What data should be captured during IV treatment in community to answer questions which various stakeholders might have?

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A dissertation submitted to the University of Dublin in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics

Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university.

Signed

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Abstract

The objective of this research is to explore the potential for secondary use of community nursing intervention data. There is potential to capture ancillary data that can be leveraged to inform all stakeholders where the community nursing interventions are managed electronically (e.g. OPAT). This research had explored this potential in the context of community IV treatment. It looked at the questions which the various stakeholders wished to answer (the ones they identify explicitly and ones which emerge from literature or questions identified by the author), and what data that can be collected or is required to answer them.

A qualitative research method is chosen. Two different types of questionnaire sets were prepared for the eight identified stakeholder groups for the semi structured telephonic interviews. The participants were given an opportunity to discuss their needs for information irrespective of the data that is or is not currently captured electronically during the delivery of IV treatment at home. The captured interview data was systematically analysed to elicit requirements and themes were obtained. Each theme was further analysed to identify potential analysis questions. The second part of analysis was related to stakeholder interviews. In that regard, two different types of questionnaire sets were prepared for the eight identified stake holders groups for the semi structured telephonic interviews. The captured interview data was systematically analysed to elicit requirements in the form of potential analysis questions. After that, a deduplication process was performed on all identified analysis questions to obtain a unique list of analysis questions. At the end, a comprehensive data model was produced (based on the findings from interview and literature review) to answer uniquely identified analysis questions which answered the research question.

The outcome of the research can help improve patient care from the perspective different stakeholders identified in this dissertation, inform the development of new community nursing software solutions and inform improvements to existing software solutions' data capturing and reporting functions.

Dedication

I would like to dedicate this dissertation to my inspirational and most loving mother Shaffia Maalik and my father

Mohammad Maalik

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List of abbreviations

IV	Intravenous
WHO	World Health Organization
OPAT	Outpatient Antimicrobial Treatment
PCA	Patient-Controlled Analgesia
KPI	Key Performance Indicator
HSE	Health Service Executive
BSAC	British Society of Antimicrobial Chemotherapy
EOC	End of Care
BMI	Body Mass Index
SPID	Specialist Infectious Disease
PICC	Peripherally Inserted Central Cannulas
TC	Tunnelled Central
TCP	Temperature Control Pharmaceutical
DRMCU	Department of Respiratory Medicine Children University
NWPD	Negative Pressure Wound Dressing
IDSA	Infection Disease Society of America
NHS	National Health Service
AIDS	Acquired Immunodeficiency Syndrome
PCA	Patient-controlled Analgesia
TPN	Total Parenteral Nutrition
SMAC	Standing Medical Advisory Committee

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1 Introduction

1.1 Background to the research topic

The last two decades have seen the beginning of key healthcare reforms taking place around the world particularly in WHO European member states. Healthcare systems in most of these countries are in transition with the focus is on shortening patients' stays at hospital by treating patients in community for number of conditions. Early patient discharges from hospital are creating opportunity and space for more acutely ill patients to be treated in the hospitals. Under the WHO guidance, increasing ageing population, social and financial pressures are driving governments gradually to focus more on treating patients in community (Margaret F. Alexander et. al, 2010). Today in the world, there are more than 19 million trained nurses and midwives playing a central role in delivering care to patients in multidisciplinary roles (Linda Sarna et al., 2012).

A nurse administering IV treatment to a patient in their own home performs a number of semi-structured steps. Much data is generated at each step over the course of the treatment starting with, the initial visit to the patient's home, subsequent repeat visits and the final visit on completion of the IV treatment (HSE. 2015, TCP. 2015). Due to technological advancement it is now possible to capture a complete set of 'patient treatment activities' performed by nurse in community (Valentiatech, 2015). The data captured from stakeholders could be used to answer a number of questions from the various perspectives of stakeholders groups e.g. patient, community nurse, community nursing agency, hospital consultant, GP, drug manufacturer and HSE.

1.2 Intravenous (IV) Treatment

According L. Williams et al. (2009), an intravenous treatment (IV) is one of a number of treatments for various conditions which are delivered to a patient in the inpatient or outpatient healthcare setting. IV treatment can be delivered to patient by a community nurse, GP or through an ambulatory care unit. In some cases patients are trained to self-administer IV at home. Few of such treatments includes:

Table 1: List of IV treatment Conditions

Condition	Treatment
Acute or chronic infection	Antibiotics
Cytomegalovirus	Antivirals
Serious fungal infection	Antifungals
Haematological disorders	Blood/platelets
Cancer	Chemotherapy
Nausea/vomiting	Anti-emetic
Acute/chronic pain	Analgesia
Gaucher's disease	Ceredase
Dehydration	Intravenous fluid
Hyperemesis	Intravenous fluid

1.3 IV Treatment in Community

IV therapy is practiced frequently in the hospitals, often it is the reason for admission to hospitals globally. In context of scarce resources, prolonged waiting lists, and increasing demand of acute

hospital beds is resulting into building up pressure on healthcare providers to start treating patients in community for some conditions that require IV therapy (Kayley J., 1999). Healthcare providers foresee a lot of potential for new service delivery models to expedite treatment and improve responsiveness (Department of Health UK, 2001). New research findings in the field of technology and medicine with pharmacokinetic profiling e.g. some antimicrobials with multiple dose frequencies daily has enable IV treatment in community a more viable and realistic option going forward (Kayley J. *et al*, 1996).

Like many other countries in the world, Ireland is also moving towards providing efficient, safer, effective and viable care to patients in community, as result reducing work load on the acute healthcare settings in secondary care (Liam Doran, 2013). National OPAT program is another major initiative by HSE to treat patients in community for cellulitis and cystic fibrosis conditions including additional services e.g. negative pressure wound dressing and blood specimen collection. HSE uses services of the community infusion teams as well as private nursing agency to deliver IV therapy at home. As per the available data 9011 bed days were saved in the year 2006 and 2008 (HSE, 2015) while another 51100 bed days saved in 2013 (TCP, 2015).

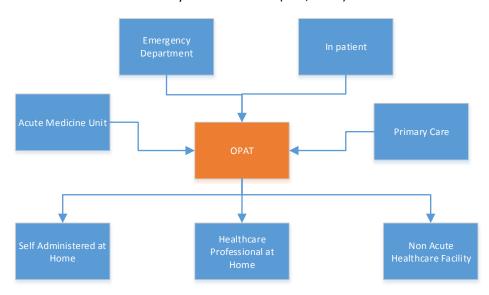


Figure 1: OPAT Referral Model

National Haemophilia program is another HSE project which serves about 2000 haemophiliacs in community for the IV treatment. In this project patients are trained to perform self-infusion at home while the drugs are delivered through a well-coordinated and sophisticated supply chain delivery model all the way from manufacturing unit to patient home. The service resulted in provision of better patient management at home, medical errors reduced from 12 to 0, drug wastage reduced from €90,216 to €0 and €5,000,000 worth of drugs were removed from the supply chain due to the an optimized service delivery model (GS1, 2010).

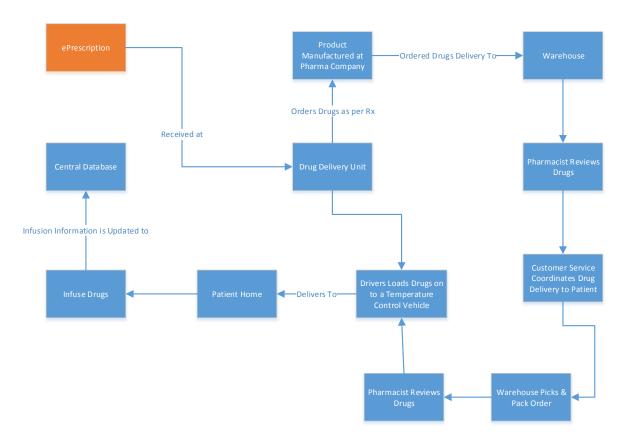


Figure 1: Haemophilia supply chain delivery and IV infusion at home model

There are number of other IV treatment services being delivered in community by different private healthcare providers for a range of different conditions which are discussed in greater detail in the literature review chapters.

1.4 Research Question

What data should be captured during the administration of IV treatment to a patient at home delivered by a community nurse to answer the questions which the various stakeholders might have?

1.5 Research Objective

The objective of this research is to explore the potential for secondary use of community nursing intervention data.

There is potential to capture ancillary data that can be leveraged to inform all stakeholders where the community nursing interventions are managed electronically (e.g. OPAT). This research will explore this potential in the context of community IV treatment. It will look at the questions which the various stakeholders might wish to answer (both ones they identify explicitly and ones which emerge from literature), and what data that can be collected or is required to answer them.

1.6 Motivation

Author is working as a project manager in an IT company that develops healthcare software. He has been part of the Outpatient Antimicrobial Treatment project development and rollout in Ireland.

Author is motivated by the need for better and more widespread use of information technology to support IV treatment at patient home, while exploring the benefits to health service stakeholders in terms of analysing the captured information.

1.7 Scope

The scope of this research project has following potential outcomes:

- 1. A comprehensive dataset for in community treatment that could be used for the development of new community healthcare system for IV administration at patient home
- 2. Insight into the dataset to show the results that can be achieved by analysing the captured dataset from the perspective of different stakeholders
- 3. Any potential information gap between the stake holders prospective questions and the currently captured data in IV treatment in community
- 4. Identification of potential missing information (as per point 3) which if added to the dataset could result in further improvements to the outcome of patient treatment, as well as improvements in the existing community healthcare systems

1.8 Dissertation Outline

This dissertation will describe following sections in detail:

- 1. Chapter 1: Introduction and background to the research topic
- 2. Chapter 2: Literature review on the IV treatment in community and identification of potential analysis questions from literature
- 3. Chapter 3: The research methodology used to answer the research question
- 4. Chapter 4: Stakeholder Interviews and identification of potential analysis questions from Interviews data
- 5. Chapter 5: Unique analysis questions, interview and literature review outcome correlation
- 6. Chapter 6: Conclusion, future recommendations and limitations of the study followed by references and appendices.

2. Introduction to Literature Review

A literature review allows researcher to gain in depth understanding of the necessary knowledge related to research topic. This chapter describes the use of secondary health data briefly and explores in detail the published material on key concepts related to patient's IV treatment in community. The data collected as result of a comprehensive research on the topic is broken into themes by performing qualitative analysis of the found information.

2.1 Key Concepts

The key concepts that has been reviewed includes Intravenous therapy, outpatient treatment, nurse led model of community nursing, outpatient antimicrobial treatment program (OPAT) and identification of potential analysis questions from the literature review.

2.1.1 Outpatient IV Treatment

Outpatient IV treatment is one of the most widely used therapy to delivery IV treatment to patients in community, it allows patients requiring antimicrobial treatment in an outpatient setting. Antibiotics and other IV treatments can be administered to patients in an ambulatory care unit, at patient home by a specialist nurse, by carer or self-administered by the patient (Ann L N Chapman, 2013). Use of outpatient antimicrobial treatment is currently being used an effective IV service delivery model to number of infections such as cellulitis, resistant urinary tract infection, cystic fibrosis low risk neutropenic sepsis and central nervous system infections (Bazaz R et al., 2010).

2.1.2 Secondary Use of Health Data

Secondary use of health data is the different applications of personal healthcare information for indirect uses of the healthcare delivery information. It encompasses number of activities such as data analysis and research to find the appropriate quality and safety measures. It also includes secondary use of data for provider accreditation or certification, public health, payments marketing and various other business applications. The secondary use of health data can improve awareness about disease and possible treatments, expand knowledge about effectiveness of healthcare systems. However, there are complex political, ethical and social issues related to healthcare data which limits its secondary use (C. Safran et al. 2006).

2.2 Literature Review

An extensive qualitative review of literature was carried which resulted into 5 different themes. This section describes each theme in detail followed by a conclusion at the end of this chapter.

2.2.1 Service Delivery

There are three different types of models which have proven to be effective for the delivery of outpatient IV treatment (Tice AD et al. 2004). In first model, patient visits one of the acute care setting e.g. an outpatient clinic frequently for the treatment of IV, this model is one of the most widely used in developing countries (P. Berman, 2000). However, governments globally are trying to develop processes to encourage nurse lead patient IV treatment in the community (E. G. Muldoon et al. 2014). The last model "patient self-administration" involves patients in managing their own care, it also allows more flexibility of timing, dosage frequency and reduction in cost. The literature shows that patient's "self-administration" of IV therapy is equally safe as the IV therapy administered by a healthcare practitioner in community (Matthews PC et al. 2008, Barr DA et al. 2012). All three models are becoming increasingly common for the delivery of IV therapy in community. However, the treatment model is chosen and customized based on patient's unique circumstances (Tice AD et al. 2004). As per literature, predominantly the most outpatient IV therapy services are based in acute hospital's SPID units (Chapman ALN et al. 2009, Barr DA et al. 2012, Esposito S et al. 2007, Amodeo MR et al 2009). IV therapy services may also be setup by hospital specialist teams, acute medicine or emergency units (Corwin P et al. 2005).

The outpatient IV treatment model defines the type of IV access. Various available options includes insertion and removal of "butterfly" needles for every dose, peripheral cannulas for short treatment duration, PICC or TC lines for longer IV antibiotic courses. Other options include infusions or bolus injections depending on infection severity and the prescribed antimicrobial agent. Infusion requires additional training and administration due to the higher dose administration (Royal College of Nursing 2010). The availability of different types of delivery devices have given patients greater flexibility to perform their routine daily activities. For instance, patient can pocket carry a portable elastomeric infusion device to deliver continuous infusions for a whole day (Howsden BP et al. 2002).

It is evident from several published studies that an outpatient treatment delivered through a proper service structure is safer and effective than any informal or temporary arrangements. The aim of having an effective delivery and governance procedure is to minimize risks linked to delivery of IV in community (Tice AD et al. 2004, Howden BP et al. 2002 and Nathwani D et al. 2000). The BSAC and UK senses have published recommendations for the outpatient IV treatment service delivery structure, patient selection criteria, monitoring during treatment episode and the outcome recording on treatment completion. BSAC suggests that an outpatient IV therapy team should ideally consist of a

doctor, a specialist nurse, microbiologist and pharmacist. The referring doctor should take responsibility of overall decision making related to patient care (Laura JV P. 2014).

Selection of the suitable patient is critical to all outpatient IV service delivery models. An infectious disease specialist consultant decides whether a patient should be referred to an outpatient treatment or not. Generally, the selection criteria includes patient's clinical state, living circumstances, other associated risks, patients consent, availability of required drugs and nurse depending on service delivery model (M. R. Amodeo et al. 2009). A Scottish study showed that about 86% of patient's treated in the hospitals were found suitable to be treated in the out of hospital setting for infections, the surveyed patients were also found to be interested in having full IV treatment in the community (RA Seaton et al. 1999).

2.2.1.1 Prospective Analysis Questions

Following table shows the prospective analysis questions identified by qualitative analysis of the service delivery theme, details of this analysis are attached in the Appendix D.1.

Table 2: Service Delivery Analysis Questions

ID	Question
1	List of patients or sum of patients referred from one or multiple hospital departments?
2	a) Complete audit trail of a patient visit with each of the data element e.g. number of patients visits over a period of time?b) Frequency of patient visits?c) Number of visits carried out by a nurse (other parameter includes nurse type and organisation?
3	Comparison between self-administered IVs VS carer administered IVs from the safety and cost saving point of view?
4	What are number of devices used for a type of infusion in order to find consumption and cost of peripheral devices required during IV treatment?
5	What is the percentage of patients not accepted for outpatient treatment by rejection reason?
6	What are the total number of patients accepted for outpatient treatment in each month?
7	What is the percentage of patients who are currently receiving inpatient IV treatment can be safely treated in outpatient settings?

2.2.2 Clinical Effectiveness

Analysis of available data shows that the most commonly treated infections in community for the IV treatment are soft tissue sepsis and cellulitis (Chapman ALN et al., 2009). In England Cellulitis accounts between 1 to 2 % of the emergency cases which is about 80000 annual admissions (Phoenix G, 2012). About 30% patients who visited hospitals do not have severe systemic sepsis that require inpatient treatment. These patients could have been treated in community for moderately sever Cellulitis infection by administering IV antibiotics in community (CREST, 2005).

Cefazolin is an antibiotic used for treating number of infections. A randomised trial involved patients administered Cefazolin twice daily through IV in the inpatient and at patient home setting showed no major difference in the outcomes and overall duration of IV therapy but showed improved patient satisfaction with home treatment (Corwin P et al., 2005). However, large data study shows that once daily Ceftriaxone has proven to be effective and safe. It also showed number of other positive clinical outcomes which has lead the most wide spread use of Ceftriaxone for the IV treatment of Cellulitis in

the UK (Duncan CJA et al., 2012). The nurse led model of patient IV treatment in community is proving to be clinically effective for management of Cellulitis (Seaton RA et al., 2005). The available data shows that about 25% patients developed complications during the course of their IV treatment in community, some of the issue were life threatening line infections other were mild diarrhoea associated with the administered antibiotic (SE Parker et al. 1998, D Prete et al. 1999). However, only 10% of patients discontinue treatment after developing sever complication (AD Tice 1996). Patient readmission were noted from 4% to 12% for different reasons which emphasizes the need for a proper pathway for readmission (G Milkovich 1995, S. Parker et al. 1998, D Nathwani et al. 2000 and F D Lalla 1998). The research suggests that there is an increased number of patients who developed complications (particularly changes related to blood parameters) for longer treatment durations (AD Tice 1996 and S. Parker et al. 1998). A study carried out in Ireland showed that 98% patients were happy to receive IV treatment in community while 92% of the patient termed quality of care they received was excellent (Brian Whately, 2013). In another study from DRMC university hospital analysed the outpatient IV treatment outcomes in paediatric population as effective and safe (L. Glackin et al., 2014).

A study published by AR Berendt et al. (1996) shows that IV therapy administered at home for various infections can be delivered safely using the existing community or district nursing network in NHS (AR Berendt et al 1996).

2.2.2.1 Prospective Analysis Questions

Following table shows the prospective analysis questions identified by qualitative analysis of the clinical effectiveness theme, details of this analysis are attached in the <u>Appendix D.2</u>.

Table 3: Clinical Effectiveness Analysis Questions

ID	Question
1	List of patients referred for outpatient treatment for an IV treatment by diagnosis?
2	What is the percentage of patients presenting to hospital with problems that can be treated in community for IV treatment?
3	What is the percentage of patients by diagnosis (suitable for community IV treatment) having different infection severity levels?
4	Patient improvement percentage comparison between home vs inpatient care setting by using same drug and IV infusion frequency?
5	What is the percentage of adverse events reported during the use of same drug and IV infusion frequency in the home vs inpatient care setting?
6	What is the patient satisfaction level comparison between home vs inpatient care setting in general (as well as comparison by using same drug and IV infusion frequency in both care settings)
7	What is the percentage of most commonly used antibiotics for outpatient IV treatment?
8	What is the average recovery time period for each prescribed drug for a diagnosis (based on the infusion frequency and infection severity)
9	What is the percentage of adverse events reported against each drug used for outpatient IV treatment over a period of time?

2.2.5 Patient Monitoring

Patient treatment in the community can be termed as hospital outside a hospital, literature review shows that it brings number of challenges regarding patient monitoring during the entire course of treatment in community which is mainly due to limited clinical observation especially in comparison to an inpatient setting (FDA 2013, A. Kumar et al 2006, and M. Morgan et al 2007). The need of having effective patient monitoring procedure is well known and recognised by the clinicians, the findings from analysis of available data helped in establishing a working group to produce comprehensive recommendations about patient progress monitoring and rapid adverse event response in an outpatient setting (Jevons MP 1961, Wenzel RP et al. 1991). It is critical for all clinicians involved in patient care in the community that an instance of complication require more effective, fast and appropriate response when treating patients in a non-hospital setting. A study shows that by early detection and continued monitoring of the developing complication signs can help reduce number of patients discontinue from the outpatient treatment (AD Tice 1996). Usually, progression of a complication if not treated appropriately results into discontinuation of patient treatment from the community setting, especially patients with endocarditis require more close monitoring as they more often develop health complication during the course of IV treatment (MC Rahimy et al. 1999). A study suggested that there is a substantial need to effectively monitor and examine instances related to patient's unplanned access to advice, the available data analysis shows that there were 6% patients who requested unplanned home visits while another 6% patients requested urgent telephone consult (D Nathwani et al. 2000).

There are number of research publications advocating more frequent patient clinical reviews, findings suggest that patient receiving outpatient treatment for cellulitis and soft tissue infection should be clinically reviewed almost on daily basis or at the end of each dose administration, this will allow clinicians to rapidly switch patients from IV to oral therapy if clinical indicated (G Milkovich 1995, RA Seaton et al. 1999, D Nathwani 1998). Patient's daily treatment reviews may be performed by a trained specialist nurse instead of a doctor (RA Seaton et al. 1999). Two studies showed that stable patients could be less frequently monitored especially when they are on prolonged IV antibiotic courses (AD Tice 1996, S. Parker et al. 1998). Other studies suggests that patients on prolonged IV treatment in community should be regularly clinically reviewed, however frequency of reviews should be decided by the local care team (W Balinsky et al. 1998, AD Tice 1996, D Nathwani 1998). Some published studies recommends twice monthly reviews for stable patients in long term while once weekly review for unstable patients at the initial stage of their community based IV treatment (G Milkovich 1995, S. Parker et al. 1998, MC Rahimy et al. 1999, AD Tice 1998).

A working group advocated that patients progress should be assessed at weekly multidisciplinary meetings, their presented recommendations suggested number of patient care aspects that require close monitoring during the course of treatment e.g. biochemical and haematology test results, adverse events and NPWD progress. The regular clinical assessment reviews can help collection of rich clinical data for greater in depth analysis of the overall patient treatment outcome monitoring (Ann L. N. Chapman et. al, 2012). Some additional tests such as creatinine kinase's result monitoring may also be required for patients on daptomycin (C Donaldson et al. 1992). Other recommended patient monitoring on long term aminoglycoside includes vestibular function (PG Davey et al. 1996, C Rahimy et al. 1999, DZ Louis et al. 1999).

Table 4: Patient Monitoring Analysis Questions

Following table shows the prospective analysis questions identified by qualitative analysis of the patient monitoring theme, details of this analysis are attached in the <u>Appendix D.3</u>.

ID	Question
1	What are the number of unplanned occasions when patient contacted for clinical advice during the course of IV treatment in community?
2	What is the percentage and list of patients receiving IV treatment in community setting reported an adverse reaction?
3	What is the percentage of adverse events by reason and severity level?
4	What are the percentage and list of adverse events that could have be prevented by effective early monitoring and interventions?
5	What is the percentage and list of patients discontinued from outpatient treatment?
6	What is the percentage and list of patients readmitted?
7	What is the percentage and list of patients who did not followed the formal readmission pathway?
8	List of patients with reason the formal readmission pathway was not followed?
9	What is the percentage and listing of patients who requested for unplanned urgent phone advice?
10	What is the percentage and listing of patients who requested for unplanned home visits?
11	What is the percentage of adverse events in less frequently monitored patients?
12	What are the common outcomes that appear during the discussion with patients over the course of their IV treatment?

2.2.5.1 Clinical Governance

According to ALN Chapman et al. (2012) number of research papers and guidelines recommends of importance of monitoring patient treatment outcome data by having local dedicated database. BSAC also maintains a national database of OPAT outcomes for research and analysis of the different aspects of the service (A R. White, 2012). Outpatient treatment model require equally sophisticated clinical governance model as for inpatient care setting. This can ideally be achieved by having dedicated team to centrally coordinate all service delivery and management activities. Clinical governance and monitoring existing aspects of outpatient IV service delivery allows not only surveillance but also helps in the evaluation of the treatment outcomes (SMAC, 1998).

ALN Chapman et al. (2012) recommends that it is critical to monitor at least minimum patient's clinical status, administered antibiotic, any adverse events, overall treatment episode outcome, bacterial infection status and any additional outcome measures.

Table 5: Clinical Governance Analysis Questions

Following table shows the prospective analysis questions identified by qualitative analysis of the clinical governance theme, details of this analysis are attached in the <u>Appendix D.4</u>.

ID	Question
1	What is the percentage and list of patients by clinical outcome status (improved, clinical failure or no change)?
2	What is the percentage and list of patients by bacterial infection status (culture negative, persistent pathogen or new pathogen)?
3	What is the percentage and list of patients by programme outcome (treatment completed as planned, or reason for non-completion)?
4	What is the percentage and list of patients by antibiotic use (course completed as planned, or reason for non-completion)?
5	What is the percentage and list of patients by vascular access complications?

6	What is the percentage and list of patients by additional outcome measures (return to work, survival status or performance against physician expectations)?
7	What is the percentage and list of patients admitted to hospital as result of outpatient treatment failure?
8	List of patient monitoring outcomes after completion of treatment?
9	What is the average satisfactory level of patients about their outpatient IV treatment?
10	How good patient's quality of life improved over the course of treatment?
11	Which staff involved in outpatient IV treatment have missed one or more service related training sessions?

2.2.7 Treatment Outcome

In Ireland 9011 bed days were saved by successfully treating 909 patients in the community which is about 10 days per patient. Analysis of the available inpatient data for 2009 shows that there were number of patients treated in hospital for the conditions that could have been effectively treated in the community by an outpatient IV treatment program. A well-organized outpatient IV treatment service delivery program can result into reduction in admission and patient stay at hospital while treating some of the conditions like cellulitis, endocarditis, osteomyelitis, pyelonephritis, septic arthritis and pneumonia in community (HSE, 2014). A study carried out by Brian Whately (2013) in partnership with TCP explains that there were 1680 and more patients requiring IV antibiotics to treat a range of different infections were able to spend 18221 less days in hospital by successfully receiving their IV treatment at home. A retrospective review was conducted by DMRC university hospital of 3 years of outpatient paediatric respiratory unit. As per the findings a total 3688 days of antibiotics were successfully administered during 362 episodes of care for 30 children having cystic fibrosis and remaining 2 had pneumonia, whereas only patient was readmitted after completion of treatment. (L. Glackin et al. 2014).

Usually patients on outpatient IV treatment were able to discharge in 2nd week for viridans streptococci, while in 3rd week of treatment due to S. aureus, hospital stays were extended for patients who required surgical procedures. In this study, the researchers found outpatient IV treatment effective as they did not come across any instance of treatment failure case. There were two deaths noted due to other causes (not related to treatment) post treatment completion, other causes in the treatment follow-up period were unrecognized as New Zealand has nationwide database of mortality register with limited information (M. R. Amodeo et al, 2009).

Historically, there has been lot of data generated from the cost-benefit context on OHPAT in North America. Lately, more data is becoming available from the European countries for the limited out of hospital patient IV treatment analysis. For instance, retrospective data analysis of patients with SSTI over the period of 1 year showed most patients did not develop complications, on average each patient occupied 5 hospital bed days. As per an estimate from this study about 606 bed days could have been saved for alternate use even if 75% of the admissions were treated in community. In Scotland an estimated £0.65 million can be saved if one out of 4 average hospital bed days are saved by treating patients with cellulitis or erysipelas in community care setting (D. Nathwani et al. 2000).

Patient treatment in community has lot of potential in terms of providing a cost-effective, safer and better care to patient without compromising care quality. The use of outpatient IV treatment model is likely to continue to expand in many countries for number of reasons such as patient choice and cost savings etc. The combination of primary and secondary care services will create opportunity and space to treat acute patients in hospital on high priority, while treating number of conditions in community such as infections (Ann L N Chapman et al. 2013).

Table 6: Quality of Care Identified Analysis Questions

Following table shows the prospective analysis questions identified by qualitative analysis of the quality of care theme, details of this analysis are attached in the <u>Appendix D.5</u>.

ID	Question
1	What are the number of successfully treated patients in community for IV treatment?
2	What are the number of hospital bed days saved by successful treatment of the conditions in community?
3	What are the percentage and list of patients discharged in 2nd and 3rd week of the treatment?
4	What are the number of patients who could not recover post in community treatment?

2.2.8 Adverse Events

Adverse events monitoring, treatment and measures to reduce such events from happening is the most critical aspect of patient treatment in community. The need of having effective patient monitoring procedure is identified by clinicians as one of the core area to focus, the published research shows comprehensive recommendations about patient progress monitoring and rapid response to an adverse event in an outpatient setting (Jevons MP 1961, Wenzel RP et al. 1991).

Data available from a study showed adverse events were noted in twenty seven outpatient care episodes. Seventeen minor cases were managed in community. Three of the adverse events were caused by drugs e.g. ototoxicity due to gentamicin, drug induced hepatitis, and itch. Eleven other were related to PICC line, in three cases PICC were completely replaced. The study shows that adverse events were greater with cephazolin vs. flucloxacillin (SJ Berman et al. 2001).

An OPAT case study revealed that two deaths were reported in the post IV treatment completion period. In first case an eighty year old male died three months after completion of the second treatment of SAIE. The cause of death was attributed to myocardial infarction without autopsy. In the second case of death, a male 73 year old was admitted to hospital in the post outpatient IV treatment period, he had oesophageal varices and Hepatitis C diagnosed and later also developed native valve and culture negative IE health issues. The average number of days between treatment completion and the adverse event notification were 220 (MR. Amodeo et al, 2009).

A study published by D. Nathwani et al. (1998) on skin and soft tissue infection after analysing one year of data showed that 2% patients on IV treatment developed an adverse reaction mainly due to infused drug reaction, whereas between 6% to 7.5% cases resulted in patient readmissions. In another study mainly the serious complications were found in 3 care episodes all occurring in patients with AIDS and had lines for more than 6 months (AR Berendt et al 1996).

Table 7: Adverse Event Identified Analysis Questions

Following table shows the prospective analysis questions identified by qualitative analysis of the adverse events theme, details of this analysis are attached in the <u>Appendix D.6</u>.

ID	Question
1	What are the total number of adverse events occurred during a certain number of episodes and dates?
2	What percentage of adverse events were managed in primary care?
3	What is the percent and list of adverse events by adverse event reason?

4	What is the percent and list of actions taken by the clinician in response address adverse event?
5	What percent of adverse events were resolved by the action taken by clinician in response to the event?
6	What is the percentage and list of patients who were admitted to hospital as result of an adverse event?
7	What percentage and list of patients developed some other health problem after completion of their treatment?
8	What are percentage and list of patients by each reported problem type?
9	What are the percentage and list of patients who developed health problems in which week/month after completion of their outpatient treatment?

2.3 Conclusion

The literature review helped author in gaining an in depth knowledge and the global perspective of IV treatment in the community. The Data discovered during literature review was broken down into 7 different themes followed by further analysis of each theme which resulted into 60 analysis questions in total. Analysis questions were identified by a detail analysis (appendix D) of each line of text written in the literature review.

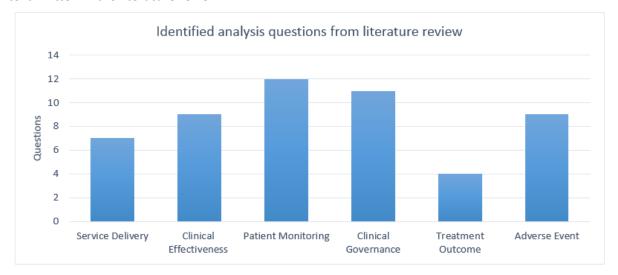


Figure 3: Identified analysis questions from literature review

The themes identified in this chapter describes various aspects of a community IV treatment service model. The different delivery models for outpatient treatment such as patient iv treatment in an ambulatory care setting e.g. patient visit care facility frequently for an antibiotic administration (as per prescription) by a nurse or practitioner, in some cases hospital outreach nurse or the community nurse visits patients at their home to administer drugs, or a patient is trained to self-administer therapy. Outpatient IV treatment delivered through a formal structure is safe, in this case effective clinical governance and patient monitoring becomes more imperative than any ad hoc arrangements. Literature review shows that with subject to data availability there is a great potential to improve service delivery, clinical governance and patient outcome assessment.

Comparison between self-administered and carer administered IV treatments from the safety and cost saving point of view provides greater insight into possibilities around further optimization of the community based IV treatment service. Healthcare practitioners have expressed much emphasis on

complete, timely and accurate reporting in case of an adverse event. As per the literature review patient's treatment outcome analysis is an under explored area, further research into this crucial aspect can give carers actionable information.

3. Research Design and Methodology

This chapter describes the overall research strategy to answer the research questions outlined in chapter 1. The chapter discusses literature review, stakeholder interviews and the step by step strategy to reach to the conclusion of this dissertation.

3.1 Literature Review

A qualitative research method was chosen. The chapter 2 gave a detail overview of literature published about the IV treatment in community. The literature has been systematically analysed to elicit themes (analysis attached in Appendix D). Each theme was further analysed to identify potential analysis questions.

3.2 Stakeholders Interviews

Two different types of questionnaire sets were prepared (Appendix C) for the eight identified stake holders groups for the semi structured telephonic interviews. The participants were given an opportunity to discuss their needs for information irrespective of the data that is or is not currently captured electronically during the delivery of IV treatment at home. The captured interview data will be systematically analysed in chapter 4 to elicit requirements in the form of potential analysis questions (Appendix E).

3.2.1 Dual Aspect of Community Nurse & Patient Interview

Both the community nurse and patient interviews in this research have a dual aspect, as the activities of these two stakeholders generate data in addition to their potential requirement for information about the given treatment. The nurse activities during the entire course of delivering IV treatment at patients' homes forms the basis to correlate and analyse generated data to answer stakeholders' questions.

3.4 Analysis Question's Identification

The outcome of the literature review in addition to the stakeholder groups' processed interview results will be used to find and discuss additional analysis questions identified by the author about the secondary use of patient IV treatment data captured in community. Each statement is captured in the literature review (Appendix D) and stakeholder's interviews (Appendix E) is assessed to identify potential analysis questions.

3.5 Analysis Question's Deduplication

The combined list of identified analysis questions from literature review and stakeholder's interviews may have duplications. In order to find a unique list of potential analysis questions, each question will be compared with all other identified questions for the similar or variation of the same question for deduplication. The identified duplicate questions will be removed from the final list of unique questions.

3.6 Data Model & Analysis Question Mapping

A comprehensive data model will be produced presenting data tables and the intertable relationships. One or multiple data elements from different data tables required to answer a question will be mapped against each uniquely identified analysis question.

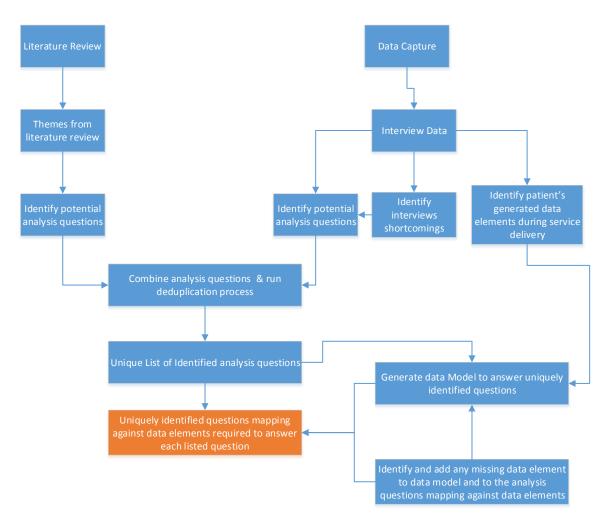


Figure 4: Research framework used in this research

4. Interview Outcome

4.1 Consultant Perspective

A consultant in a hospital identifies patients that are suitable for self-administered or nurseadministered outpatient IV treatment in community. Various parameters are considered before selecting a patient for outpatient treatment including a patient's clinical information and also social demographics. During the course of treatment a consultant recalls patients for weekly check-ups in an outpatient clinic to review their treatment progress. The frequency of patient recall is less frequent once their IV treatment course is completed. Consultant expects an adverse event report in case of any issue. The report should provide detailed information on the event including type of adverse event, pre and post infusion vital observations, treatment given, treated by and the outcome. If the community nurse is unable to remedy the issue then she may call the referring consultant's office to organise an appointment to further evaluate the patient. At the end of each patient's visit a consultant expects an EOC (end of care) report with complete details of all activities performed by the nurse while administering to the patient. The end of care report should contain patient demographic details, and details of any drugs administered, dressings used, blood samples taken, pre and post vital observations and any additional clinical notes. A consultants also wishes to be notified of any changes in the patient e.g. if a patient has developed a new allergy. At the end of a patient's treatment episode the consultant records the treatment outcome and discharges the patient from the treatment. Consultants feels that a patient's progress during treatment and outcome recording at the end of treatment are two key areas where they lack information.

Table 8: Identified Analysis Questions from Consultant Interview

The following table shows the analysis questions identified during the qualitative analysis of consultant interview, details of this analysis are attached in <u>Appendix E.1</u>.

ID	Question
1	List of patients referred by each consultant for monitoring purpose?
2	List of patients not accepted for outpatient IV treatment group by the rejection reason?
3	List of patients due for weekly check-up?
4	Progress of patients noted over the period of time captured during the weekly check- up meetings?
5	List of all patient adverse events by reason and outcome?
6	Detail report of a patient adverse event incident consisting of reason of adverse event, pre and post infusion vital observations, treatment given, treated by and the outcome?
7	Detail of all EOC visit report for patients containing patient demographic details, drugs administered, dressing, blood samples taken, pre and post vital observations and any additional clinical notes?
8	Newly developed allergy name, type and description of patients?
9	List of top 5 allergies reported by patients over the period of a year?
10	List of all patients grouped by treatment outcome?
11	List and percentage of patient's successfully or not successfully completed their treatment outpatient IV treatment?

4.2 General Practitioner Perspective

In the Irish model of care GPs are not involved in the monitoring or efficacy of IV treatment. Currently this community based service is provided by:

- 1) Private insurance e.g. VHI. GP can contact patients but usually do not get involved as it's the insurance company's own doctor who asses what is needed and deals with it. Details of this treatment go to the doctor employed by the insurance company and not the GP.
- 2) Alternatively a hospital consultant may refer a public patient for community IV treatment or chemotherapy. In this scenario a specialised community based nurse provides the treatment to the patient in their home. Similarly to the above details of this treatment go to the referring hospital consultant and not the patient's GP.

GPs would find it beneficial to receive a patient's evaluation of care report electronically if their software would support it for all community based treatments. They would like to see a final report as opposed to a daily progress report on the patient. The evaluation of care report should provide patient information including details of treatment, the method of treatment e.g. if IV was through peripheral line, safety of the line, line cleanliness status and was it inflated.

Currently GP clinics are extremely busy and GPs don't have enough resources to go out and administer IV treatments to patients at home. GPs are very proactive in other areas including inviting patients for diabetic check-up or flu vaccination. GPs however think it's beneficial to treat patients outside hospital and providing details of a patient's treatment outcomes including vital signs, temperature, blood pressure, reaction to drugs, prostrate information and also that how patient is feeling in general (e.g. any new symptoms etc.) whilst on treatment will certainly help GPs provide better care to their patients.

Table 9: Identified Analysis Questions from GP Interview

The following table shows the analysis questions identified during the qualitative analysis of GP interview, details of this analysis are attached in <u>Appendix E.2</u>.

ID	Question
1	List of patient with the administered drug information?
2	The number of patients who have developed any side effects as a result of administered drugs?
3	The patient's vital signs captured during the IV infusion especially if they are outside normal range?
4	The percentage and list of patients by treatment outcome?
5	End of care report of each patient visit?
6	List of patients being administered through different types of line, safety and line cleanliness status?
7	List of patients getting IV treatment at home by provider?
8	List of patients due for their diabetic check-up and/or flue vaccination?
9	List of patients (with their clinical information) who are diagnosed with any new symptom?

4.3 Community Nurse Perspective

The community nurse receives an email list of patients that need to be seen usually by 6pm the night before the first visit. The nurse then rings the patient confirming the time the nurse would be going to their house as per the dose and time in the prescription. Sometimes a patient may not be present at home when the nurse arrives, in that event the nurse rings the patient on their mobile and waits until the patient returns home.

Prior to the treatment commencing the nurse checks each patient's details including patient prescription, past medical history and what treatment she would be giving to the patient during her visit to patient home. The nurse also has a copy of the patient's medical profile consisting of past medical history, comorbidities e.g. if the patient has cancer or any surgical procedure, blood results that were submitted with original referral, list of current medication, allergies and details of any previous adverse reactions.

When the nurse presents at the patient's home on the day of the visit the nurse will again go through the patient profile and medical services that she/he is about to provide during the visit. The nurse speaks with the patient about the treatment and how the patient is feeling in general before administering treatment. The nurse takes vitals observations e.g. temperature, blood pressure and respiration to make sure all within the normal range, note the dose, route, after that she validates the drug against prescription, records and the start and end time of administration as well as her comments (if any). Once the treatment is completed the nurse takes another set of vital observations to make sure patient is well post procedure and then marks treatment session complete. At the end of the treatment session the nurse records her comments and concerns with patient e.g. feeling unwell, anxious or if they had any upcoming out-patient appointment.

In the event of an adverse event the details of actions that are recorded include drug and severity of reaction, whether drug was stopped or not, post reaction vital observations. The nurse will also contact the patient's medical team to determine if the patient needs to visit hospital, or in case of severe reaction call the ambulance to take the patient back to the hospital. A patient's medical team is usually the referring consultant, senior registrar and SHO within the hospital, it will also include the nurse manager from the community nursing agency.

Nurses finds it useful to have patient up to date details during the visit e.g. blood results and detail of any previous adverse event, next out-patient appointment date (most of the time patient provides this detail to nurse as they receive call from hospital consultant), an overall plan of care from the team e.g. treatment end date and plan after the treatment ends as lot of time patient ask these questions from nurse which she is not aware of at the moment. For instance if a patient is waiting for hip replacement while they are on IV antibiotic then patient would be asking nurse if they will be going back on IV antibiotic are not which at the moment nurses cannot answer due to absence of overall patient care plan. Any change of prescription is fax to the nursing agency and pharmacy, it is then scanned and emailed to community nurse so that they have up to date information.

Nurses maintain a time sheet for the visit they have done which they submit at the end of each month to get paid. In case of any ambiguity the nurse may contact their nursing agency to get information regarding patient they have seen.

Table 10: Identified Analysis Questions from Community Nurse Interview

The following table shows the analysis questions identified during the qualitative analysis of community nurse interview, details of this analysis are attached in Appendix E.3.

ID	Question
1	What are the list of patients who are scheduled to be seen by nurse tomorrow?
2	What is the total volume and duration of calls nurses have made to patient for the visit time confirmation between certain dates?
3	What are the total number of occasions and duration nurses had wait for patient after arriving at patient home?
4	What are the medical profile details that were submitted as part of original referral for all scheduled patients for the next day nurse visit? (e.g. patient demographic, prescription, past medical history, allergies, comorbidities, blood results, surgical history, current medications, previous adverse reactions and referral details)
5	List of patients having abnormal vital observations over a period of time recorded before completion of their IV treatment in community?
6	List and percentage of patient by the outcome recorded by nurse at the end of visit during as well as after completion of overall patient treatment?
7	What are the pre and post IV administration vitals observations of patient where outcome recorded by nurse are other than satisfactory?
8	What are complete details of a patient adverse event e.g. reason, action taken, outcome, pre and post administration vital observations, have all clinical stakeholder been informed?
9	List of previous patient visits and details e.g. blood results, vital observations, drugs administered, labs, and adverse events?
10	What are details of patient's care plan e.g. future appointments, other planned procedures, goals and interventions?
11	What are the list of patients who have been issued a new prescription?
12	List of visits performed by nurse over a period of time?

Table 11: Data Generated by Nurses

This table shows the data elements that are generated by a nurse during administration of IV therapy to a patient in community:

ID	Visit Data Elements
1	Visit Date
2	Visit Type
3	First Visit
4	Dressing Image
5	Dressing Date
6	Patient Progress Status
7	Patient Risks
8	Temperature
9	Heart Rate
10	Systolic
11	Diastolic
12	Oxygen Saturation
13	Respiration Rate
14	Reading Date
15	Recording Stage
16	Temperature

17	Issue Date
18	Issue Description
19	Reported By
20	Duration of Issue
23	Treatment Detail
24	Comments
25	Issue Date
26	Drug Name
29	Current Drug Status
30	Outcome of Adverse Event
31	Drug Name
32	Current Drug Status
33	Outcome Detail
34	Infusion Status
35	Start Time
36	End Time
38	Infusion Status
39	Travel time
40	Waiting time
41	Distance
42	No of calls to patient

4.4 Nursing Agency Perspective

In a community nursing agency the role of a nurse manager in relation to outpatient's IV treatment initially begins with accepting or declining a referral for a patient to be treated in community. The manager will review all referrals to ensure that all the clinical information is present and correct. A referral typical consists of patient demographics, prescription, allergies, weight, past medical history, blood results, vital signs, comorbidities, any antibiotics patient may have had in the hospital, surgical procedures, swab, emergency medications and doctor signature. There is an inclusion and exclusion criteria for the referral acceptance, and she asses the patient's suitability for the outpatient IV treatment based on this. In addition the nurse manager also checks if the antibiotic is restricted or prohibited and verity's that the appropriate antibiotic is prescribed for the appropriate condition. The nurse manager may also contact the hospital consultant by phone call or email for any additional information that may be required. . Once all required referral information is available and reviewed the nurse manager signs the prescription and also ensures that the pharmacist has also reviewed it. The pharmacist reviews the prescription from a pharmacological point of view e.g. blood results with regards to the antibiotic dose to make sure that it is safe for the patient to receive that prescribed dose. After pharmacy approval of the prescription, the delivery and dispensing of all medication for the patient is coordinated and delivered to the patient's address so that all the drugs are there when the nurse arrives at the patient's home for the scheduled visit.

The nurse manager schedules nurses with the required skill set to visit a patient at their home. Usually, the nurse roster is planed 3 to 4 weeks in advance e.g. holidays, shifts, start and end time. They also need to know when the patient is scheduled to go back to the hospital. It is important for the nurse

manager from a nurse scheduling point of view to know their nurses and patients geographical location. The important factors for effective nurse scheduling include nurse skillset, patient dose regime, drive time between nurse and first patient and to subsequent patients, visit duration (including IV antibiotic infusion time), general risks (e.g. nurse safety), visit time (should be consistent for the full duration of the treatment), From an agency point of view it is important to have effective management of the nurse's time as well managing appropriate spacing between a patient's treatment. Ongoing nurse training is conducted by the agency so that nurses are continuously upskilled and qualified to do their jobs in community.

The nursing agency would contact referring hospital if the patient is not responding to a treatment. It is important for the nursing agency from the nurse scheduling point of view to know their nurses and patients geographical location for the effective nurse scheduling. The important factors for effective nurse scheduling includes nurse skillset, patient dose regime, drive time between nurse and first patient and to the subsequent patient, visit duration (including IV antibiotic infusion time), general risks (e.g. nurse safety), visit time (should be consistent for the full duration of the treatment), effective management of the nurse time as result of managing appropriate spacing between IV infusions if a patient is to be administered 3 doses a day and patient outpatient appointment in the hospital. An email with list of patient is sent to nurses daily for every following day visits. Nursing agency ensures that patient has the required antibiotic dose supplies are with them in case of an OPD appointment, this is important as some antibiotics are very expensive which the hospital may not have in their stock especially if the nursing agency has government funded antibiotic stock, in this case antibiotics are administered by the hospital nurse. The nursing agency has very limited visibility to the visit details when patient is administered by the hospital nurse.

The nursing agency expects an evaluation of care report from the nurse at the end of each visit. This report is shared with the referring consultant, the patient's GP and the medical director at the nursing agency as the patient remains under their clinical governance. The evaluation of care report must contain details of a patient consent (if it's a first visit), risk assessment, referring doctor name, allergies, current medication, vital observation, administered IV drugs (batch no, expiry date and dose), infusion duration, post administration vital signs, dressing, specimen collection, post visit summary check list, stock request or bill collection request, patient and nurse signature at the end of the report. The nursing agency also requires completed details of an adverse event if the patient becomes unwell at any time during the nurse visit.

Nursing agency would prefer if they could receive more information from the hospital on the referral such as patient's concurrent medication, any oral tablets. This information will help them make a better clinical judgement if an IV antibiotic is appropriate for the patient. Also a tracker report which can help the nursing agency see where the referral is in the process from the initial referral received to the nurse visit completion e.g. referral has been received, approved, antibiotic has been picked, packed, delivered or ready to be delivered and nurse events. The nursing agency also needs information from logistics e.g. if the required drugs have been delivered to the patient's home before the nurse arrives at the patient's home for the administration of those drugs.

Finally the visit completion report is one of the most important reports that is required by the nursing agency for a service operation and billing point of view.

Table 12: Identified Analysis Questions from Nurse Agency interview

The following table shows the analysis questions identified during the qualitative analysis of nursing agency interview, details of this analysis are attached in <u>Appendix E.4</u>.

ID	Questions
1	What are the list and percentage of patients not accepted for community IV treatment
	by the rejection reason and date?
2	What are the complete details of a referral received from hospital?
3	What are the total number of referrals received from a hospital over a period of time?
4	What number of times referrals have been found incomplete by reason?
5	What amount of delay has been caused due to the incomplete referral details?
6	List of restricted drugs?
7	List of approved drugs for each condition?
8	List of available nurses between a certain duration for patient visits?
9	List of nurses and their qualification details?
10	What are the number of incidents and details when a nurse contacted hospital about patients not responding to a treatment?
11	List of available nurses for scheduling based on nurse skillset, patient dose regime, drive time between nurse and first patient and to the subsequent patient, visit duration (including IV antibiotic infusion time), general risks (e.g. nurse safety), visit time (should be consistent for the full duration of the treatment?
12	Daily patient monitoring list with details e.g. visit date, nurse assigned, drugs availability and visit location?
13	List and details of patient's hospital visit during the course of IV treatment in community?
14	List and detail of patients end of care report having patient consent, risk assessment, current medication, vital observation, administered drugs, infusion duration, post visit vitals observations, dressing, specimen, visit summary checklist and sharps bin collection?
15	List and detail of all adverse events?
16	List of concurrent medication or any oral tablets for each referred patient from hospital?
17	List of referrals and status report?
18	Availability status of the required drugs at patient home before nurse visit commencement?

4.5 Pharma Company Perspective

The pharma company manufactures the IV antibiotics that are used by the nurses and doctors in the hospital or in the community setting. The IV antibiotics manufactured in the pharma company are produced as patient specific or non-patient specific. In order to manufacture patient specific IV antibiotics the pharma company requires a valid prescription with attributes such as patient name, prescriber name and contact, drug name, total prescribed quantity, duration of infusion, frequency, form and diluent. The pharma company takes the drug expiry date into account while planning the manufacture of the prescribed IV antibiotics.

The pharma company would like to know if all the pumps are being used by the patient or nurse at the same time or the supplied drugs will be used over the period of time, have nurse or patient encountered any problems during infusion of the drug, did the IV infusion pump infused the drug within programmed time. In the event o of an adverse event the pharma company requires the drug name, batch no, type of reaction, date and other details e.g. did reaction happened during two simultaneous infusions, was it a single drug infusion, or was the primary drug infused along with another drug which could be potentially be the reason for an adverse event.

"We will be in position to investigate our manufacturing process we get information from the patient, nurse or the doctor about the batch no that resulted into the adverse event (Pharma interviewee)"

Pharma companies do not have drug usage information in real-time from patients, therefore the manufacturing forecast is based on assumption that can potentially result into over manufacturing or waste in case of shorter shelf life drugs.

Table 13: Identified Analysis Questions from Pharma Company Interview

The following table shows the analysis questions identified during the qualitative analysis of pharma company interview, details of this analysis are attached in Appendix E.5.

ID	Question
1	What are the total number of patient specific or non-patient specific IV antibiotics used by nurses in the community?
2	List and percentage of drugs used by patient's age group and demographics?
3	Prescription details of all patients for the manufacturing of patient-specific IV antibiotics?
4	What is the prescribed frequency of each drug to be manufactured?
5	Did the IV infusion pump infused the drug within programmed time?
6	Complete details of an adverse event (e.g. drug name, batch no, type of reaction, date and other details e.g. did reaction happened during two simultaneous infusions, was that a single drug infusion, or the primary drug was infused along with some other drug which could be potentially be the reason for an adverse event)?
7	List of used and unused drugs that were previously to patient home for the IV infusion?

4.6 Insurance Company Perspective

Insurance is all about taking risk from the insurer's point of view. An insurance company takes money from people and spends it on their patients mainly for chronic disease management. Generally, people aged between 18 to 50 pay a big premium relatively speaking as they do not get sick very often, and mostly require straightforward interventions e.g. broken leg etc. which are accidental in nature.

The biggest challenge faced by insurance companies is the management of patients with chronic disease, infections and carrying a long term injury. The availability of data from community can greatly help an insurance company to introduce more effective insurance packages which can help prevent patients from getting sick and can potentially result into cost savings.

"Idea is to identify those patients who are at risk of getting sick from the available data, manage and treat them before they end up in hospital"

A patient's treatment in primary care costs less than hospital treatment. Therefore, Insurance companies prefer patient treatment to be community based instead of hospital based depending upon the suitability of patient's living circumstances, medical condition and treatment.

Insurance companies also like to engage in preventative measures such as immunisation to prevent children getting measles or polio or a subsidised regular health check-up at GP clinic or by providing free gym membership etc. to keep their members out of hospital. .

Subject to the data availability from community, insurance companies can do cost-benefit analysis between patient's treatments in hospital and treatment in community as generally there is a perception that patients get better treatment in a hospital than home, so the data related to quality

standards for community based treatments including e.g. using the right IV and the outcomes can help insurance companies improve their services for their members. However, it increases costs for the insurer if they ask patients to go to a homecare facility for a treatment, then if something goes wrong with the treatment and the patient has to go to the hospital costing the insurance company double (in community treatment in first place and then treatment in the hospital).

"From an insurer's point of view it's a matter of which is better and which is cheaper between community or hospital treatment (Insurance company interviewee)".

With this information insurance companies can lower s risk and save costs. Most of the insurance companies in Ireland have their own nurses and clinical directors to monitor their patients getting treatment in community while also providing an on-call clinical advice for minor health issues. Patient treatment information e.g. nurse visit details are processed by the insurance company's internal care team.

Table 14: Identified Analysis Questions from Insurance Company Interview

The following table shows the analysis questions identified during the qualitative analysis of an insurance company interview, details of this analysis are attached in Appendix E.6.

ID	Question
1	List of insured population by their age and immunization status?
2	List of insured patients diagnosed with infections suitable for treatment in community?
3	List of insured patient's diagnosed with infection not suitable for IV treatment in community by reason?
4	What are the list of factors identified by nurse that can help expedite patient recovery from IV treatment in community?
5	No of bed days saved of insured patients by completing their successful IV treatment in community for infections?
6	What are the list and percentage of insured patients with reason they were discontinued from treatment in community and referred to hospitals for admission?
7	List of insured patient's visit details in community?

4.7 HSE Perspective

In Ireland traditionally IV antibiotics have occurred in a controlled environment such as acute/in-patient settings. However, there is a growing trend to deliver IV antibiotic in the community. The HSE as the national healthcare policy maker and funder and is the major stake holder who needs information generated the patient and nurse during the delivery of IV infusion in community. At present HSE requests this information from the public hospitals and various contracted sources e.g. community nursing agency, pharmacies and compounding units. HSE uses this information to get better understanding of the healthcare needs of patients requiring various IV treatments in non-inpatient settings.

To understand the workload on hospitals HSE wishes to know the number of patients being referred every day for outpatient treatment from all hospitals by the speciality, consultant, type (self/home) and date. However, the effectiveness of outpatient treatment is measured by patient recovery outcomes and the number of hospital bed days saved.

HSE also wishes to have access to maximum information generated by the patient directly or indirectly during the delivery of IV services for well informed decision making. Additional information such as a

patient's living conditions, adverse events, prescription compliance, quality of service and patient satisfaction would help analyse patient's IV treatment in non-inpatient settings from different aspects.

Table 15: Identified Analysis Questions from HSE Interview

Following table shows the identified analysis questions from the qualitative analysis of HSE interview, details of this analysis are attached in the Appendix E.7.

ID	Question
1	What are the total number of patients referred from all hospitals by the speciality, consultant, type (self/home) and date?
2	List and percentage of patients by treatment outcome of an episode?
3	List of patients on IV treatment in community group by various living condition factors?
4	List and percentage of the total number of adverse events by their outcome?
5	What are the total number of bed days saved by successfully treating patients in community for infections?
6	What is patient's feedback about the IV treatment they have received in community?

4.8 Patient Perspective

The patient initially expects a briefing from their nurse or doctor about their entire course of treatment and its objectives. As the treatment begins more specific information is required by the patient from their nurse e.g. visiting nurse name, nurse contact number, visit date and time, duration of visit, type of visit e.g. training or IV administration, duration of infusion if the visit is an IV administration.

"For me the most important thing was the liaison nurse explaining the whole procedure before I left from the hospital for home treatment (Patient interviewee)"

Patients feel more comfortable with the treatment they receive at home mainly due to the level of attention they receive from the nurse at home which is generally greater than the attention they receive in hospital. Patients also likes to see their blood pressure and other vital observations readings in a graphical form and are also able to inquire about their recovery progress from the visiting nurse. Patients think that "little things means a lot for instance if the same nurse performs most of the visits as it builds up a patient-carer relationship". In the absence of a shared care the patient has to explain to multiple care team members about his available on a certain day.

Table 16: Identified Analysis Questions from Patient Interview

The following table shows the analysis questions identified during the qualitative analysis of patient interview, details of this analysis are attached in Appendix E.8.

ID	Question
1	Complete details of patient care plan (e.g. nurse visit dates, hospital appointments, dressings, lab results, trainings, care team contact details)?
2	List of all previous vital observations e.g. blood pressure, blood sugar level etc.?
3	Progress on the status of all planned health goals during the treatment?

Table 17: Patient Generated Data

ID	Patient Feedback Data Elements
1	Feedback Status

2	Other Comments
3	Date
4	Patient Name

4.9 Conclusion

The stake holder interviews helped in the exploring processes involved in understanding of the nurse lead model of care for patient's IV treatment in community. This process is key to understanding working of all interviewed stakeholders in providing a coordinated patient care in community. As per the interview findings a patient is evaluated for their "clinical" suitability for outpatient IV treatment by a hospital consultant in emergency room (Acute setting) or in an out-patients department. Patients are assessed for their clinical suitability based upon their medical condition, living circumstances, prescribed medication, availability of drugs, logistics and nurse scheduling for the patient visit. A patient can be referred by a consultant for self-administration or to a nurse lead community IV administration team. The nursing agency receives that referral and performs a detailed clinical review of the referral. Once a referral is accepted by the nursing agency, the medication that needs compounding is requested from a compounding facility. Respective manufacturing and delivery schedule with the pharma company is agreed as per prescription, drug expiry and delivery schedule to the patient's home prior to the scheduled nurse visit. A well-coordinated shared care plan is prepared and agreed between all stakeholders for the entire course of patient IV treatment in community. At the end of each nurse visit a complete end of care report including adverse event report is produced and circulated to all stakeholders involved in patient's shared care plan.

A total of 120 questions were identified either explicitly by 9 stakeholder groups during the interviews or identified by the author (complete analysis of identifying interview questions is attached in appendix \underline{E}). In addition to analysis questions the nurse and patient interview analysis showed a list of 46 data elements that are currently being captured during the nurse's patient home visit.

The identified analysis questions shows the importance of patient monitoring during the treatment in community. Capturing and analysis of adverse events data and the treatment outcome were two common areas of requirements for all stakeholders. It was noted that treatment outcome analysis which all stakeholders were interested in is an under explored area, also there is no effective mechanism in place for recording patient's feedback during or after completion of their IV treatment in community.

The outcome analysis of the interviews shows that the community pharmacist plays an important role in dispensing and pharmacovigilance of the prescribed drugs for the patient's IV treatment in community. Addition of the pharmacist to the stakeholder group for interviews could have added more value to this research.

5. Unique Analysis Questions, Interview & Literature Review Outcome Correlation

5.1 Introduction

This chapter shows the comprehensive data model produced based on the literature review and analysis questions findings. The chapter also lists the uniquely identified analysis questions as well mapping of the required data elements to answer each analysis question.

5.2 Data Model – Patient Medical Profile

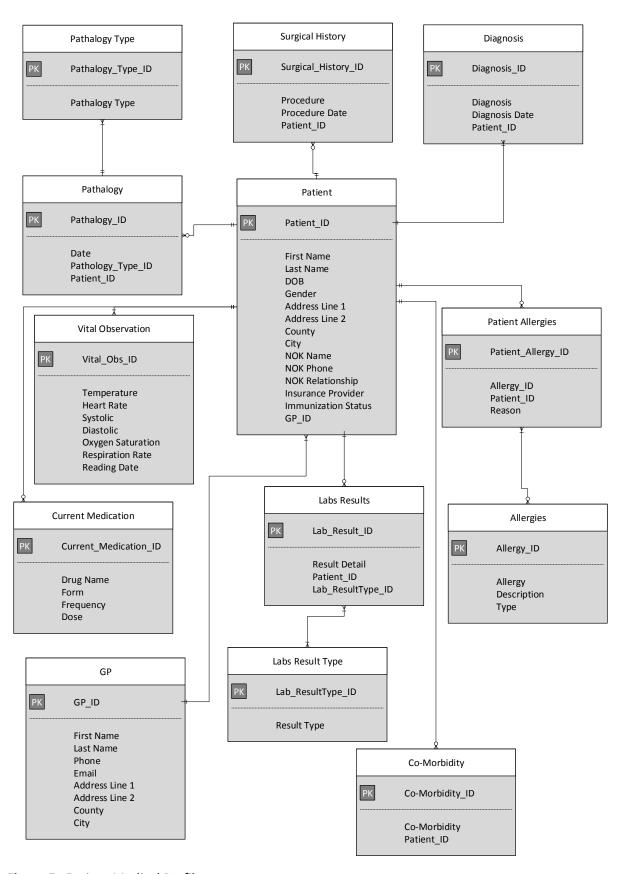


Figure 5: Patient Medical Profile

5.3 Data Model – Patient Referral

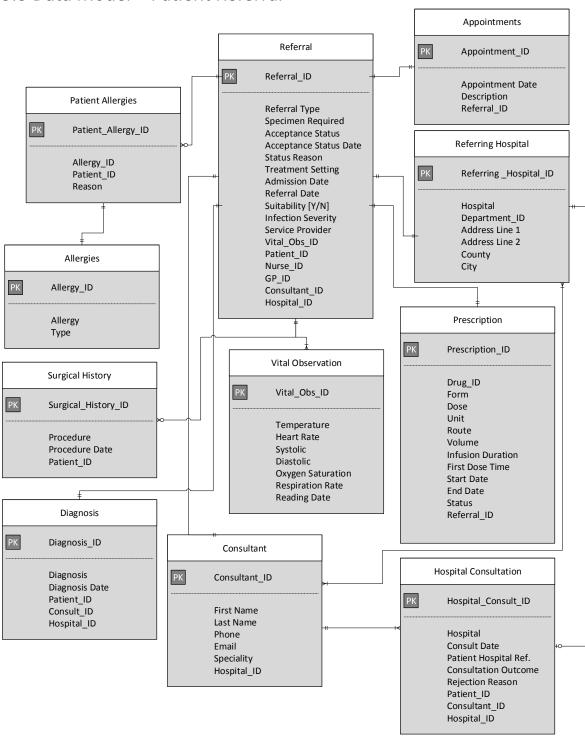


Figure 6: Patient Referral

5.4 Data Model – Patient Visit & Adverse Event

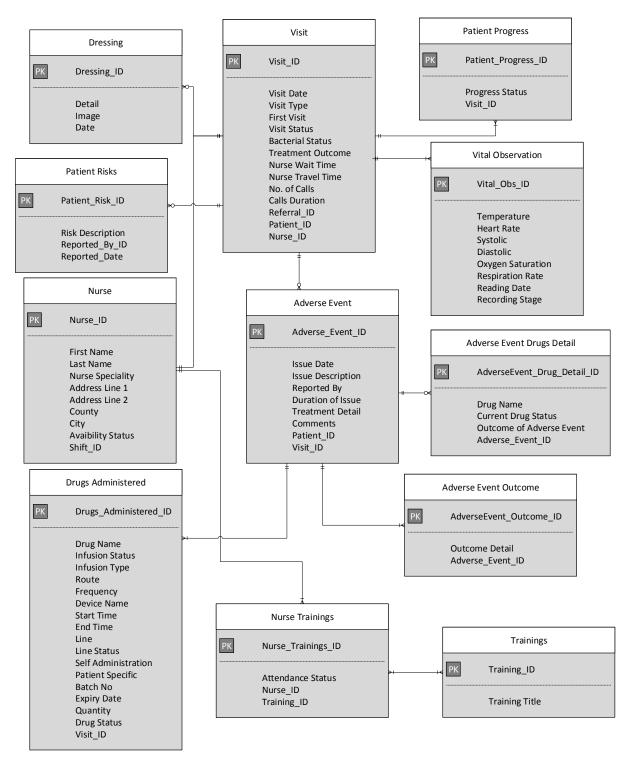


Figure 7: Patient Visit & Adverse Event

5.5 Data Model – Patient Care Plan & Feedback

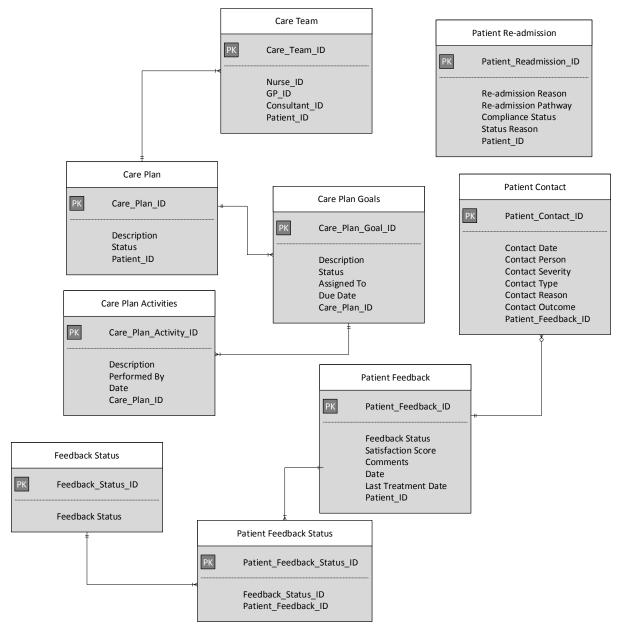


Figure 8: Patient care plan and feedback

5.6 Data Model – Table Aliases

Aliases defined in Table 18 will be used as shortcut representations of the data table defined in section 5.2 to 5.5 to reference the required table elements while mapping data elements to analysis questions in section 5.3.

Table 18: Table Aliases

Table Name	Alias
Patient	P
Nurse	N
Consultant	С
GP	G
Referring Hospital	RH

Visit	V
Prescription	Rx
Referral	R
Dressing	D
Diagnosis	DG
Surgical History	SR
Patient Allergies	PA
Pathology	PT
Vital Observation	VO
Lab Results	LR
Allergies	A
Co-Morbidities	CM
Care Plan	СР
Care Plan Goal	CPG
Care Plan Team	CPT
Care Plan Activities	СРА
Patient Feedback	PF
Patient Progress	PP
Adverse Event	AE
Adverse Event Drug Detail	AEDD
Adverse Event Outcome	AEO
Hospital Consultation	HC
Patient Contact	PC
Patient Readmission	PR
Nurse Training	NT
Appointments	APT
Surgical History	SH

5.7 Unique Analysis Questions & Data Elements Mapping

This table shows list of unique analysis questions obtained by performing the deduplication process (Attached in Appendix d)

Table 19: Unique analysis questions and data elements mapping

ID	Analysis Question	Data Element
1	List of patients or sum of patients referred from one or	RH. Hospital Name
	multiple hospital departments?	RH. Hospital Department
2 Complete audit trail of a patient visit with each of the		V. Visit Date
	data element e.g. number of patients visits over a period	Rx. Dosage Frequency
	of time?, frequency of patient visits? Number of visits	Rx. Drug Name
	carried out by a nurse (other parameter includes nurse	V. Visit Location
N.		N. Nurse Name
		N. Nurse Type
		N. Nurse Organization
3	Comparison between self-administered IVs VS carer	Rx. Dose Frequency
	administered IVs from the safety and cost saving point	Rx. Dose Time
	of view?	D. Line Infection [yes/no]
		V. Administration Type
		[self/professional]

4	What are number of devices used for a type of infusion in order to find consumption and cost of peripheral devices required during IV treatment?	DA. Infusion Type DA. Device Name		
5	List of patients referred for outpatient treatment for an IV treatment by diagnosis?	RH. Hospital D. Diagnosis R. Referral Type R. Treatment Setting		
6	What is the percentage of patients presenting to hospital with problems that can be treated in community for IV treatment?	P. Name V. Visit Date D. Diagnosis		
7	What is the percentage of patients by diagnosis (suitable for community IV treatment) having different infection severity levels?	V. Type R. Treatment Setting R. Suitability [Y/N] R. Infection Severity		
8	Patient improvement percentage comparison between home vs inpatient care setting by using same drug and IV infusion frequency?	AEDD. Drug Name P. Frequency DA. Route [IV/Oral]		
9	What is the percentage of adverse events reported during the use of same drug and IV infusion frequency in the home vs inpatient care setting? DA. Notice [IV/Oral] DA. Notice [IV/Oral] DA. Notice [IV/Oral] V. Self-Administered R. Setting [Home/Inpatient]			
10	What is the patient satisfaction level comparison between home vs inpatient care setting in general (as well as comparison by using same drug and IV infusion frequency in both care settings)	AE. Adverse Event [Record Count] PF. Feedback Status PF. Patient Satisfaction [Score] V. Treatment Date		
11	What is the percentage of most commonly used antibiotics for outpatient IV treatment?	DA. Drug Name DA. Quantity		
12	What is the average recovery time period for each prescribed drug for a diagnosis (based on the infusion frequency and infection severity)	DA. Frequency R. Infection Severity Level DA. Date		
13	What is percentage of adverse events reported against each drug used for outpatient IV treatment over a period of time?	AE. Adverse Event [Record Count] R. Setting [Home/Inpatient]		
14	What is the percentage of patients not accepted for outpatient treatment by rejection reason?	HE. Consult Date HE. Consultation Outcome		
15	What are the total number of patients accepted for outpatient treatment in each month?	tal number of patients accepted for [Accepted/Rejected]		
16	What are the number of unplanned occasions when patient contacted for clinical advice during the course of IV treatment in community?	PC. Patient Contact Date PC. Clinical Contact Person PC. Contact Type [Planned/Unplanned] PC. Contact Reason		
17	What is the percentage and list of patients receiving IV treatment in community setting reported an adverse reaction?	AE. Adverse Event Date AE. Severity R. Setting [Home]		
18	What are the percentage and list of adverse events that could have be prevented by effective early monitoring and interventions?	AE. Outcome V. Treatment Outcome		
19	What is the percentage and list of patients discontinued from outpatient treatment?			
20	What is the percentage and list of patients readmitted?	V. Treatment Outcome		

21	What is the percentage and list of patients who did not followed the formal readmission pathway? PR. Re-admission Pathway PI		
22	List of patients with reason the formal readmission	Compliance Status	
	pathway was not followed?	PR. Status Reason	
23	What is the percentage and listing of patients who	PC. Contact Type	
24	requested for unplanned urgent phone advice?	[Planned/Unplanned] PC. Contact Severity	
24	What is the percentage and listing of patients who requested for unplanned home visits?	[Urgent/Non Urgent]	
	requested for displanifed finite visits.	PC. Contact Outcome [Phone	
		Advice/Home Visit]	
25	What is the percentage of adverse events in less	Rx. Frequency	
	frequently monitored patients?	V. Date	
26	What are the common outcomes that appear during the	V. Treatment Outcome	
	discussion with patients over the course of their IV treatment?	V. Date R. Setting	
	treatment:	PF. Comments	
27	What is the percentage and list of patients by clinical	V. Treatment Outcome Status	
	outcome status (improved, clinical failure or no change)?	V. Bacterial Status	
28	What is the percentage and list of patients by bacterial	DA. Drug Name	
	infection status (culture negative, persistent pathogen		
	or new pathogen)?		
29	What is the percentage and list of patients by antibiotic use (course completed as planned, or reason for non-		
	completion)?		
30	Which staff involved in outpatient IV treatment have	NT. Training Status	
	missed/attended one or more service related training	Ğ	
	sessions?		
31	What are the number of hospital bed days saved by	V. Treatment Status	
32	successful treatment of the conditions in community?	D. Diagnosis R. Admission Date	
32	What are the percentage and list of patients discharged in 2nd and 3rd week of the treatment?	R. Referral Date	
33	What are the total number of adverse events occurred	AE. Date	
	during a certain number of episodes and dates?	AE. Visit ID [Count]	
		AE. Referral ID	
35	What percentage of adverse events were managed in	AEO. Outcome Detail	
25	primary care?	AE Janua Description	
35	What is the percent and list of adverse events by adverse event reason?	AE. Issue Description	
36	What is the percent and list of actions taken by the	AE. Treatment Detail	
	clinician in response address adverse event?		
37	What percentage and list of patients developed some	AEO. Outcome Detail	
	other health problem after completion of their		
20	treatment?	DE Fardhard Cont	
38	What are the percentage and list of patients who	PF. Feedback Status	
	developed health problems in which week/month after completion of their outpatient treatment?	PF. Feedback Description V. Status	
	completion of their outpatient treatment:	V. Visit Date	
39	List of patients referred by each consultant for	C. First Name, C. Last Name	
monitoring purpose? R. Referral D		R. Referral Date	
40	List of patients due for weekly check-up?	HA. Appointment Date	

41	Progress of patients noted over the period of time captured during the weekly check-up meetings? V. Comments V. Type V. Visit Date			
42	Detail report of a patient adverse event incidents consisting of reason of adverse event, pre and post infusion vital observations, treatment given, treated by and the outcome?	VO. Vital Obs. [Pre & Post List] AE. Issue Description AE. Treatment Detail AEDD. Drug Name AEDD. Current Drug Status		
43	Detail of all EOC visit report for patients containing patient demographic details, Risks, drugs administered, dressing, pre and post vital observations and any additional clinical notes?	P. Demographics [Name, Addr] DA. Drugs Administered D. Detail, D. Image VO. Vital Obs. [Pre & Post List] PR. Risk Description		
44	Newly developed allergy name, type and description reported by patients?	A. Allergy A. Type		
45	List of top 5 allergies reported by patients over the period of a year?	A. Description A. Date		
46				
47	List of patients being administered through different types of line, safety and line cleanliness status?	DA. Line DA. Line Status		
48	List of patients getting IV treatment at home by different providers?	R. Setting R. Service Provider		
49	List of patients due for their diabetic check-up and/or flue vaccination?	APT. Date APT. Description		
50	List of patients (with their clinical information) diagnosed with any new symptom?	A. Date A. Type V. Treatment Outcome		
51	List of patient with the administered drug information	P. First Name, P. Last Name DA. Quantity DA. Drug Name		
52	What are the list of patients who are scheduled to be seen by nurse tomorrow?	V. Visit Date V. Status		
53	What is the total volume and duration of calls nurses have made to patient for the visit time confirmation between certain dates?	V. No. of Calls V. Calls Duration V. Date V. Status		
54	What are the total number of occasions and duration nurses had to wait for patient after arriving at patient home? V. Nurse Wait Time V. Visit Date			
55	What are details of patient's care plan e.g. future appointments, other planned procedures, goals and interventions?	CPG. Description CPA. Description CPA. Date		

56	What are the list of patients who have been issued a new prescription?	R. Referral Date Rx. Start Date		
57	What are the list of visits which a nurse has performed over a period of time? N. First Name, N. Last Na V. Date V. Visit Status			
58	What are the total number of patients referred from all hospitals by the speciality, consultant, type (self/home) and date?	R. Referral Date R. Treatment Setting R. Referral Type RH. Hospital RH. Department		
59	List of patients on IV treatment in community group by various living condition factors?	R. Risks		
60	What is patient's feedback about the IV treatment they have received in community?	PF. Feedback Status PF. Feedback Description		
61	List of all previous vital observations e.g. blood pressure, blood sugar level etc.?	VO. Temperature VO. Heart Rate VO. Systolic VO. Diastolic VO. Oxygen Saturation VO. Respiration Rate VO. Reading Date VO. Recording Stage		
62	What are the total number of patient specific or non- patient specific IV antibiotics used by nurses in the community?	DA. Patient Specific DA. Drug Name N. Nurse Name		
63	List and percentage of drugs used by patient's age group and demographics?	P. DOB P. County DA. Drug Name DA. Quantity		
64	What is the prescribed frequency of each drug to be manufactured?	Rx. Drug Name Rx. Frequency		
65	Did the IV infusion pump infused the drug within programmed time?	DA. Infusion Duration		
66	List of used and unused drugs that were previously to patient home for the IV infusion? DA. Drug Name Date DA. Administration DA. Date DA. Batch DA. Quantity			
67	List of insured population by their age and immunization status?	P. Insurance Provider P. DOB P. Immunization Status		
68	What are the list of factors identified by nurse that can help expedite patient recovery from IV treatment in community?	V. Comments V. Treatment Outcome		
69	No of bed days saved of insured patients by completing their successful IV treatment in community for infections?	P. Insurance Provider R. Referral Date V. Visit Date V. Treatment Outcome		
70	70 List of insured patient's visit details in community? P. Insurance Provider R. Setting			

		V. Treatment Outcome V. Visit Date	
71	What are the complete details of a referral received from hospital?	R. [All Elements] V. [All Elements]. H. [All Elements] PA. [All Elements] Rx. [All Elements] C. [All Elements] D. [All Elements] SH. [All Elements]	
72	What amount of delay has been caused due to the incomplete referral details?	R. Referral Status R. Referral Date R. Acceptance Status R. Acceptance Date	
73	List of restricted drugs & approved drugs for each condition?	DA. Status D. Diagnosis	
74	List of available nurses for scheduling based on nurse skillset, patient dose regime, drive time between nurse and first patient and to the subsequent patient, visit duration (including IV antibiotic infusion time), general risks (e.g. nurse safety), visit time (should be consistent for the full duration of the treatment?	N. Shift N. Availability Status	
75	List of nurses and their qualification details?	N. Name T. Training Title NT. Attendance	
76	What are the number of incidents and details when a nurse contacted hospital about patients not responding to a treatment? AE. Incident Detail N. Nurse Name AE. Date		
77	Daily patient monitoring list with details e.g. visit date, nurse assigned, drugs availability and visit location? DA. Availability V. Location N. Name		
78	List of concurrent medication or any oral tablets for each referred patient from hospital?	CM. Drug P. Name	

5.8 Conclusion

Chapter 5 effectively links findings of this research back to the research question by presenting a detailed data model, a list of unique analysis questions and a mapping between analysis questions and the data elements. The unique list of 78 identified analysis questions was achieved by removing duplications by the process of comparing each question with other 125 identified analysis questions for their similarity from the chapter 3 and chapter 4, analysis of which is attached in Appendix F.

Analysis of total identified questions

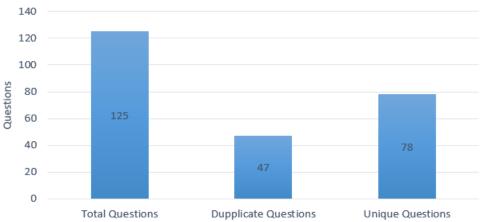


Figure 9: Analysis of total identified questions

The data model consists of 11 tables and 150 data elements. It also shows relationship and cardinality between different data tables. The core logical data grouping can be described as patient medical profile, hospital referral, nurse visit and patient feedback. A consultant from a hospital can refer one or multiple patients to an outpatient care setting. Depending upon the drug administration frequency a nurse may perform one or recurring patient home visits. A nurse must record a treatment outcome at the end of each visit, whereas the patient has an option to submit feedback about their condition in context of current or previous nurse home visits before or after completion of their IV treatment. During an entire course of patient treatment there may or may not be any adverse event, however multiple adverse events can be recorded against an episode of care. Some of the prominent analysis questions are related to nurse scheduling, adverse events and treatment outcome analysis.

There were 14 treatment outcome related variations of questions identified during the analysis questions duplication removal process, all of those requirements can be addressed by producing a list of patients by their clinical outcome status (improved, clinical failure or no change etc.). The other most repeated question was about a detail report of a patient adverse event incident consisting reason for the adverse event, pre and post infusion vital observations, treatment given, treated by and the outcome.

Most fequently identified analysis questions

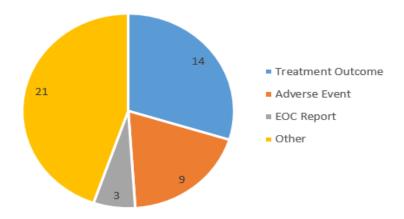


Figure 10: Most frequently found analysis question during the literature and interview data analysis

6. Conclusion

The first objective of this research was to identify analysis questions which the various stakeholders might wish to answer. This included questions a) identified by stakeholders, b) which emerged from literature, and c) identified by the author. While the second objective was to come up with a data element list that can be used to answer the identified analysis questions. The objectives of the research were achieved by producing a comprehensive list of unique analysis questions, list of required data elements and the data elements' mapping against each question to the level of data element's identification which was required to answer each identified analysis question. A data model was also produced to effectively represent data elements and their relationship between different data objects.

6.1 Research Summary

The literature review and interview data addressed core aspects that were critical to the delivery of a complex IV treatment service in the community. Patient treatment in the community is very challenging as compare to an inpatient care setting, but it also provides huge opportunity for improving patient care by having effective governance procedures in place. The literature analysis highlights such important areas e.g. service delivery, clinical governance, patient monitoring, adverse events, quality of care, patient suitability and clinical effectiveness.

6.2 Implication of the Research Findings

Findings of this research shows a list of 78 unique analysis questions and the required data elements to answer those questions. The inspiration behind this research topic was to identify mainly the potential of data which is either being currently captured or not during the community lead nursing intervention for the IV treatment. The outcome helps to fill the information gap between the stake holder's prospective questions and the currently captured data in IV treatment in community. By using the data and questions analysis presented in this research can help improve patient care in several ways for clinicians, pharma companies, insurance companies, HSE and existing and new software vendors involved in developing software for outpatient settings in particular.

6.3 Limitations of the Research Findings

The current Irish model of national outpatient antimicrobial treatment was the main case study behind this research, which limits the depth of this research from the perspective of its global impact. It also has to be stated that majority of the interviewees who participated in this research were directly or indirectly involved in OPAT program. The author was unable gain access to HSE staff for an interview for this study, however he manage to interview a staff member of a private community nursing agency, the person interviewed for this study directly deals with HSE's routine and frequent queries related OPAT program. Another limitation includes the author's potentially, but unintentional, biased opinion about some aspects of the research which may have influenced the direction of this research due to his previous involvement as software vendor to the Irish OPAT project.

6.4 Future Recommendations

The result of this research produced 78 distinct analysis questions which showed the importance of data availability, analysis and its requirement for various stakeholders involved in community IV treatment. However, quality of the 78 uniquely identified questions is undetermined in this research. Further analysis on the identified questions and data elements identified in this research can produce a definitive quality list of various stakeholder's information requirements.

During the interview with community nursing agency it was noticed that pharmacists also play an important role in community IV interventions for dispensing of the medicine along with other care

givers. It is recommend that the future researchers on this topic should interview pharmacists and explore their role in greater detail to add more value to this research area.

Finally, the data on objective patient outcome, such as quality of life and return to work or on subjective outcomes relating to the patient experience are more limited, and this is an area where further work is needed.

References

Appendix A: Ethics Approval

On 30 January 2015 at 03:33, Sara Gutierrez Llaneza <<u>Sara.Gutierrez@scss.tcd.ie</u>> wrote:

Dear Sarfaraz,

Many thanks for this update. The Research Ethics Committee has approved your application. You may proceed with this study.

We wish you success in your research.

Kind Regards,

Sara

Appendix B: Interview Protocol

B.1 Stakeholders

The stakeholders identified for this research study were following:

B.2 Patients

Patient selected for this study are patients who receive IV treatment at home. The data generated (patient feedback) with respect to pain, bleeding, nauseas etc. (over the course of treatment) could possibly be used to answer potential stakeholder questions. This information may be used for patient stakeholders as it may answer questions they would have in respect of their treatment. It may also serve to guide other stakeholders (e.g. consultants) and guide them in their choice of treatments.

B.3 Community Nurse

A community nurse plays vital role in capturing data that is generated as a result of administering IV treatment at home. The data generated and or captured by the nurse and patient could potentially be used to answer many questions which may arise from other stakeholders face to face interviews.

B.4 Community Nursing Agency

A Community Nursing agency is an important stakeholder to determine their needs of information in particular context of their employed nurse treating patient in community. In this research project the community nursing agency will be interviewed in addition the literature review to find out the potential secondary use of data for the community nursing agency.

B.5 Hospital Consultant

Hospital Consultants refer patients for IV treatment at home. IV treatment is administered to the patient as per the prescription issued by the consultant. Patient's IV treatment data is critical for the referring consultant to monitor patient condition during the course of treatment. Consultants could potentially benefit by analysing patient treatment data for the improvement of patient treatment etc.

B.6 General Practitioner

As a primary care provider GPs could benefit from the use of the patient IV treatment at home data to increase their understanding of patient health, especially in the shared care settings.

B.7 Insurance Company

Insurance companies may refer patients to a community nursing agency for the delivery of IV treatment. Insurance companies could benefit from the use of secondary data captured during the delivery of IV treatment and their perspective will be sought.

B.8 Drug Manufacturer

Pharmaceutical companies are an important stakeholder group who manufacture antibiotic IV drugs that are used by the community nurse to deliver IV treatment to a patient. Pharma companies could benefit from the use of secondary data captured during the delivery of IV treatment and their perspective will be sought.

B.9 Health Service Executive (HSE)

HSE could benefit and plan effective healthcare strategies by analysing the data that is generated as result of patients IV treatment in community.

Appendix C: Interview Questionnaire

C.1 Patient Questionnaire

- 1. Would you like to have any information in preparation of the nurse visit? (Please elaborate)
- 2. Would you like to have access to information about your treatment during or afterwards? (Please elaborate)
- 3. Would you like to be able to provide feedback positive or negative on your experience of IV treatment? (Please elaborate)

C.2 Other Stakeholders

Other stakeholders includes Community Nurse, Community Nursing Agency, Consultant, GP, Insurance Company, HSE and Drug Manufacturer. The questionnaire for these stakeholders includes following three questions:

- 1. What is your role in relation to outpatient IV treatment?
- 2. What information do you use to carry out your role?
- 3. What information could help you to perform better?

Appendix D: Literature Review Themes Analysis

				,	
Α	В	С	D	E	F
Sevice Delivery	Patient Monitoring	Clinical Governance	Clinical Effectiveness	Treatment Outcome	Adverse Event
There are three	However, at the end of	According to ALN Chapman	Analysis of available data	On the day to day bases	Adverse events monitoring, treatment
different types of	patient visit consultant	et al. (2012) number of	shows that the most	consultants would only	and measures to reduce such events
models which have	expects an end of care	research papers and	commonly treated	like to be contacted if	from happening is the most critical
proven to be	report containing complete	guidelines recommends of	infections in community	there are any issues	aspect of patient treatment in
effective for the	details of the activities that	importance of monitoring	for the IV treatment are	during self or nurse-	community. The need of having effective
delivery of	a nurse performed. The end	patient treatment outcome	soft tissue sepsis and	administering IV in	patient monitoring procedure is
outpatient IV	of care report should	data by having local	cellulitis (Chapman ALN	community. An adverse	identified by clinicians as one of the core
treatment (Tice AD	contain patient	dedicated database	et al., 2009).	event report is generated	area to focus, the published research
et al. 2004).	demographic details, drugs			in case of any issue or in	shows comprehensive recommendations
	administered, dressing,			some cases if a	about patient progress monitoring and
	blood samples taken, pre			community nurse unable	rapid response to an adverse event in an
	and post vital observations			to fix a problem herself	outpatient setting (Jevons MP 1961,
	and any additional clinical			then she may call	Wenzel RP et al. 1991).
	notes (Consultant			referring consultant's	
	Interview)			office to organise an	
				appointment to evaluate	
				patient	
In first model,	Patient treatment in the	Outpatient treatment	In England Cellulitis	In Ireland 9011 bed days	Data available from a study showed
	community can be termed	model require equally	accounts between 1 to 2	were saved by	adverse events were noted in twenty
the acute care	as hospital outside a	sophisticated clinical	% of the emergency cases		seven outpatient care episodes.
setting e.g. an	hospital, literature review	governance model as for	which is about 80000	patients in the	Seventeen minor cases were managed in
outpatient clinic	shows that it brings number		annual admissions	community which is	community. Three of the adverse events
frequently for the	of challenges regarding	can ideally be achieved by	(Phoenix G, 2012).	about 10 days per	were caused by drugs e.g. ototoxicity due
•	patient monitoring during	having dedicated team to		patient. Analysis of the	to gentamicin, drug induced hepatitis,
	the entire course of	centrally coordinate all		available inpatient data	and itch. Eleven other were related to
	treatment in community	service delivery and			PICC line, in three cases PICC were
developing	which is mainly due to	management activities.			completely replaced. The study shows
countries (P.	limited clinical observation	Clinical governance and			that adverse events were greater with
Berman, 2000).	especially in comparison to	monitoring existing aspects		conditions that could	cephazolin vs. flucloxacillin (SJ Berman et

D.1 Service Delivery Analysis for Prospective Questions

1	Context	Self Identified Prospective Analysis Questions from Service Delivery Theme
	Most OPAT services described in the literature are based in acute	List of patients or sum of patients referred from one or multiple hospital
	hospitals, predominantly in specialist infectious diseases units (Chapman	departments?
	ALN et al. 2009, Barr DA et al. 2012, Esposito S et al. 2007, Amodeo MR et	
	al 2009). Services may also be established by other inpatient specialist	
	teams or in frontline emergency or acute medicine units (Corwin P et al.	
2	2005):	
	In the ambulatory care centre model, the patient attends a healthcare	Complete audit trail of a patient visit with each of the data element e.g.
	facility daily, or as required, with antibiotics administered by a healthcare	number of atients visits over a period of time?, frequency of patient visits?
	practitioner. Treatment in the patient's home may be administered by	Number of visists carried out by a nurse (other parameter includes nurse type
	community nurses, outreach nurses from the acute hospital, or nurses	and organisation?
	provided through a private healthcare company	
3		
	In the third model patients (or carers) are taught to administer therapy;	Comparison between self-administered IVs VS carer administered IVs from the
	this has the advantages of engaging patients in their care, allowing more	safety and cost saving point of view?
	flexibility of dose frequency and timing, and reducing staffing costs.	
	Despite theoretical concerns about line infections, two large retrospective	
	studies have shown that self-administration is as safe as administration by	
	a healthcare worker in the community (Matthews PC et al. 2008, Barr DA	
4	et al. 2012)	
	The model of OPAT used largely determines the type of intravenous	· · · · · · · · · · · · · · · · · · ·
	access. Options include temporary "butterfly" needles that are inserted	
	and removed for each dose, short term peripheral cannulas, or, for longer	
	antibiotic courses, peripherally inserted central cannulas or tunnelled	
	central lines. Bolus injections or infusions may be used, depending on the	
	choice of antimicrobial agent(s). Infusions allow higher doses to be	
	administered but require additional administration time and training	
	(Royal College of Nursing 2010). Novel delivery devices allow patients	
	greater freedom to continue normal daily activities. For example, portable	
	elastomeric infusion devices can be carried in the patient's pocket or a	
	carrying pouch and deliver continuous infusions over 24 hours (Howden	
5	BP et al. 2002).	

D.2 Clinical Effectiveness Analysis for Prospective Questions

1	Context	Self Identified Prospective Analysis Questions from Clinical Effectiveness Theme
	OPAT is most widely used for patients with soft tissue sepsis, mainly	List of patients referred for outpatient treatment for an IV treatment by diagnosis?
2	cellulitis as per the analysis of available data (Literature)	
	Around 30% of patients presenting to hospital with cellulitis have	1. What is the percentage of patients presenting to hospital with problems that can
	moderately severe infection that requires intravenous antibiotics but do	be treated in community for IV treatment?
	not have severe systemic sepsis necessitating inpatient care (CREST,	
3	2005).	2. What is the percentage of patients by diagnosis (suitable for community IV
	One randomised controlled trial of twice daily intravenous cefazolin	1. Patient improvement percentage comparison between home vs inpatient care
	administered by a nurse at home compared with standard inpatient care	setting by using same drug and IV infusion frequency?
	showed no significant difference in duration of intravenous or	
	subsequent oral antibiotic therapy, patient functional outcomes, or	2. What is the percentage of adverse events reported during the use of same drug
	complications but reported improved patient satisfaction with home	and IV infusion frequency in the home vs inpatient care setting?
	treatment (Corwin P et al., 2005).	
		3. What is the patient satisfaction level comparison between home vs inpatient care
		setting in general (as well as comparison by using same drug and IV infusion
4		frequency in both care settings)
	Data from several large retrospective case series show that outpatient	What is the percentage of most commonly used antibiotics for outpatient IV
	treatment with once daily ceftriaxone is also safe and effective, with	treatment?
	good short and long term clinical outcomes, and this is now the	
	predominant antibiotic used for outpatient intravenous treatment of	2. What is the average recovery time period for each prescribed drug for a diagnosis
	cellulitis in the UK (Duncan CJA et al., 2012).	(based on the infusion frequency and infection severity)
5		3. What is percentage of adverse events reported against each drug used for

D.3 Patient Monitoring Analysis for Prospective Questions

1	Context	Self Identified Prospective Analysis Questions from Patient Monitoring Theme
	The findings from various studies helped a working group to establish that it	1. What are the number of unplanned occasions when patient contacted for
	was very important to produce clear recommendations on how to monitor	clinical advice during the course of IV treatment in community?
	patients' progress during therapy, and on developing pathways for rapid access	
2	to clinical care if problems arise (Jevons MP 1961, Wenzel RP et al. 1991).	
	Overall, at least 25% of patients receiving IV antibiotics in community settings	2. What is the percentage and list of patients receiving IV treatment in
	will develop adverse reactions, which range from mild antibiotic-associated	community setting reported adverse an reaction?
	diarrhoea to life-threatening line infections (SE Parker et al. 1998, D Prete et al.	
3	1999).	3. What is the percentage of adverse events by reason and severity level?
	Therefore, it is critical that physicians, nurses, consultant and other concerned	4. What are the percentage and list of adverse events that could have be
	medical staff managing outpatient IV treatment are familiar with potential	prevented by effective early monitoring and interventions?
	complications and informed so that these can be detected early. Up to 10% of	
	patients on OPAT will discontinue their therapy early because of adverse events	
	(AD Tice 1996), most of which relate to either the antibiotic or the line (S.	
4	Parker et al. 1998, S. D. Prete et al. 1999, P Jones 1992)	
	Progression of infection on therapy is an unusual cause of discontinuation of	5. What is the percentage and list of patients discontinued from outpatient treatn
	OPAT, although it is more frequent in patients with endocarditis (MC Rahimy et	
5	al. 1999).	
	Rates of readmission for any reason fro-m OPAT range from 4%–12%,	6. What is the percentage and list of patients readmitted ?
	emphasizing the need for a formal readmission pathway (G Milkovich 1995, S.	7. What is the percentage and list of patients who did not followed the formal
	Parker et al. 1998, D Nathwani et al. 2000, F D Lalla 1998)	readmission pathway?
		8. List of patients with reason the formal readmission pathway was not
6		followed?
	In addition, one study demonstrated that there is a significant need for	9. What is the percentage and listing of patients who requested for unplanned
	unplanned access to advice or review, with 6% of patients requesting urgent	urgent phone advice?
	telephone advice, and a further 6% requesting unscheduled home visits (D	10. What is the percentage and listing of patients who requested for unplanned
7	Nathwani et al. 2000).	home visits?
	Complications appear to increase with the duration of OPAT, particularly	11. What is the percentage of adverse events in less frequently monitored
	changes to blood parameters (AD Tice 1996, S. Parker et al. 1998), and thus the	patients?
	proposal that stable patients on prolonged antimicrobial courses could be	
8	monitored less frequently may not be appropriate.	
	The adoption of a regular team meeting with discussion of patients currently	12. What are the common outcomes that appear during the discussion with
	receiving OPAT (the so-called 'virtual ward round') would facilitate the collation	patients over the course of their IV treatment?
9	of data for outcome monitoring and clinical governance purposes.	
		t e e e e e e e e e e e e e e e e e e e

D.4 Clinical Governance Analysis for Prospective Questions

1	Context	Self Identified Prospective Analysis Questions from Clinical Governance Theme
	Many studies report the use of simple outcome measures, e. g. 'cure',	1. What is the percentage and list of patients by clinical status (improved, clinical
	'improvement', 'readmission' or 'no change', with additional monitoring of	failure or no change)
	adverse events, in particular vascular access complications. The IDSA	2. What is the percentage and list of patients by bacterial infection status (culture
	guidelines describe a more complex series of outcome parameters	negative, persistent pathogen or new pathogen)
	1. Clinical status (improved, clinical failure or no change)	3. What is the percentage and list patients by programme outcome (treatment
	2. Bacterial infection status (culture negative, persistent pathogen or new	completed as planned, or reason for non-completion)
	pathogen)	4. What is the percentage and list patients by antibiotic use (course completed as
	3. Programme outcome (treatment completed as planned, or reason for	planned, or reason for non-completion)
	non-completion)	5. What is the percentage and list patients by vascular access complications
	4. Antibiotic use (course completed as planned, or reason for non-	6. What is the percentage and list patients by additional outcome measures
	completion)	(return to work, survival status or performance against physician expectations)
	5. Vascular access complications	
	6. Additional outcome measures (return to work, survival status or	
2	performance against physician expectations)	
	More practical outcome measures includes OPAT success or OPAT failure	
	(including admission following initiation of OPAT, any adverse event and	7. What is the percentage and list of patients admitted to hospital as result of
3	progression of infection)	outpatient treatment failure?
	In most OPAT series, outcomes were measured on completion of	8. List of patient monitoring outcomes after completion of treatment?
	intravenous therapy, and longer (potentially more useful) follow-up data	
4	were less frequently recorded.	
	These GPRs incorporate a statement relating to the need to monitor	9. What is the average satisfactory level of patients about their outpatient IV
	patients' views of the service that they are receiving, to ensure that it	treatment?
5	remains truly patient-focused	
	However, the data on objective patient outcome, such as quality of life and	10. How good patient's quality of life improved over the course of treatment?
	return to work or on subjective outcomes relating to the patient experience	
6	are more limited, and this is an area where further work is needed	
	The final statement in this section refers to the requirement for each OPAT	
	team member to maintain and update their knowledge to ensure best	10. Which staff involved in outpatient IV treatment have missed one or more
7	clinical practice	service related training sessions?

D.5 Quality of Care Analysis for Prospective Questions

1	Context	Self Identified Prospective Analysis Questions from Quality of Care Theme
	HSE (2014) in Ireland has successfully treated 909 patients in community,	1. What are the total number of successfully treated patients in community for IV
	which as result saved 9011 bed days (10 days per patient). Review of	treatment?
	hospital inpatient data for 2009 shows that there were number of	
	admissions and hospital bed days used for some of the conditions	2. What are the number of hospital bed days saved by sucessful treatment of the
2	potentially treatable by an OPAT programme.	conditions in community?
	patients were usually able to be discharged to the OPAT service in the 3rd	3. What are the percentage and list of patients discharged in 2nd and 3rd week of
	week of treatment for IE due to S. aureus, and in the 2nd week for disease	the treatment?
	due to viridans streptococci although hospital stay was often prolonged in	
	those requiring surgery as described in other studies. In our study	4. What are the number of patients who could not recover post in community
	population OPAT was effective and no cases of treatment failure were	treatment?
	identified. There were 2 deaths in the follow-up period attributable to other	
	causes and as the New Zealand mortality register is a nationwide database	
	it is unlikely further cases are unrecognised (M. R. Amodeo et al, 2009).	
3		

D.6 Adverse Events Analysis for Prospective Questions

1	Context	Self Identified Prospective Analysis Questions from Quality of Care Theme
	Adverse events were encountered in 27 episodes of IE treated with OPAT	1. What are the total number of adverse events occurred during a certain
		number of episodes and dates?
2		
3	In 17 episodes, minor adverse events were able to be managed in the clinic	What percentage of adverse events were managed in primary care?
	Three of these were drug related (1 episode each of ototoxicity due to	3. What is the percent and list of adverse events by adverse event reason?
	gentamicin, drug induced hepatitis, and itch) and 11 were related to the PICC	
4	line (6 episodes of PICC line occlusion, 2 episodes each of line migration and phlebitis and 1 of cellulitis)	
	In 3 instances, the PICC line required replacement. High residual infusate (>10 mL of residual fluid on 2 days within a week) that was unrelated to the	address adverse event?
5	PICC line patency occurred in three treatment episodes, all while receiving flucloxacillin 8 g/day. Infusion failure was significantly greater with flucloxacillin vs. cephazolin (3/9 vs. 0/18; pZ0.029 Fisher's exact test).	15. What nercent of adverse events were resolved by the action taken by
6	The reason for admission in the other 3 episodes were, worsening congestive heart failure after failing to take prescribed frusemide which resolved quickly after restarting, flank pain secondary to renal sub-capsular haemorrhage in a patient who had experienced a renal embolus during initial admission and recurrence of longstanding angina.	
	Among patients treated with OPAT, there were 2 deaths in the follow-up	7. What percentage and list of patients developed some other health problem
	period. An 80 year old male had 2 episodes of SAIE within 3 months died	after completion of their treatment?
	suddenly 3 months after the 2nd treatment was completed. The S. aureus	
	isolates from each episode had different antibiotic susceptibility profiles.	8. What are percentage and list of patients by each reported problem type?
	Death was attributed to myocardial infarction without autopsy. The second	
	was a 73 year old male with cirrhosis due to Hepatitis C and oesophageal	
	varices who developed native valve, culture negative IE and was admitted 5 months after treatment was completed with urosepsis and died in hospital.	
7		
	Five patients were re-admitted with further episodes of IE. The mean	9. What are the percentage and list of patients who developed health
	number of days between completion of OPAT and re-admission with further	problems in which week/month after completion of their outpatient
0	IE was 220. Two patients were re-admitted for investigation of possible IE but this was not confirmed.	treatment?
Ö	but this was not confirmed.	

Appendix E: Interview Analysis

E.1 Consultant Interview Analysis

1	Context	Analysis Questions Identified from Consultant Interview
	A consultant in hospital identifies patient that are suitable for self-	List of patients referred by each consultant for monitoring purpose?
	administered or nurse-administered outpatient IV treatment in	
	community. Various parameters that are considered for patient	2. List of patients not accepted for outpatient IV treatment group by the rejection
	assessment for outpatient treatment includes patient's clinical details as	reason?
2	well as patient living conditions such as social demographics	
	During the course of treatment consultant recalls patients for weekly	3. List of patients due for weekly check-up?
	check-up in outpatient clinic to review their treatment progress. The	3. Elst of patients due for weekly effect up:
	frequency of patients is less frequent once their IV treatment course is	4. List progress of patients noted over the period of time captured during the
	completed Consultant in the hospital examines patient and	weekly check-up meetings?
3	determines patient recovery progress.	weekly elleck up meetings.
	Issue related to patients IV treatment during course of treatment is	5. List of all patient adverse events by their reason and outcome?
	referred as an 'adverse event'. Consultant expects an adverse event	,
	report in case of any issue. The report should consist of complete	6. Detail report of a patient adverse event incident consisting of reason of adverse
	incident information e.g. reason of adverse event, pre and post infusion	event, pre and post infusion vital observations, treatment given, treated by and the
	vital observations, treatment given, treated by and the outcome.	outcome?
4		
	At the end of each patient visit consultant expects an EOC (end of care)	7. Detail of all EOC visit reports for patients contain patient demographic details,
	report having complete activity details nurse performed while	drugs administered, dressing, blood samples taken, pre and post vital observations
	administering patient. The end of care report should contain patient	and any additional clinical notes?
	demographic details, drugs administered, dressing, blood samples taken,	
	pre and post vital observations and any additional clinical notes	
5		
	Consultants also wants to be notified if patient has developed a new	8. Newly developed allergy name, type and description of patients?
	allergy. At the end of patient treatment episode consultant records the	
	treatment outcome and discharge patient from the treatment.	9. List of top 5 allergies reported by patients over the period of a year?
6	- '	
	At the end of patient treatment episode consultant records the	10. List of all patients grouped by treatment outcome?
	treatment outcome and discharge patient from the treatment.	
		11. List and percentage of patient's successfully or not successfully completed their
7		treatment outpatient IV treatment?
-		

E.2 GP Interview Analysis

1	Context	Analysis Questions Identified from GP Interview
	When antibiotics are given in the home, the sort of information GP want to know	List of patient with the administered drug information?
	are what drug has been given, has that been tolerated, has there been any side	
	effects, patient's vital signs, whether patient are improving or not improving. It's	2. What number of patients have developed any side
	the same sort of information that would be important to know for the patients	effects as result of administered drugs?
	getting chemo or other IV treatments in community.	
		3. What are patient's vital signs captured during the IV
		infusion especially if they are outside normal range?
		4. What is the percentage and list of patients by treatment
		outcome?
2		outcome:
	It will be useful to receive patient's EOC (end of care report) electronically or by	5. End of care report of each patient visit?
	other means. Patient information such as if IV is going to be given through	
	peripheral line, safety of the line, line cleanliness status and is it inflated. In case	6. List of patients being administered through different
	of a central line it's different. In Ireland GP don't get involved in patient's IV	types of line, safety and line cleanliness status?
	treatment at home at all, the only way IV antibiotics are done in Ireland are two	
	ways 1) private insurance 2) Public	7. List of patients getting IV treatment at home by
		different providers?
3		
	GP do not call patients to recall them in clinic for IV treatment primarily due to	8. List of patients due for their diabetic check-up and/or
	the funding cuts and lack of staff, but they invite patients for diabetic check-up or	flue vaccination?
	flue vaccination.	
		9. List of patients (with their clinical information) who are
		diagnosed with any new symptom?
4		

E.3 Community Nurse Interview Analysis

1	Context	Analysis Questions Identified from Community Nurse Interview
	The nurse gets visit allocation the night before visit around 6 pm,	What are the list of patients who are scheduled to be seen by nurse
2	usually she receives an email with list of patients that needs to be seen	tomorrow?
	Nurse rings patient that evening to let them know what time nurse	2. What is the total volume and duration of calls nurses have made to patient
	would be going to their houses as per the dose timing given in the	for the visit time confirmation between certain dates?
	prescription. A lot of time patient forget to be present at home when	
	nurse arrives, in that case nurse rings patient on their mobile and wait	3. What are the total number of occasions and duration nurses had wait for
3	until patient is comes back home	patient after arriving at patient home?
	The nurse checks each patient details including patient prescription,	4. What are the medical profile details that were submitted as part of original
	past medical history and what treatment she would be giving to the	referral for all scheduled patients for the next day nurse visit? (e.g. patient
	patient during her visit to patient home. A patient's medical profile	demographic, prescription, past medical history, allergies, comorbidities,
	consists of past medical history, comorbidities such as if patient has	blood results, surgical history, current medications, previous adverse
	cancer or any surgical procedure, blood results that were submitted	reactions and referral details)
	with original referral, list of current medication, allergies and details of	
4	any previous adverse reactions The nurse takes vitals observations e.g. temperature, blood pressure	5. List of patients having abnormal vital observations over a period of time
	and respiration to make sure all within the normal range, note the	recorded before completion of their IV treatment in community?
	dose, route, after that she validates the drug against prescription,	recorded before completion of their tv treatment in community:
5	records and the start and end time of administration as well as her	
5	records and the start and end time or administration as wen as ner	6. List and percentage of patient by the outcome recorded by nurse at the end
	Once the antibiotic is completed the nurse does another set of vital	of visit during as well as after completion of overall patient treatment?
	observations just to make sure patient is well post procedure and then	or visit during as well as after completion of overall patient treatment:
	marks treatment session complete. At the end nurse records her	7. What are the pre and post IV administration vitals observations of patient
	comments and concerns with patient e.g. feeling unwell, anxious or if	where outcome recorded by nurse are other than satisfactory?
6	they had any upcoming out-patient appointment.	· · · · · · · · · · · · · · · · · · ·
	In case of an adverse event the details of actions that are recorded	What are complete details of a patient adverse event e.g. reason, action taken, outcome, pre and post administration vital observations, have all
	includes drug and severity of reaction, whether drug was stopped or	clinical stakeholder been informed?
	not, post reaction vital observations, contact patient medical team to	chincal stakeholder been informed:
_	determine if patient needs to visit hospital, or in case of severe	
7	reaction call the ambulance to take patient back to the hospital.	9. List of previous patient visits and details e.g. blood results, vital
	It will be useful for nurses to have patient's up to date blood results and detail of any previous adverse event, next out-patient	observations, drugs administered, labs and adverse events?
	and detail of any previous adverse event, next out-patient appointment date (most of the time patient provides this detail to	observations, drugs administered, labs and adverse events:
	nurse as they receive call from hospital consultant), an overall plan of	10. What are details of patient's care plan e.g. future appointments, other
	care from the team e.g. treatment end date and plan after the	planned procedures, goals and interventions?
	treatment ends as lot of time patient ask these questions from nurse	L
8	which she is not aware of at the moment	
_	Any change of prescription is fax to the nursing agency and pharmacy, it	11. What are the list of patients who have been issued a new prescription?
	is then scanned and emailed to community nurse so that they have up	
9	to date information.	
	Nurses maintain a time sheet for the visit they have done which they	12. What are the list of visits which a nurse has performed over a period of
	submit at the end of each month to get paid. In case of any ambiguity	time?
	the nurse may contact their nursing agency to get information	
10	regarding patient they have seen.	

E.4 Nursing Agency Interview Analysis

A	В
	Analysis Questions Identified from Community Nurse Interview
	 What are the list and percentage of patients not accepted for community IV treatment by the rejection reason and date?
A referral typical consists of patient demographics, prescription, allergies, weight, past medical history, blood results, vital signs, comorbidities, any antibiotics patient may have had in the hospital, surgical procedures, swab,	2. What are the complete details of a referral received from hospital?
emergency medications and doctor signature.	3. What are the total number of referrals received from a hospital over a period of time?
In addition she reviews all referrals to ensure that all the clinical information is present and correct	4. What number of times referrals have been found incomplete by reason?
	5. What amount of delay has been caused due to the incomplete referral details?
	6. List of restricted drugs?
Nurse manager also checks if the antibiotic is not restricted or prohibited and verify that the appropriate antibiotic is prescribed for the appropriate condition	7. List of approved drugs for each condition?
	8. List of available nurses between a certain duration for patient visits?
planed 3 to 4 weeks in advance e.g. holidays, shifts, start and end time. They also needs to know when the patient is	
scheduled to go back to the hospital Nursing	
Training of the nurses is conducted on regular bases for the services they provide so that nurses are qualified to do	9. List of nurses and their qualification details?
their jobs in community.	
	10. What are the number of incidents and details when a nurse contacted hospital about
	patients not responding to a treatment?
location for the effective nurse scheduling	
	11. List of available nurses for scheduling based on nurse skillset, patient dose regime, drive
	time between nurse and first patient and to the subsequent patient, visit duration (including
	IV antibiotic infusion time), general risks (e.g. nurse safety), visit time (should be consistent
	for the full duration of the treatment?
	12. Daily patient monitoring list with details e.g. visit date, nurse assigned, drugs availability
	and visit location?
some antibiotics are very expensive which the hospital may not have in their stock especially if the nursing agency	
has government funded antibiotic stock, in this case antibiotics are administered by the hospital nurse. The nursing agency has very limited visibility to the visit details when patient is administered by the hospital nurse.	13. List and details of patient's hospital visit during the course of IV treatment in community
The nursing agency expects an evaluation of care report at the end of each visit, in addition this report is shared with	
	current medication, vital observation, administered drugs, infusion duration, post visit vitals
	observations, dressing, specimen, visit summary checklist and sharps bin collection?
, , , , , , , , , , , , , , , , , , , ,	15. List and detail of all adverse events?
during the nurse visit Nursing agency would prefer if they can receive more information from hospital on the referral such as patient's	16. List of concurrent medication or any oral tablets for each referred patient from hospital?
concurrent medication, any oral tablets. This information will help them make a better clinical judgement if an IV	20. List of concurrent medication of any oral tablets for each referred patient from hospitals
	17. List of referrals and status report?
referral in the process at glance from the referral received to the nurse visit completion e.g. referral has been	27. List of Teremora and status report.
received, approved, antibiotic has been picked, packed, delivered or ready to be delivered and nurse events.	

E.5 Pharma Company Interview Analysis

1	Context	Analysis Questions Identified from Pharm Company Interview
	Pharma Company manufactures IV antibiotics that are used by the nurses and doctors in	What are the total number of patient specific or non-patient
	the hospital or in community setting. The IV antibiotics manufactured in the pharma	specific IV antibiotics used by nurses in the community?
	company are produced as a patient specific or non-patient specific	
		2. List and percentage of drugs used by patient's age group and
2		demographics?
	In order to manufacture patient specific IV antibiotics the pharma company requires a	3. Prescription details of all patients for the manufacturing of patient-
	valid prescription with attributes such as patient name, prescriber name and contact,	specific IV antibiotics?
3	drug name, total prescribed quantity, duration of infusion, frequency, form and diluent	
	Pharma Company would like to know if all the pumps are being used by the patient or	4. What is the prescribed frequency of each drug to be
	nurse at the same time or the supplied drugs will be used over the period of time?, have	manufactured?
	nurse or patient encountered any problems during infusion of the drug?, did the IV	
	infusion pump infused the drug within programmed time	5.Did the IV infusion pump infused the drug within programmed
		time?
4		
	In case of an adverse event pharma company require drug name, batch no, type of	6. Complete details of an adverse event (e.g. drug name, batch no,
	reaction, date and other details e.g. did reaction happened during two simultaneous	type of reaction, date and other details e.g. did reaction happened
	infusions, was that a single drug infusion, or the primary drug was infused along with	during two simultaneous infusions, was that a single drug infusion, or
	some other drug which could be potentially be the reason for an adverse event	the primary drug was infused along with some other drug which
5		could be potentially be the reason for an adverse event)?
	There are instances where patient would not have used all IV infusion pumps. Pharma	7. List of used and unused drugs that were previously to patient
	companies do not have drug usage information in real-time from patients, therefore the	home for the IV infusion?
	manufacturing forecast is based on assumption that can potentially result into over	
6	manufacturing or waste in case of shorter shelf life drugs.	

E.6 Insurance Company Interview Analysis

1	Context	Analysis Questions Identified from Insurance Company Interview
	Generally, people aged between 18 to 50 pay the big premium as mostly	1. List of insured population by their age and immunization status?
	they do not get sick quite often, however within this cohort there are	
	patients that get sick while some of them require straightforward	
	interventions particularly in the later part e.g. broken leg etc. which are	
	accidental in nature. But there are other preventative measures which	
2	insurance company can take such as immunization to prevent children from	
	The bigger challenge however is the management of patients with chronic	2. List of insured patients diagnosed with infections suitable for treatment in
3	disease, infections and carrying a long term injury	community?
	Due to early intervention patient's treatment in primary care costs less than	3. List of insured patient's diagnosed with infection not suitable for IV
	hospital treatment. Therefore, the Insurance companies prefer patient	treatment in community by reason?
	treatment in community instead of hospital depending upon the suitability	
4	of patient's living circumstances, medical condition and treatment.	
	Insurance company does not want their patient to be dependent on the	4. What are the list of factors identified by nurse that can help expedite patient
	system which happens once patient reaches hospital, therefore they prefer	recovery from IV treatment in community?
	to spend some money from patient's premium to keep them healthy e.g.	
5	subsidised regular health check-up at GP clinic or by providing free gym	
	Subject to the data availability from community the insurance companies	5. No of bed days saved of insured patients by completing their successful IV
	can do cost-benefit analysis between patient's treatments in hospital and	treatment in community for infections?
	treatment in community as generally there is a perception that patient get	
	better treatment at hospital than home, so the data related to quality	
	standards e.g. using the right IV and finally the outcomes can help insurance	
6	companies improver their services for their members	
	However, it adds risk to the insurer part if they ask patients to go to a	6. What are the list and percentage of insured patients with reason they were
	homecare facility for a treatment, then if something goes wrong with the	discontinued from treatment in community and referred to hospitals for
	patient's will have to go to the hospital which can cost insurance company	admission?
	double (in community treatment in first place and then treatment in the	
7	hospital).	
	"From an insurer's point of view its matter of which is better and which is	7. List of insured patient's visit details in community?
	cheaper between community or hospital treatment", with this information	
	insurance company can lower its risks and save costs. Most of the insurance	
	companies in Ireland have their own nurses and clinical directors to monitor	
	their patients getting treatment in community while also provides on call	
	clinical advice for minor health issues. Patient treatment information e.g.	
8	nurse visit details are processed by the insurance company's internal care	

E.7 HSE Interview Analysis

1	Context	Analysis Questions Identified from HSE Interview
	To understand the workload on hospitals HSE wishes to know the number of	1. What are the total number of patients referred from
	patients being referred every day for outpatient treatment from all hospitals by	all hospitals by the speciality, consultant, type
	the speciality, consultant, type (self/home) and date. However, the effectiveness	(self/home) and date?
	of outpatient treatment is measured by patient recovery outcomes and the	
	number of hospital bed days saved.	2. List and percentage of patients by treatment
		outcome of an episode?
2		
	"We would like to have access to maximum information generated by the	3. List of patients on IV treatment in community group
	patient directly or indirectly during the delivery of IV services for well informed	by various living condition factors?
	decision making". Additional information such as patients living condition,	
	adverse events, prescription compliance, quality of service and patient	4. List and percentage of the total number of adverse
	satisfaction would help analyse patient's IV treatment in non-inpatient settings	events by their outcome?
	from different aspects.	
		5. What are the total number of bed days saved by
		successfully treating patients in community for
		infections?
		6. What is patient's feedback about the IV treatment
		they have received in community?
3		

E.8 Patient Interview Analysis

	A	В
1	Context	Analysis Questions Identified from Patient Interview
	Patient initially expects a briefing from their nurse or doctor about entire	1. Complete details of patient care plan (e.g. nurse visit dates, hospital appointments, dressings, lab
	course of treatment and its objectives. As the treatment begins more	results, trainings, care team contact details)?
	specific information is required by the patient from their nurse e.g. visiting	
	nurse name, nurse contact number, visit date and time, duration of visit,	
	type of visit e.g. training or IV administration, duration of infusion if the visit	
	is an IV administration.	
	In absence of a shared care the patient has to explain multiple care team	
	members about his available on a certain day	
2		
		2. List of all previous vital observations e.g. blood pressure, blood sugar level etc.?
	Patient likes to see blood pressure and other vital observations readings in a	
	graphical form but also inquire about their recovery progress from the	3. Progress on the status of all planned health goals during the treatment?
3	visiting nurse	

Appendix F: Deduplication Analysis

	В	С	D
1	Question	Context	Matching Question Variation
2	5. What is the percentage and list of patients discontinued	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
3	7. What is the percentage and list of patients admitted to	Clinical Governance	What is the average satisfactory level of patients about their outpatient IV
	2. What is the percentage and list of patients by additional	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
4	outcome measures (return to work, survival status or		(improved, clinical failure or no change)?
	3. What is the percentage and list of patients by programme	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
5	outcome (treatment completed as planned, or reason for		(improved, clinical failure or no change)?
	6. What is the percentage and list of patients by additional	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
6	outcome measures (return to work, survival status or		(improved, clinical failure or no change)?
7	What is the percentage and list of patients by vascular access	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
	10. How good patient's quality of life improved over the	Clinical Effectiveness	What is the patient satisfaction level comparison between home vs
8	course of treatment?		inpatient care setting in general (as well as comparison by using same
9	8. List of patient monitoring outcomes after completion of	Patient Monitoring	What is the percentage and list of patients readmitted?
	What is the average satisfactory level of patients about their	Clinical Effectiveness	What is the patient satisfaction level comparison between home vs
10	outpatient IV treatment?		inpatient care setting in general (as well as comparison by using same
11	1. What are the total number of successfully treated	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
12	4. What are the number of patients who could not recover	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
13	5. What percent of adverse events were resolved by the		2. What percentage of adverse events were managed in primary care?
14	6. What is the percentage and list of patients who were	Patient Monitoring	2. What is the percentage and list of patients readmitted?
15	2. List of patients not accepted for outpatient IV treatment	Patient Suitability	2. What is the percentage of patients not accepted for outpatient
16	5. List of all patient adverse events by their reason and	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
17	10. List of all patients grouped by treatment outcome?	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
18	11. List and percentage of patient's successfully or not	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
19	2. What number of patients have developed any side effects	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
20	4. What is the percentage and list of patients by treatment	Clinical Governance	1. What is the percentage and list of patients by clinical outcome status
	End of care report of each patient visit?	Consultant Interview	7. Detail of all EOC visit reports for patients contain patient demographic
21			details, Risks, drugs administered, dressing, pre and post vital
	5. List of patients having abnormal vital observations over a	Consultant Interview	7. Detail of all EOC visit report for patients containing patient
22	period of time recorded before completion of their IV		demographic details, drugs administered, dressing, blood samples taken,
	C list and narrantara of nations but ha autonma ranardad bu	Clinical Covernance	1 What is the accounters and list of national burdinisal autooms status

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