car. For now, it is a leased car therefore another car is a must. The extra person would help the duties we perform in here too. For bds and tds that would be another issue

HCP07: looking back, the requests which were refused were on a bd and definitely tds we don't even mention

HCP06: cause of our shifts

HCP04: yes, not a lot of patients on daily cropped up

HCP07: exactly the major increased would be in the eight-hourly dosing. Most patients who are not even refer stop at 8hrly

HCP03: when we are talking about the major expansion would be in the tds because right now and even a little bit more daily would be manageable but the bds that cannot increase but if you foreseen the expansion to be in tds doses it would obviously not just the car, but human resources, changes in rosters and I would see a coordinating hub , people visiting different parts of the island because at 10pm and you have four patients you cannot just go out with one car because you'd see the last patient at 2am which is not human. If you have four and one car visiting four patients. What we are talking about is coordinating. We have to have simultaneously people

HCP05: a shift in the evening


Figure 6.1 Example of coding the transcript using NVivo® v12

To align with the aims of the project, SEIPS-based modelling was used to carry out a process level analysis based on the 'work-as-described' by the OPAT team during the session. The various entities were identified and categorised according to the model's conceptual framework. Following the thematic analysis, a set of patient selection criteria (not biased by those predefined in the local OPAT SOPs) were generated from on the team's discourse with the intent of modelling the 'right' patient for this local service, as perceived by the service providers (Section 6.4.1).

Throughout the focus group session, it was evident that the members of the OPAT team were attributing shortcomings of the service specifically to the referral process. In order to address this cumulative barrier, a Human Factors approach was applied to address the overarching task and subsidiary tasks involved in the referral of a patient by using a Hierarchical Task Analysis. The tasks were derived from the OPAT team's discourse and supplemented by the service's SOPs. This analysis was drawn up by the principal researcher and reviewed by the principal supervisor. The referral of a patient to the service was assigned to the top level goal. In order to carry out this task, six tasks were assigned to the next level of the hierarchy. Plan O refers to the sub goals that need to be carried out to achieve the goal and in which order (Section 6.3.5).

## 6.3 Results

### 6.3.1 Participant Demographics

All the HCPs constituting the OPAT team agreed to participate in the focus group session (a total of ten HCPs). However, on the day, one nurse was unable to attend due to illness. Table 6.4 shows the demographics for the focus group participants.

Table 6.4 Demographics for the focus group participants

| Participant Identification Number | Age | Gender | Profession | Year of Experience |
|---|---|---|---|---|
| H1 | 54 | Female | Nurse | 30 |
| H2 | 37 | Male | Nurse | 14 |
| H3 | 44 | Female | Nurse | 21 |
| H4 | 54 | Female | Nurse | 30 |
| H5 | 33 | Male | Nurse | 10 |
| H6 | 37 | Male | Nurse | 16 |
| H7 | 53 | Male | Doctor | 30 |
| H8 | 36 | Male | Doctor | 13 |
| H9 | 31 | Female | Nurse | 8 |

Considering two nurses of the same age (n=54 years) and with the same duration of experience (n=30years) were recruited, participation/identification numbers were used to ensure correct attribution of comments. Professional grades were not included to preserve confidentiality.

### 6.3.2 Coding and thematic analysis

Figure 6.2 features a graphical representation of the parent and child nodes identified from the transcript using NVivo®. The different colours visually aid to differentiate between the different parent nodes whilst the size of each box is proportionate to the number of coding references (presented in Table 6.5 to 6.10).

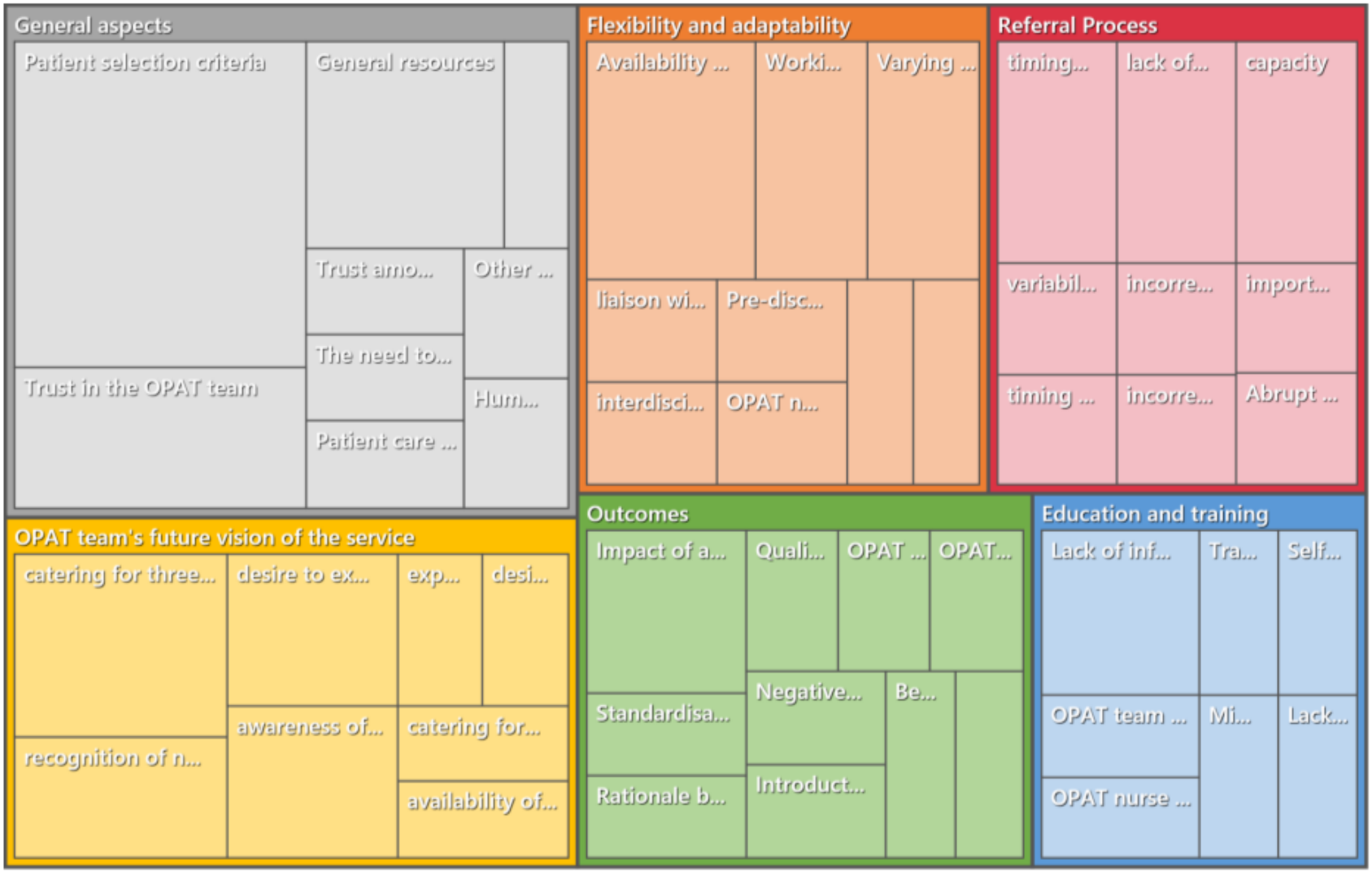


Figure 6.2 Comparison of coding references or each parent and child node

### 6.3.3 Key themes

The following tables (Table 6.5 to 6.10) illustrate the key themes, axial coding and participants' quotes extracted from the focus group transcript. Of note, three consecutive dots (i.e. …) indicate that there was transcribed discourse which was not considered relevant for the required code. The text in square brackets refers to discourse which was not said but was added by the researcher for completeness and better understanding of the intended context. The code at the end of each quote indicates the OPAT team member who made the remark (Table 6.4) whilst the letter "M" refers to the moderator.

6.3.3.1 Theme 1: OPAT team's future vision of the service

Table 6.5: Participants' quotes for extracted codes pertaining to the theme of the OPAT team's future vision of the service

| **Axial code** | **Participants' discourse** |
|---|---|
| Desire to expand | "obviously you always want more…the trend shows a good trend, a good potential" (H6) |
| Desire to increase workforce | "our request was for another workmate working full time and if the daily administrations are increased, if there is the demand for dailies another car. For now, it is a leased car therefore another car is a must" (H6) |
| Awareness of constraints | "yes I think it should keep on growing but at a gradual pace" (H3) |
| | "make it grow slowly and effective rather than quickly and disastrous" (H3) |
| Expensive drug administration equipment | "even the financial aspect limits consultant infectious diseases physicians across the UK in procuring" (M) |

| | |
|---|---|
| Recognition of need for gradual/cautious expansion | "having to tell consultants who refer look I cannot take in patients because we do not have enough people that will backfire in my opinion" (H7) |
| | "if we increase our workload exponentially, we obviously run the risk that our service standard of care might be less" (H7) |
| Catering for three times daily dosing regimens | "eight hourly which is the most common antibiotic regimen, we cannot cope at the time being so that has limited our service" (H7) |
| | "to see the introduction of the tds dosing we would require more resources, stock, people" (M) |
| | "[patients were refused] cause of our shifts" (H6) |
| Catering for more once daily administrations | "Having another car with another person, these 6 to 7 patients [receiving once daily administrations] would double to 12 to 14 on a daily basis" (H6) |
| Availability of antimicrobial treatment | "I think there are very few antibiotics that we have not used in OPAT except for aminoglycosides which I don't think they should be used outside hospital" (H8) |

6.3.3.2 Theme 2: Referral process

Table 6.6: Participants' quotes for extracted codes pertaining to the theme of the referral process

| **Axial code** | **Participants' discourse** |
|---|---|
| Variability in quality | "it could be better" (H3) |
| | "we could know about the patients before they actually get the PICC line inserted because there |

| | |
|---|---|
| Timing when patient is flagged | are certain things and precautions which we might highlight like… we've had referrals where PICC lines were already inserted or going to be inserted either way" (H3) |
| | "so, the earlier you know about the potential patient, the better" (H7) |
| Timing of patient discharge | "and the patient is going home today we usually asked them to delay discharge and they usually delay discharge by a day or two until we get everything sorted" (H8) |
| Importance of prior MRSA screening | "if we do get to know before we can make sure that the MRSA swab is taken, give them the chlorhexidine as to prep them properly" (H3) |
| Incorrect pre-referral procedures | "…they do not know they have to liaise with [OPAT doctors] first then we proceed. They phone here telling us that we have a patient with PICC line being discharged just tell us what to do" (H6) |
| Lack of pre-referral procedures | "We would have preferred if the ID consultants were informed before so that the process can go seamless and timely. Then it takes much more time, since we tell them first you need to speak to an infectious disease consultant then it takes longer" (H6) |
| | "Then there are those teams who have seldom done it like orthopaedic teams and so they might know less how to go about it, they leave it till the last minute, and they don't call the right people" (H8) |
| Abrupt pre-discharge procedures | "but having talked to them, reassured them, and it would be a little bit more easy you know to do the process rather than telling them tomorrow I'm |

| | |
|---|---|
| | coming home and they ask when are you coming home? at what time? How? (in a hurried tone), it's a little bit?" (H3) |
| Incorrect pre-discharge procedures | "Yes, constantly for the covering letter to cover the service" (M) |
| Capacity | "there were times when there weren't enough [time] slots" (H3)<br>"but it's because we didn't have place" (H8) |

6.3.3.3 Theme 3: Flexibility and Adaptability

Table 6.7: Participants' quotes for extracted codes pertaining to the theme of flexibility and adaptability

| **Axial code** | **Participants' discourse** |
|---|---|
| OPAT nurses' current skill set to make independent decisions | "he mentioned even the fact that they didn't hesitate to admit, advise to go to hospital maybe a GP would have hesitated by a day see how it goes and see tomorrow" (M) |
| Interdisciplinary backgrounds of the OPAT team | "the fact that we have the right medical background, the right pharmaceutical background, everything you know it" (H3) |
| Liaison with different departments | "let alone if we didn't have a pharmacist with us like liaising directly because we would find a lot of problems Saturday, Sundays, Public Holidays to get treatment" (H6) |
| Pre-discharge procedures | ""can we do it that way meaning we inform the OPAT nurses that there is a potential case, someone will inform you and then you contact us" (H7) |

| | |
|---|---|
| Availability of treatment | "whenever we have requested other antibiotics to be included, we did not have problems which is positive" (H7) |
| | "once daily dosing is the principal recommended regimen although we are also aiming for the tds" (M) |
| | "to most tds antibiotics there is a bd or od alternative like piperacillin/tazobactam which we do in fact switch most of the times so we usually if the patient is suitable for OPAT we try to come up with a working solution" (H8) |
| Varying role of the GP | "You see that there isn't that relationship or that trust that they are going to find him if they call for him" (H3)<br><br>"some GPS nowadays don't go out for home visits let alone at night so they cannot tell you. Yes, I have a GP and once in a while, they are not certain if they can rely on him and most of the time" (H6) |
| Working in patient's home environment | "the environments are quite subjective what is a clean environment for me might be a dirty environment for somebody else, so it is very subjective perception. You learn how to adapt" (H3) |
| | "[the Gozitan] he arranged to stay in his sister's flat in Malta. That was one of our needs to get the service" (H3) |
| Amending the current working schedules | "if you foresee the expansion to be in tds [three times daily] doses it would obviously not just the car, but human resources, changes in rosters and I would see a coordinating hub" (H3) |

| | |
|---|---|
| Amending setting of administrations | "…if we're going to have a new centre of operations, we'll be able to give not just antibiotic forms but also antibiotics on the side" (H7). |

6.3.3.4 Theme 4: Education and Training

Table 6.8: Participants' quotes for extracted codes pertaining to the theme of education and training

| **Axial code** | **Participants' discourse** |
|---|---|
| OPAT nurse training | "it's going to take time to train to because you have to train them, into dealing with PICC lines, antibiotic administrations and everything" (H3) |
| Misconceptions about the service | "nurses or consultants themselves they think that as an OPAT project we are nurse led" (H6) |
| Lack of information about the service | "I don't think that throughout the hospital the service is that well known" (H6) |
| | "not everyone knew about the service and the director herself told them it lacked marketing cause of the limitations it has" (H6) |
| Lack of adherence to pre-referral procedures | "Eventually it's kind of trickles down and eventually this is a learning experience for everyone so it's very understandable that they kind of…it's not something they do every day. It's the occasional patient that they have to refer to us so it's understandable, a give or take situation so we have to, until everyone gets used to it" (H8) |
| Training through integrated informatics | "…when they actually order the PICC line it alerts you for the MRSA [swab]" (H3) |

| | |
|---|---|
| Self-administration training | "she knows how the system works and infection control since she has an indwelling drain, but you cannot imagine an eighty-year-old OPAT patient trying to do it" (H5) |
| OPAT team skillset | "one of our strengths is our level of experience. Everyone comes with a background. Nothing was very new or very out of this world and everybody brings his own experience which is very valuable" (H3) |

6.3.3.5 Theme 5: Outcomes

Table 6.9: Participants' quotes for extracted codes pertaining to the theme of outcomes

| **Axial code** | **Participants' discourse** |
|---|---|
| Negative emotional impact on refusal | "if someone would have spoken to the patient tell him there is a service we can offer then disappoint him by telling him we cannot offer this service" (H7) |
| OPAT standard of care comparable to inpatient setting | "this is a very sensitive service since we are giving the service at home and the standard of care should be similar to hospital" (H7) |
| OPAT care as opposed to inpatient care | "We always took care of them holistically. We're not concerned just about the PICC line and that's it, we took care of everything" (H7)<br>"appointments" (H5)<br>"treatments, diets, drinks, we used to tell them and help them in everything" (H1) |

| | |
|---|---|
| Quality of the OPAT service | "That shows that there is a standard everyone is keeping. I mean people do notice things and people also do complain on a lot of things so" (H3) |
| Standardisation of OPAT nurse care delivery | "As much as you can you keep everything the same, it will limit the complications, your risk of infection and everything. There is quite outcome from the rate of infections and complications related to the lines" (H3) |
| Better pre-referral procedures from care teams with high referrals | "teams who are using our service more frequently for example the vascular teams, they know very well how to do it, they do it in a timely fashion, because they got used to it" (H8) |
| Impact of abrupt referral procedures in terms of patient selection criteria | "we were concerned since we didn't know the home situation... regarding OPAT we can make some arrangements for example cleaning the living room for us to you know administer antibiotics, we had issues with some patients with house cleaning you know" (H5) |
| Introduction of the self-administration model | "[patients] self-administer at home and the nurse just visits them or sees them in hospital once a week to see how they are going, access the line and see if they have any issues" (H3) |
| Rationale behind readmissions | "Most of them came in very short intervention which were actually planned and were discharged back either not on OPAT services or they continue the OPAT service" (H3) |
| Awareness about the service | "think this will grow with time and if we are looking in four years' time, I think all consultants will know even from higher authorities they will push for it "(H1) |

6.3.3.6 Theme 6: General aspects of the service

Table 6.10: Participants' quotes for extracted codes pertaining to the theme of general aspects of the service

| **Axial code** | **Participants' discourse** |
|---|---|
| General resources | "Obviously, the resources are what they are" (H6) |
| | "we have quite a lot of constraints" (H3) |
| | "it is always a balance between what you can offer and what you ideally should offer" (H7) |
| Human resources | "staff, manpower" (H5) |
| Other work commitments taken up by the OPAT nurses | "…as a team it is burdened since there will be an increase in hospital work as discharge liaison nurses" (H7) |
| Working relationships between consultants in the institution | "I understand that it may not always be possible from your end according to what is your position between consultants" (H3) |
| Patient selection criteria | "since he wasn't at home during the working hours since he used to work, and he used to go to MITU" (H5) |
| | "he couldn't open the door… he lived upstairs, and it was quite terrible" (H8) |
| | "he had to walk to get things done because he had no one to support him which did not make sense" (H3) |
| | "if older patients would accept us to go at 10pm or 11 pm in their home not knowing who is behind the door… because I think they would prefer to come here" (H6) |

| | |
|---|---|
| | "we started to alarm ourselves to much at first. We had patients not living adequately but we went there, had our space, we kept aseptic technique it was quite satisfactory" (H6) |
| | "What I remember is the only case we refused was the IVDU case but that's not" (H6) |
| Trust amongst OPAT team members | "we have very good support from the medical point and we work quite well together" (H3) |
| Patient care led by the head of service's care team | "we've been working in the speciality for a longer period of time our outreach is more" (H7) |
| Trust in the OPAT team | "this is a particular service, this means that people are trusting the team to go into their house which is something which is completely different from being in hospital" (H7) |
| | "they rely on us to coordinate and listen to their concerns/issues and they know that they come forward to you or their consultants and we go answered questions" (H6) |
| | "we always found support from everyone" (H4) |
| The need to provide patient reassurance | "they're comfortable in their home and they know they have contacts and it makes a difference" (H1) |

### 6.3.4 The SEIPS 2.0 model

Using SEIPS-based modelling, 'work as reported' by the OPAT team was categorised according to the model's elements as shown in Table 6.11.

Table 6.11 SEIPS 2.0 model

| **Work System Factors** |
|---|
| **Person Factors** |
| • Ability of HCPs to work in a multidisciplinary team<br>• High level of trust in the competence of HCPs to treat patients in their residences<br>• Diverse level of experience and skill set<br>• The influence of the general practitioner in managing a patient's clinical status and readmissions<br>• Lack of training in (and awareness of) referral process<br>• Lack of experience in referral process |
| **Task Factors** |
| • The need for patients to be reassured about their vascular access device<br>• The need for patients to be reassured about co-morbidities'<br>• The need to train and mentor new staff when they are recruited to the OPAT team<br>• Failure of non-OPAT staff to follow the correct referral process<br>• The need to train medical staff about referral processes<br>• The need for appropriate patient selection |
| **Tools and technology factors** |
| • Improved technology options could lead to self-administration practices e.g. elastomeric pump<br>• Troubleshooting and training to use new technology<br>• Availability of antimicrobials for use through OPAT, particularly those which have a reduced dosing frequency<br>• Availability of a technology for drug administration e.g. syringe pump driver<br>• Availability of stringent patient selection criteria<br>• The use of improved technology to avoid adverse drug reactions<br>• Availability of a motor vehicle to increase the number of outreaches |
| **Environment** |

- Influence of patient comorbidities on a patient's mobility (this may affect ability to open the door for the OPAT nurses)
- The patient's solitary living situation
- The need to monitor the patient's residence for any hazards e.g. level of cleanliness
- The need to evaluate the patient's situation in terms of informal caregiver support
- Influence of providing care in patients' own residence on their morale
- Acceptability of the service could be influenced by the level of security especially in a geriatric patient
- Availability of new premises for OPAT team duties e.g. clinical reviews, patient enrolments etc.

**Organisational Factors**

- Last minute referrals result in reduced time available for education and reassurance
- The need for the OPAT nurse roster to be published in advance could make the visiting nurse model less viable for patients
- The need to have training programmes in place before recruiting new staff
- Having an appropriate referral process ensures patients are no longer carriers of MRSA prior to discharge on to service
- Workload on the OPAT nurses varies according to time of year e.g. winter season
- Marketing and raising awareness of the service within the hospital could promote referrals
- The need to recruit nurses for patient administration outreaches before enrolling more patients
- The establishment of accessible channels of communication with the OPAT team
- The need to enrol more patients on the service

**Processes**

- Vascular access device insertions

| |
|---|
| • Patient symptom assessment and monitoring<br>• Methicillin-resistant Staphylococcus aureus screening<br>• Patient selection prior to enrolment |
| **Outcomes** |
| **Patient Outcomes** |
| • Selection of the correct patient |
| **Professional Outcomes** |
| • Ensuring security measures to make late visits more feasible especially in geriatric patients<br>• Ensuring high quality care through standardised quality care<br>• Selection of the correct patient<br>• Changing work schedules to cater for increased antimicrobial regimens |
| **Organisational Outcomes** |
| • Promotion of referrals through training programs provided by the OPAT team to doctors<br>• Impact on the OPAT team with the introduction of elastomeric pumps<br>• Impact of timely referrals on MRSA screening<br>• Impact of the increased referrals on refusal rates due to the maximal capacity of the service being reached |

### 6.3.5 Hierarchical Task analysis (HTA)

From the focus group session, it was becoming apparent that a key emergent theme was the importance of the referral process, hence the decision to undertake an HTA. The HTA dissected the overarching task into six tasks namely:

(i) assess the patient

(ii) inform the OPAT consultant doctor

(iii) carry out medical assessment

(iv) carry out nursing assessment

(v) carry out pharmaceutical assessment and

(vi) accept the patient on service.

These were based on the HCPs interactions with their working environment and were guided by a plan as can be seen in Figure 6.3.

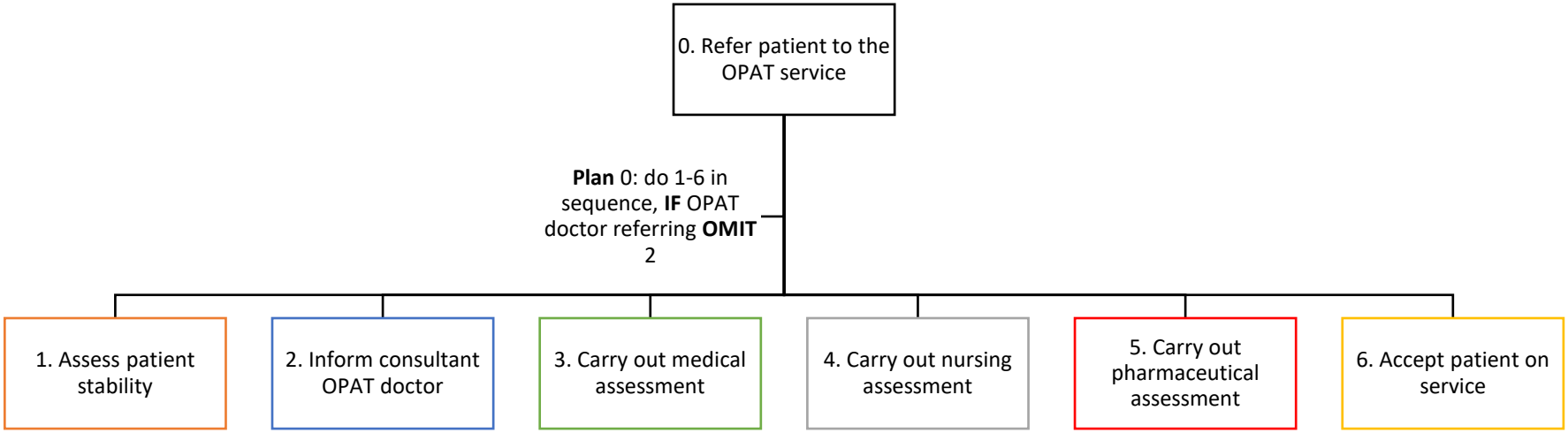


Figure 6.3 Top hierarchy of the HTA for the referral process

Of these, possibly due to large number of OPAT nurses constituting the focus group cohort, the largest number of errors were attributed to the execution of the nursing assessment (Task 4) as opposed to the other 5 tasks. The breakdown of tasks related to the nursing assessment can be seen in  Figures 6.4-6.9 whilst the other tasks are documented in Appendixes 6.4-6.8.

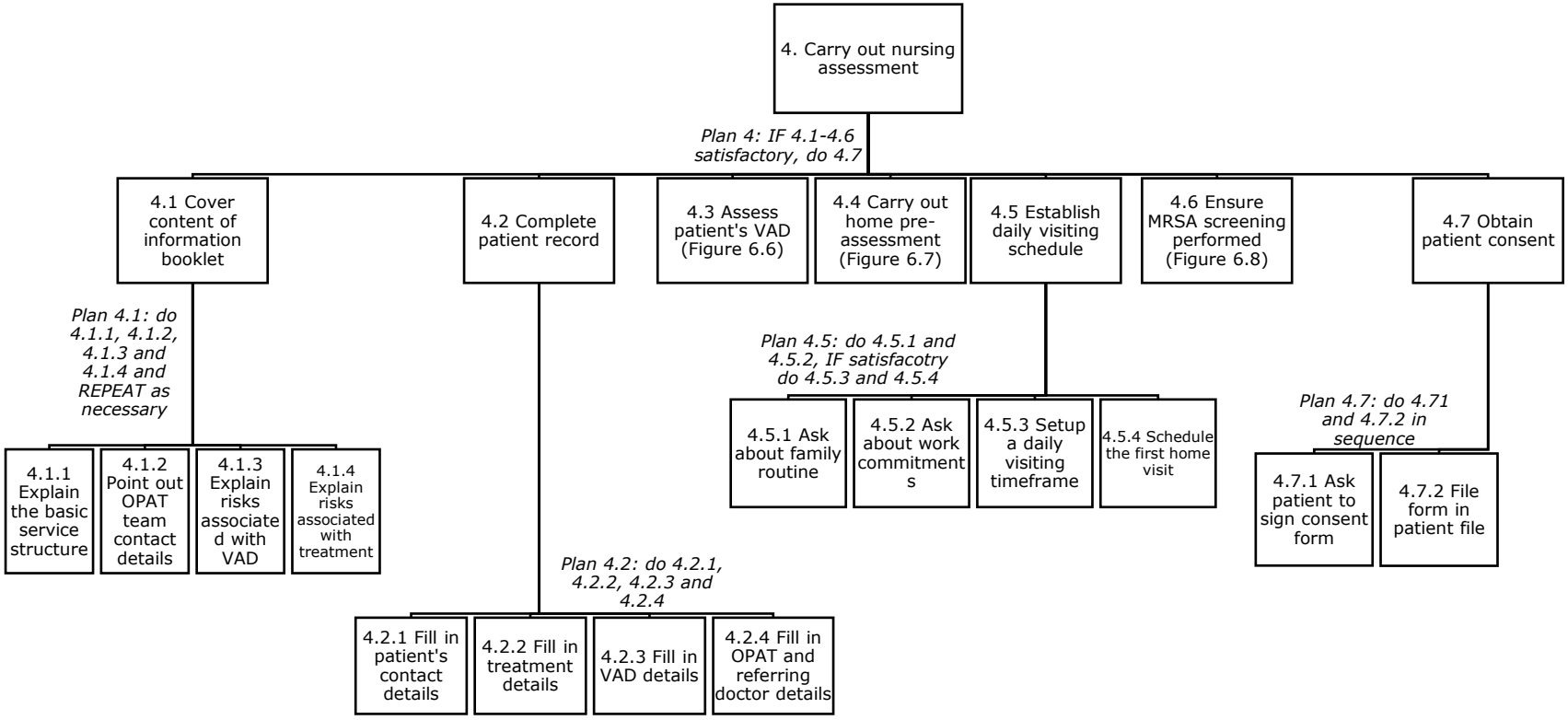


Figure 6.4 First hierarchy of tasks related to the execution of a nursing assessment

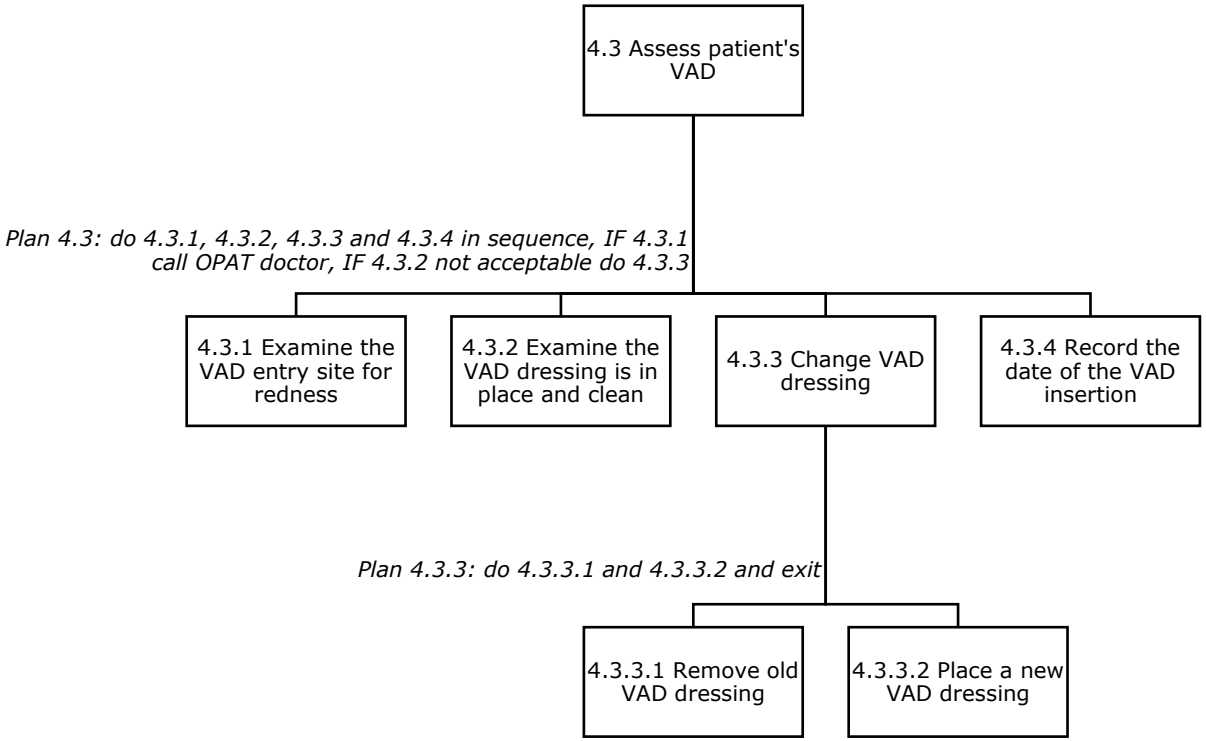


Figure 6.5 Task analysis for the assessment of the patient's VAD

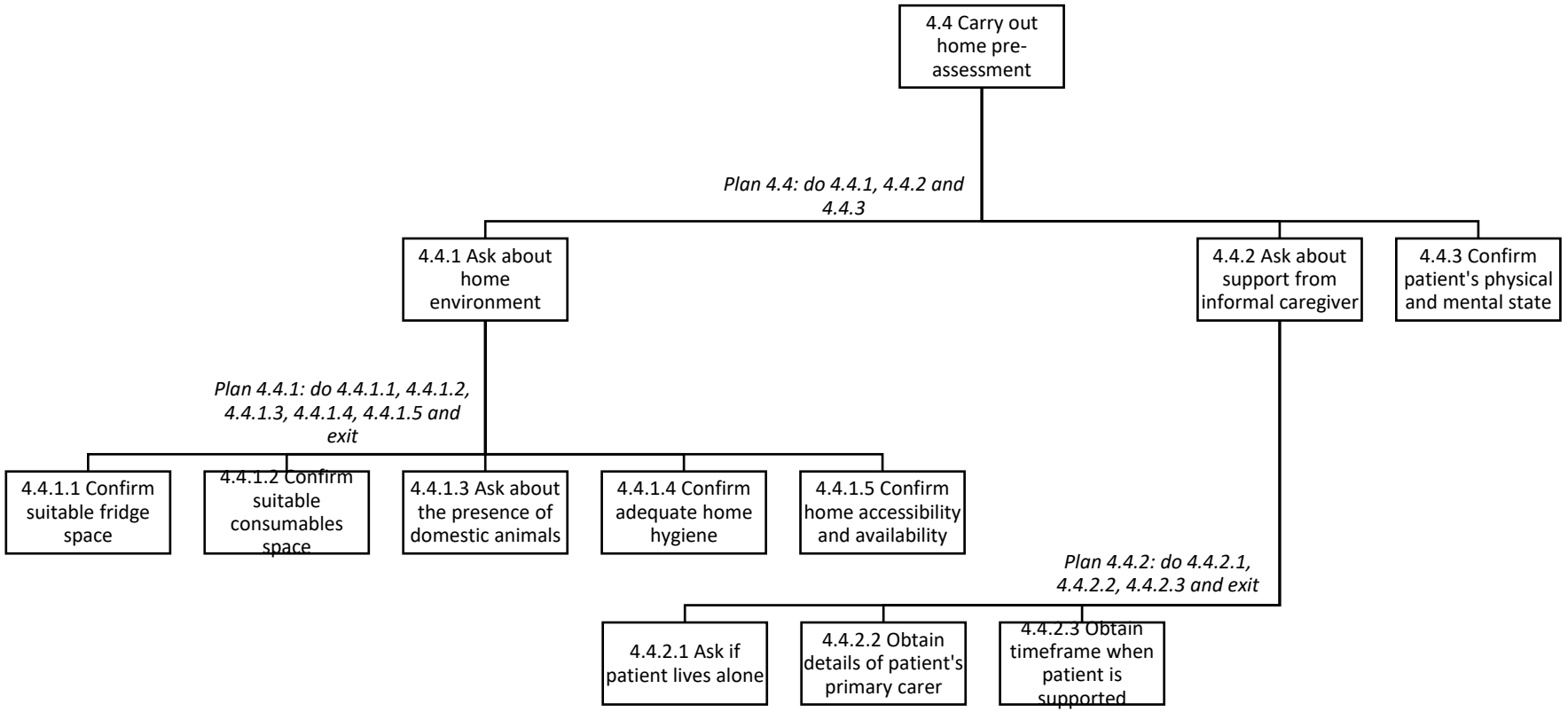


Figure 6.6 Task analysis about the execution of the patient's home pre-assessment

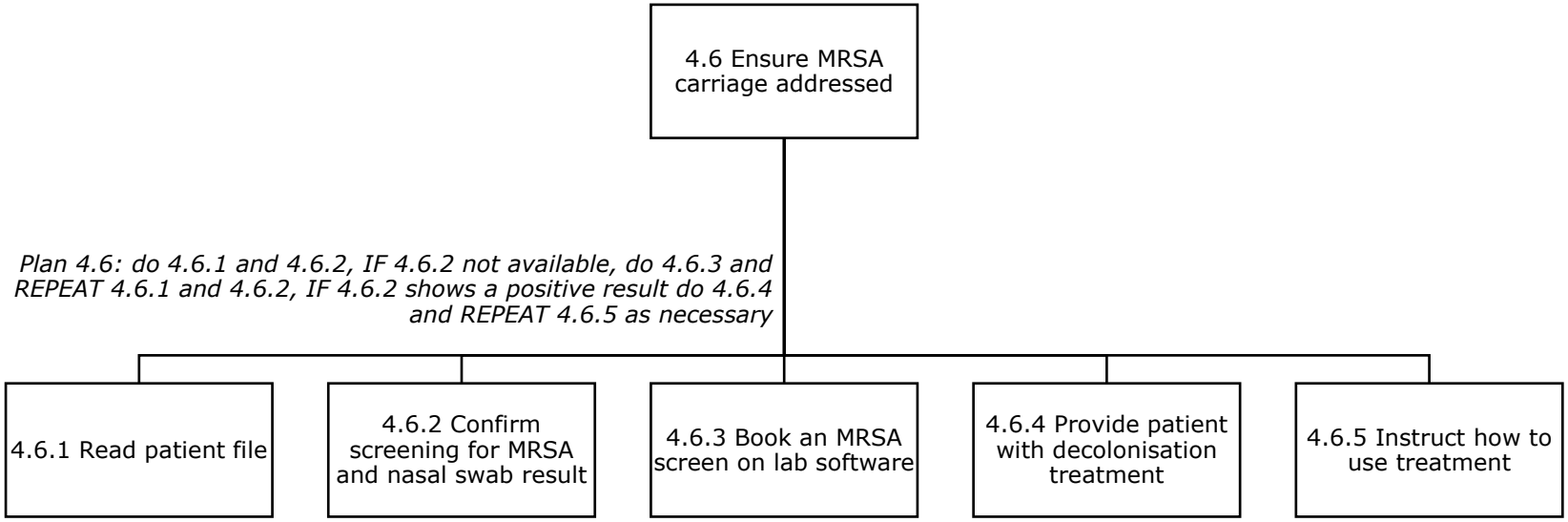


Figure 6.7 Task analysis for ensuring MRSA carriage addressed

The HTA delineated the complexity and multi-site nature of the overall process in the form of seven subtasks namely (i) cover content of information booklet (ii) complete a patient record (iii) assess patient's VAD (iv) carry out home pre-assessment (v) establish daily visiting schedule (vi) ensure MRSA screening performed (vii) obtain patient consent. These were further broken down into subordinate tasks.

## 6.4 Discussion

The thirteen-question long topic guide was designed to encourage discussion about aspects of the service that emerged from previous phases of this study (Chapters 4 and 5), as well as from the institution's SOPs and the literature on OPAT service provision at the time. The participants' ability to identify and adapt to unforeseen problematic situations resonated throughout the session. Through thematic analysis and SEIPS-based modelling, barriers and facilitators to the successful provision and eventual expansion of the service were identified. These themes are discussed below.

### Theme 1: OPAT team's future vision of the service

"...obviously, you always want more"

A major area of discussion was the future of the Maltese OPAT service. A desire to see the service expand was considered an organisational factor (as care teams were constantly under pressure to avoid unnecessary hospital stays by discharging their patients) but also a person factor, as participants expressed a strong commitment to seeing this happen. This was perhaps most clearly evidenced by the OPAT's team reticence in refusing to accept a patient onto the service because of the fear that this might negatively impact on future decisions about using the service. This, at least in part, also led to staff accepting referrals that failed to follow the institutional process, and this is discussed later. However, the analysis suggests that this is not the only interaction of this factor that has the potential to strongly influence system outcomes. For example, the team expressed concern that service expansion would require an increase in daily administration

outreaches. The 2019 good practice recommendations on OPAT stressed the importance of antimicrobial stewardship in terms of being able to switch a patient's treatment from a narrow spectrum drug with multiple daily doses to an equally effective and sensitive broad-spectrum drug which requires less frequent administrations. The authors recognised that the introduction of such agents would impact the number of outreaches thus reducing the nurses' workload and increase the service's overall capacity (Chapman et al., 2019). During the focus group, one of the OPAT doctors explained that this strategy was already implemented by the OPAT doctors to avoid refusing patients who can be treated with an equally effective but less demanding alternative.

Moreover, the 2018 IDSA OPAT guidelines argue that the choice of antimicrobial is influenced by the model of OPAT care chosen. Frequent dosing schedules are recognised as being impractical in an infusion centre model or the visiting nurse model. However, if resources are available to cater for frequent administration patterns, the guidelines suggest that the choice of antimicrobial should not be altered for the sake of convenience (Norris et al., 2018; Smismans et al., 2018). With this reasoning, the expansion of the service might bring about a shift in OPAT practices in this regard. Indeed, staff felt that the growing institution's workload needed to be met by an equivalent increase in resources. Relevant tool and technology factors considered important in optimising service expansion included the need to invest in novel longer acting antimicrobials (Bork et al., 2019), as these have the potential to reduce staff workload by reducing both frequency of dosing and influencing the administration times (Norris et al., 2018). Use of these newer agents would also require new equipment – these are not suitable for gravity-driven infusion and need to be used with elastomeric pumps (Voumard et al., 2018). Improving system interactions in this manner (alongside other interventions, such as the provision of an additional motor vehicle) would increase the time available for the OPAT team to address other task factors like the training of new recruits, which was identified as a significant barriers by the team who stressed the importance of a cautious expansion to avoid tainting the quality of care currently rendered and the overall refusal rate of flagged patients. This would be the result of a hastened service expansion that would result in the refusal of patients due to the inability to cope with a larger patient intake.

### Theme 2: Referral process

"It could be better"

An area of the service provision which was deemed to be suboptimal was the transitional phase from the referring care team to the OPAT team i.e. the referral process. Health transitions are a known target of fragmentation of care resulting in adverse events such as hospital readmissions (Radhakrishnan et al., 2018). To address this problem several studies have been conducted seeking to understand where transitions fall short including standardising medicines reconciliation (Redmond et al., 2018), improving documentation (Manias et al., 2017), establishing better communication channels (Radhakrishnan et al., 2018; Kim and Flanders, 2013) and targeting undergraduate medical education (Bray-Hall et al., 2010). Semi structured interviews and observations conducted by Scott et al. (2017) identified effective communication, patient/ family involvement and continuous adaptation of transition methods as the key facilitators to a successful referral.

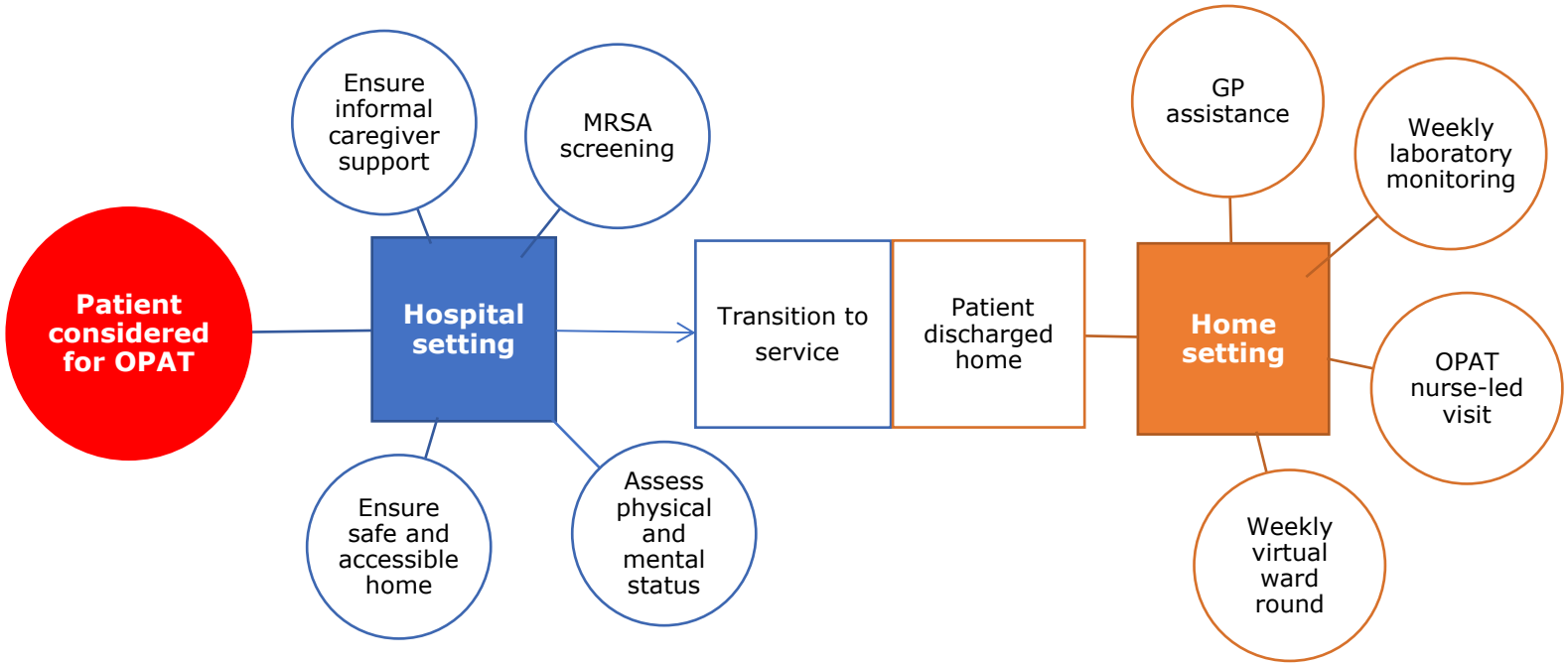


Figure 6.8 Illustration of the patient's journey through OPAT transition points

As shown in Figure 6.8, the number of potentially high-risk transition points, reveals that the OPAT service is not a standalone system but a 'system of systems'. Using the categorisation established by Siemienuich and Sinclair (2014), the OPAT service was a 'directed' form of this conceptual framework since the integral systems are subordinated to the system of systems. Best occurring within a single institution, directed forms fulfil predefined duties, using resources and policies common to all systems. This ideology, within the context of the local OPAT service, shed light on the need to shift one's consideration from the major transition (from the hospital setting to the patient's residence) to also include the smaller institutional interfaces constituting the referral process.

Not considering the relationship between overlapping systems is recognised as underpinning failure of some QI initiatives, such as the roll out of sepsis bundles. A systematic review published by Kramer et al. (2015) identified variances in terms of bundle elements and timings across the eight sepsis bundles. Only two elements were common namely lactate collection and administration of antibiotics. Despite the bundle variances, the management of sepsis required interaction of a number of different systems including clinical assessment (led by the medical care team on the ward) and diagnostic monitoring (led by the laboratory team) (for lactate levels and blood cultures) (Levy et al., 2018). In hospitals where the organisational culture supported effective integration of systems, the outcomes were positive. However, the fundamental contribution of this organisational integration was not recognised in the original bundle development which meant that roll-out was not universally successful. In contrast, the 'system of systems' approach has been used successfully to optimise design of other hospital services, such as the diagnostic testing process as described by Hallock et al. (2006).

Within the context of OPAT, Muldoon et al. proposed six OPAT therapy bundles, one of which specifically addressed care transition to address the proactive approach suggested in the 2004 IDSA OPAT guidelines (Tice et al. 2004; Muldoon et al. 2013). These propositions served as the backbone of the 'transition of care OPAT bundles' designed by other research teams who reported reductions in readmission rates as a resultant outcome (Keller et al., 2013; Saveli et al., 2015; Madaline et al., 2017). Both British and American OPAT guidelines reiterated that there was strong evidence to suggest that a dedicated team of professionals would be necessary to ensure the smooth running of such bundles (Norris et al., 2018;

Chapman et al., 2019). The recent British recommendations categorised their duties under five major categories including OPAT team and service structure, patient selection, antimicrobial management and drug delivery, monitoring of the patient during OPAT and outcome monitoring and clinical governance (Chapman et al., 2019). In a study conducted by Berrevoets et al. (2018), the transition of care (from hospital to the patient's residence) was investigated to determine whether patient centred care was being upheld at this point in the patient's OPAT journey. From the patients' feedback, the authors concluded that the availability of an OPAT expert willing to take on the responsibility of coordinating the transition process was a necessity to ensure satisfaction and quality of care.

Despite the current recommendations that patient selection should be a proactive process, at present the current referral process is through direct referral from inpatient care teams. The team recognised that this method led to erroneous or absent pre-referral and discharge procedures which acted as barriers to the execution of a proper referral. This task factor (Table 6.11) was considered to be influenced by person factors such as lack of awareness of and experience in the normal referral process. This appeared to be compounded by organisational factors such as the use of incorrect channels of communication, but also the adaptability and flexibility of the OPAT team, which historically had continued to accept patient regardless of the referral method. The lack of compliance to the documented referral procedure was the partial result of inadequate training across the institution giving rise to suboptimal practice. As described by Russ et al. (2013), training is almost always a poor way of ensuring safe practice. The former argued that training will fail to address patient safety if it is aiming to change staff behaviour such as following abbreviated discharging practices. The fact that such behaviour was seen multiple times and arose from several unrelated referring care teams, suggests it may actually be a workaround that is driven by the existing system design, and a more effective approach would be to consider system redesign.

The lack of pre-discharge procedures was evidenced by a number of occurrences of patients being signed off by the referring care team for discharge without an MRSA screen- a required step prior to the insertion of an access device within the institution (Infection control committee, 2012). The need to comply with local infection prevention and control guidance when inserting and caring for an

intravascular device was stipulated as the tenth recommendation in the recent British guidelines related to treatment management and delivery (Chapman et al., 2019). During the focus group session, one nurse pointed out that this task factor was considered to arise (at least in part) from person factors such as lack of awareness of the hospital's infection control guidelines (since patients were having a VAD inserted without a swab being taken) and lack of experience when referring a patient for a central venous catheter insertion. The implication of these person factors was negatively felt whilst the OPAT team enrolled the patient on to the service. Non-standard referral processes could also be seen to impact on patients, causing anxiety and confusion which then had to be dealt with by the OPAT team. On reflection, these issues could be the result (in part) of the lack of formal training about referral procedures, as this was limited to an internal hospital memo about the service's launch and a SOP. A reasonable strategy to circumvent these shortcomings is therefore an improved training programme which addresses standardisation of referrals using an HF-led approach (Russ et al., 2013).

The OPAT team were also responsible for ascertaining that compliance to the patient selection criteria and adherence to their standard OPAT practices did not impinge on the quality of care rendered. For example, non-standard flagging by referral care teams coupled with an impending discharge increased the workload of the OPAT team significantly, and this made it difficult for them to carry out their own tasks to an appropriately high standard. It could be seen that these situations were stressful for staff, which potentially impacts on wellbeing and resilience. Despite these limitations, a partial solution to address the rushed pre-referral process was to liaise a delayed discharge with the referring care team. Keller and her research team encountered a similar scenario where instructions were provided hastily at the point of discharge on to the service. One of the proposed strategies was to keep patients overnight to make sure that the adequate training was provided. Other solutions included early identification of patients to initiate training before and development of administration algorithms for specific cases (Keller et al., 2020a). The local situation varied from that reported in the Netherlands whereby Berrevoets and his research team (2018), following a series of focus group and individual interviews, reported unforeseen delays in discharges due to a lack of collaboration amongst professions and the absence of a responsible coordinator.

The referral process, which was generally substandard and hastened, gave rise to numerous problems. As described during the session, the quality of the referral process mainly depended on the frequency of referrals for that particular care team i.e. the more referrals they carried out, the more likely they were to follow the correct procedures. This level of experience coupled with the timeframe allocated prior to the patient's discharge in turn had a significant impact on the OPAT team's workload. If the referring care team did not execute their share of referral procedures, the OPAT team had to address these loopholes prior to commencing their referral duties. Moreover, if the referral procedures were carried out but the OPAT team was not given enough forewarning to carry out their duties e.g. patient assessment, this in turn compromised the quality of care, risking a readmission during service provision. The latter coupled with the lack of proper training about OPAT provision including referral procedures, the OPAT team and its scope of practice, eligibility criteria etc., led to the application of an HTA to model the OPAT referral process. The HTA identified the referral process to be a highly complex network of tasks, thus shedding light on its impact in ensuring a successful OPAT experience. The HTA sub goals, especially those related to the medical and nursing assessments, demonstrated the intricacies of team's procedures when liaising with other entities within the institution. This is a perfect example of the 'systems of systems' explained in Chapter 1. This complexity was intensified in the tasks related to the nursing assessment (Figures 6.4-6.7) which commence at hospital and progress organically to the patient's residence. Due to this change in environment, the tasks involved not only healthcare professionals at hospital (OPAT team members, referring care teams, ward staff etc.) but also the patient and their informal caregivers at a domestic setting. In terms of the SEIPS model, this part of the referral process is not just an example of patient-professional collaborative work but also patient-carer-professional work.

### Theme 3: Flexibility and Adaptability

"the fact that we have the right medical background, the right pharmaceutical background, everything"

The previous discussion points also feed into a strong theme emerging from this part of the study - flexibility and adaptability. This however can be deemed as both

a facilitator (as the service would continue to run smoothly and efficiently) and a barrier (too many adaptations give rise to workarounds)(Blijleven et al., 2017). As described by Debono et al. (2019), workarounds capture the differences between 'work-as-imagined' and 'work-as-done' and are attributed to the professionals' ability to adapt and be resilient. Despite the innocent intention, workarounds have the tendency to permeate one's daily practices and in turn be propagated to new recruits through modelling of unofficial practices (Johnson et al., 2008). Unfortunately, in a culture where system failures were not proactively sought out, a serious malfunction of the system e.g. an adverse event was required to bring such deviations to light. Belijleven et al. (2017) argued that system optimisation and standardisation was hindered since it strayed away from the original system design which was intended to safeguard both the professional and patient. Despite this conclusion, other research teams provide a positive outlook in that workarounds are necessary deviances which can in turn instruct system redesign through the identification of process misalignments (Beerepoot & Van de Weerd, 2018). However, considering the organic evolution of health systems over time, it is debatable whether a design was present in the first place and if so, whether they took into consideration elements pertinent to safety, satisfaction and wellbeing.

Considering the procedural workarounds carried out by the referring care teams (described in theme 2 above), the OPAT team demonstrated their resilience and adaptive capacity to maintain the integrity of their own system. This was evidenced by a success rate of 82.6% which was reflective of the 109 episodes which resulted in an improved clinical status over a span of three years (October 2016 to October 2019). From a total of 132 completed referrals by the team, 23 episodes were terminated prematurely due to a readmission, 20 (87.0%) of which were unplanned and 3 electives (13.0%). One death was reported, but the aetiology was not service related. Despite these challenges, the team were able to carry out administrations using four different VADs, of which the PICC line was the most common (n=112, 84.8%). With the 8 different antimicrobials agents at their disposal, the team administered a total of 149 antimicrobial courses of which 17 reflected the concomitant administration of two agents, with the teicoplanin-ertapenem combination being most prevalent (n=9, 52.9%) as described in Chapter four.

It is important that the team are capable not only of reactive adaptation to a current situation but also able to anticipate future disruptions and to monitor the system after adaptive changes have taken place (Branlat and Woods, 2010). A number of person factors could be seen to contribute to this adaptability, and these included their skill set, prior experience and ability to liaise with other professionals. These support task factors such as the ability to take independent decisions in the patient's residence, ensure maintenance of appropriate stock levels in the patient's residence, the need to carry out more daily administration outreaches and the acquirement of resources from other departments e.g. pharmacy. Focus on the resultant outcomes is important especially since studies demonstrate that a lack of coordination and communication amongst OPAT stakeholders leads to negative outcomes including delayed discharges (Berrevoets et al., 2018), missed doses (Quintens et al., 2020), lack of patient reassurance (Twiddy et al., 2018) and readmissions (Saveli et al., 2015; Madaline et al., 2017). This was exemplified locally by the strategic manner one of the OPAT nurses handled a patient's deteriorating clinical condition which involved liaising with the GP to review the patient and then collectively taking the decision to admit the patient.

The course of action described by the OPAT nurse complied with the sixth recommendation of the recent British guidelines which states that a system should be in place to guide the OPAT team member in case of an emergency and that there should be communication with other professionals involved in the patient's care including the GP (ninth recommendation for service structure) (Chapman et al., 2019).

The OPAT team recognised that their ability to perform their duties successfully was complicated by environmental factors. During OPAT, the internal environment is the patient's residence, and this is not entirely under the control of the team. A study by Keller et al. (2019a) identified home hygiene, domestic pets, general clutter and extremes in temperature as attributable hazards which could impinge the quality of OPAT duties. As more outreaches were performed, the local team recognised that they had to become more versatile in rendering the service, within acceptable limits. The team deduced that the level of home hygiene was a subjective opinion and hence the importance of the pre-discharge assessment in this regard. This resonates with the third recommendation concerning patient

selection in the British recommendations, which included logistical assessment prior to discharge (e.g. of the patient's home environment) as part of the comprehensive eligibility assessment (Chapman et al., 2019).

The adaptability of the service was also evidenced by the inclusion of new antimicrobials within the service's scope of practice to cater for infective conditions not previously covered. The team's person factors of diligence and adaptability facilitated their training to administer new treatment agents. As described in Chapter four of this thesis, the OPAT team treated patients diagnosed with a variety of infectious disease conditions, hence the requirement of a wide range of antimicrobial agents. This in turn reflected the type of care offered by our acute general teaching hospital MDH. Worldwide, most centres, including the United Kingdom (Durojaiye et al., 2019), Spain (Miron-rubio et al., 2016), Australia (Li et al., 2018), Switzerland (Gardiol et al., 2016) and Japan (Hase et al., 2020), strive to cater for a spectrum of conditions including. Other teams focus on findings specific to a disease condition such as bone and joint infections (Seaton et al., 2019; Marks et al., 2020), infective endocarditis (Tattevin et al., 2019), diabetic foot infections (Malone et al., 2015; Atack and Waterhouse, 2020) and tonsillopharyngitis (Al Alawi et al., 2015).

Another barrier which could not be overcome through flexibility or adaptability of the service was the high frequency of administrations to the same patient-specifically three doses to the same patient daily. Currently, the OPAT nurses have a fixed roster for administration outreaches (7am to 6pm), thus the necessary time intervals required for three times daily administrations to the same patient would be impossible. Moreover, this logistical impasse was further complicated by environmental factors particularly seen in the level of security at a geriatric patient's residence which created an obstacle to this administration pattern. Possible resolutions included restructuring the current working schedules to cater for outreaches late at night and secondly to administer treatment in the team's new premises once built. The team felt that treating a geriatric patient late at night without the support of informal caregivers was going to be problematic. The inconvenience posed to both OPAT nurse and patient in terms of evening administrations to accommodate multiple dosing frequency has been seen in other settings (Steffens et al., 2019). Therefore, amendments to the local patient selection criteria were identified to cater for such a vulnerability. In fact, support

from family members was considered as one of the patient selection criteria required for enrolment in the recent British recommendations (Chapman et al., 2019).

As described by Tice et al. (2000), the level of flexibility and adaptability of the service should reach a point whereby the OPAT team can offer different models of care such as the infusion centre model, visiting nurse model etc depending on the needs of the patient. This goal would be truly tested if the patient were to start with one model and due to unforeseen circumstances e.g. work commitments, require a change in care. This flexibility would thus require the introduction of the self-administration model to enable a wider variety of care options to the patients.

**Theme 4: Education and Training**

"it's going to take time to train..."

Another emergent theme from the session was the requirement of standardised education and training for all the directly interconnected stakeholders namely patients and informal caregivers, new OPAT recruits and the institution's professionals at large. Considering the local service has not yet introduced self-administration model of care, patient education and training is delivered using an information booklet about the following topics: general information about the service, management of the access device and logistics governing the nurses' visits. This is considered good practice as evidenced by other services rendered globally (Steffens et al., 2019). According to the fifth recommendation on patient selection in the recent British OPAT guidelines patients and informal caregivers should have comprehensive information about the nature of OPAT. Moreover, it was suggested that user friendly methods e.g. visual aids and mobile phone applications should be utilised to facilitate patient education (Chapman et al., 2019; Keller et al., 2020b).

Despite the need for more human resources, the OPAT team felt that strengthening training-related organisational factors was important. This included increasing the scope of training and ensuring that any training programme is standardised. It was considered that the content of this should include drug administration, patient selection and infection control procedures. The team did not question whether they

possessed appropriate person factors (e.g. competence) needed to train and mentor new recruits. However, considering their request for more staff one can infer that person factors such as stress, work-related burnouts, fatigue, anger etc. would be exacerbated if a significant training burden was added to their workloads. Despite their expertise, the OPAT team must undergo continuous professional development to keep abreast of new clinical practice as per the sixth recommendation about clinical governance in the British guidelines (Smismans et al., 2018; Chapman et al., 2019).

The team's educational campaign about the service was deemed crucial to address any misconceptions or absence of information. As described by one of the OPAT doctors, "eventually it kind of trickles down and eventually this is a learning experience for everyone so it's very understandable that they kind of…it's not something they do every day. It's the occasional patient that they have to refer to us so it's understandable, a give or take situation so we have to, until everyone gets used to it". This view is in keeping with recommendations outlined by Russ et al. (2013) who identified the value of offering training if it is absent or deemed to be inadequate. In addition, the authors also discuss the benefit of a Human Factors-led approach when addressing training strategies, especially when it is used to rectify team processes and interactions.

Providing training about good clinical governance is in keeping with two recommendations of the British guidelines with respect to team and service structure. The second recommendation clearly states that the team should portray clear lines of responsibility whilst the eighth recommendation states that there should be no grey area in terms of responsibility between the lead OPAT clinician and the referring clinician so much so that it should be documented (Chapman et al., 2019). Within the remit of the local service, the need to divulge correct information was considered a means to overcome current barriers leading to incorrect referrals and missed opportunities for eligible patients. In addition to this initiative, other OPAT settings identified proactive strategies whereby professionals trained in OPAT enrolled patients through their involvement in committees, and meetings (O'Hanlon et al., 2017) or the utilisation of informatics e.g. Melzer et al. (2017) used the blood culture database to identify the eligibility of inpatients diagnosed with bacteraemia for OPAT.

Potential training opportunities were considered if the service had to expand to offer the self-administration model of care. This, of course, brings in another task factor, which is the need to train the patient to self-administer, and in this case, the need to select the correct patient is likely to become even more important. New administration technology as well as the need to train the patient about adequate home environment standards are also going to be increasingly important (Smismans et al., 2018). Eventually, the hope is for the service to cater for patients who self-administer using elastomeric pumps, a course of action that is already gaining traction in the literature (Saillen et al., 2017). Furthermore, this model of care has been facilitated by the use of the non-electronic design of elastomeric pumps, which have circumvented problems seen with programming errors and complex user designs (Smismans et al., 2018). When prompted by the topic guide, the cohort only nominated one patient as being adequately skilful to self-administer due to previous experience with an in-dwelling device. The lack of confidence of the cohort was expressed in a recent study by Tonna et al. (2019) who gathered patient feedback to determine barriers and facilitators to the possibility of self-administration. The study concluded that patients were willing to self-administer if adequately trained especially considering the resultant implication on their daily activities and work commitments. However, they expressed concern about dealing with future complications and the reliability of their newly acquired skillset. Gardiol et al. (2016) also commented on the financial implications of self-administration stating that the expenditure to provide and prepare an elastomeric pump for administration works out cheaper when compared to the fee of a nurse's visit or the cost of a treatment room in a hospital setting.

**Theme 5: Outcomes**

Throughout the session it was evident that the team were determined to maintain successful proximal and distal outcomes when possible. Unfortunately, on a global scale, the different settings and reporting styles make it difficult to deduce the added benefit of offering OPAT over IPAT in terms of economic and health outcomes (Bryant and Katz, 2018; Boese et al., 2019). Nevertheless, the team felt that their standard of care was comparable to the inpatient setting in terms of

avoiding adverse events, ensuring successful infection resolutions and holistically responding to the patient's needs e.g. considering their lifestyle measures. They believed that their success could be evidenced by a low readmission rate (17.4%, Chapter 4), and the fact that most readmissions were unplanned (n=20/23), mostly due to a deterioration of the presenting infection rather than arising as a complication of the service as reported in Chapter four. Despite these positive outcomes, barriers were encountered in the form of abrupt referrals which tested the quality of enrolment procedures as described in the second theme above. A negative outcome of the service was the restrictive maximum patient capacity of the service. To avoid disappointment to the patient, the referring clinician was immediately advised by the OPAT doctors if all the timeslots were occupied by other patients. The team argued that a steady increase in patient referrals could help them make a case with the hospital's administration to employ more nurses to join the OPAT team. Considering the variability in OPAT team structures globally, the British recommendations reported whole time equivalent scores based on 100 episodes per year to guide OPAT staffing requirements in terms of doctors, nurses and pharmacists (Chapman et al., 2019).

**Theme 6: General aspects**

When episodes resulted in a readmission, the patient selection criteria were viewed as inadequate gatekeepers to successfully filter patients for enrolment. For example, for a particular patient, the team concluded that the inpatient setting was more appropriate since limited mobility impeded the nurses access to the residence (Gardiol et al., 2016; Erba et al., 2019). Lack of consideration of stringent work commitments (Berrevoets et al.,2018; Twiddy et al., 2018), commitment by informal caregivers (Fisher et al., 2017) and residential limitations (e.g. stairs, patient's perception of home hygiene (Keller et al., 2019a)) were other aspects overlooked by the team.

These scenarios were in keeping with the British recommendations which suggested a shift from stringent patient selection criteria to a more case-by-case individualistic assessment including comorbidities, support, preferences, availability of resources and suitability of the setting e.g. opening hours of infusion clinics (Chapman et al., 2019; Norris et al., 2018). Despite the team's efforts to

work around patient limitations by opting for other options such as possible informal caregiver support and home hygiene education, continuation of the service failed and led to a readmission. This suggests an important area of focus for system re-design: improving the sensitivity of the selection criteria for the local context at the early stages of referral rather than promoting workarounds once the patients were already enrolled.

The team stressed the importance of resources and classified human resources as one of the greatest weaknesses of the service. Recruiting and mentoring new members of staff would seem as a barrier at first however once they have gained their professional independence, they would potentially reduce the workload. The team also identified the importance of establishing strong relationships and liaisons amongst themselves as team members, with patients and with referring care teams. This collaborative nature could be seen to comply with the ninth recommendation of the British guidelines on team and service structure which promoted communication amongst the stakeholders involved in managing the patient's care including the GP, referring clinician and if required the community team (Chapman et al., 2019; Erba et al., 2019).

### 6.4.1 Key Findings

Identifying the 'right' patient for the local service

As demonstrated in Figure 6.2, a high coding frequency was noted in relation to patient selection. These references described scenarios where the success of the service was impacted, sometimes to the extent that a patient required a readmission. The importance of identifying patients who are likely to benefit from OPAT is well-recognised in the literature, and is reflected in guideline development, where patient selection criteria occupy a prominent position. However, data arising from this part of the study supported the identification of a broader set of patient characteristics, some of which have not previously been recognised, and are likely to improve patient selection for the Maltese context. With this rationale, a patient selection model delineating the 'right' patient based on the team's rendition of 'work-as-described' was devised. Patient selection criteria need to be considered from a physical, social and logistical point of view (Chapman et al., 2019). Some

selection characteristics were specific to the patient's mobility (Gardiol et al., 2016; Fisher et al., 2017) and history of intravenous drug use (Ho et al., 2012; Buehrle et al., 2017; Smismans et al., 2018; Marks et al., 2020; Appa et al., 2020). The possibility of offering this service to people who inject drugs was considered in the good practice guideline for OPAT, but low follow-up rates impeded this expansion trajectory.

The 2019 British guidelines suggested the addition of gatekeeping measures to patient selection such as the inclusion of lifestyle measures (Chapman et al., 2019). This was picked up by the team who mentioned the need to consider the patient's work commitments prior to enrolment (Twiddy et al., 2018). Other criteria focused on the logistics to administer the treatment to the patient including the dosage frequency (Steffens et al., 2019), residence location and level of hygiene (Smismans et al., 2018; Keller et al., 2019a). The others focused on the patient's varying support system including informal caregivers (Fisher et al., 2017), their GP (Twiddy et al., 2018; Erba et al., 2019) and the OPAT team prior to discharge.

Based on the group's discourse, a set of criteria describing 'the right patient' were formulated incorporating pre-existing criteria, as shown in Table 6.12 and Figure 6.9. The circle size in Figure 6.9. reflects the weighting of a particular criterion on the team's judgement when referring a patient. For example, the circles representing IV drug use and long-acting antimicrobials criteria were smaller in size since at present, patients who fall under these categories are immediately refused by the service providers. Moreover, circle sizes for criteria related to work commitments and supportive GPs were also smaller. When work arrangements were not possible, service providers allocated a different visiting time or a different model of care i.e. the infusion centre model. In the absence of a supportive GP, patients were asked to make use of the helpline or in the worst-case scenario, should they feel a deterioration of symptoms, the emergency department.

Table 6.12 Proposed criteria for the new patient selection criteria

| **Proposed criteria** | **Previous criteria** |
|---|---|
| 1. Mobility: patient must be capable of providing accessibility to the OPAT nurses e.g. be able to open main door. | Inquiries are made about home accessibility during the pre-assessment process. |
| 2. Work commitments: patient must be available at home during a specific timeframe (as appointment time can vary due to unforeseen delays e.g. traffic, enrolment of patients who reside at a geographical distance etc.). | Inquiries are made about home availability during the pre-assessment process. |
| 3. Known case of intravenous drug use: patient must not have a history or current use of intravenous drugs due to unsupervised use of VAD. | These patients are automatically refused by the OPAT team. |
| 4. Home environment: patient's home environment must be conducive to overall good hygiene practices to ensure safe drug administration and preservation of device dressing integrity. | Inquiries are made about suitable fridge space and area for consumables, presence of pets and the level of hygiene during the pre-assessment process. |
| 5. Informal caregiver support: patient must have assistance at home if mobility is questionable or administration must take place late during the day. | Information about the patient's living situation (alone or with family/friends) is gathered during the pre-assessment process. |
| 6. Antimicrobial dosing frequency: patient must be on an antibiotic which requires either daily or twice daily administration (maximum). | Patients who required administration three times a day are automatically refused by the OPAT team. |

| | |
|---|---|
| 7. MRSA screening: patient must be screened for MRSA carriage and provided with decolonisation therapy (if they test positive). | Hospital infection control policy recommends the nasal screening of patient for MRSA prior to a central venous catheter insertion. |
| 8. Residence location: patient must reside in Malta (not Gozo). | Inquiries are made about home accessibility during the pre-assessment process. |
| 9. Service education: patient must be fully aware of the care they shall receive in a timely fashion to prevent negative emotional repercussions (i.e. anxiety, confusion etc.). | Provision of service education is confirmed when gaining patient's consent. |
| 10. Supportive GP: patient must ideally have an easily accessible GP to monitor for any clinical deterioration between nursing visits. | Contact number of the primary carer is requested during the pre-assessment process. |

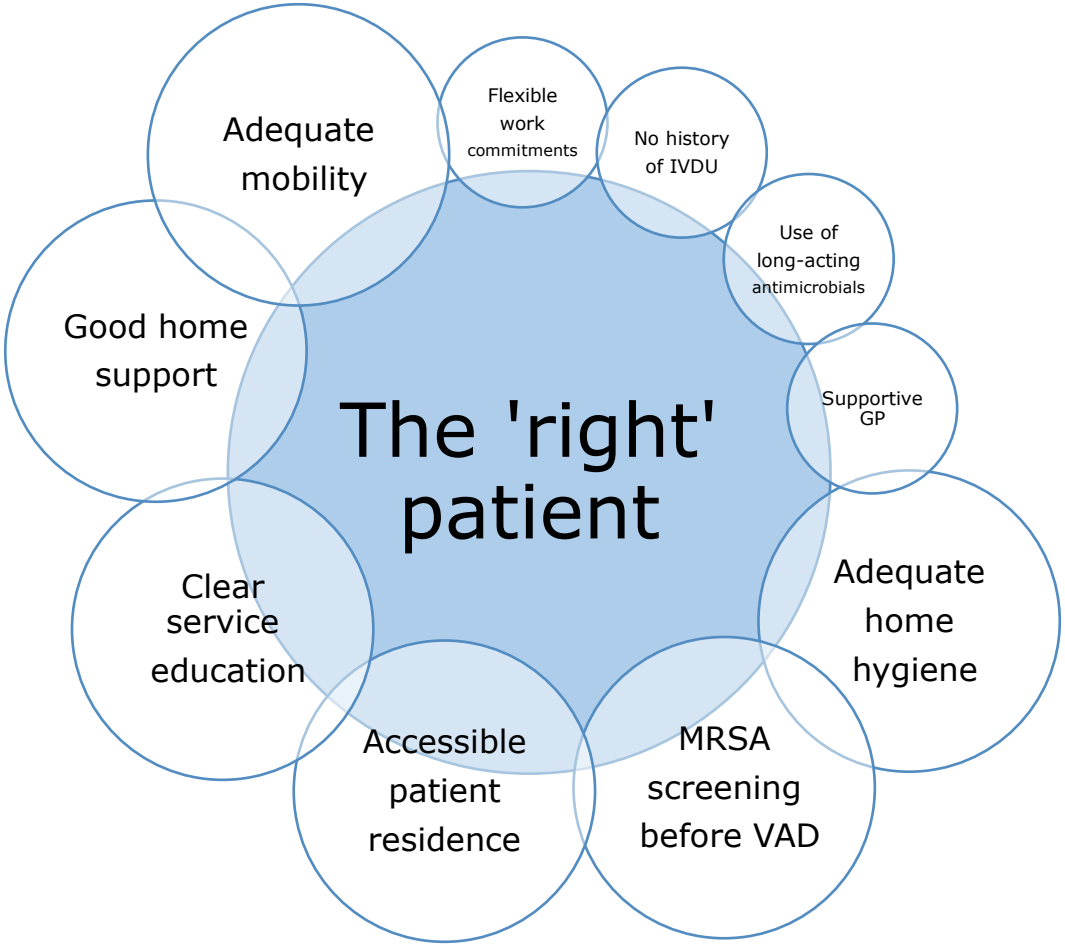


Figure 6.9 Radial Venn diagram of the newly identified selection criteria specific to the local service

### 6.4.2 Strengths and weaknesses

This discussion was based on the OPAT team members based in Malta thus limiting the generalisability of the data. However, such an exercise offered a unique opportunity to understand the successes and limitations of the Maltese OPAT service rendered from the national acute general hospital to a population of around half a million inhabitants. Moreover, considering the scope of the research questions, it was necessary that the cohort was a natural/pre-existing group of people and thus could not benefit from the lack of conformity seen in natural groups (i.e. where participants are complete strangers). However, pre-established groups offer the advantage of easier recruitment, familiarity amongst participants and the previous knowledge of shared experiences (Liamputtong, 2011).

Moreover, the dual position of the principal researcher as the moderator and a member of the OPAT team might have inflicted bias. However, this was overcome by using a topic guide and ensuring minimal involvement in the discussion (except for facilitation and note-taking). The involvement of the principal researcher was considered appropriate from a participatory ergonomics point of view which is defined as "the involvement of people in planning and controlling a significant amount of their own work activities, with sufficient knowledge and power to influence both processes and outcomes in order to achieve desirable goals" (Carayon et al., 2020).

For the purpose of this phase, tasks were identified as being erroneous when members of the OPAT team highlighted them as such during the course of the focus group session. This method might have instilled an element of bias since errors were reported from the perspective of the team (whereby 7 out of 9 were nurses) and must thus be accounted for. Having said that, this HTA gains strength when used in conjunction with error prediction models such as SHERPA, to identify the impact of errors to the tasks and their resolutions (Lane et al., 2006). Lastly, since the HTA was based on the team's discourse (work-as-reported) and the locally available SOPs and not on direct observations and thorough data collection means e.g. think-aloud protocol, certain tasks could have been omitted. Similarly, task analysis is normally done individually, but for all workers (or a representative sample of the workforce) and then these are merged to produce a composite that

reflects all observed actions as alternative behaviour 'options'. In effect, we compiled a retrospective composite analysis, and so this will of course have significant limitations. In spite of this limitation it proved very useful in capturing the complexity of this recurrent barrier to service optimisation. This analysis can serve as the foundation for the development of education tools targeting referring teams. This approach will help them understand the importance of adhering to the process as laid out in the guidance.

## 6.5 Conclusion

The focus group session offered an opportunity for the team to comprehensively evaluate the current running of the service and identify any gaps which could improve the quality of care for their varied patient cohort. This person-centred approach is in keeping not only with the SEIPS 2.0 model which regards the 'person' at the centre of a work system (Carayon et al. 2006; Holden et al., 2013; Carayon et al., 2020) but with OPAT services globally which are shifting towards this rationale (Berrevoets et al., 2018; Yi et al., 2019; Chapman et al., 2019).

# Chapter 7

## Discussion

This chapter provides an overview of the aims and key findings of this case study research together with a detailed comparison between the SEIPS model generated in the systematic review and that for the local OPAT service. In conjunction, this chapter postulates the potential impact of this work and further research options in the fields of Human Factors and OPAT.

## 7.1 Contribution to knowledge using a case study methodology

This work is an original contribution to OPAT research using a Human Factors systems approach in the context of a convergent mixed methods case study methodology. The need to audit the local service was crucial considering the absence of prior data and the importance of benchmarking and quality assurance procedures stressed in the recent OPAT guidelines (Chapman et al., 2019). In view of the context specific cohort and real world scenario under study, the overarching aim for this work was to investigate the OPAT service in Malta by applying a case study methodology. This aim informed the other phases as seen in Sections 7.1.1 to 7.1.4.

### 7.1.1 Chapter 3- Systematic literature review

The aims of Chapter three were (i) to critically appraise, synthesise and present the available evidence relating to adult OPAT services (ii) to explore if the OPAT service is amenable to analysis using the SEIPS 2.0 framework.

The review identified 27 studies of which only two articles published by Keller et al. [which looked at patient/caregiver task analysis (2019b) and the impact of the home environment on OPAT tasks (2019a)] mentioned the Human Factors discipline.

### 7.1.2 Chapter 4- Prospective observational cohort study

The aim of Chapter four was to appraise system outcome measures of the service including but not limited to referral, treatment and outcome details for patients flagged. Moreover, this phase aimed to evaluate the cost required to run the service. The national OPAT service resulted in 3,287 hospitalisation days saved over the three-year period. This achievement is due to the service provision of 132 episodes to a total of 117 patients. From these episodes, only 23 episodes (17%) resulted in the patient's readmission to hospital thus the success rate was of 82.6%. Moreover, using an activity-based approach, it was deduced that a mean of €455.57 was required per week to run the service from the organisation's perspective.

### 7.1.3 Chapter 5- Patient cross-sectional survey

The aim of Chapter five was to evaluate the service through the experiences of those patients enrolled in the service following cessation using a questionnaire. The closed ended questions revealed that patients were extremely content with the service since approximately half of the patients (n=45/96) gave a score of 19 points or higher (out of a possible 21 points). Thematic analysis performed on the data gathered from the open ended questions identified four themes namely (i) patient wellbeing, (ii) standardisation of OPAT procedures, (iii) availability of resources and (iv) informal caregiver support.

### 7.1.4 Chapter 6- Focus group session with OPAT team

The aim of Chapter six was to capture the perspective of the service providers i.e. OPAT team using a focus group method. Thematic analysis of the OPAT team's discourse generated a total of six themes namely (i) OPAT team's vision of the service (ii) referral process (iii) flexibility and adaptability (iv) education and training (v) outcomes and (vi) general aspects. The theme related to the referral process shed light on the need to investigate this transition. For this reason, an HTA was carried out, which resulted in a six tasked process to ensure the execution of the overarching task i.e. to refer the patient to the service. Lastly, overlap from the themes highlighted the importance of identifying the 'right' patient for the service and the need to address the selection criteria routinely.

## 7.2 Contribution to knowledge through SEIPS-based modelling

Human Factors systems approaches are paramount to improve the quality of healthcare and ensure patient safety. Since the first Human Factors and Ergonomics study performed on medication safety in the early 1960s, and its formal recognition in the late 1990s following the Institute of Medicine report " To Err is human: Building a safer health system", this field of research has made positive contributions towards redesigning healthcare systems. This has been made possible through the application of well-designed tools such as the SEIPS model to healthcare research and practice (Carayon et al., 2014).

An HFE approach is characterised by the application of a systems approach. In the case of complex sociotechnical systems like OPAT, this involves using an appropriate systems framework to inform data collection, extraction and synthesis. The framework ensures that multiple stakeholder perspective are obtained, allowing the building of a working model that all stakeholders at least recognise. In this study, this was done on two instances: once to reflect the global context as part of the SLR (Chapter 3) and secondly for the Maltese system (Chapter 5 and 6). Figure 7.1, 7.2 and sections (7.2.1-7.2.3) highlight similarities and differences between the components of the SEIPS 2.0 model generated in this study (Chapters 5 and 6) against the baseline model designed in the SLR (Chapter 3).

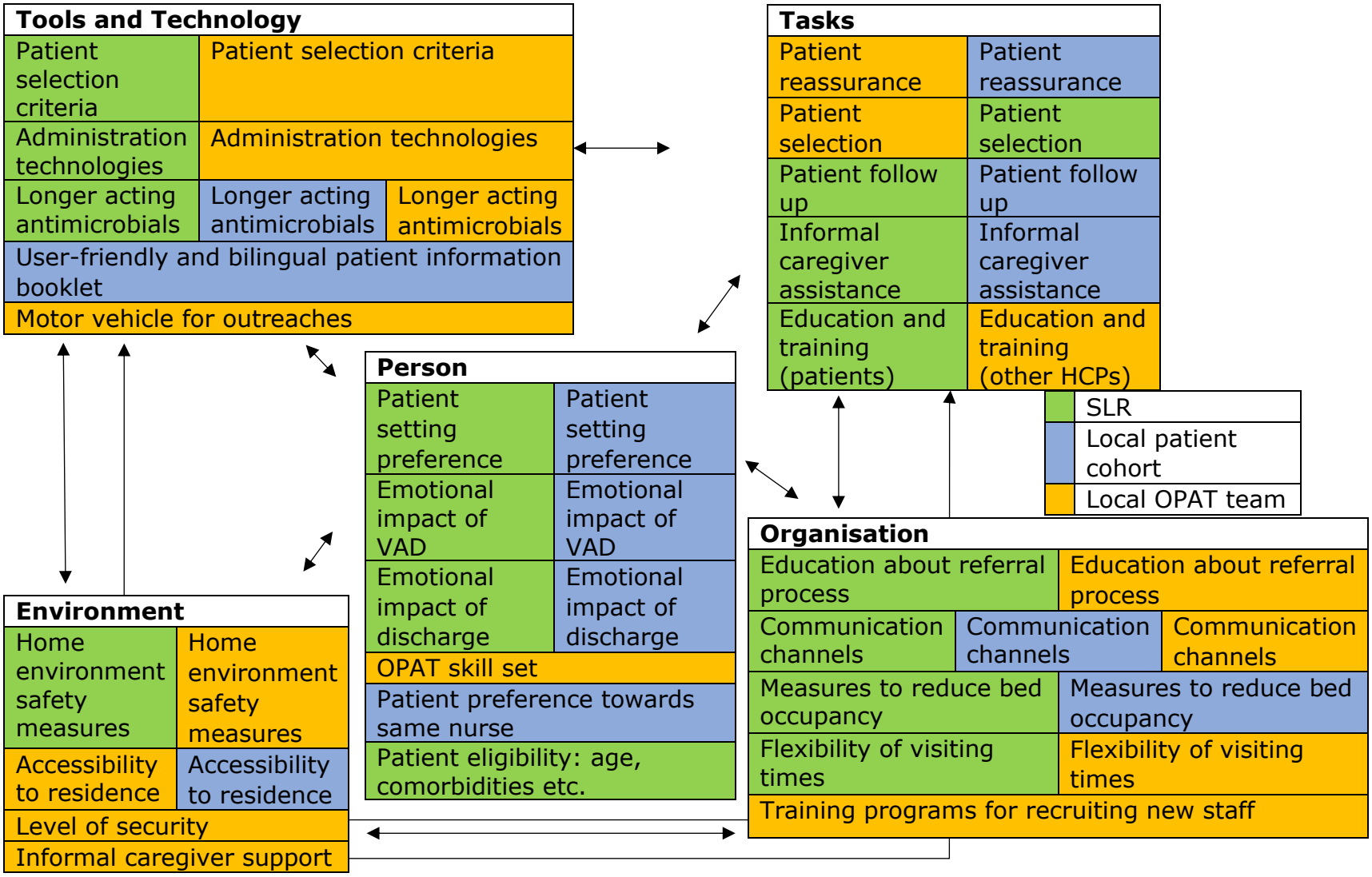


Figure 7.1 SEIPS 2.0 work system component for global (SLR) and local OPAT services

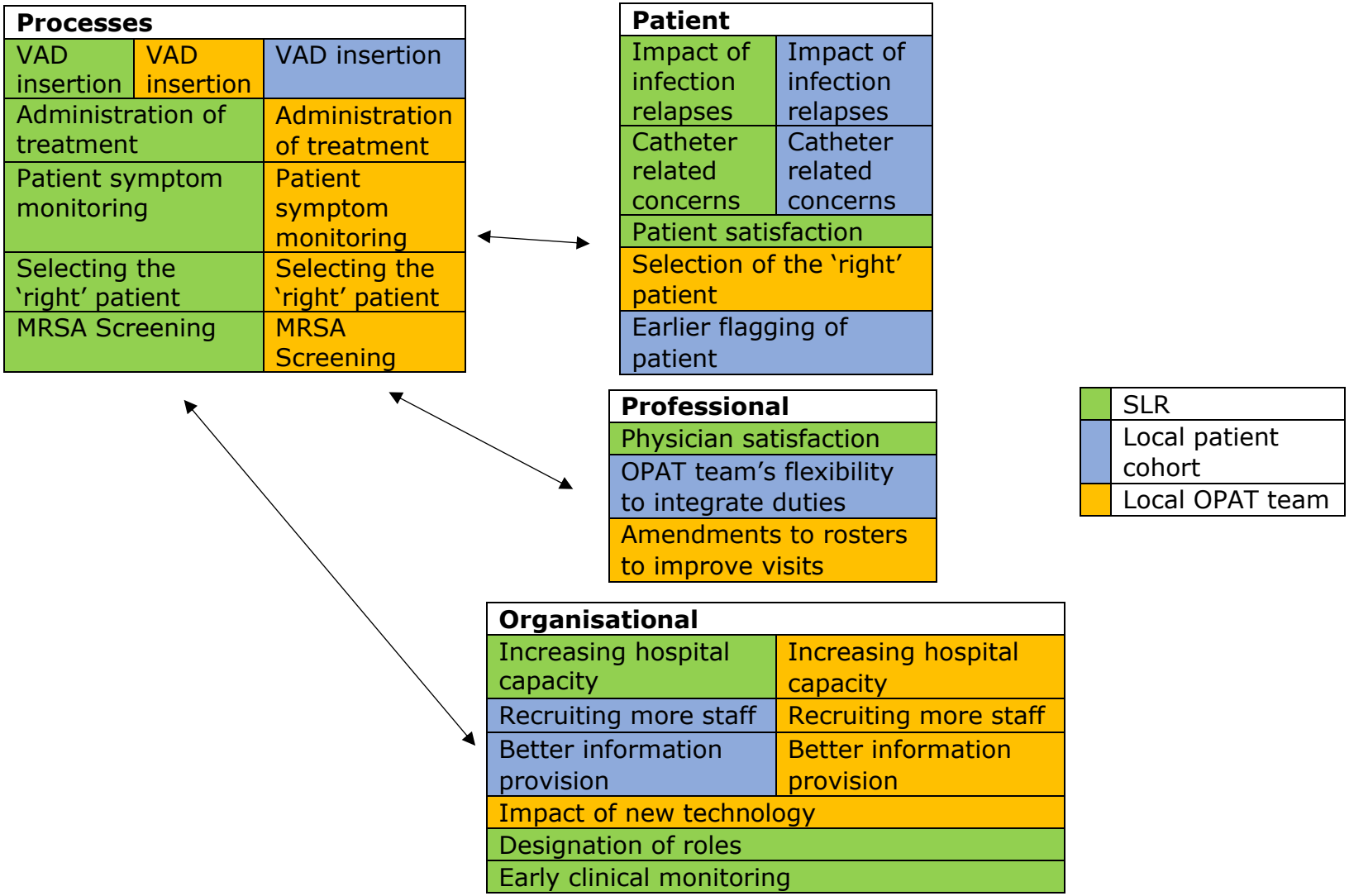


Figure 7.2 SEIPS 2.0 processes and outcomes components for global (SLR) and local OPAT service

### 7.2.1 Outcomes

#### 7.2.1.1 Patient Outcomes

The patient outcome related to early discharge due to a more structured procedure of selecting (i.e. flagging and enrolling) patients at ward level was only extracted from the local study. Despite this, there were other outcomes mutual to the review and patient cohort study namely the improved quality of life and social functioning (Bernard et al., 2001; Goodfellow et al., 2012; Berrevoets et al., 2018), and catheter and treatment adverse event related concerns (Hernandez et al., 2016; Cox et al., 2007; Keller et al., 2013; Williams et al., 2015; Duncan et al., 2013; Seaton et al., 2011). Other outcomes extracted from the review included improved patient satisfaction with respect to performing daily activities (Goodfellow et al., 2002; Twiddy et al., 2018), mental health (Perez-lopez et al., 2008) and readmission rates due to comorbidities (Perez-lopez et al., 2008; Cox et al., 20707; Seaton et al., 2011) and clinical efficacy (Al Alawi et al., 2015).

#### 7.2.1.2 Professional Outcomes

There were no common outcomes extracted from the SEIPS-based modelling. The review picked up outcomes such as physician satisfaction (Esposito et al., 2004), detection of prescribing errors (Keller et al., 2013; Seaton et al., 2011) and regular follow up measures and notifications (Keller et al., 2013). The patient cohort delved into professional outcomes related to the OPAT team's ability to liaise an unexpected admission and the administration of doses at hospital in the event of a simultaneous outpatient visit. Lastly, the OPAT team discussed security measures during late administration visits, the dedication to high quality and standardised care and modification of rosters to cater for more complex antimicrobial regimens.

#### 7.2.1.3 Organisational Outcomes

The need to address the hospital's capacity by offering the service was identified in both the review and discussed during the focus group. Common organisational outcomes were only picked up from the local setting namely the impact of recruiting more staff and better information provision across the hospital. The patients also discussed the impact of new admission of visiting times and the lack of efficient hospital transport systems to ensure their presence at home. The OPAT team referred to the service's maximal capacity, timely MRSA screen bookings and the impact of new technologies e.g. elastomeric pump on the OPAT team. The extraction from the review was more fruitful possibly owing to the numerous organisations that were covered in this phase of the study. Outcomes such as increased hospital capacity, cost cutting through enrolments on the service, early clinical monitoring, reduced transmission of nosocomial infections and designation of roles especially within the OPAT team.

### 7.2.2 Processes

Considering the in-depth number of processes extracted from the review, all the processes extracted from the local study were identified in the review including the insertion and removal of the VAD, the provision of education by the OPAT team, the administration of antimicrobials, the monitoring of patient symptoms and MRSA screening.

### 7.2.3 The work system

#### 7.2.3.1 Person Factors

Despite the local patient cohort differed from the patient samples described in the systematic review, there were some person factors pertinent to both patients groups following SEIPS-based modelling. These included patient's willingness to be offered the service, patient's improved morale in view of their discharge and

the emotional impact of having an indwelling device. There were other person factors which were similar in nature but differed in context. For example, the provision of information in the systematic review influenced the patient's willingness to enrol in the service whilst in this study, such information clarified a potential role for the informal caregiver and provided the patient with the necessary reassurance. Person factors which differed between the two sources included mention of the required patient characteristics e.g. comorbidities, age etc. (systematic review) and the patients' level of literacy and preference towards a punctual visit conducted by the same nurse (questionnaire feedback).

With respect to the group of healthcare professionals entrusted with the provision of the service, SEIPS-based modelling of the systematic review and focus group data highlighted the importance of being knowledgeable and experienced when rendering the service. The local team went on to emphasise the importance of being sufficiently trained and experienced to (i) refer the patient to the team e.g. referring care team (ii) manage the patient's clinical status when at home e.g. GP.

#### 7.2.3.2 Task Factors

The structure of the local OPAT service was modelled and revised to reflect international guidelines (Chapman, 2012; Tice et al., 2004; Norris et al., 2018; Chapman et al., 2019). Therefore it is not surprising that there was a high degree of overlap between the task factors extracted from the systematic literature review and the qualitative data generated in this study. Task factors included the need for appropriate patient selection, regular patient follow-up and monitoring, presence of informal care giver support, the need for patient reassurance and education/training. Since the systematic review covered all models of OPAT care, reference to patient selection criteria with respect to the self-administration model (currently not available locally) was made (Htin et al., 2013; Perez-lopez et al., 2008). In this study, the local team associated the need for appropriate patient selection with the requirement of standardising the referral process. Common task factors attributable to informal caregivers included understanding information imparted prior to discharge (Berrevoets et al., 2018) and domestic assistance (Twiddy et al., 2018; Keller et al., 2019a). Patient reassurance in the systematic

review was reflected in the provision of instructions to execute in case of an adverse event (Al Ansari et al., 2013) whilst in the local study, both patients and the OPAT team focused specifically on patient concerns regarding the VAD. With respect to training and education, setting abroad which offered the self-administration model focused on administration and sterility techniques (Htin et al., 2013; Cox et al., 2007; Twiddy et al., 2018) whilst the local service providers focused on the need to train new OPAT staff recruits and to train referring care teams about standardised handover procedures.

#### 7.2.3.3 Tools and technology Factors

There was some overlap in the tools and technology factors extracted from the systematic literature review and the local scenario. Common factors included (i) the introduction/utilisation of improved administration devices (Barr et al., 2012; Williams et al., 2015; Gardiol et al., 2016; Miron-Rubio et al., 2016) (ii) the availability of a spectrum of antimicrobials to treat more conditions (Barr et al., 2012), consider new routes (Al Alawi et al., 2015) and reduce dosing frequency (Miron-rubio et al., 2016) and (iii) the availability of standard patient selection criteria (Al Alawi et al., 2015). Factors such as the introduction of a user friendly information booklet in Maltese and the setup of an OPAT team helpline were extracted from the local study.

#### 7.2.3.4 Organisational Factors

Despite variances in organisations rendering OPAT services internationally, factors such as (i) implementing communication channels (Lane et al., 2014; Berrevoets et al., 2018), (ii) educating referring care teams (Hitchcock et al., 2009), (iii) increasing the number of enrolments resonated with the local scenario. In the review, the scope of education campaigns for referring care teams was to address erroneous enrolment refusals. On the other hand, in the local context, the aim was to address incorrect referral procedures to avoid unwanted repercussions such as MRSA nasal carriage, hastened discharges etc. Moreover, the review recognised

that increasing enrolments would decrease hospital bed occupancy. The ramifications of this in terms of the local setting were discussed including avoiding patient relocations due to inadequate bed management and the need for more staff recruitment for OPAT tasks. The review generated a greater number of organisational factors including provision of formal guidelines, utilisation of electronic databases, introduction of a reporting system, provision of supportive medical services and the designation of the roles and responsibilities of the OPAT director and infectious disease physician.

#### 7.2.3.5 Environmental Factors

Similar to the explanation provided for the organisational factors, the environmental factors extracted varied according to the setting of the study evaluated in the systematic review. One factor which was picked up during the review and focus group session was the level of safety (Twiddy et al., 2018) and cleanliness of the home environment (Keller et al., 2019a). Despite these similarities, there were a multitude of factors extracted from the review including geographical distribution of patients (Lane et al., 2014), transmission of infection within the hospital environment (Twiddy et al., 2018) and versatility of the facilities to cater for more than one OPAT model (Barr et al., 2012; Esposito et al., 2004). The local OPAT team looked at other environmental factors namely the influence of the patient's comorbidities in their home setting, level of home security and facilities for informal caregiver support.

## 7.3 Implications of this work

Through data triangulation, facilitators and barriers influencing local performance and wellbeing were identified from the results generated from the case study methodology and SEIPS-based modelling. These results can be used as recommendations to instruct service redesign through iterative adaptive processes.

By using narrative synthesis and SEIPS-based modelling of the systematic review as a baseline, it was possible to determine aspects of the service which were at par in terms of quality with respect to international OPAT services. When the local quality lacked in comparison, it was possible to identify working solutions which might resolve shortcomings encountered by the local providers. For example, the implication of introducing new administration technologies (such as elastomeric pumps)(Norris et al., 2018) on: (i) the patients' morale (Gardiol et al., 2016), (ii) the ability to introduce more antimicrobial agents (Miron-rubio et al., 2016), (iii) the introduction of the self-administration model of care (Gardiol et al., 2016) and (iv) the ability to treat new conditions (Barr et al., 2012) when the current service only makes use of gravity drop set.

The inverse scenario also held true, when the methods employed in this research unveiled more data with respect to patient experiences grounded in the local service provision which were overlooked by international services (from the systematic review) but where still generalisable to a larger audience. For example, the local patient cohort suggested solutions to address the current patient referral to the service including (i) earlier flagging (ii) clearer handover information from the referring care team to the OPAT team and (iii) better organisational marketing and awareness strategies to promote the service. These strategies would in turn influence the timing of referrals, the length of hospital stays, the transmission of nosocomial infections, patients morale, awareness of the service and patient hospital relocations. The local OPAT team considered the use of (i) training programs for potential referring care teams and (ii) emphasising the selection of the correct patient as strategies to address current erroneous referrals. The research niche related to patient referrals is scarcely covered in OPAT research mainly due to differences prevalent to service structures and level of proactivity in terms of patient enrolment (Chapman et al., 2019). Despite this, the local result shed light on the struggles faced by the local service providers and the solutions suggested by the end users.

## 7.4 Recommendations to redesign the current local service

Collecting data by way of the SEIPS model ensured a dynamic and comprehensive snapshot of the local OPAT service. As expected with any service evaluation, barriers impeding the smooth delivery of the service were identified as the target of recommendations to system redesign. This adaptation was deemed crucial not only to improve outcomes (as per the SEIPS model flow) but to ensure the 'best' quality of the service prior to the planned expansion envisaged by the team (Chapter 6). The recommendations required to redesign the service are described in depth in section 7.2. However, the following subsections offer the most pertinent recommendations derived from this research methodology and results:

### 7.4.1 Inclusion of tools developed in this research

First and foremost, the prospective observational cohort study conducted in this study made a case for the need to integrate a repository into the local service's current informatics. Within the remit of this research, the repository enabled a cohesive standalone source of data for auditing and benchmarking exercises over the three year period. This tool would prove useful to the OPAT team during virtual ward round sessions and during outpatient appointments conducted by OPAT doctors. Moreover, it should be stored on an online platform and accessibility should be extended to all members of the OPAT team who are in a position to relay information from the referring care team as well as amongst themselves. Such a system is already incorporated in certain foreign settings and is the foundation for compiling data for OPAT research- indicating that the local service is yet to gain from such an initiative.

In addition, the local OPAT service could stand to gain from two other tools designed and validated in this study namely the patient satisfaction questionnaire (Chapter 5) and the focus group guide (Chapter 6). As described in preceding chapters, the experiences of end-users cannot be stressed enough as appropriated depicted in the SEIPS model framework. Integration and routine use of these tools in OPAT practices can ensure that system redesign strategies continuously reflect the shortcomings experienced by end users at that point in time. For example, the importance of gauging the impact of the COVID-19 virus threat on OPAT related tasks.

### 7.4.2 Education and training initiatives

Considering the stark difference in knowledge, expertise and training between the OPAT team and other stakeholders to include referring care teams, patients, informal caregivers, ward staff, new recruits etc. the need for education and training programs cannot be emphasised enough. Such initiatives need to be tailored to the target population. In view of the OPAT model studied in this research, little involvement is required from patients and informal caregivers from a technical point of view. Despite this, education strategies should gravitate towards a better understanding of the service structure and the impact of this method of care on their daily lives in the form of user-friendly audio-visual tools and better verbal communication at ward level.

Although the team's practices were commended by the patient cohort, the former felt that this quality could only be maintained if new recruits were offered a standardised training programme thus ensuring a homogenous workforce. This was further reiterated seeing as applicants often differed in skillsets and previous experience. One of the most important skills the team felt was necessary to impart was the ability to select the 'right' patient for the service. This mandatory skill was befitting both to the referring care team as well as the new recruits to ensure a smooth running of the service by decreasing the probability of readmissions. As evidenced by the HTA described in Chapter six, the referral process is complex in nature involving many active actors at different stages of the patient's journey with most of the tasks falling under the responsibility of the OPAT team. Regardless, the referring care team are responsible for the initial task of confirming the patient's suitability for the service which is then further confirmed by the other professionals of the OPAT team (i.e. medical, nursing and pharmaceutical). Placing the referring care team at the forefront of the service thus infers that they must be equipped with the appropriate skills and knowledge. This can be achieved through targeted training program agendas which impart skills related to the patient selection criteria, OPAT service information resources, OPAT service workflow and HTA for the referral process.

### 7.4.3 Introduction of new resources

In view of the heterogenous cohort of patients treated over the three year period, it was expected that the resources available would not be adequate for every OPAT episodes. This could be addressed by procuring new treatment agents and equipment (e.g. longer acting antimicrobials, administration devices etc.), more user-friendly information aids; renting another motor vehicle and increasing human resources to address the limitations of the current outreaches.

## 7.5 Future research

As described in Chapter two, Human Factor projects are underpinned by both a pragmatic philosophy and methodology. Considering the 'case' under study was the local OPAT service, a real world research approach was taken to understand the components of this system to inform overall practice, performance and wellbeing. While conducting this case study research, potential research projects worth pursuing were identified. These are described below.

1. The application of the SEIPS model to other outpatient services rendered by the institution which are identified as lacking in quality and endangering patient safety. Initially, the amenability of this model needs to be verified prior to using this Human Factors systems approach to inform system redesign based on the discovered facilitators and barriers.

2. The application of the SEIPS 3.0 model (described by Carayon et al., 2020) to prospective patients enrolled on the service. The idea of emphasising the importance of the patient's journey in the SEIPS 3.0 model resonated in this study when concepts including 'system of systems' and nested systems (described in chapter 1) were deemed applicable to this niche of healthcare.

3. An explanatory sequential mixed methods case study approach can be employed to study those patients' whose OPAT episode resulted in a readmission. Using a prospective cohort method, details of their readmission including rationale for readmission, duration of OPAT episode etc. and eventual outcome (i.e. reinstated on the service, discharged on oral treatment, discharged without treatment and

retained as an inpatient) can be compiled and audited. A phenomenological study using interviews with the patients can provide further insight about their experience thus shedding light on the 'failure' of the OPAT service.

4. A cost-effectiveness pharmacoeconomic study can be carried out by comparing the cost to run the OPAT service as opposed to the cost to deliver IPAT. Such a study would require a more robust financial analysis of the current healthcare fees to determine the cost of the latter. Despite this, the novel activity-based costing proforma designed in this study can be used to generate the cost of OPAT. The cost to run the service will vary only if different durations are allocated to OPAT duties and if there are variances in the OPAT team composition in terms of salary scales which would in turn affect the average annual salary for that profession.

5. A ethnographic study can be performed with the patients and the informal caregivers who are receiving the home visiting nurse OPAT model since the cross-sectional questionnaire utilised in this study did not give the opportunity to probe the patients further. Possibly, using an interview as the data collection tool, more data can be extracted regarding the patients' experiences. Moreover, a maximum variation sampling strategy would be most apt in this scenario to make sure various age groups, presenting infections and OPAT episode durations are reflected in their accounts. Such a strategy should reattempt to study patients over the age of eighty years of age, as they might respond better to an interview as opposed to a questionnaire.

6. Fieldwork through direct observation of the referral process at ward level can mitigate limitations encountered in this study whereby the task analysis was based on 'work-as-reported' and institutional SOPs and not 'work-as-done'.

7. Direct observation fieldwork at the patient's residence to include audio and visual recording with the aim of developing education tools in the form of bed guides and informational videos targeting (i) referring care teams to be better informed about the 'clinical' practice occurring at this extra-institutional location and (ii) patients to address feelings of concern and anxiety identified in this study when initially educated about the service.

## 7.6 Conclusion

The application of knowledge and tools pertinent to Human Factors to instruct system redesign has already been established in the literature (Xie and Carayon, 2015) and is further reiterated in this service evaluation study. By using the local OPAT service as the setting for this case study research, important contributions to the local OPAT service could be made through recommendations informing current practice.

Despite the implications of this work to the Maltese service, the fact that the study reflects the entire OPAT patient and professional population, suggests that these findings are generalisable and transferrable to OPAT system redesign initiatives launched in other countries.

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# Appendices

**Appendix 2.1 Robert Gordon University Ethical Approval**

**SCHOOL OF PHARMACY & LIFE SCIENCES** Robert Gordon University

Sir Ian Wood Building Garthdee Road Aberdeen

AB10 7GJ United Kingdom

Tel: 01224 262500/2800 www.rgu.ac.uk

Ref: S137

Dear Helen

Re.: The Application of a Human Factors Approach to the Evaluation of a Novel Outpatient Parenteral Antimicrobial Therapy Service

The School Research Ethics Committee has assessed your application and the overall decision is that there are no ethical issues with your project. However, they have provided some comments that you may find useful going forward.

I can now confirm that you are able to proceed with your research and any further ethics applications.

Should there be any amendments to this project during the research we would advise you to consult with the convener of the ethics committee as to whether a further ethical review would be required.

Please use the reference number above in any future correspondence.

We wish you success with your project.

Regards

Dr Colin Thompson

Convener of the School Ethics Review Panel

**Appendix 2.2 FREC/UREC Approval**

L-UNIVERSITÀ TA' MALTA

Msida – Malta
Skola Medika
Sptar Mater Dei

UNIVERSITY OF MALTA

Msida – Malta
Medical School
Mater Dei Hospital

Ref No: **FRECMDS_1819_004**

Wednesday 27th February 2019

Ms Sara Jo Bugeja,
3, Bagend,
Triq Surmast Francis Falzon,
Zurrieq.

Dear Ms Sara Jo Bugeja,

Please refer to your application submitted to the Research Ethics Committee in connection with your research entitled:

**The Application of a Human Factors Approach to the Evaluation of a Novel Outpatient Parenteral Antimicrobial Therapy Service**

The Faculty Research Ethics Committee granted ethical approval for the above mentioned protocol.

Yours sincerely,

Professor Pierre Mallia
Chairman
Research Ethics Committee

**Appendix 3.1: Systematic Literature Review Protocol in Prospero®**

**PROSPERO International prospective register of systematic reviews**

NHS National Institute for Health Research

Human factors approaches to evaluating outpatient parenteral antimicrobial therapy services: a systematic review protocol

*Sara Jo Bugeja, Helen Vosper, Derek Stewart, Alison Strath*

Citation

Sara Jo Bugeja, Helen Vosper, Derek Stewart, Alison Strath. Human factors approaches to evaluating outpatient parenteral antimicrobial therapy services: a systematic review protocol. PROSPERO 2017 CRD42017071901 Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017071901

Review question

1. What human factors, in terms of the Systems Engineering Initiative for Patient Safety (SEIPS) framework, have been reported in service development, implementation and evaluation?

2. What human factors related enablers and barriers have been reported in service development, implementation and evaluation?

3. What are the outcomes of (Outpatient Parenteral Antibiotic Therapy) OPAT service development, implementation and evaluation?

4. What is the methodological quality of the literature retrieved in terms of OPAT and human factors?

Searches

The search strategy aims to find published studies. A three-step search strategy will be utilized in this review as follows:

(1) An initial scoping search of MEDLINE and CINAHL will be undertaken, using search terms of [("outpatient parenteral antimicrobial therapy" OR "outpatient parenteral antibiotic therapy" OR "OPAT") AND ("human factor" OR "ergonomic" OR "adaptation"].

(2) Using the keywords and main title and abstract words/phrases identified, searches of all databases will be undertaken.

(3) The search string will be applied with results and exceptions recorded. The reference lists of all identified papers will be reviewed for additional studies. Studies will be identified from the following bibliographic databases: MEDLINE, Embase, Cumulative Index to Nursing and Allied Health Literature (CINAHL), International Pharmaceutical Abstracts (IPA) and PsychoInfo.

## Types of study to be included

All study designs being quantitative (e.g. RCT, observational etc.), qualitative (e.g. narrative, phenomenology etc.) or mixed methods in nature will be used. Moreover, primary research studies, systematic reviews and meta-analysis will be included. No studies will be omitted due study design. Only peer reviewed papers will be included; abstracts, letters and grey literature will be excluded.

## Condition or domain being studied

Malta's commitment towards the enhancement of national healthcare has been evidenced by various publications issued by the department of health. These publications have tackled the importance of patient centred care through the Patient Charter (November 2016), health systems through the national health strategy to last until 2020 (June 2014) and patient safety in the Health Act (2013).

With patient safety on the political agenda, investments both educational and financial have started to shape the local healthcare setting as recommended by international organizations such as the World Health organization (WHO). In fact, one of the topics of the WHO guideline on patient safety focuses human factors engineering (HFE). The WHO has identified patient safety factors which are mainly related to human factors engineering such as resilience, system failures etc (WHO, 2004).

Human factors is defined by the International ergonomics association as "the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance. The physical, cognitive and organizational factors which compose a health care system can be modelled through human factors to support needs and limitations of the people involved (Carayon 2010).

One must appreciate that health care systems are dynamic and hence the necessity to map the processes involved is crucial to pick up patient safety issues in human system interfaces (Gilchrist 2008). The Systems Engineering Initiative for Patient Safety (SEIPS) model is an approach proposed for enhancing patient safety within healthcare settings. Finding its roots in the Donabedian model (structures, processes and outcomes) and the work system model (person(s), organisations, internal environment, tasks, tools and technology) of Carayon and Smith, there is an emerging evidence base to support the SEIPS model when considering redesign and evaluation of healthcare developments.

In 2015, Xie and Carayon published a systematic review of how human factors and ergonomics (HFE) applied to redesign of healthcare work systems and processes could improve quality and safety. Twenty-three studies from 12 projects were included addressing different physical, cognitive and organisational HFE issues in a variety of healthcare systems and care settings. Positive outcomes resulted when healthcare systems underwent change through the application of human factor tools, knowledge or the involvement of human factors professionals. Outcomes included the positive impact on the care processes (e.g. reduction in task completion and error rates), patient outcomes (e.g. in hospital mortality and complication rates) and outcomes (e.g. improved level of satisfaction and safety awareness). In concluding that evidence exists for the effectiveness of HFE-based healthcare system redesign in improving process and outcome measures of quality and safety of care, they highlighted the need for further research.

The systematic review to be undertaken as part of this doctoral research is within the field of outpatient parenteral antimicrobial therapy (OPAT). OPAT is defined as "the provision of parenteral antimicrobial therapy in at least two doses on different days without intervening hospitalization" (Tice 2004). The key elements required for any OPAT program include a health care team, communication channels, guidelines for patient follow ups, written policies and procedures as well as monitoring of outcomes (Tice, 2004). Ever since its introduction in the early 1970s, the provision of OPAT has been redesigned in terms of its analysis, design, implementation and evaluation.

The OPAT service is governed by a complex system which generally involves: identifying the patient; verifying the eligibility criteria; and proceeding to a delivery models which could comprise physicians' offices, hospital clinics, specialized infusion centres, and self-administration in patients' homes (Paladino and Esposito, 2010). The various elements of the OPAT work system (the tools, organisation, tasks, environment and people) have undergone revisions since first introduced. There is now greater emphasis on self-administration at home, empowering patients to maintain their daily activities and reducing exposure to nosocomial infections. Such revisions have resulted in a positive impact on institutions through increased inpatient capacity and reduced financial burdens and even more so on patients as evidenced by their level of satisfaction and improved quality of life (Chapman 2012; Davis 2016)

Whilst acknowledging these developments in OPAT, there is evidence that there remain drawbacks in terms of clinical complications which may result in admission to hospital with potential consequences of withdrawing OPAT. (Allison 2014; Williams 2015; Yan 2016). Despite efforts to reduce early termination from the OPAT service through detailed patient eligibility criteria, limitations are still reported in the literature. In light of unnecessary treatment durations, antibiotic reactions and/or vascular complications, undesired hospital readmissions will have to be scheduled (Tice 2000; Muldoon 2013).

A commentary by Keller in 2016 reported the application of the human factors approach within the OPAT field postulated potential benefits by relating OPAT to other complex domestic health scenarios such as enteral tube feedings, dialysis and home ventilators (Keller 2016). A comprehensive literature search has identified that to date, no systematic review relating to a human factors approach and OPAT has been published.

### Participants/population

This systematic review will consider papers which include any stakeholders (e.g. patients, policy makers, nurses, pharmacists, infectious diseases physicians etc.) researched as part of adult OPAT service development, implementation and evaluation.

### Intervention(s), exposure(s)

This systematic review will consider papers which research adult OPAT service development, implementation and evaluation.

### Comparator(s)/control

It is unlikely that the papers included in this review will include any comparators. Where comparators are included, these are likely to be reread to before and after studies and controlled studies.

Context

Main outcome(s)

This systematic review will consider papers which include studies which have researched outcomes measures relating to human factors aspects of service development, implementation and evaluation to include the number of patients enrolled, adverse reactions, readmissions, treatment success amongst others.

Additional outcome(s) None.

Data extraction (selection and coding)

All studies identified during the database search will be assessed for relevance to the review based on information via the title, abstract and description by two independent reviewers. A third reviewer will be consulted if consensus cannot be reached. The full article will be retrieved for all those that appear to meet the inclusion criteria. A search of Google Scholar will be undertaken to further ensure that all relevant studies have been identified.

Quantitative and qualitative data will be extracted independently by two reviewers from papers included in the review using a standardised data extraction tool, with specific focus on human factors.

Risk of bias (quality) assessment

All studies will be assessed for methodological quality by two independent reviewers. A third reviewer will be consulted if consensus cannot be reached. Standardised critical appraisal instruments will be used, selected appropriate to study design (e.g. Critical Appraisal Skills Programme tools). Generic tools will also be considered, including that described by Young and Solomon (2009) as can be seen below:

How to critically appraise an article [Adapted from Young and Solomon 2009] 1 Is the study question relevant?

2 Does the study add anything new?

3 What type of research question is being asked?

4 Was the study design appropriate for the research question?

5 Did the study methods address the most important potential source of bias? 6 Was the study performed according to the original protocol?

7 Does the study test a stated hypothesis?

8 Were the statistical analyses performed correctly? 9 Do the data justify the conclusions?

10 Are there any conflicts of interest?

## Strategy for data synthesis

All results will be subject to double data entry for verification and validation. It is considered that pooling of data derived from quantitative studies is likely to be inappropriate due to an observational study design; hence the findings will be presented in narrative form.

Qualitative research findings will, where possible be pooled. This will involve the aggregation or synthesis of findings to generate a set of statements that represent that aggregation, through assembling the findings (Level 1 findings) rated according to their quality, and categorising these findings on the basis of similarity in meaning (Level 2 findings). These categories are then subjected to a meta-synthesis in order to produce a single comprehensive set of findings (Level 3 findings) that can be used as a basis for evidence-based practice. Where textual pooling is not possible, the findings will be presented in narrative form. Tests will be presented as aforementioned.

## Analysis of subgroups or subsets None planned.

## Contact details for further information Sara Jo Bugeja

s.bugeja@rgu.ac.uk

## Organisational affiliation of the review Robert Gordon University

**PROSPERO**

**International prospective register of systematic reviews**

http://www.rgu.ac.uk/

Review team members and their organisational affiliations Mrs Sara Jo Bugeja. RGU

Dr Helen Vosper. RGU Professor Derek Stewart. RGU Professor Alison Strath. RGU

Anticipated or actual start date 01 October 2017

Anticipated completion date 01 October 2018

Funding sources/sponsors None

Conflicts of interest None known

Language English

Country Malta

Stage of review Review_Completed_not_published

Subject index terms status Subject indexing assigned by CRD

Subject index terms

Ambulatory Care; Anti-Bacterial Agents; Anti-Infective Agents; Humans; Outpatients

Date of registration in PROSPERO 17 July 2017

Date of publication of this version 22 November 2018

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

| Stage | Started | Completed |
|---|---|---|
| Preliminary searches | Yes | Yes |
| Piloting of the study selection process | Yes | Yes |
| Formal screening of search results against eligibility criteria | Yes | Yes |
| Data extraction | Yes | Yes |
| Risk of bias (quality) assessment | Yes | Yes |
| Data analysis | Yes | Yes |

17 July 2017

22 November 2018

PROSPERO

This information has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.

**Appendix 3.2: Data Extraction Template**

| | |
|---|---|
| **Publication Info** | Principal Author<br>Year<br>Publication type e.g. abstract, article, book<br>Type of study e.g. randomized control, control before and after, interrupted time series, other<br>Aim |
| **Participants** | Number of participants<br>Age<br>Disease state<br>Recruitment procedure<br>Inclusion/Exclusion criteria utilized |
| **Intervention** | Focus<br>Duration<br>Setting/Country<br>Providers of intervention e.g. nurses, doctors, pharmacists |
| **Outcomes** | Description of outcomes related to human factors |
| **Results** | Details of statistical analysis<br>Limitations<br>Specific mention of the term human factors: Yes/No<br>Human factors related to healthcare professional<br>Human factors related to patient |

**Appendix 3.3: Quality Extraction Tool**

Was there a clear statement of the aims/ objectives of the research?

Was the research design appropriate to address the aims of the research?

Was the recruitment strategy appropriately described?

Were the data collected in a way that addressed the research issues?

Were participant characteristics described in detail?

Have ethical issues been taken into consideration?

Is there a clear statement of findings?

Did the authors mention facets of the service which can be considered as HF?

Were failures of the service mentioned?

Did the authors declare that there were no conflicts of interest or bias?

**Appendix 3.4 References and sources of articles which were included in the review**

| Article | Source Database | Reference |
|---|---|---|
| | IPA | KELLER, S.C. et al., 2013. The Impact of an Infectious Diseases Transition Service on the Care of Outpatients on Parenteral Antimicrobial Therapy. *Journal of Pharmacy Technology,* 29(5), pp.205-214. |
| | Medline | HTIN, A.K. et al., 2013. Outpatient parenteral antimicrobial therapy is safe and effective for the treatment of infective endocarditis: a retrospective cohort study. *Internal Medicine Journal,* 43(6), pp.700-5. |
| | Medline | PEREZ-LOPEZ, J. et al., 2008. Safety and efficacy of home intravenous antimicrobial infusion therapy in older patients: a comparative study with younger patients, 62(8), pp. 1188-92. |
| | Medline | SULEYMAN, G. et al., 2017. Safety and efficacy of outpatient parenteral antibiotic therapy in an academic infectious disease clinic. Journal of Clinical Pharmacy and Therapeutics, 42(1), pp. 39-43. |
| | Medline | AL ALAWI, S. et al., 2015. Outpatient parenteral antimicrobial therapy with ceftriaxone for acute tonsillopharyngitis: efficacy, patient satisfaction, cost effectiveness, and safety. *Infection and Drug Resistance,*8, pp. 279-285. |
| | Medline | HERNANDEZ, W. et al., 2016. Oral Parenteral Antimicrobial Therapy Administration in a Homeless Population. *Journal of Infusion Nursing,* 39(2), pp. 81-5 |
| | Medline | LANE, M.A. et al., 2014. Outpatient parenteral antimicrobial therapy practices among adult infectious disease physicians. *Infection Control and Hospital Epidemiology,* 35(7):839-44 |
| | Medline | MIRÓN-RUBIO, M. et al., 2016. Intravenous antimicrobial therapy in the hospital-at-home setting: data from the Spanish Outpatient Parenteral Antimicrobial Therapy Registry. *Future Microbiology*, 11(3), pp. 375-90 |
| | Medline | MULDOON, E.G., et al., 2015. A national survey of infectious disease practitioners on their use of outpatient parenteral antimicrobial therapy (OPAT). *Infectious diseases (London, England)*, 47(1), pp.39-45. |

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| | Medline | WILLIAMS, D.N. et al., 2015. The history and evolution of outpatient parenteral antibiotic therapy (OPAT). *International Journal of Antimicrobial Agents*, 46(3), pp. 307-12. |
| | Medline | TWIDDY, M., et al., 2018. A qualitative study of patients' feedback about Outpatient Parenteral Antimicrobial Therapy (OPAT) services in Northern England: implications for service improvement. BMJ open, 8(1), p.e019099. |
| | Medline | KELLER, S.C. et al., 2019. It's Complicated: Patient and Informal Caregiver Performance of Outpatient Parenteral Antimicrobial Therapy-Related Tasks. *American Journal of Medical Quality*, p.1062860619853345. |
| | Medline | DUROJAIYE, O.C. et al., 2018. Clinical efficacy, cost analysis and patient acceptability of outpatient parenteral antibiotic therapy (OPAT): a decade of Sheffield (UK) OPAT service. *International journal of antimicrobial agents,* 51(1), pp.26-32. |
| | Medline | KELLER, S.C. et al., 2019. Hazards from physical attributes of the home environment among patients on outpatient parenteral antimicrobial therapy. American journal of infection control, 47(4), pp.425-430. |
| | Medline | GARDIOL, C. et al., 2016. Setting up an outpatient parenteral antimicrobial therapy (OPAT) unit in Switzerland: review of the first 18 months of activity. European Journal of Clinical Microbiology & Infectious Diseases, 35(5), pp.839-845. |
| | Medline | BERREVOETS, M.A. et al., 2018. Quality of outpatient parenteral antimicrobial therapy (OPAT) care from the patient's perspective: a qualitative study. BMJ open, 8(11), p.e024564. |
| | CINAHL | COX, A.M. et al., 2007. Home intravenous antimicrobial infusion therapy: a viable option in older adults. *Journal of American Geriatrics Society*, 55(5), pp. 645-50. |
| | Other Sources | BERNARD, L. et al., 2001. Outpatient parenteral antimicrobial therapy (OPAT) for the treatment of osteomyelitis: evaluation of efficacy, tolerance and cost. *Journal of Clinical Pharmacy and Therapeutics*, 26(6), pp. 445-51. |
| | Other Sources | BARR, D.A., SEMPLE,L. and SEATON, R.A., 2012. Outpatient parenteral antimicrobial therapy (OPAT) in a teaching hospital-based practice: a retrospective cohort |

| | | |
|---|---|---|
| | | study describing experience and evolution over 10 years. *International Journal of Antimicrobial Agents*, 39(5), pp. 407-13. |
| | Other Sources | GOODFELLOW, A.F. et al., 2002. Quality-of-life assessment in an outpatient parenteral antibiotic program. *Annals of Pharmacotherapy*, 36(12), pp. 1851-5. |
| | Other Sources | DUNCAN, C.J., et al., 2013. Risk factors for failure of outpatient parenteral antibiotic therapy (OPAT) in infective endocarditis. *Journal of Antimicrobial Chemotherapy*, 68(7), pp. 1650-4. |
| | Other Sources | ESPOSITO, S. et al., 2004. Outpatient parenteral antibiotic therapy (OPAT) in different countries: a comparison. *International Journal of Antimicrobial Agents*, 24(5), pp. 473-8. |
| | Other Sources | GILCHRIST, M., FRANKLIN, B.D. and PATEL, J.P., 2008. An outpatient parenteral antibiotic therapy (OPAT) map to identify risks associated with an OPAT service. *Journal of Antimicrobial Chemotherapy*, 62(1), pp.177-83. |
| | Other Sources | HALILOVIC, J., CHRISTENSEN, C.L. and NGUYEN, H.H., 2014. Managing an outpatient parenteral antibiotic therapy team: challenges and solutions. *Therapeutics and Clinical Risk Management*, 18;10, pp. 459-65. |
| | Other Sources | SEATON, R.A. et al., 2011. Factors associated with outcome and duration of therapy in outpatient parenteral antibiotic therapy (OPAT) patients with skin and soft-tissue infections. *International Journal of Antimicrobial Agents*, 38(3), pp. 243-8. |
| | Other Sources | HITCHCOCK, J. et al., 2009. Establishment of an outpatient and home parenteral antimicrobial therapy service at a London teaching hospital: a case series. *Journal of Antimicrobial Chemotherapy*, 64(3), pp. 630-4. |
| | Other Sources | AL ANSARI, A. et al., 2013. Outpatient parenteral antimicrobial therapy (OPAT) in the kingdom of Bahrain: efficacy, patient satisfaction and cost effectiveness. *The Open Infectious Diseases Journal*, 7, pp. 90-95. |

**Appendix 3.5 References and sources of the excluded studies with reasons for exclusion**

Medline [71]

| | | |
|---|---|---|
| | VAZIRIAN, M. et al., 2018. Outcomes of outpatient parenteral antimicrobial therapy in patients with injection drug use. Psychosomatics, 59(5), pp.490-495. | Specific to injection drug use patients |
| | RAE, N., KENNY, C. and MULDOON, E.G., 2019. Can intravenous antifungal therapy be safely used in the outpatient parenteral antimicrobial therapy (OPAT) setting?. Mycoses, 62(3), pp.196-203. | Specific to antifungals |
| | MORGAN, S.A., 2019. The Infusion Nurse's Role in Antibiotic Stewardship. Journal of Infusion Nursing, 42(2), pp.75-80. | Restricted to the nurse's role in a specific niche |
| | SANROMA, P. et al., 2018. Effectiveness and safety of ertapenem used in hospital-at-home units: data from Spanish Outpatient Parenteral Antimicrobial Therapy Registry. Future microbiology, 13(12), pp.1363-1373. | Specific to ertapenem |
| | OLIVER, G., 2016. Optimising patient safety when using elastomeric pumps to administer outpatient parenteral antibiotic therapy. British Journal of Nursing, 25(19), pp. S22-S27. | Elastomeric pumps specific |
| | O'CALLAGHAN, K. et al., 2019. Outcomes of patients with a history of injecting drug use and receipt of outpatient antimicrobial therapy. European Journal of Clinical Microbiology & Infectious Diseases, 38(3), pp.575-580. | Specific patient group i.e. injection drug using patients |
| | DOBSON, P.M., LOEWENTHAL, M. and HARRIS, L., 2017. Determining the risk of sepsis using nurse-compounded elastomeric pumps for continuous infusion in outpatient parenteral antibiotic therapy. Journal of Infusion Nursing, 40(5), pp.282-285. | Side effect triggered by elastomeric pumps |
| | SCHRANK, G.M. et al., 2018. A retrospective analysis of adverse events among patients receiving daptomycin versus vancomycin during outpatient parenteral antimicrobial therapy. Infection Control & Hospital Epidemiology, 39(8), pp.947-954. | Drug comparison in an OPAT setting |
| | BHAVAN, K.P., BROWN, L.S. and HALEY, R.W., 2015. Self-administered outpatient antimicrobial infusion by uninsured patients discharged from a safety-net | Specific to one OPAT model i.e. self-administration |

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| | hospital: a propensity-score-balanced retrospective cohort study. PLoS medicine, 12(12), p.e1001922. | |
| | KELLER, S.C. et al., 2016. Learning from the patient: Human factors engineering in outpatient parenteral antimicrobial therapy. American journal of infection control, 44(7), pp.758-760. | Commentary not an article |
| | REITZEL, R.A. et al., 2019. Epidemiology of Infectious and Noninfectious Catheter Complications in Patients Receiving Home Parenteral Nutrition: A Systematic Review and Meta-Analysis. Journal of Parenteral and Enteral Nutrition. | Catheter complications specific |
| | WILLIAMS, P.C.M., and BERKLEY, J.A., 2018. Guidelines for the treatment of severe acute malnutrition: a systematic review of the evidence for antimicrobial therapy. Paediatrics And International Child Health, 38 (sup1), pp. S32-S49 | Specific to a paediatric population |
| | CAMPAGNA, S. et al., 2019. A retrospective study of the safety of over 100,000 peripherally-inserted central catheters days for parenteral supportive treatments. Research in nursing & health, 42(3):198-204. | Specific to parenteral supportive treatments |
| | AKAR, A., SINGH, N. and HYUN, D.Y., 2014. Appropriateness and safety of outpatient parenteral antimicrobial therapy in children: opportunities for pediatric antimicrobial stewardship. *Clinical pediatrics*, 53(10), pp.1000-1003. | Specific to a paediatric population |
| | LAM, P.W. et al., 2018. Predictors of peripherally inserted central catheter occlusion in the outpatient parenteral antimicrobial therapy setting. *Antimicrobial agents and chemotherapy,* 62(9), pp. e00900-18. | Specific to a complication i.e. catheter occlusion |
| | TALAN, D.A. et al., 2019. Methods of conservative antibiotic treatment of acute uncomplicated appendicitis: A systematic review. *Journal of Trauma and Acute Care Surgery,* 86(4), pp.722-736. | Specific to the treatment of uncomplicated appendicitis |
| | TOWNSEND, J. et al., 2018, October. Outpatient parenteral therapy for complicated Staphylococcus aureus infections: a snapshot of processes and outcomes in the real world. In Open forum infectious diseases (Vol. 5, No. 11, p. ofy274). US: Oxford University Press. | Specific to infections caused by Staphylococcus aureus |

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| | SEATON, R.A. et al., 2013. Daptomycin for outpatient parenteral antibiotic therapy: a European registry experience. *International journal of antimicrobial agents*, 41(5), pp.468-472. | Specific to daptomycin antimicrobial courses only |
| | Keller, S.C. et al., 2017. Rates of and risk factors for adverse drug events in outpatient parenteral antimicrobial therapy. Clinical Infectious Diseases, 66(1), pp.11-19. | Article only describes one aspect of the service i.e. adverse events |
| | ENGLANDER, H. et al., 2019. Tools to support hospital-based addiction care: Core components, values, and activities of the Improving Addiction Care Team. *Journal of addiction medicine,* 13(2), pp.85-89. | Not related to the subject matter |
| | ARENSDORFF, L. et al., 2017. Adequate plasma drug concentrations suggest that amoxicillin can be administered by continuous infusion using elastomeric pumps. Journal of Antimicrobial Chemotherapy, 72(9), pp.2613-2615. | Not related to the subject matter |
| | MULDOON, E.G. et al., 2013. Are we ready for an outpatient parenteral antimicrobial therapy bundle? A critical appraisal of the evidence. *Clinical infectious diseases,* 57(3), pp.419-424. | Article is a guideline for clinical practice |
| | Keller, S.C. et al., 2018, June. Health-Related Quality of Life in Outpatient Parenteral Antimicrobial Therapy. In *Open forum infectious diseases* (Vol. 5, No. 7, p. ofy143). US: Oxford University Press. | Specific to particular scoring outcomes for the service; The article was a brief report |
| | ATTARD T.M. et al., 2019. Pediatric elective diagnostic procedure complications: A multicenter cohort analysis. *Journal of gastroenterology and hepatology,* 34(1), pp.147-153. | Specific to a paediatric cohort |
| | WONG, K.K. et al., 2015. Low incidence of Clostridium difficile infection (CDI) in patients treated with outpatient parenteral antimicrobial therapy (OPAT). *Infection control & hospital epidemiology,* 36(1), pp.110-112. | This letter to the editor is specific to an adverse event of OPAT |
| | ALLISON, G.M., WEIGEL, B. and HOLCROFT, C., 2015. Does electronic medication reconciliation at hospital discharge decrease prescription medication errors?. *International journal of health care quality assurance*, 28(6), pp. 564-573. | Not related to subject matter |

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| | LAM, P.W. et al., 2018. Impact of Defaulting to Single-Lumen Peripherally Inserted Central Catheters on Patient Outcomes: An Interrupted Time Series Study. *Clinical Infectious Diseases,* 67(6), pp.954-957. | Not related to subject matter |
| | DEAN, E. 2017. Infusion Therapy. Emergency Nurse: The Journal Of The RCN Accident And Emergency Nursing Association 24 (9), pp. 13; | Not related to subject matter |
| | NATHWANI, D., 2009. Developments in outpatient parenteral antimicrobial therapy (OPAT) for Gram-positive infections in Europe, and the potential impact of daptomycin. *Journal of antimicrobial chemotherapy,* 64(3), pp.447-453. | Specific to the implications of daptomycin |
| | CROSS, M.B., and BERGER, R., 2014. Feasibility and safety of performing outpatient unicompartmental knee arthroplasty. *International orthopaedics*, 38(2), pp. 443-447. | Not related as it is specific to unicompartmental knee arthroplasty |
| | MAXWELL, R.R. et al., 2017. Management of chemotherapy-induced febrile neutropenia in pediatric oncology patients: A North American survey of pediatric hematology/oncology and pediatric infectious disease physicians. *Pediatric blood & cancer*, 64(12), p.e26700. | Specific to paediatric cohort suffering from a common side effect i.e. febrile neutropenia |
| | ORTIZ-COVARRUBIAS, A. et al., 2016. Efficacy, safety, tolerability and population pharmacokinetics of tedizolid, a novel antibiotic, in Latino patients with acute bacterial skin and skin structure infections. *Brazilian Journal of Infectious Diseases*, 20(2), pp.184-192. | Specific to tedizolid |
| | MORAN, G.J. et al., 2014. Tedizolid for 6 days versus linezolid for 10 days for acute bacterial skin and skin-structure infections (ESTABLISH-2): a randomised, double-blind, phase 3, non-inferiority trial. *The Lancet Infectious Diseases,* 14(8), pp.696-705. | Specific to tedizolid |
| | Dean E., 2017. Infusion therapy. Nursing Management (Harrow, London, England: 1994), 23 (9), pp. 13 | Not related to the subject matter |
| | de FIJTER, C.W. et al., 2016. Intraperitoneal meropenem for polymicrobial peritoneal dialysis-related peritonitis. *Peritoneal Dialysis International,* 36(5), pp.572-573. | Specific to a condition and antimicrobial agent |
| | TEUFFEL, O. et al., 2011. Outpatient management of cancer patients with febrile neutropenia: a systematic | Specific to patient group suffering |

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| | review and meta-analysis. *Annals of oncology*, 22(11), pp.2358-2365. | from a specific side effect |
| | LO PRIORE, E. et al., 2017. The role of a surveillance programme for introducing peripherally inserted central catheters: a 2-year observational study in an academic hospital. *Swiss medical weekly*, 147(w14441), p.w14441. | Only related to vascular access device and not to the service |
| | SAWTELLE, A.L., CHAPPELL, N.P. and MILLER, C.R., 2017. Actinomyces-related tubo-ovarian abscess in a poorly controlled type II diabetic with a copper intrauterine device. *Military medicine*, 182(3-4), pp.e1874-e1876. | Specific to a condition not related to the subject matter |
| | RODRÍGUEZ-CERRILLO, M. et al., 2010. Patients with uncomplicated diverticulitis and comorbidity can be treated at home. *European journal of internal medicine,* 21(6), pp.553-554. | Not related to subject matter |
| | JOLLEY, J.A. and WING, D.A., 2010. Pyelonephritis in pregnancy. *Drugs*, 70(13), pp.1643-1655. | Not related to subject matter |
| | KELLER, S., PRONOVOST, P. and COSGROVE, S., 2015. What Medicare is missing? *Clinical Infectious Diseases*, 61(12), pp.1890-1891. | Not related to subject matter |
| | CRANENDONK, D.R. et al., 2014. Comparing short to standard duration of antibiotic therapy for patients hospitalized with cellulitis (DANCE): study protocol for a randomized controlled trial. *BMC infectious diseases*, 14(1), p.235. | Not related to subject matter |
| | TEUFFEL, O. et al., 2011. Cost-effectiveness of outpatient management for febrile neutropenia in children with cancer. *Pediatrics,* 127(2), pp. e279-e286. | Specific to a paediatric cohort suffering from a particular diagnosis |
| | FRASER, J.D. et al., 2010. A complete course of intravenous antibiotics vs a combination of intravenous and oral antibiotics for perforated appendicitis in children: a prospective, randomized trial. *Journal of pediatric surgery*, 45(6), pp.1198-1202. | Not related to subject matter |
| | Wing DA, Pyelonephritis in pregnancy: treatment options for optimal outcomes. Drugs [Drugs], Vol. 61 (14), pp. 2087-96; | Not related to subject matter |
| | GESSER, R.M., MCCARROLL, K.A. and WOODS, G.L., 2004. Evaluation of outpatient treatment with | Specific to one antimicrobial |

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| | ertapenem in a double blind controlled clinical trial of complicated skin/skin structure infections. *Journal of Infection*, 48(1), pp. 32-38. | agent i.e. ertapenem |
| | AMMANN, R.A., TISSING, W.J., and PHILLIPS, B., 2012. Rationalizing the approach to children with fever in neutropenia. *Current Opinion In Infectious Diseases,* 25 (3), pp. 258-65 | Specific to a paediatric cohort suffering from a particular diagnosis |
| | SHOJANIA, K.G. et al., 2001. Making health care safer: a critical analysis of patient safety practices. *Evid Rep Technol Assess* (Summ), 43(1), p.668. | Not related to subject matter but rather patient safety practices |
| | THIEL, J. and GAMELIN, A., 2003. Outpatient total laparoscopic hysterectomy*. The Journal of the American Association of Gynecologic Laparoscopists,* 10(4), pp.481-483. | Not related to subject matter |
| | MORGANROTH, J. et al., 2005. A randomized trial comparing the cardiac rhythm safety of moxifloxacin vs levofloxacin in elderly patients hospitalized with community-acquired pneumonia. Chest, 128(5), pp.3398-3406. | Not related to subject matter |
| | GLASSER, M.H., HEINLEIN, P.K. and HUNG, Y.Y., 2009. Office endometrial ablation with local anesthesia using the HydroThermAblator system: comparison of outcomes in patients with submucous myomas with those with normal cavities in 246 cases performed over 5½ years. *Journal of minimally invasive gynecology*, 16(6), pp. 700-707. | Not related to subject matter |
| | KLEVENS R.M., TOKARS J.I., and ANDRUS M., 2005. Electronic reporting of infections associated with hemodialysis. *Nephrology News & Issues*, 19 (7), pp. 37-8, 43 | Not related to subject matter |
| | ABBOTT, J. and GEE, L., 2003. Quality of life in children and adolescents with cystic fibrosis. *Pediatric drugs*, 5(1), pp. 41-56. | The article's cohort is based on a paediatric population and the treatment of cystic fibrosis |
| | SIEVERS, E.L. et al., 2001. Efficacy and safety of gemtuzumab ozogamicin in patients with CD33-positive acute myeloid leukemia in first relapse. *Journal of Clinical Oncology*, 19(13), pp.3244-3254. | Not related to subject matter |

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| | SOMERVILLE, K.T., 2003. Cost advantages of oral drug therapy for managing cytomegalovirus disease. *American journal of health-system pharmacy*, 60(suppl_8), pp.S9-S12. | Not related to subject matter |
| | NAUGHTON, B.J., MYLOTTE, J.M. and TAYARA, A., 2000. Outcome of nursing home-acquired pneumonia: derivation and application of a practical model to predict 30 day mortality. *Journal of the American Geriatrics Society*, 48(10), pp.1292-1299. | Not related to subject matter; discusses a prediction model of mortality for nursing home |
| | CHAPUIS, T.M. et al., 2010. Prospective monitoring of cefepime in intensive care unit adult patients. Critical Care, 14(2), p.R51. | Specific to cefepime monitoring |

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| | KELLER, S.C., et al., 2019. Hazards from physical attributes of the home environment among patients on outpatient parenteral antimicrobial therapy. American journal of infection control, 47(4), pp.425-430. | Double |
| | SULEYMAN, G. et al., 2017. Safety and efficacy of outpatient parenteral antibiotic therapy in an academic infectious disease clinic. Journal of Clinical Pharmacy and Therapeutics, 42(1), pp. 39-43. | Double |
| | KELLER, S.C. et al., 2016. Learning from the patient: Human factors engineering in outpatient parenteral antimicrobial therapy. *American journal of infection control,* 44(7), pp.758-760. | Double |
| | SCHRANK, G.M. et al., 2018. A retrospective analysis of adverse events among patients receiving daptomycin versus vancomycin during outpatient parenteral antimicrobial therapy. Infection *Control & Hospital Epidemiology,* 39(8), pp.947-954. | Double |
| | OLIVER, G., 2016. Optimising patient safety when using elastomeric pumps to administer outpatient parenteral antibiotic therapy. British *Journal of Nursing*, 25(19), pp.S22-S27. | Double |
| | Atkinson, D. et al., 2015. Providing an outpatient antimicrobial therapy service. *British Journal of Nursing*, 24(Sup19), pp.S28-S29. | Description of the service and |

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| | | not primary research |
| | CAMPAGNA, S. et al., 2019. A retrospective study of the safety of over 100,000 peripherally-inserted central catheters days for parenteral supportive treatments. *Research in nursing & health,* 42(3):198-204. | Double |
| | MORGAN, S.A., 2019. The Infusion Nurse's Role in Antibiotic Stewardship. *Journal of Infusion Nursing*, 42(2), pp.75-80. | Double |
| | EATON, E.F. et al., 2018. A 9-point risk assessment for patients who inject drugs and require intravenous antibiotics: focusing inpatient resources on patients at greatest risk of ongoing drug use. *Clinical Infectious Diseases*, 68(6), pp.1041-1043. | Not related to subject matter |
| | TALAN, D.A. et al., 2019. Methods of conservative antibiotic treatment of acute uncomplicated appendicitis: A systematic review. *Journal of Trauma and Acute Care Surgery,* 86(4), pp.722-736. | Double |
| | BHAVAN, K.P., BROWN, L.S. and HALEY, R.W., 2015. Self-administered outpatient antimicrobial infusion by uninsured patients discharged from a safety-net hospital: a propensity-score-balanced retrospective cohort study. *PLoS medicine,* 12(12), p.e1001922. | Double |
| | Case Management Monthly, 2018. Treating infections related to IV drug use without creating additional risks for patients. 15(3): 1-3. 3p | Not related to subject matter |
| | PANDYA, K.H. et al., 2017. Safety of continuous antibiotic infusions administered through an australian hospital in the home service: a pilot study. *Journal of Pharmacy Practice and Research*, 47(5), pp.333-339. | continuous antibiotic infusions through an ambulatory infusion device |
| | LANE, M.A. et al., 2014. Outpatient parenteral antimicrobial therapy practices among adult infectious disease physicians. Infection Control & Hospital Epidemiology, 35(7), pp.839-844. | Double |
| | AKAR, A., SINGH, N. and HYUN, D.Y., 2014. Appropriateness and safety of outpatient parenteral antimicrobial therapy in children: opportunities for | The article's cohort is based on a paediatric population |

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| | pediatric antimicrobial stewardship. *Clinical pediatrics*, 53(10), pp. 1000-1003. | |
| | BAKER, A. and LYDEN-RODGERS, M., 2016. IV antibiotic therapy in the community: clinically effective and cost effective. *British Journal of Nursing,* 25(Sup2), pp.S4-S8. | Specific to setting and does not address subject matter |
| | LAM, P.W. et al., 2018. Impact of Defaulting to Single-Lumen Peripherally Inserted Central Catheters on Patient Outcomes: An Interrupted Time Series Study. *Clinical Infectious Diseases*, 67(6), pp.954-957. | Double |
| | ARENSDORFF, L. et al., 2017. Adequate plasma drug concentrations suggest that amoxicillin can be administered by continuous infusion using elastomeric pumps. *Journal of Antimicrobial Chemotherapy*, 72(9), pp.2613-2615. | Double |
| | MAXWELL, R.R. et al, 2017. Management of chemotherapy-induced febrile neutropenia in pediatric oncology patients: A North American survey of pediatric hematology/oncology and pediatric infectious disease physicians. *Pediatric blood & cancer*, 64(12), p.e26700. | Double |
| | HERNANDEZ, W. et al., 2016. Oral Parenteral Antimicrobial Therapy Administration in a Homeless Population. *Journal of Infusion Nursing,* 39(2), pp. 81-5 | Double |
| | MORAN, G.J. et al., 2014. Tedizolid for 6 days versus linezolid for 10 days for acute bacterial skin and skin-structure infections (ESTABLISH-2): a randomised, double-blind, phase 3, non-inferiority trial. *The Lancet Infectious Diseases,* 14(8), pp.696-705. | Double |
| | PETTIT, R.S. et al., 2015. Population pharmacokinetics of meropenem administered as a prolonged infusion in children with cystic fibrosis. Journal of Antimicrobial Chemotherapy, 71(1), pp.189-195. | Specific to the pharmacology of meropenem |
| | SAWTELLE, A.L., CHAPPELL, N.P. and MILLER, C.R., 2017. Actinomyces-related tubo-ovarian abscess in a poorly controlled type II diabetic with a copper intrauterine device. *Military medicine,* 182(3-4), pp.e1874-e1876. | Double |
| | SHARP, R. et al., 2014. The safety and efficacy of midlines compared to peripherally inserted central catheters for adult cystic fibrosis patients: a | Specific to administration devices |

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| | retrospective, observational study. *International journal of nursing studies*, 51(5), pp.694-702. | |
| | WING, D.A., Pyelonephritis in pregnancy: treatment options for optimal outcomes. *Drugs*, 61 (14), pp. 2087-96; | Double |
| | CARDONE, K.E. et al., 2011. Pharmacokinetics and pharmacodynamics of intravenous daptomycin during continuous ambulatory peritoneal dialysis. *Clinical Journal of the American Society of Nephrology*, 6(5), pp.1081-1088. | Specific to daptomycin |
| | PRESCOTT, W.A. et al., 2011. Continuous-infusion antipseudomonal Beta-lactam therapy in patients with cystic fibrosis. Pharmacy and Therapeutics, 36(11), p.723. | Specific to a class of antimicrobial agents |
| | MORGANROTH, J. et al., 2005. A randomized trial comparing the cardiac rhythm safety of moxifloxacin vs levofloxacin in elderly patients hospitalized with community-acquired pneumonia. Chest, 128(5), pp.3398-3406. | Double |
| | SIEVERS, E.L. et al., 2001. Efficacy and safety of gemtuzumab ozogamicin in patients with CD33-positive acute myeloid leukemia in first relapse. *Journal of Clinical Oncology*, 19(13), pp.3244-3254. | Double |
| | JOLLEY, J.A. and WING, D.A., 2010. Pyelonephritis in pregnancy. *Drugs*, 70(13), pp.1643-1655. | Double |
| | ELOUBEIDI, M.A. et al., 2006. Frequency of major complications after EUS-guided FNA of solid pancreatic masses: a prospective evaluation. Gastrointestinal endoscopy, 63(4), pp.622-629. | Not related to the subject matter |
| | KLEVENS R.M., TOKARS J.I., and ANDRUS M., 2005. Electronic reporting of infections associated with hemodialysis. *Nephrology News & Issues*, 19 (7), pp. 37-8, 43 | Double |
| | NAUGHTON, B.J., MYLOTTE, J.M. and TAYARA, A., 2000. Outcome of nursing home-acquired pneumonia: derivation and application of a practical model to predict 30 day mortality. *Journal of the American Geriatrics Society,* 48(10), pp.1292-1299. | Double |
| | CRANENDONK, D.R. et al., 2014. Comparing short to standard duration of antibiotic therapy for patients hospitalized with cellulitis (DANCE): study protocol for a | Double |

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| | randomized controlled trial. *BMC infectious diseases*, 14(1), p.235. | |
| | MCKERNAN, C., 2008. Exploring the literature on delivering home IV therapy. *Nursing Times*, 104(34), pp.28-29. | Too generic |
| | BROOKS, B., and MEYERS, R., 2008. Safety and efficacy of home intravenous therapy*. Journal of the American Geriatrics Society*, 56(1), p177 | Generic topic and only mentions one model of OPAT |
| | AMMANN, R.A., TISSING W.J., PHILLIPS, B., 2012. Rationalizing the approach to children with fever in neutropenia Current Opinion In Infectious Diseases, 25 (3), pp. 258-65 | double |

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| | HTIN, A.K. et al., 2013. Outpatient parenteral antimicrobial therapy is safe and effective for the treatment of infective endocarditis: a retrospective cohort study. *Internal Medicine Journal,* 43(6), pp.700-5. | Double |
| | SULEYMAN, G. et al., 2017. Safety and efficacy of outpatient parenteral antibiotic therapy in an academic infectious disease clinic. Journal of Clinical Pharmacy and Therapeutics, 42(1), pp. 39-43. | Double |
| | PEREZ-LOPEZ, J. et al., 2008. Safety and efficacy of home intravenous antimicrobial infusion therapy in older patients: a comparative study with younger patients, 62(8), pp. 1188-92. | Double |
| | LUCASTI, C. et al., 2014. Multicenter, double-blind, randomized, phase II trial to assess the safety and efficacy of ceftolozane-tazobactam plus metronidazole compared with meropenem in adult patients with complicated intra-abdominal infections. *Antimicrobial agents and chemotherapy*, *58*(9), pp.5350-5357. | Drug combination comparison versus single antimicrobial |
| | FLANAGAN, S. et al., 2014. Tedizolid population pharmacokinetics, exposure response, and target attainment. *Antimicrobial agents and chemotherapy*, *58*(11), pp.6462-6470. | Specific to tedizolid |

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| | TICE, A.D. et al. 2004. Practice guidelines for outpatient parenteral antimicrobial therapy. *Clinical infectious diseases*, *38*(12), pp. 1651-1671. | The article is a guideline for clinical practice |
| | KONYCHEV, A. et al., 2013. Safety and efficacy of daptomycin as first-line treatment for complicated skin and soft tissue infections in elderly patients: an open-label, multicentre, randomized phase IIIb trial. *Drugs & aging*, *30*(10), pp.829-836. | Specific to daptomycin |
| | GO, A.C., BARBER, G.R. and DRESKIN, S.C., 2013. Implementing standardized intravenous antibiotic desensitizations among hospital inpatients. *American Journal of Health-System Pharmacy*, *70*(6), pp.540-548. | Not related to subject matter |
| | TEUFFEL, O. et al., 2011. Outpatient management of cancer patients with febrile neutropenia: a systematic review and meta-analysis. *Annals of oncology,* 22(11), pp.2358-2365. | Double |
| | SAYET, G., SINEGRE, M. and REGUIGA, M.B., 2014, January. Development of a Fourier transform infrared spectroscopy coupled to UV-Visible analysis technique for aminosides and glycopeptides quantitation in antibiotic locks. In *Annales pharmaceutiques francaises* (Vol. 72, No. 1, pp. 41-50). Elsevier Masson. | Not related to subject matter |
| | HUANG, D.B. et al., 2017. A phase 3, randomized, double-blind, multicenter study to evaluate the safety and efficacy of intravenous iclaprim vs vancomycin for the treatment of acute bacterial skin and skin structure infections suspected or confirmed to be due to gram-positive pathogens: REVIVE-1. *Clinical Infectious Diseases*, *66*(8), pp.1222-1229. | Drug comparison between intravenous iclaprim vs vancomycin |
| | COREY, G.R. et al., 2018. Single intravenous dose of oritavancin for treatment of acute skin and skin structure infections caused by Gram-positive bacteria: summary of safety analysis from the phase 3 SOLO studies. *Antimicrobial agents and chemotherapy*, *62*(4), pp.e01919-17. | Not related to subject matter |
| | MAERTENS, J. et al., 2014. Phase 1B study of the pharmacokinetics and safety of posaconazole intravenous solution in patients at risk for invasive fungal disease. *Antimicrobial agents and chemotherapy*, *58*(7), pp.3610-3617. | Not related to subject matter |
| | FALAGAS, M.E. et al., 2012. Clinical outcomes with extended or continuous versus short-term intravenous | Not related to subject matter |

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| | infusion of carbapenems and piperacillin/tazobactam: a systematic review and meta-analysis. *Clinical infectious diseases*, *56*(2), pp.272-282. | |
| | NIWA, T. et al., 2009. Retrospective cohort chart review study of factors associated with the development of thrombocytopenia in adult Japanese patients who received intravenous linezolid therapy. *Clinical therapeutics*, *31*(10), pp.2126-2133. | Not related to subject matter |
| | WOODWARD, Z. et al., 2018. Adsorption and Leachable Contamination of Flucloxacillin, Cyclosporin and Amiodarone Following Delivery Through an Intravenous Administration Set. *Pharmaceutical research*, 35(6), p.121. | Not related to subject matter |
| | HOOVER, R.K. et al., 2018. Clinical Pharmacokinetics of Sulfobutylether-β-Cyclodextrin in Patients With Varying Degrees of Renal Impairment. The Journal of Clinical Pharmacology, 58(6), pp.814-822. | Not related to subject matter |
| | WAGENLEHNER, F. et al., 2018. Explorative randomized phase II clinical study of the efficacy and safety of finafloxacin versus ciprofloxacin for treatment of complicated urinary tract infections. *Antimicrobial agents and chemotherapy*, 62(4), pp.e02317-17. | Drug comparison between finafloxacin and ciprofloxacin |
| | SUN, S.L., 2007. Implementation of pharmacy services in a pediatric emergency department (ED). ASHP Midyear Clinical Meeting, vol. 42. | The abstract's cohort is based on a paediatric population |
| | WELTE, T. et al., 2005. Treatment with sequential intravenous or oral moxifloxacin was associated with faster clinical improvement than was standard therapy for hospitalized patients with community-acquired pneumonia who received initial parenteral therapy. *Clinical infectious diseases*, 41(12), pp.1697-1705. | Not related to subject matter |
| | LASHOF, A.O. et al., 2012. Safety and tolerability of voriconazole in patients with baseline renal insufficiency and candidemia. Antimicrobial agents and chemotherapy, 56(6), pp.3133-3137. | Not related to subject matter |
| | VAZQUEZ, J.A. et al., 2012. Efficacy and safety of ceftazidime–avibactam versus imipenem–cilastatin in the treatment of complicated urinary tract infections, including acute pyelonephritis, in hospitalized adults: results of a prospective, investigator-blinded, | Drug comparison between ceftazidime–avibactam and |

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| | randomized study. *Current medical research and opinion,* 28(12), pp.1921-1931. | imipenem–cilastatin |
| | SAYRE, B, 2012. Consolidation of intravenous medication compounding services in a tertiary care health system leads to operational efficiencies and inpatient cost avoidance ASHP Midyear Clinical Meeting 2012, vol. 2011, pp. 003. | Not related to subject matter |
| | WELLER, S. et al., 2013. Pharmacokinetics of zanamivir following intravenous administration to subjects with and without renal impairment. *Antimicrobial agents and chemotherapy*, 57(7), pp.2967-2971. | Specific to zanamivir |
| | Schneider, J.L., 2012. Improvement in medication turnaround time: a process improvement initiative. ASHP Midyear Clinical Meeting 2012, vol. 2011, pp. P-82(D) | Not related to subject matter |
| | MERRY, A.F. et al., 2011. Multimodal system designed to reduce errors in recording and administration of drugs in anaesthesia: prospective randomised clinical evaluation. *Bmj*, 343, p.d5543. | Not related to subject matter |
| | Marchese, C. R., 2000. Pediatric standardized doses to improve patient safety. ASHP Midyear Clinical Meeting, Dec 2000, vol. 35, pp. P-130D | Not related to subject matter |
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| | VAN WART, S.A. et al., 2006. Population pharmacokinetics of tigecycline in patients with complicated intra-abdominal or skin and skin structure infections. Antimicrobial agents and chemotherapy, 50(11), pp.3701-3707. | Specific to tigecycline |
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| | McNEIL, N, Safety and quality pearls 2006 ASHP Midyear Clinical Meeting, Dec 2006, vol. 41, pp. P1-43 | The subject matter is too generic |
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| | SKLEDAR, S, 2004. ASHP Midyear Clinical Meeting, DEC 2004, vol. 39, pp. P224D. Documenting the role of the pharmacist in promoting medication patient safety | Not related to subject matter |
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| | SCHLESSELMAN, M, ASHP Midyear Clinical Meeting, Dec 2006, vol. 41, pp. pi-119<br>Informatics pearls 2006 | Not related to subject matter |
| | GAUNT, R. C., ASHP Midyear Clinical Meeting, Dec 2001, vol. 36, pp. P-64D<br>Improving pharmacy services and patient safety in a neonatal intensive care unit | Not related to subject matter |
| | CARSON, CN, ASHP Midyear Clinical Meeting, DEC 2007, vol. 42, Preparing staff pharmacists for intensive care rounds: a pharmacotherapeutic tool for managing patient care | Not related to subject matter |
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| | CHANT, C., WILSON, G. and FRIEDRICH, J.O., 2005. Validation of an insulin infusion nomogram for intensive glucose control in critically ill patients. Pharmacotherapy: *The Journal of Human Pharmacology and Drug Therapy*, 25(3), pp.352-359. | Not related to subject matter |
| | MANFULL, K. L., 2001. ASHP Midyear Clinical Meeting, Dec 2001, vol. 36, pp. P-67D<br>Medication error reduction strategies: implementation of a pediatric antibiotic syringe program | Not related to subject matter |
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| | KEATING, G.M., Lenograstim A Review of its Use in Chemotherapy-Induced Neutropenia, for Acceleration of Neutrophil Recovery Following Haematopoietic Stem Cell Transplantation and in Peripheral Blood Stem Cell Mobilization. *Drugs* (New Zealand), Jun 2011, vol. 71, pp. 679-707 | Not related to subject matter |

Other sources

| Reference | Reason for Exclusion |
|---|---|
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| PALADINO, J.A. and PORETZ, D., 2010. Outpatient parenteral antimicrobial therapy today. Clinical Infectious Diseases, 51(Supplement_2), pp. S198-S208. | This article is generic and does not focus on the subject matter |
| CHUNG, E.K. et al., 2016. Development and implementation of a pharmacist-managed outpatient parenteral antimicrobial therapy program. American Journal of Health-System Pharmacy, 73(1), pp. e24-e33. | The article is a guideline for clinical practice |
| MACKENZIE, M., RAE, N. and NATHWANI, D., 2014. Outcomes from global adult outpatient parenteral antimicrobial therapy programmes: a review of the last decade. International journal of antimicrobial agents, 43(1), pp.7-16. | This article does not present primary research |

**Appendix 4.1 System Outcomes Extraction Tool**

Patient Code

Patient age

Patient gender

Patient deceased by end of service

Discharging ward

OPAT Consultant

Vascular Access Device

First Antimicrobial Drug

Second Antimicrobial Drug

Total Number of Drugs

Estimated Duration

Date Flagged

Range in Days of Service

Cost of Bed Days Saved

Readmitted

Reason for Readmittance

Visits per day

Presenting Infection

Detection of MRSA

Complications

Organism Cultured

Referring Consultant

Number of Service Episodes

**Appendix 4.2 Results of the Kruskal-Wallis tests which compared the influence of categorical variables on the dependant variable i.e. the observed duration**

Table 1 Comparison of presenting infection for mean observed duration

| | N | Mean | Std. Deviation | Minimum | Maximum | | |
|---|---|---|---|---|---|---|---|
| | | | | | | K-W test | p-value |
| Orthopaedic | 66 | 27.71 | 17.131 | 2 | 108 | 14.868 | 0.021 |
| Cardiology | 10 | 17.80 | 7.899 | 2 | 29 | | |
| Gastroenterology | 11 | 19.55 | 16.658 | 5 | 57 | | |
| Abscess | 24 | 25.96 | 14.409 | 7 | 61 | | |
| Nephrology and urology | 6 | 26.50 | 22.863 | 3 | 54 | | |
| Bacteraemia | 7 | 9.00 | 4.243 | 5 | 18 | | |
| Oral and respiratory | 8 | 27.50 | 28.173 | 7 | 92 | | |
| Total | 132 | 24.90 | 17.182 | 2 | 108 | | |

Table 2 Comparison of patient readmission for Mean Observed Duration

| | N | Mean | Std. Deviation | Minimum | Maximum | | |
|---|---|---|---|---|---|---|---|
| | | | | | | K-W test | p-value |
| Yes | 23 | 18.65 | 20.380 | 2 | 92 | 7.874 | 0.005 |
| No | 109 | 26.22 | 16.229 | 3 | 108 | | |
| Total | 132 | 24.90 | 17.182 | 2 | 108 | | |

Table 3 Comparison of the number of visits for Mean Observed Duration

| | N | Mean | Std. Deviation | Minimum | Maximum | | |
|---|---|---|---|---|---|---|---|
| | | | | | | K-W test | p-value |
| One visit | 105 | 24.27 | 14.928 | 2 | 92 | 0.012 | 0.915 |
| More than one visit | 27 | 27.37 | 24.251 | 2 | 108 | | |
| Total | 132 | 24.90 | 17.182 | 2 | 108 | | |

Table 4 Comparison of gender for Mean Observed Duration

| | N | Mean | Std. Deviation | Minimum | Maximum | | |
|---|---|---|---|---|---|---|---|
| | | | | | | KW test | p-value |
| Male | 85 | 25.13 | 17.117 | 2 | 108 | 0.156 | 0.693 |
| Female | 47 | 24.49 | 17.475 | 2 | 92 | | |
| Total | 132 | 24.90 | 17.182 | 2 | 108 | | |

Table 5 Comparison of patient death for mean observed duration

| | N | Mean | Std. Deviation | Minimum | Maximum | | |
|---|---|---|---|---|---|---|---|
| | | | | | | K-W test | p-value |
| Yes | 1 | 10.00 | . | 10 | 10 | 0.894 | 0.345 |
| No | 131 | 25.02 | 17.197 | 2 | 108 | | |
| Total | 132 | 24.90 | 17.182 | 2 | 108 | | |

Table 6 Comparison of the vascular access device for Mean Observed Duration

| | N | Mean | Std. Deviation | Minimum | Maximum | | |
|---|---|---|---|---|---|---|---|
| | | | | | | K-W test | p-value |
| Peripherally-inserted central catheter | 112 | 27.13 | 17.283 | 2 | 108 | 20.36 | <0.001 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Peripherally-inserted intravenous catheter (midline) | 3 | 7.67 | 0.577 | 7 | 8 | | |
| Implantable venous access system | 7 | 18.43 | 10.147 | 9 | 35 | | |
| Peripherally-inserted intravenous catheter (IV cannula) | 10 | 9.70 | 9.719 | 2 | 33 | | |
| Total | 132 | 24.90 | 17.182 | 2 | 108 | | |

Table 7 Comparison of number of drugs for Mean Observed Duration

| | N | Mean | Std. Deviation | Minimum | Maximum | | |
|---|---|---|---|---|---|---|---|
| | | | | | | K-W test | p-value |
| One drug | 115 | 23.95 | 16.104 | 2 | 108 | 1.522 | 0.217 |
| More than one | 17 | 31.35 | 22.770 | 6 | 92 | | |
| Total | 132 | 24.90 | 17.182 | 2 | 108 | | |

Table 8 Comparison of presence of MRSA for mean observed duration

| | N | Mean | Std. Deviation | Minimum | Maximum | | |
|---|---|---|---|---|---|---|---|
| | | | | | | K-W test | p-value |
| Yes | 6 | 22.00 | 24.698 | 5 | 62 | 1.011 | 0.315 |
| No | 126 | 25.04 | 16.869 | 2 | 108 | | |
| Total | 132 | 24.90 | 17.182 | 2 | 108 | | |

**Appendix 4.3 Results of the Pearson Chi squared test which compared categorical variables**

Table 1 Comparison of presenting infection and readmissions

| | | Readmission | | Total |
|---|---|---|---|---|
| | | Yes | No | |
| Indication | Orthopaedic | 12 | 54 | 66 |
| | Cardiology | 2 | 8 | 10 |
| | Gastroenterology | 1 | 10 | 11 |
| | Abscess | 3 | 21 | 24 |
| | Nephrology and urology | 2 | 4 | 6 |
| | Bacteraemia | 1 | 6 | 7 |
| | Oral and respiratory | 2 | 6 | 8 |
| Total | | 23 | 109 | 132 |

$X^2(6)=2.43$, $p=0.876$

Table 2 Comparison of patient death with the presence of MRSA

| | | MRSA | | Total |
|---|---|---|---|---|
| | | Yes | No | |
| Deceased | Yes | 0 | 1 | 1 |
| | No | 6 | 125 | 131 |
| Total | | 6 | 126 | 132 |

$X^2(1)=0.048$,$p=0.827$

Table 3 Comparison of presenting infection with patient death

| | | Deceased | | Total |
|---|---|---|---|---|
| | | Yes | No | |
| Indication | Orthopaedic | 0 | 66 | 66 |
| | Cardiology | 0 | 10 | 10 |
| | Gastroenterology | 1 | 10 | 11 |
| | Abscess | 0 | 24 | 24 |

| | | | | |
|---|---|---|---|---|
| | Nephrology and urology | 0 | 6 | 6 |
| | Bacteraemia | 0 | 7 | 7 |
| | Oral and respiratory | 0 | 8 | 8 |
| Total | | 1 | 131 | 132 |

$X^2(6) = 11.084$, $p=0.086$

Table 4 Comparison of vascular access device on patient death

| | | Deceased | Total | |
|---|---|---|---|---|
| | | Yes | No | |
| Vascular Access Device | Peripherally inserted central catheter | 0 | 112 | 112 |
| | Peripherally inserted intravenous catheter (midline) | 0 | 3 | 3 |
| | Implantable venous access system | 1 | 6 | 7 |
| | Peripherally inserted intravenous catheter (IV cannula) | 0 | 10 | 10 |
| Total | | 1 | 131 | 132 |

$X^2(3)=17.993$, $p<0.001$

## Appendix 5.1: Patient Information Leaflet in English

**Title of Study:** The Application of a Human Factors Approach to the Evaluation of a Novel Outpatient Parenteral Antimicrobial Therapy Service

INFORMATION SHEET

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

### What is the purpose of the study?

The purpose of the study is to understand the level of satisfaction experienced by those patients who have received the OPAT service.

### Why have I been chosen?

All patients who have been flagged and received the OPAT service have been invited to participate.

### Do I have to take part?

No. It is up to you to decide whether or not to take part. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care that you will receive. Under the General Data Protection Regulation (GDPR) and implementing national legislation, you have the right to access, rectify, and where applicable erase the data concerning you.

### What will I be asked to do if I choose to take part?

You will be asked to undertake a structured interview about the service you have received. This will be carried out during a phone call which will last approximately thirty minutes. The questions are related to the quality of the service as delivered by the respective multidisciplinary team to include doctors, nurses and

pharmacists. You will only be asked to share data that is necessary for the research.

**What will happen to the information you take about me/the samples you take from me?**

All information which is collected about you during the course of the study will be kept strictly confidential. Patient names will be coded therefore retaining confidentiality from the moment of recruitment. Any information about you will not be held in any format that would allow anyone to trace information back to you. All information taken will be stored (5 years), accessed and destroyed in accordance with RGU ethics procedures. Audio recorded data will be retained till the next working day and transcription will take place in a secure environment at the pharmacy department at Mater Dei Hospital by the researcher. The results of the research study will be fed back to the research team, used for analysis purposes and considered for publication. Data collected will be pseudonymised and stored separately from any codes and personal data in a locked cabinet at the pharmacy department in Mater Dei Hospital. Access to the collected data will be limited to the researcher, supervisors and examiners

**What are the possible benefits of taking part?**

The results of this study will help to enhance the service based on your answers as the end users thus benefitting future patients as well as yourself should you require to make use of the service again. No physical and/or psychological risks are foreseen to participants involved in the study.

**Who has reviewed the study?**

The study has been reviewed by the Ethics Committee (SERC) at the School of Pharmacy & Life Sciences, Robert Gordon University as well as the Faculty Research Ethics Committee at the University of Malta.

**Contact for further information**

If you have any questions or require any further information, please contact:

Researcher: Sara Jo Bugeja (s.bugeja@rgu.ac.uk; 79847232)

Maltese Supervisor: Dr. Kurt Magri (gmagr02@um.edu.mt; 23401881)

Supervisory team members: Dr. Helen Vosper (h.vosper@rgu.ac.uk), Prof. Derek Stewart (d.stewart@rgu.ac.uk), Prof. Alison Strath (a.strath@rgu.ac.uk)

**If I am interested in taking part what do I need to do next?**

If you are happy to take part in the study kindly sign the consent form presented and provide a contact number which will be allocated to your code to proceed with the interview at a later stage. You are free to request a copy of this letter and consent form.

Date: 14.7.2018

Version: 1

**Thank you for reading this information sheet.**

## Appendix 5.2: Patient Information Sheet in Maltese

**Titlu ta' l-istudju:** L-Applikazjoni tal-fatturi umani fl-evalwazzjoni tas-servizz ġdid tat-terapija li tinvolvi l-amministrazzjoni tal-antimikrobjali fil-vina barra mill-isptar (OPAT).

FULJETT TA' INFORMAZZJONI

Ġejt mistieden tipparteċipa f'dan l-istudju. Qabel ma tieħu deċiżjoni, huwa importanti li tifhem għalxiex qiegħed isir dan ir-riċerka u fiex tikkonsisti. Ħu ħinek biex taqra l-informazzjoni provduta u ħossok liberu biex tiddiskutti din l-informazzjoni ma' ħadd ieħor. Tiddejjaqx issaqsi jekk xi ħaga mhux ċara jew ikollok bżonn aktar informazzjoni. Ħu ħinek biex tiddeċidi jekk tixtieq tipparteċipa. Nirringrazzjak talli qrajt dan il-fuljett.

### X'inhu l-iskop ta' l-istudju?

L-iskop ta' l-istudju hu, li jiġi mifhum il-livell ta' sodisfazzjon esperjenzat minn dawk il-pazjenti li rċevew is-servizz tal-OPAT.

### Għalxiex ġejt magħzul?

Il-pazjenti kollha li ġew iddentifikati u rċevew is-servizz ġew mistiedna biex jipparteċipaw.

### Is-sehem tiegħi huwa obligatorju?

Le. L-għażla hija tiegħek jekk tieħux sehem. Jekk taċċetta, ħa tiġi mistoqsi sabiex tiffirma formula ta' kunsens. Għandek il-liberta' biex tirtira milli tipparteċipa meta trid, mingħajr raġuni. Deċiżjoni li twassal ghal irtirar jew twaqqif ta' parteċipazjoni mhux se taffetwa l-livell ta' kura li tirċievi. Skond ir-Regolament Ġenerali l-ġdid tal-Unjoni Ewropea dwar il-Protezzjoni tad-Data ('GDPR') u l-leġizaljoni nazjonali implementata, għandek d-dritt li jkollok aċċess, tikkoreġi jew tħassar informazzjoni li tikkonċerna lilek.

### Jekk niddeċiedi nipparteċipa, x'se nigi mitlub nagħmel?

Se tiġi mitlub twieġeb mistoqsijiet waqt intervista dwar is-servizz li tkun għadek kemm rċevejt, dan permezz ta' telefonata li ddum kważi tletin minuta. Il-mistoqsijiet se jkunu mfassla fuq il-kwalita' tas-servizz li ġie provdut mit-tobba, infermiera u spiżjara. Se tiġi mitlub tagħti biss data li huwa neċessarju għal din r-riċerka.

**X'isir mill-informazzjoni tieghi?**

L-informazzjoni meħuda mingħandek matul dan l-istudju sejjer tinżamm strettament kunfidenzjali. L-ismijiet tal-pazjenti se jiġu mibdulin b'kodici mil-mument ta' rekutaġġ. Kwalunkwe informazzjoni miżmuma dwarek mhix se tħalli lil ħaddiehor jiddentifikak minnha. L-informazzjoni meħuda se tiġi miżmuma (5 snin), aċċessata u mħassra skont l-proċeduri ta' l-etika ta' RGU. Reġistrazzjoni t'awdjo jiġi miżmum sa' l-għada u transkrizzjoni ssir f'ambjent sikur fid-dipartiment tal-farmaċija fl-isptar Mater Dei mir-riċerkatriċi. Ir-riżultati tar-riċerka se jitqassmu mat-tim ta' riċerka għal-analiżi u pubblikazzjoni. Data dwarek se jiġi  psewdonimiżżat u miżmum apparti minn xi kodiċi u data personali f'kabinett msakkra fid-dipartiment tal-farmaċija fl-isptar Mater Dei. Aċċess għad-data miġbura se jkun limitat għar-riċerkatriċi, superviżuri u eżaminaturi.

**X'inhuma l-benefiċji tal-parteċipazzjoni tiegħi?**

Ir-riżultati ta' dan l-istudju se jgħinu sabiex itejbu s-servizz a bażi tar-risposti tiegħek. B'hekk kemm pazjenti futuri kif ukoll int li ħadt sehem, jekk jerġa' ikun hemm ħtiega, tista' tibbeniffikaw minn servizz aħjar. Mhemm l-ebda riskji fiżiċi jew psikoloġiki previsti għal min jipparteċipa.

**Min għamel r-reviżjoni ta' l-istudju?**

L-istudju ġie rivedut mil-kumitat ta' l-etika ta' l-Universita ta' Robert Gordon (li jinsab fl-Iskozja) kif ukoll mil-kumitat ta' l-etika ta' l-Universita ta' Malta.

**Dettalji għall-aktar informazzjoni**

Jekk għandek iktar mistoqsijiet jew tixtieq aktar informazzjoni, int ġentilment tagħmel kuntatt ma':

Ir-Riċerkatriċi: Sara Jo Bugeja (s.bugeja@rgu.ac.uk; 79847232)

Superviżur Malti: Dr. Kurt Magri (gmagr02@um.edu.mt; 23401881)

Superviżuri Barranin: Dr. Helen Vosper (h.vosper@rgu.ac.uk), Prof. Derek Stewart (d.stewart@rgu.ac.uk) , Prof. Alison Strath (a.strath@rgu.ac.uk)

**Jekk nixtieq nieħu sehem, x'inhu l-pass li jmiss?**

Jekk tixtieq tieħu sehem, inti ġentilment mitlub tiffirma l-formula ta' kunsens preżentat bil-kodici fuqha u tipprovdi numru telefoniku biex issir l-intervista' f'faži iktar tard. Jekk tixtieq tista' żżomm kopja ta' din l-ittra u l-formula tal-kunsens.

Data: 14.7.2018

Verżjoni: 1

**Grazzi tal-ħin tiegħek biex taqra dan il-fuljett.**

**Appendix 5.3: Patient Consent Form in English**

**Title of Study:** The Application of a Human Factors Approach to the Evaluation of a Novel Outpatient Parenteral Antimicrobial Therapy Service

**Name of Researcher:** Sara Jo Bugeja (s.bugeja@rgu.ac.uk; 79847232)

**Supervisor:** Dr. Kurt Magri (gmagr02@um.edu.mt; 23401881)

**Foreign Supervisory team:** Dr. Helen Vosper (h.vosper@rgu.ac.uk); Prof Derek Stewart (d.stewart@rgu.ac.uk), Prof. Alison Strath (a.strath@rgu.ac.uk)

Participant Identification Number:

Participant Contact Number:

I, the undersigned, confirm that (please initial on each line as appropriate)

| | | |
|---|---|---|
| 1. | I confirm that I have read the information sheet dated 14.7.2018 (version 1) for the above study. | ___ |
| 2. | I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | ___ |
| 3. | I voluntarily agree to participate in the project and understand that there are no related physical and/or psychological risks | ___ |
| 4. | I voluntarily agree to provide a contact number to be used at a later stage to conduct the interview over a telephone call | ___ |
| 5. | I understand I can withdraw at any time without giving reasons and that I will not be penalised for withdrawing nor will I be questioned on why I have withdrawn. | ___ |
| 6. | The procedures regarding confidentiality have been clearly explained (e.g. use of names, pseudonyms, anonymisation of data, *etc*.) to me. Data will be pseudonymised and stored apart from any codes and personal data to ensure confidentiality | ___ |
| 7. | I agree to my interview/focus group being audio/video recorded. I understand that anonymised quotations from this interview may be used for presentations and publications. | ___ |
| 8. | The use of the data in research, publications, sharing and archiving has been explained to me. I agree for my information to be stored on RGU servers for 5 years. | ___ |

| | | |
|---|---|---|
| 9. | I was informed that under the General Data Protection Regulation (GDPR) and implementing national legislation, I have the right to access, rectify, and where applicable erase the data concerning me | __ |
| 10. | Access to the collected data will be limited to the researcher, supervisors and examiners | __ |

_____ _____ _____

Name of Participant Signature Date

**Researcher:** ***I confirm that I have explained to the participant above, the nature and purpose of the study.***

_____ _____ _____

Researcher taking consent Signature Date

**Appendix 5.4: Patient Consent Form in Maltese**

**Titlu ta' l-istudju:** L-Applikazjoni tal-fatturi umani fl-evalwazzjoni tas- servizz ġdid tat-terapija li tinvolvi l-amministrazzjoni tal-antimikrobjali fil-vina barra mill-isptar (OPAT).

**Riċerkatriċi:** Sara Jo Bugeja (s.bugeja@rgu.ac.uk; 79847232)

**Superviżur Malti:** Dr. Kurt Magri (gmagr02@um.edu.mt, 23401881)

**Tim superviżorju barrani:** Dr. Helen Vosper (h.vosper@rgu.ac.uk); Prof Derek Stewart (d.stewart@rgu.ac.uk), Prof Alison Strath (a.strath@rgu.ac.uk)

Numru ta' referenza tal-parteċipant:

Numru telefoniku tal-parteċipant:

Jien bħala parteċipant nikkonferma li (jekk jogħġbok niżżel l-inizjali tiegħek)

| | | |
|---|---|---|
| 1. | Jien nikkonferma li qrajt l-fuljett ta' informazzjoni datata 14.7.2018 (verżjoni 1) għal dan l-istudju. | ___ |
| 2. | Jien kelli l-opportunità sabiex nikkonsidra l-informazzjoni, nsaqsi mistoqsijiet u jkolli tweġibiet sodisfaċenti | ___ |
| 3. | Jien naċċetta li nipparteċipa u nagħti l-kunsens volontarjament fil-proġett u nifhem li mhemmx riskji fiżiċi u/jew psikoloġiki relatati | ___ |
| 4. | Jien volontarjament naċċetta li nipprovdi numru telefoniku tiegħi biex jiġi ntużat iktar tard biex nwieġeb mistoqsijiet ta' intervista' telefonika | ___ |
| 5. | Nifhem li nista' nitlaq mill-istudju meta rrid mingħajr ma nagħti raġunijiet u li ma niġix penaliżżat jew mistoqsi għalxiex tlaqt | ___ |
| 6. | Il-proċeduri dwar kunfidenzjalità ġew spjegati b'mod ċar (e.ż. l-użu ta' ismijiet, psewdonimi, anonimita` tad-data etċ) Data se jkun psewdonimiżżat u miżmum apparti minn xi kodiċi u data personali sabiex tinżamm l-kunfidenzjalità | ___ |
| 7. | Jiena naċċetta li l-awdjo ta' l-intervista tigi rreġistrata. Nifhem li kwotazzjonijiet anonimi mill-intervista jistgħu jiġu ntużati f'preżentazzjonijiet jew pubblikazzjonijiet. | ___ |

| | | |
|---|---|---|
| 8. | L-użu tad-data fir-riċerka, pubblikazzjonijiet, qsim u arkivjar ġie spjegat. Naqbel li l-informazzjoni tiegħi tigi maħżuna fuq servers ta' RGU għal 5 snin. | ___ |
| 9. | Jien ġejt infurmat/a li skond ir-Regolament Ġenerali l-ġdid tal-Unjoni Ewropea dwar il-Protezzjoni tad-Data ('GDPR') u l-leġizaljoni nazjonali implementata, għandi d-dritt li jkolli aċċess, nikkoreġi jew inħassar informazzjoni li tikkonċerna lili | ___ |
| 10. | Aċċess għad-data miġbura se jkun limitat għar-riċerkatriċi, superviżuri u eżaminaturi. | ___ |

_____ _____ _____

L-Isem tal-Parteċipant Firma Data

***Riċerkatur li se jieħu l-kunsens tal-parteċipant: Nikkonferma li spjegajt lill-parteċipant in-natura u skop ta' l-istudju.***

_____ _____ _____

Riċerkatur Firma Data

## Appendix 5.5: Patient Satisfaction Questionnaire in English

### PATIENT SATISFACTION QUESTIONNAIRE

### Preadmission to the Service

1. Were you given enough time to ask questions to the OPAT nurses? Yes/if No, explain
2. Were you given enough time to ask questions to the OPAT doctors? Yes/if No, explain
3. Was the service explained in simple layman terms by the OPAT doctors? Yes/if No, explain
4. Was the service explained in simple layman terms by the OPAT nurses? Yes/if No, explain
5. Were you aware of any complications that may arise? Yes/if No, explain
6. Were you given adequate information where to call should you be in difficulty? Yes/if No, explain
7. Was the OPAT information booklet provided easy to follow? Yes/if No, explain
8. Did you have any questions that were left unanswered? Yes/if No, explain
9. Did all the healthcare professionals involved do their best to keep you from worrying? Yes/if No, explain
10. Do you think something should change during this step of service provision?_____

### Service Provision

1. Were you informed about foreseen delays in the nurses' arrival time? Yes/if No, explain
2. Were you affected by the fact that various nurses were providing the service? Yes/if No, explain
3. Were the nurses respectful of your residence and personal belongings? Yes/if No, explain
4. Did the nurses explain what they are doing whilst they are administering the medication, changing dressings and taking vital sign parameters? Yes/if No, explain
5. Did the nurse/doctor keep you informed of your progress? Yes/if No, explain
6. Did you ever need to phone the discharge liaison nurses? Yes/if No, explain
7. If you had any other medical appointments, were adjustments made to accommodate you? Yes/if No, explain
8. Were you made aware of any problems regarding stock levels? Yes/if No, explain
9. Do you feel that you were adequately followed up by the doctors running the OPAT service? Yes/if No, explain

10. Do you think something should change during this step of service provision? _____

**Following cessation**

1. Would you have preferred to remain as an inpatient? Yes/if No, explain
2. Were you pleased with the overall running of the service? Yes/if No, explain
3. Would you consider benefitting from the service again should the need arise? Yes/if No, explain

## Appendix 5.6: Patient Satisfaction Questionnaire in Maltese

## STĦARRIĠ DWAR S-SODISFAZZJON TAL-PAZJENTI

### Qabel ma bdejt s-servizz

1. Ġejt mogħti/ja biżżejjed ħin sabiex issaqsi mistoqsijiet lill-infermiera tas-servizz? Iva/Jekk le, għaliex?
2. Ġejt mogħti/ja biżżejjed ħin biex issaqsi mistoqsijiet lit-tobba tas-servizz? Iva/Jekk le, għaliex?
3. Is-servizz ġie spjegat b'mod mhux tekniku mit-tobba tas-servizz? Iva/Jekk le, għaliex?
4. Is-servizz ġie spjegat b'mod mhux tekniku mil-infermiera tas-servizz? Iva/Jekk le, għaliex?
5. Kont konxju/a ta' xi kumplikazzjonijiet li setgħu jinqalgħu? Iva/Jekk le, għaliex?
6. Ġie mogħti biżżejjed informazzjoni dwar fejn għandek iċċempel jekk tkun f'diffikulta`? Iva/Jekk le, għaliex?
7. Il-fuljett informattiv dwar is-servizz kien faċli biex issegwih? Iva/Jekk le, għaliex?
8. Kellek xi mistoqsijiet li bqajt mingħajr tweġiba? Iva/Jekk le, għaliex?
9. Kull professjonist tas-saħħa għamel l-għalmu tiegħu sabiex int ma nkwetajtx? Iva/Jekk le, għaliex?
10. Tħoss li xi ħaga għandha tinbidel minn din il-fażi tas-servizz? _____

### Is-Servizz

1. L-infermiera kienu jinfurmawk jekk kienu se jittardjaw? Iva/Jekk le, għaliex?
2. Ġejt affetwat mil-fatt li l-infermiera li joffrulek is-servizz kienu jinbidlu? Iva/Jekk le, għaliex?
3. L-infermiera urew rispett lejn ir-residenza u l-affarijiet personali tiegħek? Iva/Jekk le, għaliex?
4. L-infermiera spjegaw x'kienu qegħdin jagħmlu waqt li kienu qed jamminsitraw l-mediċina, ibidlu garża u jieħdu parametri vitali? Iva/Jekk le, għaliex?
5. L-infermiera u t-tobba żammewk infurmat dwar l-progress tiegħek? Iva/Jekk le, għaliex?
6. Qatt kellek bżonn iċċempel l-infermiera tas-servizz? Iva/Jekk le, għaliex?
7. Jekk kellek xi appuntamenti mediċi oħrajn, saru aġġustamenti sabiex jakkomodawk? Iva/Jekk le, għaliex?
8. Ġejt magħruf/a b'xi problemi dwar id-disponibbilta` tal-mediċini? Iva/Jekk le, għaliex?

9. Tħoss li ġejt segwit b'mod adegwat mit-tobba li qegħdin imexxu s-servizz? Iva/Jekk le, għaliex?
10. Tħoss li xi ħaġa għandha tinbidel minn din l-fażi tal-provista tas-servizz?

---

**Wara s-Servizz**

1. Kont tippreferi tibqa' pazjent ġo l-isptar minflok tibbenifika mis-servizz? Iva/Jekk le, għaliex?
2. Kont kuntent bit-tmexxija tas-servizz globalment? Iva/Jekk le, għaliex?
3. Tikkunsidra terġa' tibbenifika mis-servizz jekk jerġa' jkun hemm bżonn? Iva/Jekk le, għaliex?

**Appendix 5.7 Axial coding of open text responses**

Participants' quotes for extracted codes pertaining to the preadmission stage

| **Axial code** | Participants' discourse |
|---|---|
| **Literacy/understanding** | "Thankfully I am quite literate since at one point during my transfer to the OPAT team I was approached by an English-speaking doctor and we didn't understand each other much. Probably an elderly person would have had it much worse" (73-year-old male) |
| | "It was problematic when foreign doctors explained something in English and we usually used to ask someone to explain the same thing in Maltese (84-year-old female) |
| | "A Maltese version of the booklet would have helped both my husband and I to understand the service as we do not know much English" (40-year-old female) |
| **Caregiver assistance** | "My daughter used to translate or explain when I couldn't understand something handed by one of the members of staff" (58-year-old female) |
| **Preference of setting: Home** | "I had a very difficult patient in my room who kept waking me up at night. At that point I wanted to be discharged as quickly as possible" (64-year-old male). |
| | "I wasn't completely sure of the consequences of the treatment but trusted the team fully and wanted to go home" (58-year-old female). |
| | "You must understand where I am coming from. I am extremely scared of hospitals and if it were for me, I would never set foot in one! But this team managed to change my mentality" (61-year-old male). |
| | "I had to be moved to another ward to make way for another patient who was considered more critical than I was…. this was very uncomfortable for me as being in hospital is already unpleasant let alone needing to settle down in a new location with new patients again" (66-year-old female) |

| | |
|---|---|
| | "I wanted to go home as I didn't want to contract another infection from hospital to be honest" (59-year-old female) |
| **Preference of setting: Hospital** | "I wasn't expecting to have open heart surgery and in the interim I had managed to sell my house. As a foreigner now without a residence I was warned by the hospital that my next admission to the service would be against a charge" (54-year-old male) |
| **Treatment options** | "…it was more convenient to receive less administrations of the medicine during the day…wish I started using the service before" (66-year-old female). |
| **Delayed discharge** | "I received false hope that I was going home since the person doing the PICC lines at that time was on leave and I had to wait an extra four days before I actually got it done and could go home" (63-year-old male) |
| | "If I was sent home earlier, I probably wouldn't have to be moved to another ward whilst at hospital" (66-year-old female). |
| **Delayed flagging** | "If they picked up my febrile episodes, I would have been fagged earlier and avoided arguments with ward nurses" (57-year-old male). |
| | "A quicker referral would have helped me leave the ward earlier which would have been a blessing considering the difficult patient who was located near me" (64-year-old male). |
| **Timeslot/ Service capacity** | "I was told that I had to wait in hospital because there weren't any places when I was originally flagged… so I would suggest employing more people so that new places can be made available" (64-year-old male). |
| **Clear referral information** | "I wish the orthopaedic doctor gave me a better explanation about why I was going to be cared for by new doctors and nurses and why I needed a device inserted" (49-year-old male) |

Participants' quotes for extracted codes pertaining to the service provision stage

| **Axial Code** | Participants' discourse |
|---|---|
| **Concern about VAD** | "my fears increased when I went home" (47-year-old male) |
| | "…it's the device that truly kept me preoccupied until the very end" (60-year-old male) |
| | "…to be honest I was going back to work but was preoccupied about the PICC however the physicians were not concerned since I worked in an outpatient department" (56-year-old male) |
| **Patient reassurance** | "I phoned the nurses' helpline and they told me to come to MDH specifically to their office to make sure I was alright…it was very reassuring" (47-year-old male) |
| | "the team really managed to change my mentality and accept the changes I was undergoing at home" (61-year-old male) |
| | "I got to know that lack of staff was going to make my twice a day dosing impossible after a certain date but thankfully arrangements were made for a specific OPAT nurse to see to my afternoon doses which was perfect considering my lack of transport and mobility" (71-year-old female) |
| | "I was extremely demoralised since the medicine made me nauseous, but the nurses explained that sometimes they had these effects and I didn't have to worry" (64-year-old female) |
| | "they explained that if the nausea got too overwhelming, I just had to inform them, and they'd consult the doctors responsible for my care" (64-year-old female) |
| **Informal caregiver support** | "during one of the home visits I was unsure how to answer the nurse's questions, so she decided to phone my younger sister who managed to give her the answers she was looking for" (58-year-old female) |
| **Wellbeing associated with home environment** | "I was glad to be home, plus I didn't want to get another infection from hospital to be honest" (59-year-old female) |
| | "couldn't be happier to have left the hospital and it's all thanks to the dedication of the team" (56-year-old male) |

| | |
|---|---|
| | "I spent a long time on the service and thankfully got to spend it at home" (49-year-old male) |
| | "my family members immediately noticed that my morale improved once I started living at home again "(70-year-old male) |
| **Continuity of daily activities** | "being at home meant that I could attend my son's graduation and that meant the world to all of us" (43-year-old female) |
| | "the fact that the nurses came home was perfect for my situation since I was barely mobile and couldn't drive and more importantly, I have a new-born baby. This service was a life saver to my family, you just cannot understand how much!" (38-year-old female) |
| **Continuity of work commitments** | "I had to make changes at work to start later so that the nurse could give me my dose early in the morning…they were very accommodating and almost always on time" (61-year-old male) |
| | "I managed to get a concession to work from home whilst receiving the service" (29-year-old female) |
| | "since I work at hospital, going back to work would mean that I would take the dose at the hospital, but it wasn't a practical option for me since I do not work every day. If I took that option, it would have complicated my life to go to hospital just for the doses, so I decided to stay at home and receive the service instead" (56-year-old male) |
| **Preference of OPAT nurse** | "I would have preferred if the same nurse carried out the visits as one would manage to build a relationship over time" (49-year-old male) |
| | "this is an extra request as the service was of a very high standard, but I preferred one particular nurse over the rest and would have preferred to be cared for by him" (61-year-old male) |
| | "If I had to choose, I would have chosen the same nurse to administer my treatment everyday…I think I would have felt more comfortable" (29-year-old female) |
| | "I would have preferred if the same nurse came since I was constantly worried about getting an air bubble in the pipe and like that, I wouldn't have to explain myself every time a new nurse showed up at my door" (48-year-old male) |

| | |
|---|---|
| | "I had no problem with the change in nurse as long as they were equally competent" (40-year-old female) |
| **Regular follow up** | "even during the short span of ten days, I felt I was extremely well cared for. I attended two visits in all, which gave me the opportunity to know about my progress" (73-year-old male) |
| | "one nurse managed to pick up the first signs of what they later explained could have been a thrombosis …she seemed preoccupied about the slight reddening and reduced mobility I had in my arm and immediately contacted the medical team" (66-year-old female) |
| | "when my line got blocked, they immediately called for an ambulance to take me to hospital" (60-year-old male) |
| **Lack of travelling** | "If I was still a patient in hospital, I would have had to travel to hospital by public transport everyday which would definitely have had a detrimental effect on my respiratory condition…. especially since [I get worse] during the winter season" (63-year-old male) |
| | "I would have had a problem to travel to hospital every day for treatment, so it was definitely a more convenient option" (74-year-old female) |
| | "after the operation I could barely move so I cannot imagine what it would have been like if the nurses didn't travel themselves…probably my husband would have needed to take time off work to help out and it was enough that I had to stop temporarily from work to recover" (38 year old female) |
| | "I used the service twice and most definitely would use it again especially since it avoided a lot of transport issues for my family members" (62-year-old male) |
| | "I [patient's sister] couldn't imagine travelling every day to hospital to be with her, I can barely get by myself let alone" (84-year-old female) |
| **Flexibility of nursing visits** | "…since the hospital appointment clashed with the time, they usually administered the medicine, the nurses asked me to drop by their clinic which was very close to the outpatients' block and receive my daily dose there- I couldn't have been more grateful" (73 year old female) |
| | "…I managed to hit two birds with one stone, a medical appointment and my daily dose" (72-year-old male) |

| | |
|---|---|
| | "I phoned them once to tell them I wasn't going to be home at the usually time slot so instead they immediately made arrangements for me to take the dose at hospital. All I had to do was bring with me one of my medicine vials from home" (68-year-old male) |
| | "the nurses not only managed to work around my hospital appointments, but they even used to inform me in advance about an upcoming appointment and schedule a different time slot" (56-year-old male) |
| | "they used to take the blood samples on Saturday I was told on purpose so that when they have their weekly meetings, they can have a proper discussion about my health…I thought that was very organised on their part" (74 year old female) |
| | "I couldn't believe that not only did I get the opportunity to leave hospital and go home but when I told them that I'd be travelling abroad for health reasons, they gave my daughter who is an anaesthetist a detailed handover of my clinical situation, the medications and devices that she required to continue treatment whilst we were abroad and contact numbers should she need anything" (49 year old male) |
| **OPAT team resources: helpline** | "I was extremely grateful that the helpline was in place since on one occasion I wanted to speak to one of the nurses about a new symptom and I couldn't get hold of my usual general practitioner" (70-year-old female) |
| | "there was one occasion when I decided to phone the team just to confirm the visiting time" (53-year-old male) |
| | "one Sunday I felt an upsetting feeling in my chest and started to panic. I phoned the nurses' helpline and they told me to go to their clinic in hospital to make sure I was alright. It was very reassuring" (47-year-old male) |
| | "I phoned once because I saw a bit of bleeding near the device in my vein and they told me how to clean it, what to look for and to call them again if things changed…it was very reassuring" (50-year-old male) |
| | "had to phone the OPAT nurses since I had fever on one occasion and didn't know if I should be worried" (43-year-old female) |
| | "I thought that the medications would finish so I decided to call the nurses...they immediately assured me that |

| | |
|---|---|
| | they were going to get a new supply the following day following a meeting with the medics to make sure the treatment was not going to change" (61-year-old male) |
| | "I phoned the nurses to ask them to change the visiting time since I had to attend a funeral…they immediately saw to my request and popped by two hours after the usual time" (49-year-old male) |
| | "due to my lack of mobility I realised I wasn't able to cope at home anymore especially with a new-born, so I phoned the nurses to give them my mother in laws address for future visits" (38-year-old female) |
| **OPAT resources: PICC dressing** | "I would stress more on the availability of bigger 'sock' sizes for one's PICC line…in my case I had to use a plastic bag when having a shower" (73-year-old female) |
| **OPAT resources: Medications** | "I sent my husband to get my medications from home but thankfully the item was back in stock when I was discharged back home onto the service" (43-year-old female) |
| **Hospital Human Resources: conducting PICC insertions** | "I received false hope that I was going home since the person doing the PICC lines at that time was on leave and I had to wait an extra four days before I actually got it done and could go home" (63 year old male) |
| **Punctuality of nursing visits** | "I would shorten the established timeframe when they visit for example a two-hour window so like that, I can plan my daily tasks better" (64-year-old male) |
| | "maybe they do not need to introduce a new procedure whereby they call the patient before visiting but at least they can shorten the time frame at home for example to one hour rather than three hours" (48-year-old male) |
| | "if they called before coming, I would have made sure that I was already downstairs…rather than having to hurry down the stairs to open up for them" (78-year-old male) |
| | "they could start a system whereby they either phone exactly when they leave the previous patient's residence or if it's too tedious, they could phone only when they are going to arrive later than the established timeframe" (61-year-old male) |
| | "I would have preferred if they phoned before coming since it would help restrict the period of time I spent at |

| | |
|---|---|
| | home waiting for the nurse to arrive" (29 year old female) |
| | "It was difficult to accommodate the nurses when the time changed from 4pm to 1pm due to work related commitments" (57-year-old male) |
| | "I got to know that lack of staff was going to make my twice a day dosing impossible after a certain date but thankfully arrangements were made for a specific OPAT nurse to see to my afternoon doses which was perfect considering my lack of transport and mobility" (71-year-old female) |
| | "my visiting time changed mid-way throughout the treatment course, but I was told that a new patient was scheduled to use the service and was slightly problematic hence the delay" (59-year-old female) |
| | "my time was changed since a new patient requiring two visits a day was started…thankfully my employer was very accommodating" (53-year-old male) |
| | "the change in time occurred since a new patient was enrolled and they had to shift my time" (57-year-old male) |
| **Adverse events on patient morale** | "looking back, I would have preferred to stay in hospital because the infection got worse whilst I was at home and was a huge hassle to go back to hospital" (61-year-old female)<br><br>"I think it is important that the OPAT team emphasise more on the possibility of thrombosis and what a patient should look out for. I was lucky that the nurse was very sharp and noticed immediately but it might not be the case for someone else" (66-year-old female) |

Participants' quotes for extracted codes pertaining to the service provision stage

| **Axial Code** | Participants' discourse |
|---|---|
| **VAD removal** | "When it came to the removal of the PICC line I was extremely concerned but then the nurse decided to tell a joke and before I knew thing was out" (63-year-old male) |
| **OPAT team recruitment** | "I would suggest employing more staff to help the OPAT team with their outreaches to patient homes…. maybe in |

| | |
|---|---|
| | this way they aren't influenced when the workload starts to increase" (52-year-old male). |
| **Marketing and awareness** | "I think some more promotion would definitely do the service justice since most members of staff I came across seemed to be unaware of the service" (54-year-old female) |
| | "I had an outpatient appointment to monitor my hip bone recovery and the transport system was running late. I didn't have the helpline number on me so I decided to call the outpatients to see if they could put me through, but they kept passing me from person to person" (73-year-old male) |

**Appendix 6.1: Healthcare Professionals recruitment letter for focus group**

**Recruitment Letter for Healthcare Professionals**

Dear Participant,

My name is Sara Jo Bugeja and I am currently reading for a doctorate with Robert Gordon University. From the inception of the OPAT service, the Home Antibiotic Therapy team has played a pivotal role as a united multidisciplinary front to ensure patients' safety and the best clinical outcome. As part of my study entitled 'The Application of a Human Factors Approach to the Evaluation of a Novel Outpatient Parenteral Antimicrobial Therapy Service', I would like to organize a meeting to discuss the positive and negative facets of the service to serve as an educational experience from which we will further enhance service provision.

I will act as the meeting facilitator during this session. The discussion will be audio-taped, and recordings securely stored on a digital audio-recorder locked in a cabinet at the pharmacy department of Mater Dei Hospital. I will keep the recordings until I transcribe them and will then be destroyed. The transcription will not contain identifiable data which will be processed in line with the General Data Protection Regulation (GDPR) and implementing national legislation. Please note that your participation is voluntary, without foreseenable physical and/or psychological risks and you can withdraw at any point during the study. Moreover, you have the right to access, rectify and erase data. All data collected will not be able to identify you in any published material. Access to data will be limited to the researcher, supervisors and examiners.

Should you wish to participate kindly use the following means of communication namely email s.bugeja@rgu.ac.uk or pager on 0035679847232. In case of any queries, kindly use the latter information to make contact prior to confirming participation.

Kindest Regards,

Sara Jo Bugeja

_____ _____

Signature Date

**Researcher:** Sara Jo Bugeja (s.bugeja@rgu.ac.uk; 79847232)
**Supervisor:** Dr. Kurt Magri (gmagr02@um.edu.mt, 23401881)
**Foreign Supervisory team:** Dr. Helen Vosper (h.vosper@rgu.ac.uk); Prof Derek Stewart (d.stewart@rgu.ac.uk), Prof. Alison Strath (a.strath@rgu.ac.uk)

**Appendix 6.2: Healthcare Professionals Consent Form**

**Title of Study:** The Application of a Human Factors Approach to the Evaluation of a Novel Outpatient Parenteral Antimicrobial Therapy Service

**Researcher:** Sara Jo Bugeja (s.bugeja@rgu.ac.uk; 79847232)

**Supervisor:** Dr. Kurt Magri (gmagr02@um.edu.mt, 23401881)

**Foreign Supervisory team:** Dr. Helen Vosper (h.vosper@rgu.ac.uk); Prof Derek Stewart (d.stewart@rgu.ac.uk), Prof. Alison Strath (a.strath@rgu.ac.uk)

Participant Identification Number:

I, the undersigned, confirm that (please initial on each line as appropriate):

| | | |
|---|---|---|
| 1. | I confirm that I have read the recruitment letter dated 14.7.2018 (version 1) for the above study. | ___ |
| 2. | I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | ___ |
| 3. | I voluntarily agree to participate in the project and understand that there are no related physical and/or psychological risks | ___ |
| 4. | I voluntarily agree to give my age, gender, profession and years of experience in my current position | ___ |
| 5. | I understand I can withdraw at any time without giving reasons and that I will not be penalised for withdrawing nor will I be questioned on why I have withdrawn. | ___ |
| 6. | The procedures regarding confidentiality have been clearly explained (e.g. use of names, pseudonyms, anonymisation of data, *etc*.) to me. Data will be pseudonymised and stored apart from any codes and personal data to ensure confidentiality | ___ |
| 7. | I agree to my focus group being audio/video recorded. I understand that anonymised quotations from this interview may be used for presentations and publications. | ___ |
| 8. | The use of the data in research, publications, sharing and archiving has been explained to me. I agree for my information to be stored on RGU servers for 5 years. | ___ |

| | | |
|---|---|---|
| 9. | I was informed that under the General Data Protection Regulation (GDPR) and implementing national legislation, I have the right to access, rectify, and where applicable erase the data concerning me | __ |
| 10. | Access to the collected data will be limited to the researcher, supervisors and examiners | |

_____ _____ _____

Name of Participant Signature Date

**Researcher:** ***I confirm that I have explained to the participant named above, the nature and purpose of the study.***

_____ _____ _____

Name of Researcher Signature Date

Taking Consent

**Appendix 6.3: Topic Guide for the Focus Group Session**

**Title of Study:** The Application of a Human Factors Approach to the Evaluation of a Novel Outpatient Parenteral Antimicrobial Therapy Service

**Participant Demographics**

Age: _____

Gender:_____

Profession:_____

Years of experience:_____

**Discussion Guide**

Were you expecting less/more patients to be flagged for the service?

Were you happy with the way referral processes took place?

Do you think referrals could be improved?

Do you think more patients could have been referred but were declined due to the service's limitations? If yes, what were the limitations?

Are you content with the number of antibiotics available for use within the service? Do you think this number should increase?

Once daily dosing was set as the standard regimen to be practiced for all patients. Should this be increased, what opportunities/limitations do you envisage?

MRSA screening was deemed as one of the prerequisites prior to discharging a patient. Was this always carried out? If no, why?

A general practitioner in the community was another prerequisite prior to discharging a patient. Did they collaborate? Did they hinder or complicate a patient's prognosis?

Considering the number of readmitted cases, did you expect such a result? Could an intervention prior to discharge/at home by the team avoid a readmission from happening?

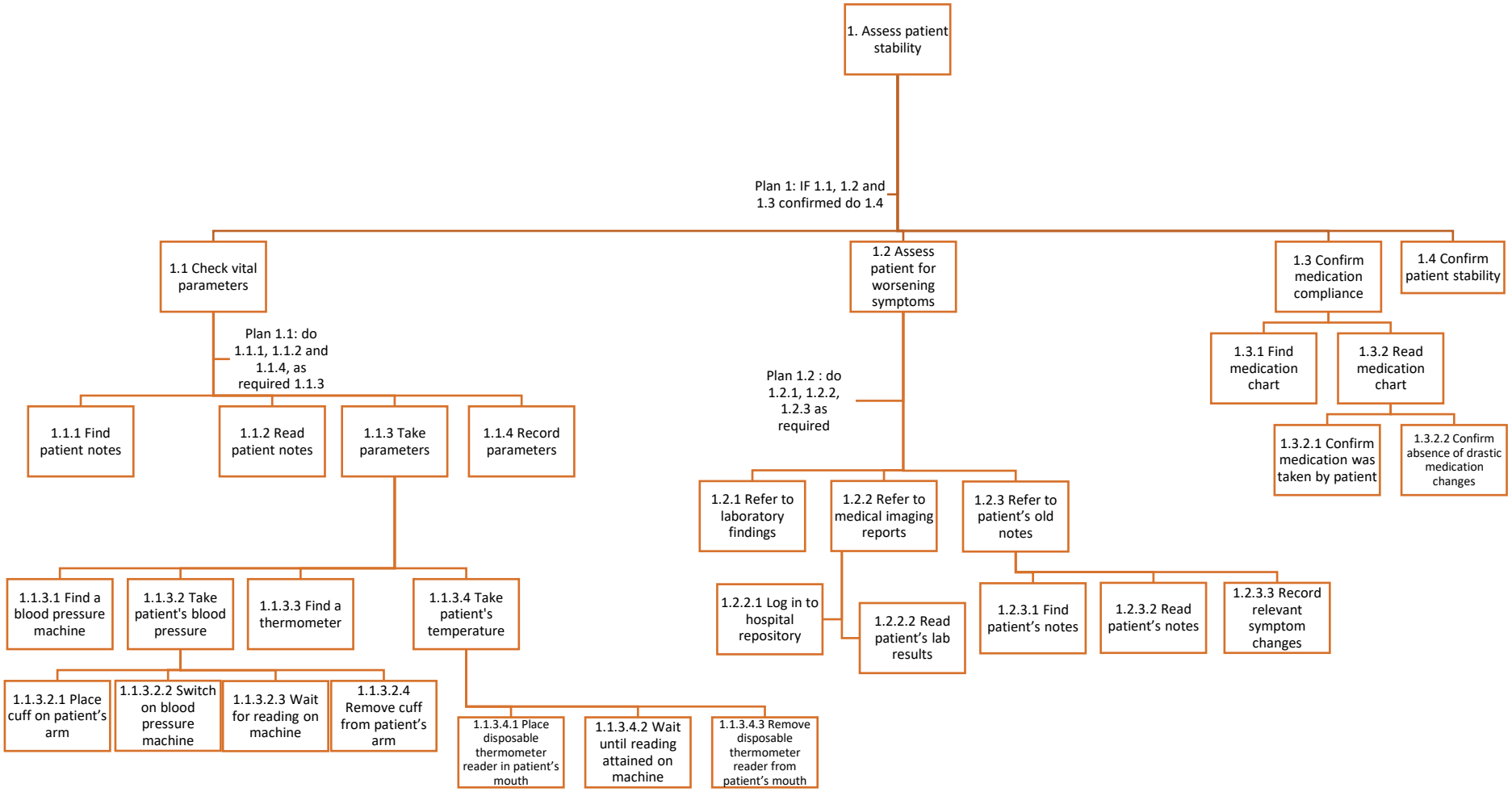
Did you encounter any complications which were related to the patient's eligibility criteria e.g. residence, social situation, co-morbidities which prior to discharge were not considered to be problematic?

Would you like to comment on any other aspect of the service not previously tackled in the questions above?

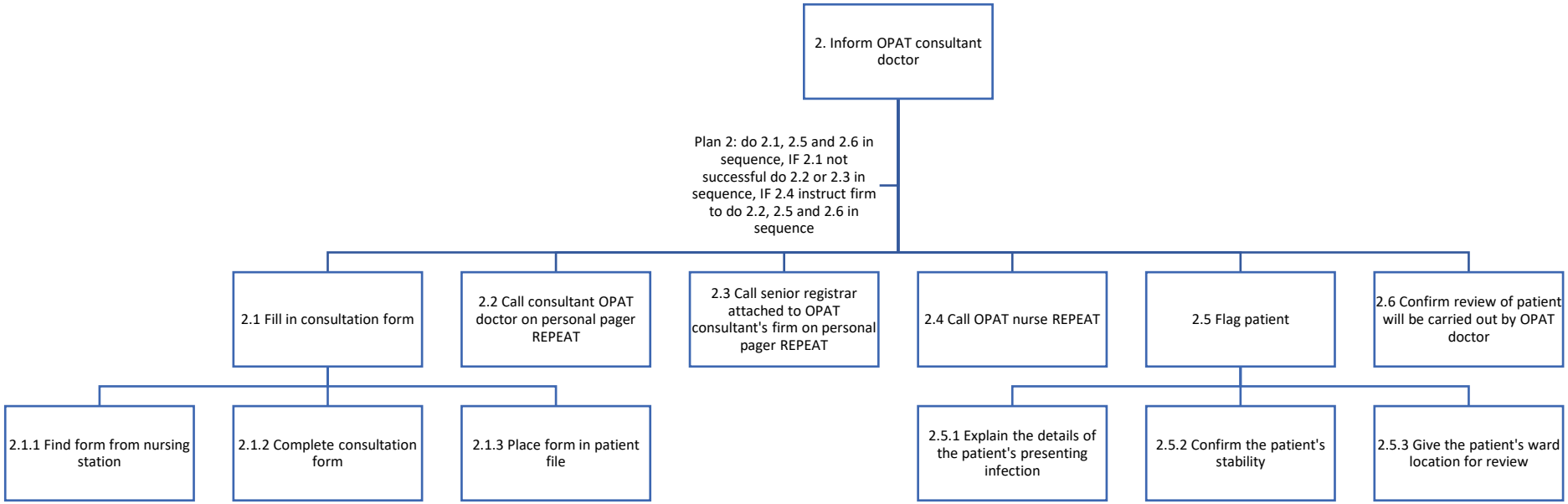
In your opinion, which is the greatest strength of the service?

In your opinion, which is the greatest limitation of the service?

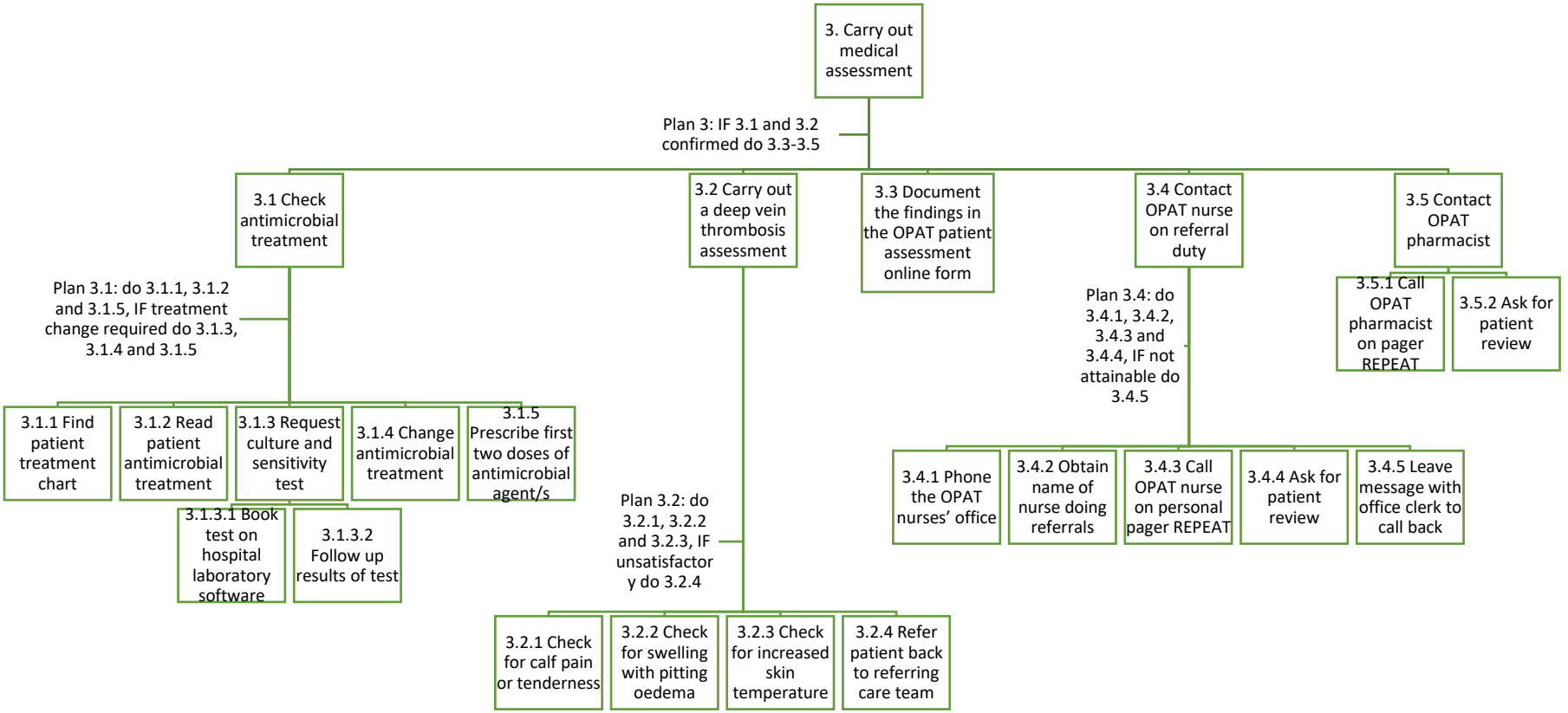
## Appendix 6.4 Hierarchical task analysis for tasks related to assessing the patient's stability



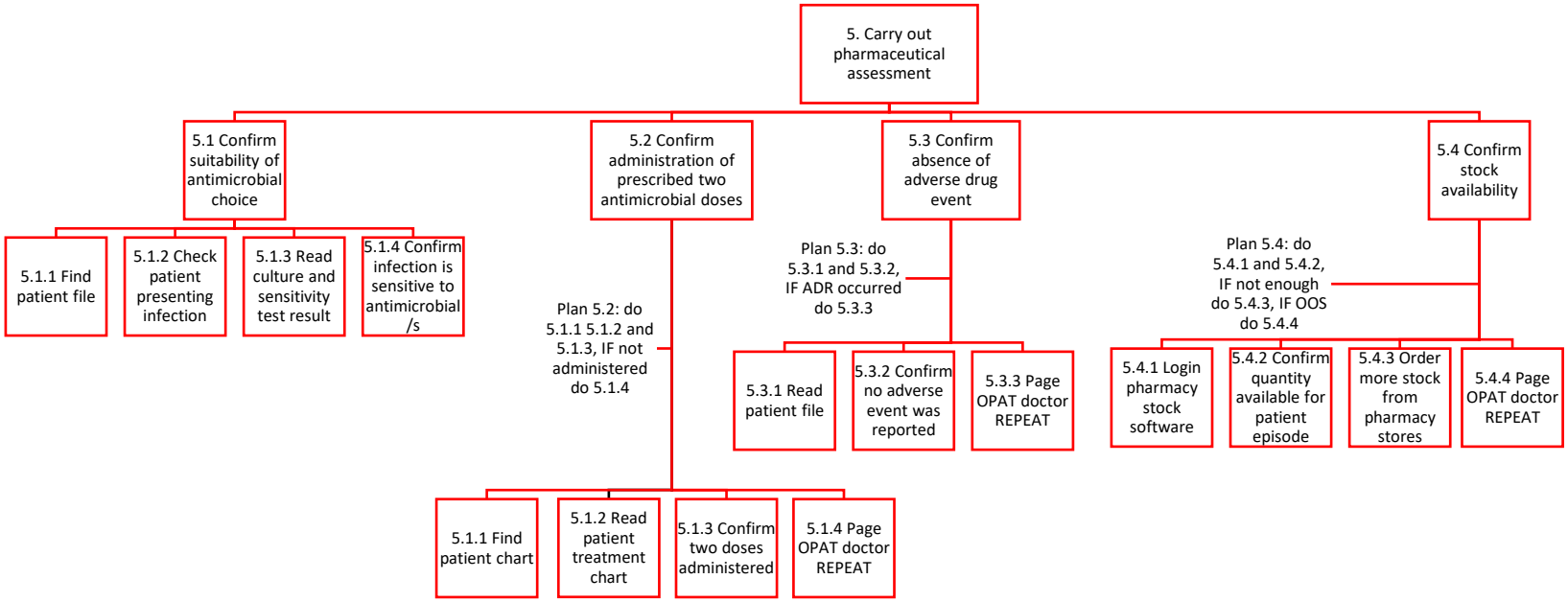
## Appendix 6.5 Hierarchical task analysis for the tasks related to informing the OPAT consultant doctor about an eligible patient



## Appendix 6.6 Hierarchical task analysis for the tasks related to the execution of the medical assessment



## Appendix 6.7 Hierarchical task analysis for the tasks related to the execution of pharmaceutical tasks



**Appendix 6.8 Hierarchical task analysis for the tasks related to accepting the patient**