The potential benefits of a traceability solution for surgical trays in the Irish Health Service

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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.

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Summary

Surgical Site Infections (SSI) are a major cause of Hospital Acquired Infections (HAI). SSIs can have an impact on both patient safety (e.g., development of a serious illness) and hospital costs (e.g., additional treatment). There are three ways in which patients can contract SSIs; by direct contact, by airborne dispersal and by self-contamination. Direct contact refers to contact from the surgical instruments or from the hands of operating theatre staff. The decontamination process of surgical instruments is therefore critical for patient safety. A nationally funded pilot traceability solution has been implemented in the Central Decontamination Unit (CDU) of eight hospitals in Ireland for surgical trays. The solution utilises GS1 standardised barcodes for device identification. GS1 are a global not-for-profit non-governmental organisation. GS1 has over 30 years of experience in the development and implementation of standards. GS1 identification numbers and barcodes allow organisations to fight the proliferation of counterfeit medicines, to establish robust recall solutions, and simply to uniquely identify products to enable traceability solutions. This dissertation examines this pilot solution and identifies its potential benefits, focussing on two of these hospitals: St James Hospital and Tullamore Hospital. The research question is: What are the potential benefits of a traceability solution for surgical trays in the Irish health service?

Methods Used

A literature review, case study research, interviews with the project stakeholders, semi-structured interviews with the hospital staff, and development of a financial model to quantify the potential cost benefits of implementing a traceability system.

Major Findings

A number of benefits were realised in the two case study hospitals including less administration, the ability to recall which instruments were used on a patient, knowing the location of the surgical instruments and quality assurance of the washer and steriliser cycles. The main issues identified in operating the system include the preparation work involved in barcoding all the surgical trays in the hospital with MS1 and GS1 barcodes. The financial model illustrates a substantial potential return on investment for the system if all SSIs associated with surgical instruments are eliminated.

Conclusion

The evidence found from literature review, case study research and the financial model strongly supports the implementation of a traceability solution for surgical trays in Irish hospitals.

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Abbreviations

CDU	Central Decontamination Unit
CJD	Creutzfeldt-Jakob Disease
GS1	Global Standards 1
HAI	Hospital Acquired Infections
HIQA	Health Information and Quality Authority
IMS	Independent Monitoring System
RFID	Radio Frequency Identification
SSI	Surgical Site Infections
WHO	World Health Organisation

Chapter 1. Introduction and Background

The Hospital Infection Society stated that the rate of surgical site infections (SSI) for patients in Ireland was 4.6% (HSPC, 2008). In the UK, the NHS (2008) found that at least 5% of patients contracted an SSI after surgery. However, a HSE survey found that just 1.1% of patients from a selected group of Irish hospitals contracted an SSI (HSE, 2006). SSIs contribute to the levels of morbidity and mortality in Irish hospitals. SSIs account for 22.5% of all Hospital Acquired Infections (HAI) and alongside Urinary Tract Infections (UTI) they are greatest cause of HAIs (see Figure 1.1 below). SSIs can have an impact on both patient safety (e.g., development of a serious illness) and hospital costs (e.g., additional treatment).

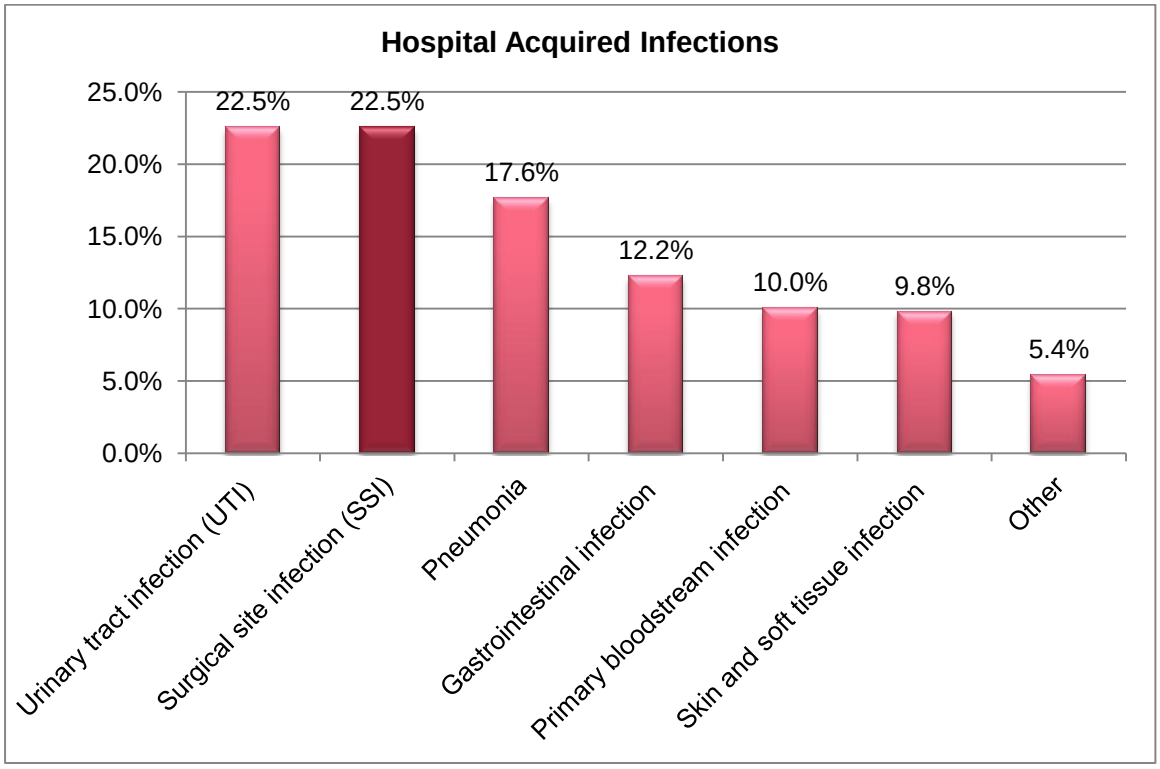

Figure 1.1; A breakdown of the most common Hospital Acquired Infections in Irish hospitals – Health Service Executive (HSE, 2006, p.24)

According to DermNet (2012) and WHO (2002) there are three ways in which patients can contract SSIs; by direct contact, by airborne dispersal and by self-contamination. Direct contact refers to contact from the surgical instruments or from the hands of operating theatre staff. The decontamination[1] process of surgical instruments is therefore critical for patient safety.

[1] Decontamination of surgical instruments involves removing any bacteria or other organisms that may be present after surgery. Any bacteria on surgical equipment can be spread from one person to another if the instrument is not decontaminated properly.

A nationally funded pilot traceability system has been implemented in the Central Decontamination Unit[2] of eight hospitals in Ireland for surgical trays. The solution utilises GS1[3] standardised barcodes for device identification.

This dissertation examines this pilot traceability system and identifies its potential benefits, focussing on two of these hospitals: St James Hospital and Tullamore Hospital.

Traceability systems have been widely used in the food industry for many years to track food products through the supply chain. They have also been used for tracking medicines in the pharmaceutical industry.

The research question is:

What are the potential benefits of a traceability solution for surgical trays in the Irish health service?

The subsidiary questions for this dissertation include:

- What are the benefits of traceability solutions in the other industries (e.g., Food and Pharmaceutical industries)?
- Why is the decontamination process of surgical devices important?
- What is the impact of SSIs for hospitals and patients?
- What benefits, if any, have been realised since the implementation of the traceability solution in St James Hospital and Tullamore Hospital?
- What were the challenges, if any, to the implementation of the traceability solution in St James Hospital and Tullamore Hospital?

The objective of this dissertation is to provide a framework to assist hospitals in evaluating the economic viability of implementing a traceability solution for surgical trays.

The research approach taken to answer the research questions and achieve the objective of the dissertation is illustrated below:

[2] A Central Decontamination Unit (CDU) is where the reprocessing (decontamination) of surgical instruments takes place.
[3] GS1 are a global not-for-profit non-governmental organisation. GS1 has over 30 years of experience in the development and implementation of standards. GS1 identification numbers and barcodes allow organisations to fight the proliferation of counterfeit medicines, to establish robust recall solutions and simply to uniquely identify products to enable track and trace solutions.

Research Approach

1	By way of a literature review, understand where traceability systems are used outside of the healthcare industry and to identify the benefits of these systems.
2	By way of a literature review, understand the benefits of similar traceability systems that have implemented.
3	Understand the importance of decontaminating medical devices, in particular, surgical instruments.
4	Identify the main causes of SSIs.
5	From walkthroughs of the Central Decontamination Units (CDU) in hospitals, understand the decontamination process and how the traceability system has changed from the manual process.
6	Carry out interviews with the project stakeholders, GS1, MS1 and Synthes to gain an appreciation for the role played by each of them.
7	Conduct interviews with the CDU managers in the hospitals to understand the understand more about the traceability solution for surgical trays.
8	Conduct interviews with the technicians working in the CDUs to understand the benefits and issues they have encountered with the traceability system.
9	Develop a financial model to evaluate the potential cost benefits of implementing the traceability system if SSIs were reduced.

The process for the literature review for this dissertation was:

- Reading articles and journals around the topics of traceability and decontamination.
- Structuring all the literature into a group of themes (e.g., traceability systems in the pharmaceutical industry, HAIs).
- Reviewing and evaluating the literature available on each theme.
- Writing the literature review with a focus on answering the research questions.

The dissertation is structured as follows:

Chapter 1: Introduction

This chapter introduces the background to the dissertation topic, the motivation for the research, the research questions and objective and the research approach.

Chapter 2: Literature Review

This chapter introduces the benefits of traceability systems in the food and pharmaceutical industries, the benefits of traceability systems for surgical instruments, the recommended standards for the decontamination of surgical instruments, HAIs and SSIs.

Chapter 3: Methodology

This chapter describes the research methodology and the approach employed in the course of this dissertation.

Chapter 4: Findings and Analysis

This chapter provides an analysis of the findings from the research, interviews and draws conclusions from the analysis. This chapter also contains a financial model which illustrates the potential cost savings of a traceability solution for surgical trays.

Chapter 5: Discussion & Conclusions

This chapter discusses the findings of the research conducted and the final conclusions of this dissertation.

Chapter 2. Literature Review

This chapter reviews the literatures available on traceability solutions and on HAIs. The objective of this chapter is to understand the traceability systems which are used outside the healthcare industry and identify the benefits of these systems. This chapter outlines the current problem of HAIs and SSIs in hospitals and the impact of these infections on the patient and the hospital. The recommended standards for decontamination by the HSE are also discussed in this chapter.

2.1 Traceability

This section examines the literature on traceability systems used in the food and pharmaceutical industries.

Golan et al. (2004) states the obvious fact that traceability systems are beneficial in helping to record and track items in the supply chain. There are two types of product traceability; tracing and tracking (Kelepouris et al., 2007). Tracing refers to being able to view the origin and attributes of a product at any stage during the supply chain. Tracking refers to being able to know the location of the product at any stage during the supply chain. It is an integral part of supply chain management to have an information system which caters for both tracing and tracking.

2.1.1 Traceability in the Food Industry

Traceability can help to quickly identify if there are any problems in the supply chain (Wilson et al., 1998). Traceability systems also help industries to manage the flow of a product through the supply chain which improves productivity, ensures food products are safe and of good quality and allows for product differentiation (Golan et al., 2004). The International Organisation for Standardisation in 1994 supported by EC regulation 178/2002 defines traceability in the food supply chain as “the ability to trace and follow a food, feed, food producing animal or ingredients, through all stages of production and distribution” (Regattieri *et al.* 2007, p.347).

The major push for the implementation of tracking systems in the fresh food sector and beef sector is customer and supplier reactions to the food scares that have occurred in recent years (Golan et al., 2004). According to Huang *et al.,* (2010) food traceability currently receives more media attention than healthcare traceability due to the numerous public food safety incidents that have occurred. Many countries have imposed mandatory systems to trace animal feed to prevent the risk of Bovine

Spongiform Encephalopathy (BSE) and to manage food safety. The EU has a number of directives and regulations in relation to food quality. A requirement was put in place by the European Union in January 2005 which stated that all food industries need to have a system in place to track and trace their products in the supply chain (Alfaro et al., 2009; Kelepouris et al., 2007)

BSE and problems with poultry have greatly affected the level of sales in the food industry. A survey conducted in 2000 found that 75 percent of customers are not at ease with food safety levels (Kelepouris et al., 2007). Research has demonstrated that one of the motivations for food industries to implement traceability systems is to provide customers with assurance their food products are of good quality (Alfaro *et al.,* 2009). Tracking systems have helped to provide customers with assurance that the food product is safe by tracking food transportation systems. This enables the food industry to inform customers the country of origin of the food product (Golan *et al.,* 2004).

2.1.2 Traceability in the Pharmaceutical Industry

Traceability systems are utilised by the pharmaceutical industry to track medicines through the supply chain. One benefit of traceability systems in the pharmaceutical industry is to eliminate counterfeit medicines from entering the supply chain.

Counterfeit medicines are a major problem for the pharmaceutical industry. According to Huang *et al.* (2010) the World Health Organisation (WHO) states that almost 10% of medicines in the world are counterfeit. In third world countries, the WHO estimates that more than 25% of medicines are counterfeit (Huang *et al.* 2010). Counterfeit drugs might consist of substances which can harm patients. The South China Business Journal in 2002 (cited in Huang et al, 2010) reported that 200,000 to 300,000 people died as a result of counterfeit medicines in China. This journal also reported that prescription and administration of medication are responsible for nearly 40% of medical errors.

Barchetti et al. (2010) state that in the pharmaceutical supply chain, medicines that move around the world each year need to be traced at the level of individual packs. It is becoming increasingly difficult to track the medicines as there has been a huge growth in the number of wholesalers and retailers working in the pharmaceutical supply chain (Barchetti et al., 2010) and there are a large number of counterfeit medicines being circulated and incorporated into the supply chain. International institutions such as the Food and Drug Administration (FDA), European Medicines Agency (EMEA) and European Federation of Pharmaceutical Industries and Associations (EFPIA), recommend using standardised coding to help improve the security and efficiency of the pharmaceutical supply chain (Barchetti et al., 2010). Traceability systems can help to standardise pharmaceutical processes and allow for all steps in the pharmaceutical supply chain to be confirmed (Huang et al., 2010). At the Electronic Product Code (EPC) global consortium, whose main representative is the GS1

organisation, the standards for developing a universal identification system were defined (Barchetti et al., 2010).

According to Huang et al. (2010) traceability can bring better care to patients and can also help pharmaceutical manufacturers, distributors and retailers to carry out their jobs successfully.. The public are not aware of an ADE (Adverse Drug Event) until the information is published on the newspapers or broadcasted on television. By which time, a person could have already purchased and taken the medicine.

2.1.3 Conclusion

Many benefits have been found in both the food and pharmaceutical industries from traceability systems and these benefits can be linked to the benefits found in implementing traceability systems to track surgical instruments. A major benefit of traceability systems in the food industry is the ability to provide reassurance to customers that a food product is safe. One of the key benefits of traceability systems in the pharmaceutical industry is the reduction of counterfeit medicines from the pharmaceutical supply chain.

Traceability systems have benefitted the food and pharmaceutical industries by allowing them to be better informed about their products and to provide reassurance to customers that their products are safe. The benefits realised by these industries provide an insight into how a traceability system for surgical instruments could benefit hospitals. Similar to how traceability systems can give assurance to the food and pharmaceutical industries that their products are monitored and checked through the supply chain, traceability systems would give assurance to hospital managers that the sterilisation process for surgical instruments is completed correctly.

2.2 Traceability of Medical Devices

According to Kreysa (2006) the problems facing the pharmaceutical industry (e.g., counterfeit products) are similar to those that relate to medical devices. The Irish Medicines Board states that a good traceability system requires a clear understanding of the objectives for the system and of the lifecycle of the medical devices that will be traced (IMB, 2010). Traceability systems in hospitals are used to trace consumable items, implants, medical equipment and surgical instruments.

The Institute of Medicine (IOM) recommended bar-coding solutions to reduce the number of medical errors (Kreysa, 2006). Kreysa (2006, p.20) notes that “unique identification of products with GS1 standards and bar code scanning in the customer world is a well-established business process, the

advantages of this process are not yet fully understood and utilised in the healthcare industry". Since 2006, more hospitals have been implementing traceability systems to monitor their medical devices as hospitals are recognising the benefits of traceability. Many hospitals in the USA and Europe have implemented traceability systems and in Hong Kong and Japan, implementing traceability solutions is mandatory (Kreysa, 2006).

2.2.1 The benefits of a traceability system for Endovascular Devices

Endovasular devices are used for patients with endovasculitis which is an inflammation of the endangium or the inner coat of a blood vessel. Examples of such devices include catheter systems and stent grafts.

A pilot project, the Clinical Laboratory Automated Stockroom System (CLASS) took place in the Galway clinic in 2011, which used RFID and bar-coding to track endovascular devices**.** According to Swedberg (2011) the reasoning behind the project was to reduce the possibility of out-of-stocks, product expiration and ultimately improve patient safety. The endovascular devices were tracked from the manufacturer to the operating room in the Galway clinic. RFID tags were attached to expensive endovascular items, including catheters and stents.

Three non-profit organisations, Georgia Tech Ireland (GTI), GS1 Ireland and the Western Vascular Institute, developed the model for the tracking system. The organisations wanted to improve the efficiency of the supply chain of endovascular devices and reduce the likelihood of items going missing in endovascular operations. The project utilised EPC RFID standards for tracking and tracing the endovascular devices through the supply chain.

The pilot project was a success, with a read rate of 99.7% (Swedberg, 2011). The system achieved its objective of reducing the possibility of out-of-stocks and product expiration. The Galway clinic is hopes to implement the system permanently.

2.2.2 Traceability of Surgical Instruments

Traceability solutions for surgical instruments have been implemented in a number of hospitals, including a hospital in France and a hospital in Manchester, England. The pilot traceability solution for surgical trays implemented in the eight hospitals in Ireland is not the first time this has been done. A number of benefits were realised from these traceability systems including faster traceability of the surgical instruments and the ability to trace the surgical instruments back to the patients.

The hospital in France which implemented a traceability solution for surgical instruments had 9,597 sterile medical devices contained in 724 surgical trays (Nicolaos *et al.,* 2010). The hospital traced the surgical trays from when they were finished in the operating theatre through to the last stage in the CDU. Since December 2008, the hospital has been tracing the surgical instruments individually. The decision was made to trace individual instruments to allow for better traceability of the instruments in a surgical tray if instruments were moved around between trays. Nicolaos *et al.,* (2010) state that French hospitals are well advanced in unique device identification; however, Nicolaos et al., (2010) also state that they need to consider an international standard such as GS1 and DataMatrix 2D barcodes.

Wythenshawe a hospital in South Manchester implemented a GS1 bar coding system to track and trace their surgical instrument trays. The hospital is the largest hospital in the NHS Teaching Trust utilising 85,000 surgical instrument trays on site (GS1, 2011b). A number of benefits were documented from this traceability solution. The traceability of trays was both quicker and more straightforward for checking if the instruments had individually gone through the entire decontamination process (GS1, 2011b). When a recall was required, the solution also allowed for instruments to be traced back to the patients (GS1, 2011b). The bar coding system also helped the hospital with managing inventory of instruments, by helping staff to easily identify which department the instruments belonged to. Another benefit was that the system facilitated the process of confirming that each surgical tray held all the appropriate instruments.

2.2.3 Conclusion

Traceability systems for medical devices have resulted in many benefits for hospitals. In the pilot project in the Galway clinic where a traceability system was implemented to trace endovascular devices, the results indicated that the system reduced the likelihood of out-of-stock devices and product expiration. Such benefits improve the quality of care for the patient and reduce any chances of patients being exposed to devices which are out of date or a patient's procedure being delayed because the device is out of stock.

The two examples outlined in France and Manchester where traceability systems were implemented for surgical instruments indicated very positive results. The traceability solution provided staff better visibility of the location of surgical instruments and allowed them to conduct a recall easily and identify which instruments were used on which patients. The system also helped staff to know which department the instruments belonged to. These benefits are likely to be realised by the traceability system implemented in Irish hospitals for surgical trays.

2.3 Decontamination Standards

Decontamination of surgical instruments involves removing any bacteria or other organisms that may be present after surgery. Any bacteria on surgical equipment can be spread from one person to another if the instrument is not decontaminated properly. When an infection is passed from one person to another, this is referred to as 'cross-infection'. Decontamination consists of cleaning, disinfection and sterilisation. Cleaning is where organic matter on the surgical instruments is physically removed. Disinfection is a process where any micro-organisms on the surgical instruments are removed. All micro-organisms may not be removed; however enough are removed so that the level of micro-organisms remaining is not harmful to the patient. The final stage of decontamination is sterilisation which removes all forms of microbial life remaining on the devices. See figure 2.1 below which illustrates the decontamination process.

Figure 2.1; The Sterilisation Process (Nicolaos et al., 2010)

2.3.1 GS1 Standards

Standards are essentially rules or guidelines that govern anything from an industry to internal company processes. GS1 was established by manufacturers and retailers to develop mutually beneficial standards. The ubiquitous bar code that is seen on almost every product in every supermarket is one of these standards.

The GS1 System components are designed to enable three activities namely;

- Identification;
- Data capture;
- Data sharing.

GS1 design and implement global standards to help industries improve the efficiency and visibility of their supply chains. Standards place a particular emphasis on interoperability between trading partners.

GS1 standards have a number of different benefits including:

- Automating processes;
- Compliance with regulatory requirements and guidance on recalls;
- Reducing business risks above and beyond legal compliance;
- Product recall and withdrawal (notably to achieve a greater degree of precision, to demonstrate control, increase efficiency and reduce the cost of product recall or withdrawal);
- Efficient logistics management;
- Effective quality management;
- Supporting product and/or patient safety;
- Providing information to end users and trading or traceability partners;
- Better traceability, providing the ability to do a product recall.

GS1 Standards are important because they provide agreed definitions around how products, assets and services are identified with a number that is globally unique. In situations where there is no standard means of identification, processes are more complex and therefore more costly. For example, dress sizes are not standardised i.e. A size 10 dress in the UK is a size 6 dress in the USA. This can cause difficulty for both the manufacturer and the customer. For a customer the risk is that they buy the wrong size dress, for the supplier or manufacturer the risk is that they produce or order hundreds or thousands of the wrong items at great cost to the company.

GS1 standards can be considered to be this common language that allows interoperability between organisations. With the traceability system for surgical trays, surgical sets which are loaned from hospitals or commercial lenders to other hospitals can be traced seamlessly into the hospital's CDU by the use of a standardised form of identification and the use of standardised barcodes. Standards

obviously work best when more organisations implement them. See Appendix A for further information on GS1 Standards.

2.3.2 Decontamination of Surgical Instruments

The Health Information and Quality Authority (HIQA) published the National Standards for Safer and Better Care which provides a summary of what a high quality and safe healthcare service should be. The HSE has acknowledged that controlling HAIs is critical to the improvement in patient safety and that effective CDU are fundamental to achieving this.

The HSE has published the following three papers relating to recommended practices in CDUs. Each paper recommends using GS1 standards to achieve effective decontamination.

- HSE Standards and Recommended Practices for CDUs
- Decontamination of RIMD Standards and Recommended Practices for Endoscope Reprocessing
- HSE Standards and Recommended Practices for Dental CDU's.

In these papers, the HSE states that a multidisciplinary approach benefits the effectiveness of decontamination. The HSE recognises that standardised procedures and workflow plays a part in improving the decontamination process. The ability to review the decontamination cycle of surgical instruments if an incident occurs is beneficial and is made possible through the traceability system.

Automatic Identification and Data Capture Standards (AIDC) for healthcare are a key component of the GS1 selection of standards. AIDC is a voluntary system of standards which allow healthcare stakeholders to have a common set of data and data carriers which they can be used for medical devices. The GS1 AIDC standards include guidelines on which GS1 identification keys, the production data (lot number) and GS1 data carriers can used.

The recommended standards for CDUs in the 'HSE Standards and Recommended Practices for CDUs' document by the HSE (2011) outlines the following recommendations/guidelines below:-

- Systems should be implemented in CDUs to record the decontamination process and link the medical devices, i.e. the surgical instruments, to patients.

- More specifically the standards recommend that the medical devices should be tracked after each stage of the decontamination process to verify that the devices have been sterilised correctly.

- Records should be kept for all cycles of cleaning, disinfection and sterilisation processes, the name of the person carrying out each process, the date and time, the result, and the description of the devices being decontaminated (HSE, 2011).

- Devices should be individually identified with a Global Standard 1 barcode.

- Traceability systems should be able to verify which devices were used on which patients.

- In the event of a problem with the decontamination process, clinicians will be able to determine which patients may have been affected and patients who were not exposed will not be subjected to unnecessary concerns/stress.

It is important that all hospitals follow these recommendations to avoid cross contamination. In 1999, the NHS in the UK conducted a survey to ascertain the quality of decontamination in the NHS. A team reviewed the CDUs in 19 NHS trusts and conducted a technical analysis of their methods for cleaning and sterilising surgical instruments. In some hospitals, the reprocessing of the surgical instruments was below current standards and in a few hospitals, the decontamination process was found to be extremely poor (Kerr, 2003). In 2007, Health Protection Scotland completed a study which identified a poor compliance rate of 17% with the government and manufacturer guidelines (Crawford, 2007). Hospitals need to follow the recommended guidelines to ensure cross contamination does not occur.

The key driver for decontaminating surgical instruments is the prevention of cross contamination among patients. Crawford (2007) states that cross contamination of endoscopes, which are used to measure the inside of an organ or cavity in a patient, are usually caused by mistakes during the decontamination process. The following errors during the decontamination process can cause contamination of endoscopes:

- Devices not being rinsed or dried fully.

- Not cleaning the more inaccessible areas of devices properly.

- Not using the right disinfectant.

- Using a diluted sterilant.

According to Crawford (2007) a number of cases have been reported whereby patients have contracted respiratory infections. In Northern Ireland in 2005, five endoscopes were contaminated and as a result 100 patients had to be tested for a blood-borne virus (Crawford, 2007). Thankfully no patients tested positive.

2.3.3 Conclusion

This chapter describes the decontamination process and the recommended standards for decontamination. Not all hospitals are following the recommended guidelines for decontamination which is a cause for concern. One of the potential benefits of a traceability system for surgical instruments is that it would be possible to verify that the recommended standards have been complied with.

GS1 standards provide the structured data and unique identification that is needed for processes in CDUs. The use of GS1 Standards allows surgical trays to be scanned at each step of the decontamination process. GS1 standards also provide the benefit of interoperability between hospitals. Surgical sets which are loaned from hospitals or commercial lenders to other hospitals can be traced seamlessly in the hospital's CDU with standardised barcodes. The GS1 barcodes also provide a high level of security in comparison with non-standardised barcodes.

2.4 Impact of Hospital Acquired Infections

This section introduces the topic of HAIs, in particular, SSIs. One potential benefit of a traceability solution for surgical instruments is preventing the possibility of a SSI. Surgical equipment which has not been sterilised properly is a cause of SSIs (EHA, 2012), DermNet (2012) and WHO (2002).

2.4.1 The cost of Hospital Acquired Infections

A presentation given by Professor Barry Cookson who works in the Laboratory of Healthcare Associated Infection stated that it is recognised that monitoring the level of infection control in a hospital is a good indicator of the level of patient care in the hospital. Cookson states that HAIs can have an extremely negative impact for a hospital and that the prevention of HAIs is critical. The National Patient Choice Survey in 2008 claims that 74% of patients see low hospital infection rates as a key reason for choosing a hospital. There are two types of costs that can result from HAIs; direct costs and indirect costs. Direct costs comprise of fixed costs associated with staff time required and variable costs associated with increased demand for medications. The indirect costs relate to opportunity costs including a lost bed day and intangible costs which relate to the cost of the patient's quality of life. Cookson states in his presentation that when rheumatoid arthritis patients were asked what they would pay not to have a complication, the patients said they would pay 20% of their income if this would guarantee that they would not suffer any complications (Cookson, 2010). Certain calculation techniques were carried out to ascertain patient's willingness to pay to support infection control. HAIs increases the length of stay for patients and the risk of contracting HAIs increases as

the patient spends longer in the hospital. Research proves that HAIs are a major cost for the healthcare industry and that the degree of severity of HAIs is dependent upon the location of the infection in the patient. It has been found that 15% - 30% of HAIs could be avoided through advanced infection control (Cookson, 2010).

The effect of HAIs is significant for both the patients and the hospital. Patient's length of stay in hospitals can be increased; patients may require additional surgery resulting in further time off work and a possible loss of income. According to Tarricone *et al.,* (2010), HAIs are a huge problem today, with more than 1.4 million patients worldwide having a HAI at any time. Barnett (2007) supports these findings of Tarricone et al., (2010) and states that 5% of patients contract a HAI which ultimately results in higher costs for the hospital, additional care for the patient and a higher chance of mortality for the patient. Spelman (2002) also supports these studies, claiming that between 5% and 10% of patients acquire a HAI when they are admitted to hospital. The 1984 National Nosocomial Prevalence Survey illustrated that 6.3% of 28,643 patients who had been admitted to hospitals in Australia contracted a HAI (Spelman, 2002). It was also noted by this survey, that more HAIs occurred in the larger hospitals. Tarricone *et al.,* stated that studies have shown that HAIs occur more frequently in Intensive Care Units (ICU). This could be related to the increased time that patients spend in Intensive Care Units (ICU) compared with other hospital departments. Spelman (2002) states that HAIs can result in both readmission for the patient and additional surgery for the patient.

HAIs are strongly linked with higher mortality rates and higher costs for the hospital. According to Barnett (2007) there is an increase of 10.6% in the mortality rate of patients who have contracted SSII. In the UK evidence shows that approximately 320,000 patients contract a HAI which costs the NHS over £1 billion every year (Tarricone *et al.,* 2010). The same study showed that HAIs increased the patient length of stay by 20 days. A report completed by the National Audit Office in 2004 which utilised information from a London School of Hygiene[4] and Tropical Medicine Study supported this evidence and stated that the cost of treating HAIs is at least £1 billion each year in the UK and that the NHS pay £4,300 for every HAI (Comptroller and Auditor General, 2009).

The Pennsylvania Health Care Cost Containment Council (PHC4) stated that the additional cost of treating one patient who has contracted a HAI is US$52,600 (Barnett, 2007). If 20 patients contract a HAI each costing approximately US$50,000, this would cost the hospital US$1 million. Barrett (2007) rightly states that no hospital can afford this. Following HAIs, hospitals also have to face potential litigation costs. The total amount of compensation paid to patients for HAI associated claims was over £16 billion in the period 2005 – 2009 (Comptroller and Auditor General, 2009).

[4] The London School of Hygiene and Tropical Medicine is recognised internationally for the research they conduct on healthcare costs.

2.4.2 The impact of SSIs

SSIs fall under the umbrella of HAI. There are a number of different reasons why patients contract SSIs. According to DermNet (2012) and WHO (2002) there are three ways in which SSIs can be contracted; by direct contact, by airborne dispersal and by self-contamination. Direct contact refers to contact from the surgical instruments or from the hands of operating theatre staff. Airborne dispersal refers to microorganisms in the air getting into the open wound of a patient. Self-contamination refers to the patient's own endogenous flora on the skin getting into the wound.

Barrett (2007) makes the point that SSIs are underreported. According to Barrett (2007) SSIs are usually reported by a hospital's infection control nurse but are not always reported by surgeons. Barrett (2007) claims that SSI's are the third most common HAI, accounting for one fourth of all HAIs. A survey conducted by the HSE (2006) supports this, stating that SSIs account for 22.5% of HAIs. According to Whitehouse et al., SSIs account for nearly one third of all HAIs. It can be concluded from these studies, that SSIs cause approximately 20% - 30% HAIs. According to Spellman (2002) 10% of patients who have clean surgery contract a SSI. Whitehouse *et al.,* (2002) claim that approximately 500,000 SSIs occur each year in the USA. This breaks down to 2.8% of operations resulting in an infection. While the results were found to be higher in Ireland and in the UK, with the rate of SSIs for patients undergoing surgery being 4.6% in Ireland (HSPC, 2008) and 5% in the UK (NHS, 2008).

According to Barnett (2007), a patient who has contracted a SSI spends an additional 16.1 days in hospital compared with a patient who has not contracted a SSI following the same surgical procedure. DermNet (2012) estimation was lower, finding that a SSI increases a patient's length of stay by approximately 7-10 days. Brachman *et al.,* (1980) supports DermNet with the estimation that a patient who contracts a SSI increases their length of stay by 7.4 days. Whitehouse *et al.,* (2002) supports all of these studies as it found that SSIs can increase the length of stay for patients from 7 days to 19.5 days.

Many studies have focussed on measuring the increase of costs as a result of SSIs. Broex *et al.,* (2009) state that when a patient contracts an SSI, the healthcare costs for treating this patient are twice as much as a patient who has not contracted an SSI. Barnett (2007) states that SSI's can result in an added US$50,000 to the health care costs for each patient. A study in the American Journal of Infection found that the average cost of treating a patient with a SSI in the USA was almost US$20,000 (De Lissovoy et al., 2009) An Australian study calculated the additional cost of a patient contracting an infection after coronary artery bypass graft (CABG) surgery to be AUS$12,419 (Spelman, 2002). Whitehouse *et al., (*2002) stated that one study in the 1990s found that the average additional cost for hospitalising patients was US$4,500 per patient.

Over 18 million patients have surgery every year in the US (Whitehouse *et al.,* 2002). Whitehouse *et al.,* (2002) states that 25% of surgeries are orthopaedic related and that the rate of SSI contracted after orthopaedic surgery was in the range of 0.7% to 7.9%. This would amount to 31,500 to 355,000

patients contracting an SSI from orthopaedic surgery. An SSI following orthopaedic surgery can result in massive costs for the hospital. A study at Duke University Medical Centre, Durham, North Carolina, showed that if a patient has a SSI after orthopaedic surgery, they are twice as likely to be readmitted to the hospital in the year following surgery (Whitehouse *et al.,* 2002). If this happens, this would triple the cost of hospitalisation for the patient. For 30 patients with SSI at the centre, the total additional cost was almost US$1 million (Whitehouse *et al.,* 2002). This illustrates that even for a small number of cases; the costs of SSIs can have a dramatic impact on hospital costs.

One study found that the cost for removing prosthesis and then surgically implanting a new prosthesis is approximately $50,000 for each patient (Whitehouse *et al.,* 2002). In another study the cost for the hospital for infected knee replacements was $84,000 for each patient (Whitehouse *et al.,* 2002). This cost was calculated based on additional hospital days and surgical procedures. Another study which looked at patients who had infections after spinal surgery found that the patient needed an additional 59 days in hospital and the average cost for treating each patient was $100,666 (Whitehouse *et al.,* 2002). The cost breakdown comprised mainly of room and board, pharmacy and laboratory costs.

2.4.3 Cross Contamination

Cross contamination occurs when a patient contracts an infection from another patient through surgical instruments. There was an incident in a hospital in Middlesbrough in 2002 whereby a patient with Creutzfeldt-Jakob Disease[5] (CJD) had a brain biopsy. It was only discovered during the brain biopsy that the patient had CJD, at which point, a number of patients, 24 in total, who had undergone surgery in the hospital were at risk of contracting CJD (Kirkup, 2002). The hospital did not have a traceability solution in place. They could not identify which surgical instruments had been used on the patients and subsequently could not determine which patients were at risk. As a result, 24 patients had to be contacted about the incident and informed that they could potentially have contracted CJD. Due to the fact that the hospital could not identify which surgical instruments had been used during the brain biopsy of the patient with CJD, the hospital had to destroy £90,000 worth of surgical instruments (Hunter, 2002).

Gamble et al., (2007) state that there was an endoscope decontamination failure and 21 reports of problems with the decontamination of endoscopes were reported from various NHS trusts. Patients had been exposed to endoscopes that had not been properly decontaminated. Nearly 1,300 patients were subsequently contacted and offered blood tests. Some of the endoscopes had received manually cleaning only and others were sterilised using the wrong disinfectant. Errors can happen in the decontamination process when processes are manually carried out and there are no checkpoints to ensure that the medical devices have been properly sterilised.

[5] Creutzfeldt-Jakob disease (CJD) is a form of brain damage which leads to a quick decline of mental function and movement. Variant CJD (vCJD) is a form of the disease which is linked with mad cow disease.

2.5 Conclusion of Literature Review

Many benefits have been found in both the food and pharmaceutical industries from traceability systems including the ability to provide reassurance to customers that a food product is safe and reducing the number of counterfeit medicines from the pharmaceutical supply chain. Traceability systems for medical devices have resulted in many benefits for hospitals.

Traceability systems have been implemented for surgical trays; however, they have only been implemented to a limited extent so far. The two examples outlined in France and Manchester where traceability systems were implemented for surgical instruments enabled staff to know the location of surgical instruments and allowed them to conduct a recall easily and identify which instruments were used on which patients. These benefits should also be realised by the traceability system implemented in Irish hospitals for surgical instruments. The decontamination process and the recommended standards for decontamination were reviewed. It was found that not all hospitals are following the recommended guidelines for decontamination. One of the potential benefits of a traceability system for surgical instruments is that the recommended standards have to be followed.

It has been recognised that monitoring the level of infection control in a hospital is a good indicator of the level of patient care in the hospital. HAI increases the length of stay for patients and research shows that HAIs are a major cost for the healthcare industry. The NHS pay £4,300 for every HAI and other studies have demonstrated that the additional cost of treating one patient who has contracted a HAI can scale as high as US$50,000. No hospital can afford this. Hospitals also have to face potential litigation costs which can be very costly. It has been found that 15% - 30% of HAIs could be avoided through advanced infection control (Cookson, 2010).

SSIs fall under the umbrella of HAI and surgical instruments are one of the causes of SSIs. However, SSIs are underreported so it difficult to know the actual numbers of SSIs occurring in hospitals. SSIs cause approximately 20% - 30% HAIs and can increase the length of stay for patients from 7 days to 19.5 days. SSI's can result in an additional US$20,000 to US$50,000 to the health care costs for treating each patient. Hospitals need to consider how they can prevent SSIs.

Cross contamination is a serious problem and occurs when a patient contracts an infection from another patient through surgical instruments. One hospital had to destoy £90,000 worth of surgical instruments and had to inform 24 patients that they could potentially have contracted CJD, because they did not have a traceability solution in place for the surgical trays/instruments. A traceability system would have enabled the hospital to know which surgical instruments were used on which patients.

In the hospital where there was an endoscope decontamination failure and nearly 1,300 patients had to be contacted and offered blood tests, a traceability system in the CDU would have prevented this

from occurring. A traceability system would have monitored the decontamination process to ensure no steps in the process were skipped.

Chapter 3. Methodology

This chapter describes the research methodology and the approach employed in the course of this dissertation. The main research question was focussed on identifying the potential benefits of a traceability solution for surgical trays in the Irish Health Service.

3.1 Research Strategy

In simple terms, 'quantitative research employs measurement and qualitative does not' (Bryman *et al.,* 2007, p.28). Quantitative research can be viewed as a 'research strategy that emphasises quantification in the collection and analysis of data' (Bryman *et al.,* 2007, p.28). Quantitative research has a deductive approach in that it tests theories using collected data. Quantitative research is objective as it views social reality as something external. Qualitative research can be viewed as a 'research strategy that usually emphasises words rather than quantification in the collection and analysis of data' (Bryman et al., 2007, p28). Qualitative research has an inductive approach as it develops theories from collected data. Qualitative research is subjective in that it focuses on the meanings that people hold and value.

A quantitative approach is conclusive in its purpose and is best used to recommend a final course of action, therefore a quantitative research strategy was taken to gain an objective insight of the traceability solution. A case study was the research design chosen to illustrate the benefits realised by two Irish hospitals. This dissertation identifies the potential benefits of a traceability solution for surgical trays by collecting data from semi-structured interviews, previous case studies and documentation. This dissertation provides a framework to assist hospital managers to evaluate the economic viability of implementing a traceability solution for surgical instruments. The research uses a deductive approach by gathering data and using this data to prove the potential benefits of a traceability solution for surgical instruments. 'Objectivism is an ontological position that implies that social phenomena confront us as external facts that are beyond our reach or influence' (Bryman et al., 2007, p. 22). The research had an objective reality as data was collected from processes, documentation, previous case studies, semi-structured interviews which were analysed and interpreted to form the basis for identifying the potential benefits of the traceability system. Quantitative research assumes that what has been discovered is universal, thus replicable. In this dissertation, there is an assumption that the potential benefits found from the research conducted, in particular, the two hospitals, is replicable in other hospitals.

There are numerous advantages in using quantitative methods. With the results found from

conducting quantitative research, a statistical analysis can be undertaken of the results and the theories validated. Quantitative research can prove useful for testing results found by qualitative research. Quantitative research rules out subjective ideas so that the results are not biased. A disadvantage of quantitative methods is that they require statistical analysis which can be difficult and time consuming and there is inevitably some ambiguity in the statistical results. Quantitative methods generate results which are either black or white, a theory is either proven or not, there is no room for uncertainty.

Positivism is 'an epistemological position that advocates the application of the methods of the natural sciences to the study of social reality' (Bryman et al., 2007, p.16). Interpretivism is based on the idea that a strategy 'is required that respects the differences between people and the objects of the natural sciences' (Bryman et al., 2007, p.19). Quantitative research is usually associated with positivism; however this is not always the case. Positivism is not 'synonymous with science and the scientific' (Bryman et al., 2007, p.17). An interpretivist approach is taken for this dissertation incorporates an appreciation of the views of the staff working with the hospital traceability system.

3.2 Case Study

Case study research is 'concerned with the complexity and particular nature of the case in question' (Bryman et al., 2007, p.62). A case can be a single organisation, a single location, a person or a single event. A case study involves an intensive analysis of the case. In this dissertation, the case studies are the traceability solutions for surgical trays implemented in two hospitals, St. James Hospital and Tullamore Hospital. A walkthrough of each of the CDUs in the hospitals was conducted to fully understand how traceability was applied. Interviews and several conference calls took place with the CDU managers and semi-structured interviews were conducted with the staff working in the CDUs. An intensive examination of the case studies was carried out. This intensive examination was required in order to fully understand the functionality of the traceability system, the impact of the system on the staff and the benefits realised from the system. Case studies are used in both qualitative and quantitative research; however, they are normally associated with qualitative research particularly in the social sciences. Case studies can be used to identify key insights which help to answer the research question. One of the concerns of case study research is its external validity (Bryman et al., 2007). In other words, how can one case study be 'representative so that it might yield findings that can be applied more generally to other cases?' (Bryman et al., 2007, p.63). In this dissertation, this raises the question of how could the benefits realised from the traceability of surgical trays in one hospital also be realised in other hospitals.

3.3 Sample

According to Bryman et al., (2007, p.180) 'the need to sample is one that is almost invariably encountered in quantitative research'. In order to be able to 'generalise your findings from your sample to the population from which it was selected, the sample must be representative' (Bryman et al., 2007, p.182). In this dissertation the sample chosen for semi-structured interviews were the staff who worked in the CDUs in the two case study hospitals as they were familiar with the traceability system for surgical trays. There are a number of different types of sampling including simple random sampling, systematic sampling and stratified random sampling.

- Simple random sampling is where each member of the population has an equal chance of being included in the sample.
- Systematic sampling is where there is a systematic approach to selecting the population, for example, every third employee on the staff list would be included in the sample.
- Stratified random sampling is where the population are stratified by a criterion, for example, if the sample needs to have staff working in different departments, 'the proportion of employees from the sales and marketing department in the sample is the same as that in the employee population and so on' (Bryman et al., 2007, p.187).

Simple random sampling was chosen to select the participants for the semi-structured interviews in this dissertation. The sample group were randomly selected from the group of technicians who work in the CDUs and the surgical nurses as they all use the traceability system. The interviews for each hospital were completed in one day. The sample was based on the staff that were firstly, working that day and secondly, were available to partake in the interviews. The sample was random as the selection was dependent on who was rostered to work on the day the interviews took place and who was available to participate. A sample of seven employees was taken from each case study hospital. The sample included both males and females with different levels of experience. Each semi-structured interviews lasted approximately 15 minutes.

3.4 Interviews

According to Bryman et al., (2007, p.210) 'the research interview is a prominent data collection strategy in both quantitative and qualitative research'. Semi-structured interviews were used to interview the relevant technicians and nurses in both hospitals. A semi-structured interview 'refers to a context in which the interviewer has a series of questions that are in the general form of an interview schedule but is able to vary the sequence of questions' and the questions are not as specific as in

structured interviews (Bryman et al., 2007, p. 213). In total, 14 interviews were conducted. Contact was made with CDU managers in the hospitals to arrange a date to go to the hospitals to carry out the interviews. The manager informed the employees who would be working in the hospital that day that the interviews were taking place. Consent forms and an information sheet were provided to the participants on the day of the interviews (see Appendix B). An interview guide was prepared in advance of the interviews so that the same questions were asked in each interview in order to provide consistency (See Appendix B). The interview questions were open. Open questions have both advantages and disadvantages. Some advantages are that the participants can 'answer the question in their own terms' and they are useful for 'exploring new areas' (Bryman et al., 2007, p.259). Some disadvantages of open questions are that they can be time consuming for the participants, responses need to be coded and themes need to be derived (Bryman et al., 2007). The common themes of the research were the guiding elements for the set of interview questions prepared. These responses were collected and analysed.

3.5 Data Analysis

Before analysis of the data began, all 14 semi-structured interviews responses were transcribed. A systematic search of the transcribed interview responses was conducted and key words were identified relating to each interview question. These key words were then grouped into themes. For example, for the interview question 'What benefits, if any, have been realised since the implementation of the system?' the following keywords; quality assurance and reporting, relate to the theme 'report generation'. This study of interpreting written text is known as hermeneutics. The number of participants whose response contained one of the keywords in each theme was recorded. In the analysis of the data, only one keyword for each theme was taken from a participant's response to avoid any duplication in the results. For example, keywords such as 'automatic list' and 'set lists are correct' relate to the same theme of 'Generation of automatic surgical tray checklist'. If one participant mentioned both of these keywords, only one keyword is recorded from this participant so that the graph does not double count the number of participants who stated that the 'Generation of automatic surgical tray checklist' as a benefit of the system. The number of participants whose response related to a theme was recorded for each interview question. The results were then illustrated using bar charts. Then the process of univariate analysis, which refers to the analysis of one variable at a time, was carried out on the themes associated with each interview question. Findings were collected from this analysis.

Ethical Considerations

One of the ethical principles involved in the research is the need for informed consent. The principle of informed consent is that the participants be informed about how the research will be conducted and assured of confidentiality. All the interview participants were informed about the research process and the objectives of this dissertation. Approval was required from the University of Dublin to commence the research in the two hospitals chosen for the case studies. The Research Ethics Committee of the School of Computer Science and Statistics approved the application to progress with the interviews in the two hospitals. The application for ethics approval consisted of the research proposal, a consent form the participant's information sheet, for the participants and the proposed interview questions.

3.6 Limitations

'Quantitative research along with its epistemological and ontological foundations has been the focus of a great deal of criticism' (Bryman et al., 2007, p.173). Some of the criticisms of quantitative research are listed below:

- 'Quantitative researchers fail to distinguish people and social institutions from the world of nature'
- 'The measurement process possesses an artificial and spurious sense of precision and accuracy'
- 'The reliance on instruments and procedures hinders the connection between research and everyday life'
- 'The analysis of relationships between variables creates a static view of social life that is independent of people's lives.' (Bryman et al., 2007, p.174)

The most obvious preoccupation of quantitative research is with measurements. Measurements have their benefits; however, with measuring, issues of validity arise. 'There is a strong concern in most quantitative research with explanation' (Bryman et al., 2007, p.168). Quantitative research often focusses on why things are the way they are rather than focussing on how things are. With experimental design 'the independent variable is the variable that is manipulated' and there is 'little ambiguity about the direction of causal influence' (Bryman et al., 2007, p.169). With cross-sectional design which is usually used for social survey research, there is 'ambiguity about the direction of the causal influence in that data concerning variables' (Bryman et al., 2007, p.169). Quantitative researchers who use cross-sectional designs want to create techniques which will allow causal inferences to be made (Bryman et al., 2007). In this dissertation it could be assumed that the staff in the hospitals have less administration work to do because the surgical tray checklists are now printed automatically with the traceability system. Although, these inferences might be based on sound

reasoning, they can 'only be inferences and there is the possibility that the real pattern of causal direction is the opposite of that which is anticipated' (Bryman et al., 2007, p.361).

In summary a quantitative research approach was chosen for this dissertation due to its deductive nature. Quantitative data was collected from relevant participants through semi-structured interviews. This data collection helped to better understand the potential benefits of a traceability solution for surgical trays.

Chapter 4. Findings and Analysis

4.1 Background to the project

The traceability system for surgical trays was introduced to provide assurance that the surgical instruments were decontaminated properly. Currently there is a lack of visibility and traceability of surgical instruments in the hospital supply chain. A solution to potentially solve this problem is the introduction of GS1 bar codes and software to track the surgical instruments. Phase 1 of this solution involves tracing the surgical trays and phase 2 of this solution involves tracking individual surgical instruments.

The following eight hospitals in Ireland took part in the pilot phase of the nationally funded traceability solution for surgical trays:

- Beaumont Hospital
- Kerry General Hospital
- Mullingar Hospital
- Portlaoise Hospital
- St James Hospital
- Tallaght Hospital
- Tullamore Hospital
- Waterford Hospital

The two hospitals chosen as case studies for this project were St James Hospital and Tullamore Hospital. St James Hospital was chosen as this was the first hospital to implement the traceability solution and Tullamore hospital was selected to add depth to the data by including a hospital which is located outside Dublin.

St James Hospital:

St James Hospital is a major acute teaching hospital. The hospital provides a diverse range of diagnostic and treatment services. It has been credited for being innovative and open to new improvements in healthcare. The hospital has over 900 beds and the number of surgical procedures

undertaken exceeds 14,000 per year. There are 16 operating theatres with nearly 30,000 surgical sets requiring decontamination each year in the CDU. Over 530 surgical loan sets are reprocessed from other hospitals and commercial lenders each year.

Tullamore Hospital:

Tullamore Hospital is the Midland Regional Hospital. Some of the specialties in Tullamore Hospital include Cardiology, Dental Surgery, General Medicine, General Surgery, Haematology, Nephrology, Oncology, Orthopaedics, Otolaryngology and Radiology. There are 237 beds in total and five operating theatres. There are 720 surgical sets requiring decontamination. On average, over 900 surgical sets are loaned from other hospitals and commercial lenders each year.

4.2 Project Stakeholders

In order to understand the complete picture behind the traceability solution, meetings were scheduled and held with some of the stakeholders involved in the implementation of the pilot project of a traceability solution for surgical trays. The stakeholders involved are listed below:

- GS1,
- Medical Standard 1 (MS1),
- Slainte Healthcare,
- FingerPrint, and
- Irish Power and Process (IP&P).

A short background on each of the stakeholders involved in the project is given below:

GS1:

Alan Gormley from GS1 provided support in helping to progress this study by assisting with introductions to key members of the stakeholders involved in the traceability system and with the CSSU managers in the three case study hospitals.

Medical Standard 1 (MS1):

MS1 allows hospitals and commercial lenders of surgical equipment to exchange data. MS1 servers hold a copy of hospitals and commercial lenders asset inventory. MS1's role on the project was to connect traceability systems in hospitals to the commercial lenders. This would allow for loaned items to be tracked seamlessly between hospitals and commercial lenders. The managing director of MS1, Simon Jackson, was selected as a suitable candidate to be interviewed for the study to describe the role that MS1 plays in the traceability solution.

Sláinte Healthcare

Sláinte Healthcare delivers web-based software solutions which increase efficiency and reduce costs in healthcare organisations. Sláinte have helped their clients by reducing the amount of time spent doing administration tasks and increasing the time spent on patient care. Sláinte pride themselves on being able to integrate their products seamlessly with systems already in place. Sláinte provided the Shadow Patient Master Index (PMI) for this project. The Shadow PMI allows staff using the theatre system to confirm that the correct patient is in the operating theatre. This is done by reading feeds of demographic data from the hospital administration system and parsing the data into an SQL Server database. This data in this database is made available to Fingerprint while also making certain that data is not disclosed from one hospital to another. Sláinte work closely with the hospital's IT teams to integrate the Shadow PMI to enable a safe, secure and efficient way of sharing data.

FingerPrint

FingerPrint is the supplier of the traceability solution in the eight hospitals. The traceability system is linked to the Independent Monitoring System (IMS) system for the washers and the autoclaves in the CDUs. The IMS system reads data from the washer and autoclave sensors for pressure and temperature and then converts the data into files which are saved to the IMS and to personal computers. The traceability system records the lot number and the bar code identifiers of the surgical instruments in the washers and autoclaves.

Irish Power and Process (IP&P):

IP&P is an instrumentation products and solution supplier. They have contributed to the project by implementing the IMS system for the washers and autoclaves in the CDUs. The IMS system provides cycle data for the traceability of surgical instruments.

4.2.1 Semi-structured Interviews

Semi-structured interviews were scheduled with the following stakeholders to understand their role in the traceability system for surgical trays in Irish hospitals:

- Simon Jackson, Managing Director of Medical Standards 1 (MS1)
- Karl Holmes from Synthes, a commercial loan set provider

Each semi-structured interview lasted approximately one hour.

Medical Standards 1:

Medical Standard 1 (MS1) is a not-for-profit organisation which supports hospitals with the implementation of GS1 coding structures and utilising these codes to benefit asset management and supply chain management. The interview with Simon Jackson was very informative as he provided a detailed account of MS1's role in the traceability solution.

MS1's guiding principle is for hospitals to have ready access to information in order to process medical devices. MS1 is a web server environment and the tracking system links to the MS1 server through codes. The surgical trays for all hospitals involved in the project are given a unique GS1 barcode and the contents of the surgical trays are uploaded to the MS1 server. This allows for surgical trays to be shared among hospitals and interoperability between hospitals. The tracking system uploads any changes to the surgical trays (e.g., instruments removed to be repaired) on the MS1 server automatically. MS1 recommend that hospitals mark their surgical trays with GS1 barcodes.

Simon states that the ability to trace loan sets between hospitals and commercial lenders is a key benefit of the traceability system. Synthes are the first commercial loan set provider to upload to MS1. Prior to the implementation of the traceability system, a loan set which might include 20 surgical trays had to be manually uploaded. According to Simon this would take approximately 3.5 hours to upload each line item. MS1 maintains a copy of the hospital's inventory, allowing reprocessing to take place at an alternative site with full traceability. This saves time for technicians and improves patient safety.

According to MS1, the aim is to eventually have all surgical instruments marked before they are sold to hospitals and for all hospitals in Ireland to implement the traceability system so that loan sets can be tracked seamlessly around Ireland. Some loan sets, such as spinal surgical instruments are loaned from Europe and the USA.

Figure 4.1 below provides an overview of the link between GS1, MS1 and the hospitals.

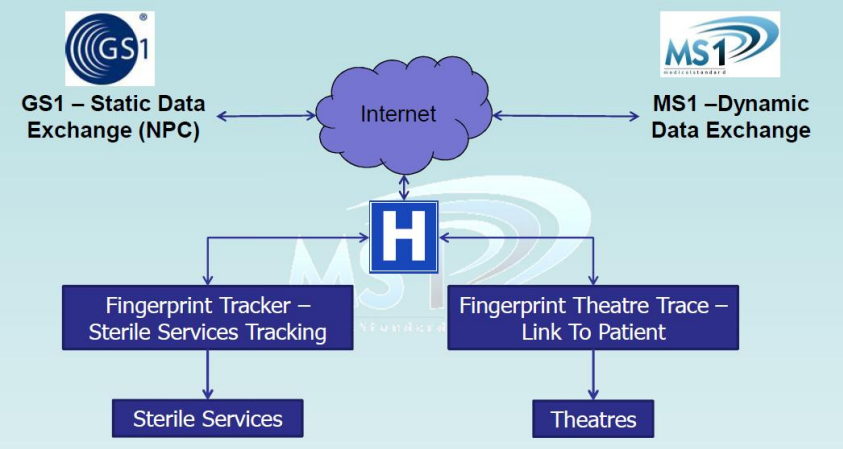

Figure 4.1; Overview of the link between GS1, MS1 and the hospital (Simon Jackson, MS1)

Synthes:

Synthes are a commercial loan set provider and have offices in Europe, North America, Latin America, Middle East & Africa and Asia & Pacific. Their head office is located in Switzerland. They were bought by Johnson & Johnson for US$21.3 million in 2011. Synthes provide quality implants and instruments to hospitals in Ireland. They also have a large stock of loan equipment available. Synthes are the first loan set provider to implement MS1 in the Republic of Ireland.

Karl Holmes from Synthes provided a tour of the factory in Synthes of the instruments, implants and biomaterials they have for surgery. 70%-80% of their business is for trauma surgeries and 10% of their business is for spinal surgeries. The remainder of their business is for power tools and Cranio-Maxillofacial Traumain (CMF) which is surgery performed on the face or skull. Their products are mainly made of either titanium or stainless steel. The choice of material is based on the surgeon's preference. See Figure 4.2 below of a locking bolt with the GS1 barcode (highlighted with a red circle) on the box and a model of a foot illustrating where these locking bolts could be used.

Figure 4.2; GS1 barcoded surgical locking bolt (Synthes Factory)

All of the instruments, implants and biomaterials are marked with GS1 barcodes. Figure 4.3 below illustrates that Synthes have full traceability of the loaned sets provided to hospitals.

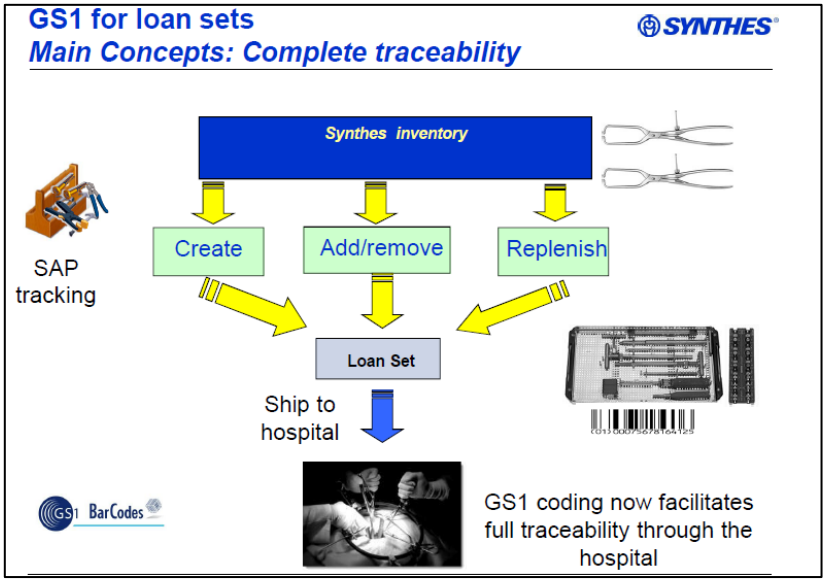

Figure 4.3; Traceability of Synthes loan sets to hospital (Synthes)

Since all of their instruments, implants and biomaterials are marked with GS1 barcodes, the sets loaned to hospitals can be easily traced using the traceability system for surgical trays. This allows for product recall if an incident occurs and a check is required on the decontamination cycle of the instruments. Synthes allow hospitals to have full traceability of the loan sets.

4.3 Case Study Research

Through GS1, contact was made with two of the pilot hospitals St. James Hospital and Tullamore Hospital which have implemented the traceability solution. The hospitals selected were Tullamore Hospital and St. James Hospital. These hospitals were chosen as GS1 have a good relationship with both of the CDU managers in these hospitals. St. James Hospital was the first hospital to implement the traceability solution in Ireland. The decontamination staff who took part in the semi-structured interviews volunteered to be involved in the study.

Semi-structured interviews were conducted with technician staff working in the CDU in the two hospitals. There were 14 interview participants in total, selected at random. Each interview lasted approximately 15 minutes. Probing was used during the interviews to discuss topics further. The participants were asked the following questions:

- Is the traceability system for surgical trays easy to use?
- Have there been any challenges with implementing the system?
- Has your day-to-day role changed since the system has been implemented?
- What benefits, if any, have been realised since the implementation of the system?
- Have any issues been encountered with the system?

These questions were chosen to help answer the main research question: **'What are the potential benefits of a traceability solution for surgical trays in the Irish health service'** and to provide an insight to the answers of the two subsidiary research questions namely:

- 'What benefits, if any, have been realised since the implementation of the traceability system in St James Hospital and Tullamore Hospital?' and
- 'What were the challenges, if any, to the implementation of the traceability system in St James Hospital and Tullamore hospital?'

4.4 Walkthroughs of the Hospital CDUs

Walkthroughs of the CDUs in St. James Hospital and Tullamore Hospital were facilitated by the CDU managers of the hospitals. The walkthroughs started from where the technicians collect the dirty instruments from outside the operating theatre to where the sterilised instruments are left at the

dispatch area for the next surgery. During the walkthrough, the CDU managers outlined the stages at which the traceability system was used. Both hospitals had the same process in their CDUs. The decontamination process is illustrated in Figure 4.4 below.

Please see Appendix C for images of the CDUs.

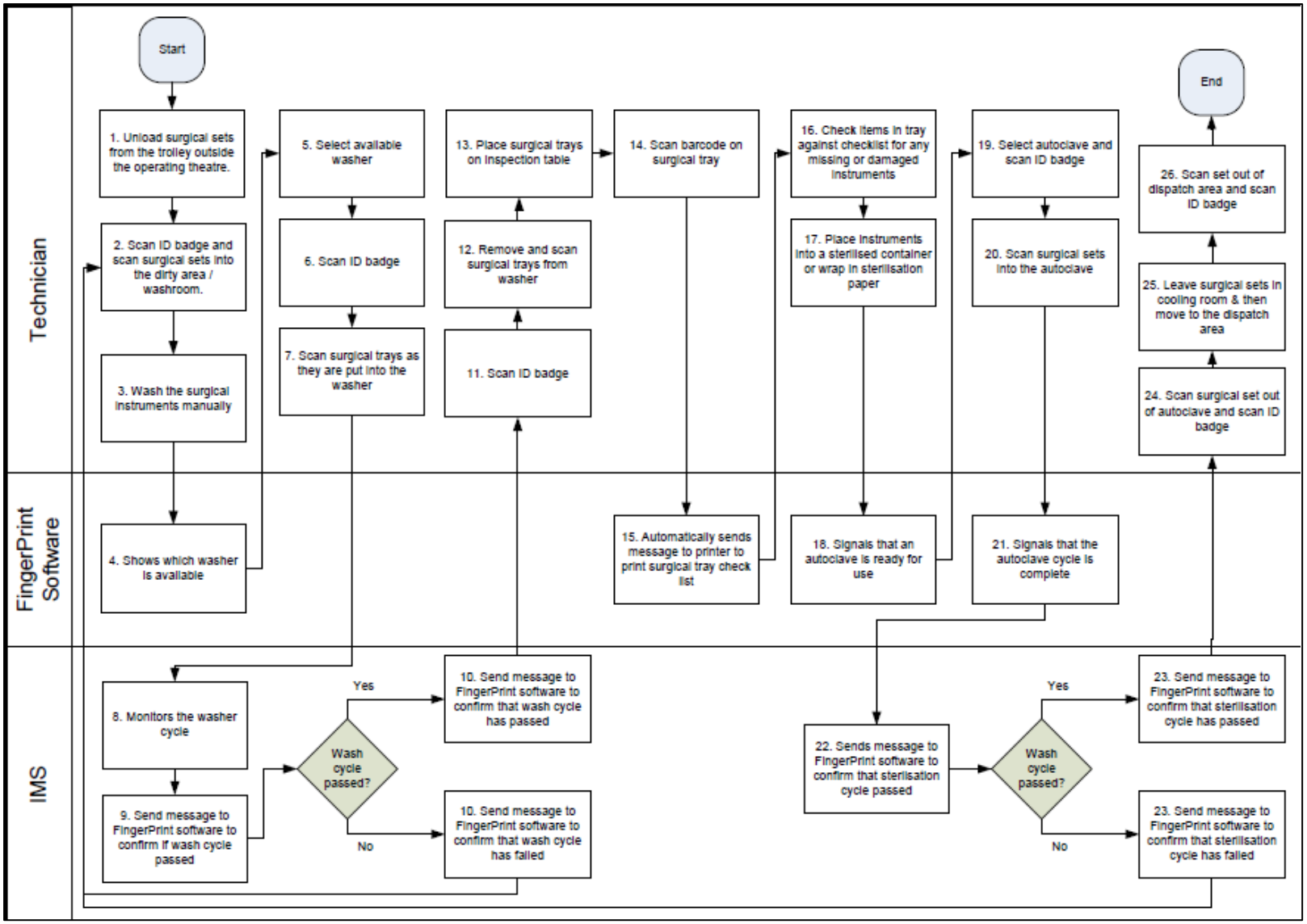

Figure 4.4; The decontamination process in St. James Hospital and Tullamore Hospital

The decontamination process can be broken down into seven distinct steps as follows:

Step 1: The Wash Room

The first step in the CDUs starts in the washroom. A theatre nurse leaves the surgical trays containing the used surgical instruments outside the operating theatre where these are collected by a technician working in the CDU. The technician scans their ID badge and scans the barcode on the surgical trays as they bring them into the wash room to begin the decontamination process. The technicians then manually pre-soak the surgical trays and instruments at this point paying particular attention to devices which are grossly contaminated and lumened instruments which require brushing through .

Step 2: Disinfection

At the disinfection stage, the surgical trays are put into washing machines called Washer/Disinfectors (W/D's). The Fingerprint software on the computer in the washroom enables the technician to see which W/D's are available. The technician is prompted to scan their ID card and then select the W/D on the computer that they wish to use. The surgical trays are then scanned as they are put into the W/D. The IMS /Datalogger attached to each W/D monitors the W/D cycle via a thermocouple probe within the W/D chamber and this probe is independent of the W/D's own probes and control panel. The datalogger then calculates the critical time/temperature data to indicate either a successful or unsuccessful meeting of these critical parameters. The IMS provides assurance that the parameters are within the acceptable tolerances.

Step 3: The Clean Room

When the W/D cycle is finished, a message is sent from the IMS on the W/D to the tracking software to confirm that the required temperature was reached for the specified time. Once the cycle has been confirmed as successful and once the technician is assured that the instruments appear clean and dry they scan their ID badge on the computer. The surgical trays are then scanned as they are removed from the W/D into the clean room.

The inspection stage takes place in the clean room and the surgical trays are placed on an inspection table. The technician scans their ID badge and then scans the surgical tray at the inspection area which automatically prints a sticky barcode label and a check list with all the instruments that are in that tray. If an instrument was sent for repair from theatre, the check list will show this. The technicians check the items in the tray against the check list for any items missing or damaged. The surgical instruments are then put into sealable containers or wrapped in sterilisation paper. The sticky barcode label is then attached to the outside of the containers and the wrapped surgical sets.

Step 4: The Sterilisation Process

Autoclaves are machines which can kill micro-organisms by using pressurised steam. The tracking software will notify a technician when an autoclave is available. The technician scans their ID badge and then the barcode label on the container or sterilisation paper against the autoclave to be used. The instruments are then left in the autoclave until the sterilisation process is complete.

Step 5: The Cooling Area and Transport

As soon as the autoclave cycle is complete, the tracking software will alert the technician. The IMS system linked to the autoclave will send a message to the tracking software to confirm if the required parameters for complete sterilisation were achieved. When the autoclave cycle is confirmed as successful, the technician will scan their ID badge and scan sets of instruments out of the autoclave. The instruments are stored in the cooling area to cool down. When ready, the sets are stored in the dispatch area.

Step 6: The Sterile Goods Store and Transport

When the sets of surgical instruments are needed, the theatre staff scan their ID badge, select which theatre or other location the sets have been dispatched to and then scan the sets as they remove them from the dispatch area.

Step 7: Theatre Use

When the surgical set is about to be used in the theatre, the set is scanned to ensure that the right instruments are being used on the right patient. The theatre tracking system is linked in with the hospital's Patient Administration System (PAS) to enable hospital staff to confirm that the correct patient is in theatre. The theatre tracking system displays the patient's demographics which reduces the likelihood of the wrong patient undergoing surgery. The data read by the theatre tracking system is transferred from the PAS system to a data server which uses a standard protocol called HL7 (Health Level 7).

Please see Appendix D for images of these steps in the decontamination process.

4.5 Analysis and Results

4.5.1 Semi-structured Interview Results with the CDU staff

There were 14 participants randomly selected to take part in the semi-structured interview. A systematic search of the interview responses was conducted and key words were identified. These

key words were then grouped into themes. This study of interpreting written text is known as hermeneutics.

A list of keywords were extracted from the responses for each interview question. See Table 4.1.

Q1	Is the traceability system for surgical trays easy to use?
1	Easy to use
2	Training useful
3	User manual helpful

Q2	Have there been any challenges to implementing the system?
1	Barcoding sets
2	Change management
3	Labelling sets
4	Learning the system
5	Marking trays
6	Not fool proof
7	Staff resistance
8	Tagging baskets
9	Transferring data

Q3	Has your day to day role changed since the system has been implemented?
1	Automated Checklist
2	Less time manually recording information
3	Logging into computers
4	More instant knowledge
5	More integrated team
6	More time interfacing with a computer
7	More time maintaining IT system
8	Paperwork gone
9	Printing checklists
10	Production sticker generation
11	Slows down process on the floor
12	Work in washroom is slower

Q4	What benefits, if any, have been realised since the implementation of the system?
1	Alerts
2	Automatic list
3	Expiry date provided
4	Instant information
5	Know person responsible
6	Know the location of sets
7	Know when set will be available
8	Know where the set is
9	Less administration
10	Linking sets to patients
11	Loan sets
12	Location of sets
13	Look backs
14	Methodical and logical
15	Missing or broken sets recorded
16	More accurate information on checklists
17	More efficient throughput of workload
18	More timely
19	No confusion with hand writing on stickers
20	No more writing
21	Organised process
22	Production reports
23	Quality assurance
24	Report generation
25	Reporting
26	No longer searching for a set
27	Set lists are clear
28	Set lists are correct
29	Straightforward process
30	Time effective
31	Warning messages

Q5	Have you encountered any issues with using the system?
1	Change in dynamics
2	Date size is too small on label
3	Downtime
4	Need to call the supervisor
5	Local printer issues
6	Manually record
7	Need upgrade in computers
8	Network crashes
9	Network server disconnects
10	Older staff had problems
11	Revert back to manual
12	Scan the wrong washer, call supervisor
13	Server issues
14	Sets not scanned out to theatre
15	Slow speeds due to server sharing
16	System is down
17	No issues

Table 4.1; List of keywords from the interview responses

These lists of keywords were then grouped together into themes within each research question. The keywords and their relevant theme are illustrated in Table 4.2 below.

Q1	Is the traceability system for surgical trays easy to use?	Number of responses:	Theme	Total number:
1	Easy to use	14	Easy to use	14
2	Training useful	5	Training was useful	5
3	User manual helpful	2	User manual was helpful	2

Q2	Have there been any challenges to implementing the system?	Number of responses:	Theme	Total number:
1	Barcoding sets	3	Barcoding the surgical sets & transferring data	10
3	Labelling sets	2		
5	Marking trays	1		
8	Tagging baskets	1		
9	Transferring data	3		
2	Change management	1	Change management for the staff	2
7	Staff resistance	1		
4	Learning the system	2	Learning how to use the system	2
6	Not fool proof	1	The system is not fool proof	1

Q3	Has your day to day role changed since the system has been implemented?	Number of responses:	Theme	Total number:
3	Logging into computers	1	More time spent using computers	3
6	More time interfacing with a computer	1		
7	More time maintaining IT system	1		
1	Automated Checklist	1	Less time spent manually recording information with the automated surgical tray checklists	9
9	Printing checklists	1		
10	Production sticker generation	2		
2	Less time manually recording information	4		
8	Paperwork gone	1		
11	Slows down process on the floor	1	Process on the floor is slower	2
12	Work in washroom is slower	1		
5	More integrated team	1	More integrated as a team	1
4	More instant knowledge	1	Access to more instant knowledge	1

Q4	What benefits, if any, have been realised since the implementation of the system?	Number of responses:	Theme	Total number:
4	Instant information	1	Report generation	5
22	Production reports	1		
23	Quality assurance	1		
24	Report generation	1		
25	Reporting	1		
13	Look backs	1	Recall which sets where used on a patient	3
10	Linking sets to patients	2		
6	Know the location of sets	1	Knowing the location of a set	5
7	Know when set will be available	1		
8	Know where the set is	1		
12	Location of sets	1		
26	No longer searching for a set	1		
1	Alerts	1	Warnings provided if a step is skipped	2
31	Warning messages	1		
15	Missing or broken sets recorded	3	Missing and broken sets recorded on checklist	3
3	Expiry date provided	1	Expiry date of sets provided on checklist	1
2	Automatic list	1	Generation of automatic surgical tray checklist	6
19	No confusion with hand writing on stickers	1		
20	No more writing	1		
16	More accurate information on checklists	1		
27	Set lists are clear	1		
28	Set lists are correct	1		
17	More efficient throughput of workload	1	Less administration & more efficient throughput of workload	4
18	More timely	1		
30	Time effective	1		
9	Less administration	1		
14	Methodical and logical	1	Process is more methodical and organised	3
21	Organised process	1		
29	Straightforward process	1		
5	Know person responsible	1	Ability to know staff productivity	1
11	Loan sets	1	Loan sets are coded	1

Q5	Have you encountered any issues with using the system?	Number of responses:	Theme	Total number:
1	Change in dynamics	1	Older staff had difficulty adjusting	2
10	Older staff had problems	1		
2	Date size is too small on label	1	Font size of date is too small on production label	1
4	Need to call the supervisor	1	If a mistake is made, the supervisor is needed	3
14	Sets not scanned out to theatre	1		
12	Scan the wrong washer, call supervisor	1		
5	Local printer issues	1	Problems with the printer	1
3	Downtime	1	When the network crashes, need to revert to the manual process	9
6	Manually record	1		
7	Need upgrade in computers	1		
8	Network crashes	1		
9	Network server disconnects	1		
11	Revert back to manual	1		
13	Server issues	1		
15	Slow speeds due to server sharing	1		
16	System is down	1		
17	No issues	2	No issues encountered	2

Table 4.2; List of keywords from the interview responses grouped into themes

The number of participants whose response contained one of the keywords was recorded. When these keywords were grouped into themes, the total number of participants whose response contained keywords related to a theme was subtotalled to record the number of participants who discussed that particular theme. For example, in relation to question 5, 'Have you encountered any issues with using the system', a discussion around the network crashing was had with nine participants, a keyword was extracted from each of the participant's responses relating to the issue of the network crashing. Only one keyword from a participant's response was extracted for each theme, to ensure that the actual number of participants who mentioned a theme was accurately recorded. The keywords related to the theme of the network crashing are listed below:

- Downtime
- Manually record
- Need upgrade in computers
- Network crashes
- Network server disconnects
- Revert back to manual
- Server issues
- Slow speeds due to server sharing
- System is down

These keywords were grouped into one theme 'When the server crashes, need to revert to the manual process'. In this case, this theme was in nine of the participants responses.

There are four main types of variables; ordinal, nominal, dichotomous and interval/ratio variables. The themes recorded from the semi-structured interviews are the variables in this analysis. Ordinal variables are those which the categories 'can be rank ordered but the distances between the catergories are not equal across the range' (Bryman et al., 2007, p.355). Nominal variables are ones which cannot be rank ordered. Dichotomous variables can only have two categories (e.g., gender). Interval/ratio variables are variables 'where the distances between the categories are identical across the range of categories' (Bryman et al., 2007, p.355). All the themes from the semi-structured interviews are nominal variables. For example, the two themes 'Report generation' and 'Knowing the location of a set' are not variables which can be ranked. It cannot be said that ability to produce reports holds more weight than knowing the location of a set. Graphs, tables and pie charts are the most commonly used ways of displaying quantitative data (Bryman et al., 2007) and diagrams have many advantages as they can be easily interpreted. Nominal variables are best illustrated in a pie

chart or a bar chart. Bar charts were selected as the best way to present the present the semi-structured interview responses. The bar chart graphs below illustrate the number of participants who mentioned a theme in response to each of the five interview questions.

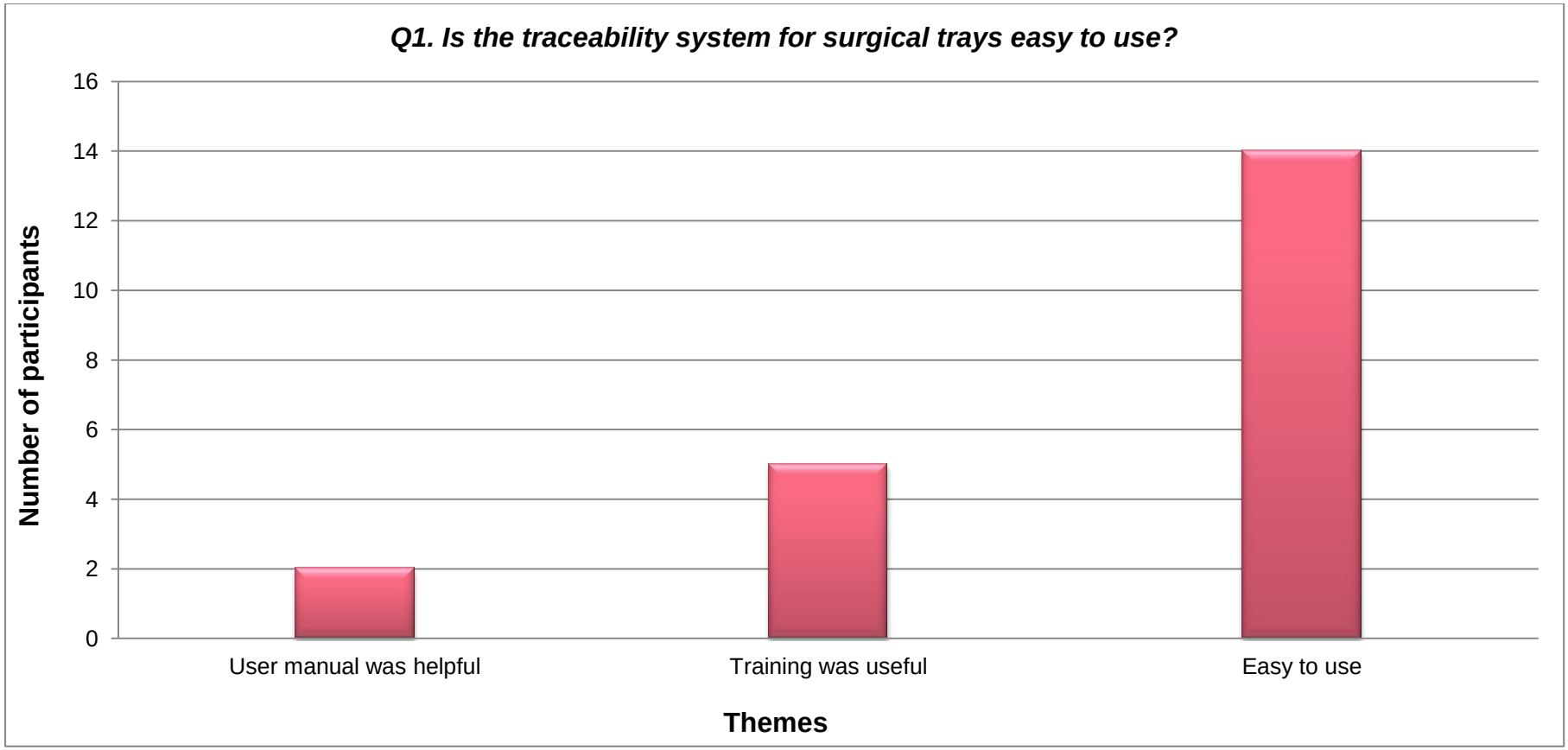

Figure 4.5; Interview responses for Q1. Is the traceability system for surgical trays easy to use?

Throughout the interviews, a number of benefits of the traceability system were identified by the staff working in the CDU in the hospitals. Overall, the responses were very positive about the system. All 14 participants stated that the system is easy to use. Five participants mentioned that the training received was helpful and two participants found the user manual helpful.

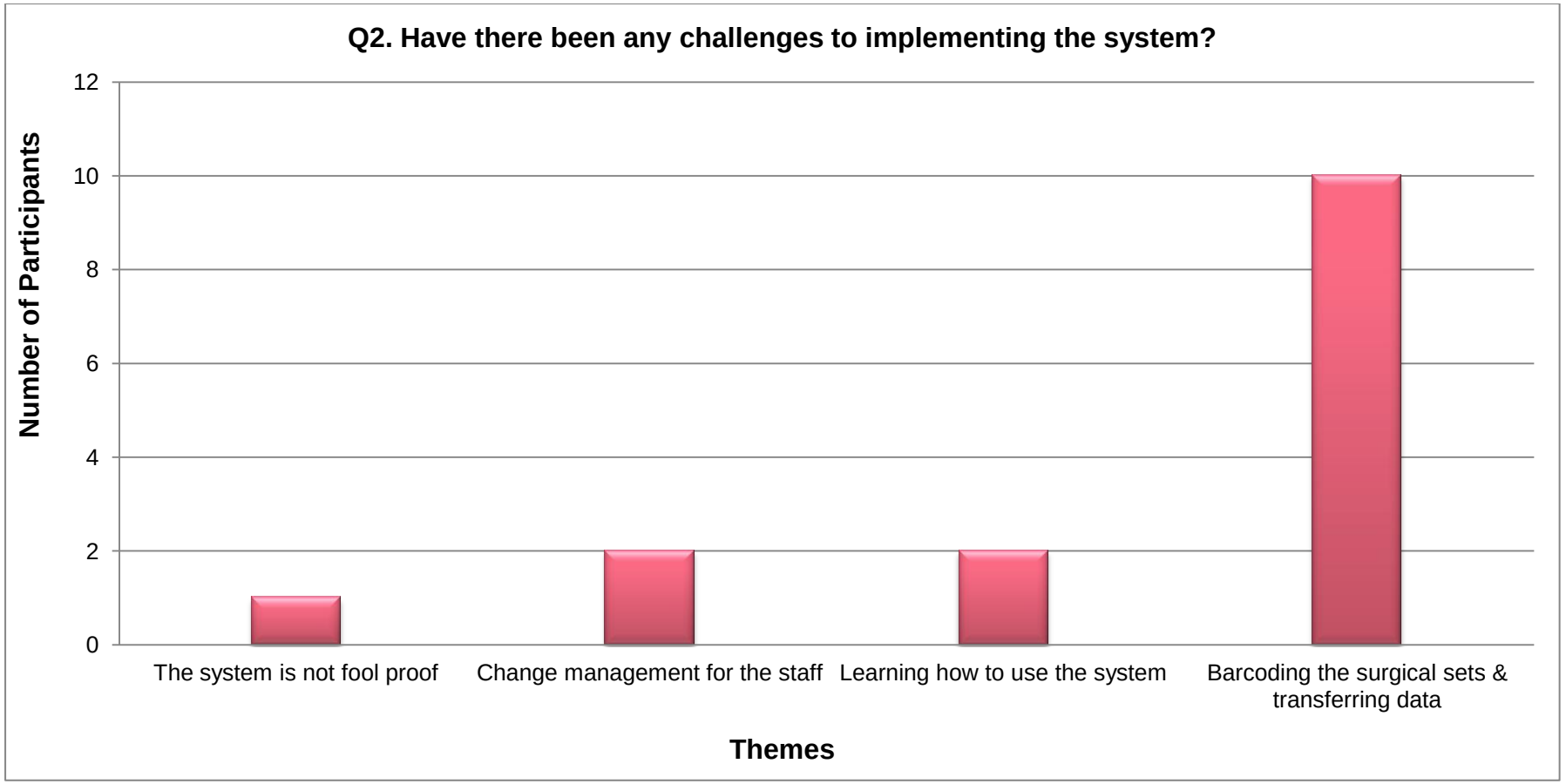

Figure 4.6; Interview responses for Q2. Have there been any challenges to implementing the system?

The participants were asked if there were any challenges with implementing the system. The most common theme found in the responses was the preparation involved before the Go Live date. Ten participants mentioned the task of setting up the surgical trays on the database and putting the GS1 and MS1 bar codes on the trays as an challenge. This process was time consuming and it was difficult to manage in addition to their daily tasks. Other challenges including change management of the staff and learning how to use the system. One person stated that the system is not fool proof and that mistakes can be made, such as not scanning the sets out of theatre.

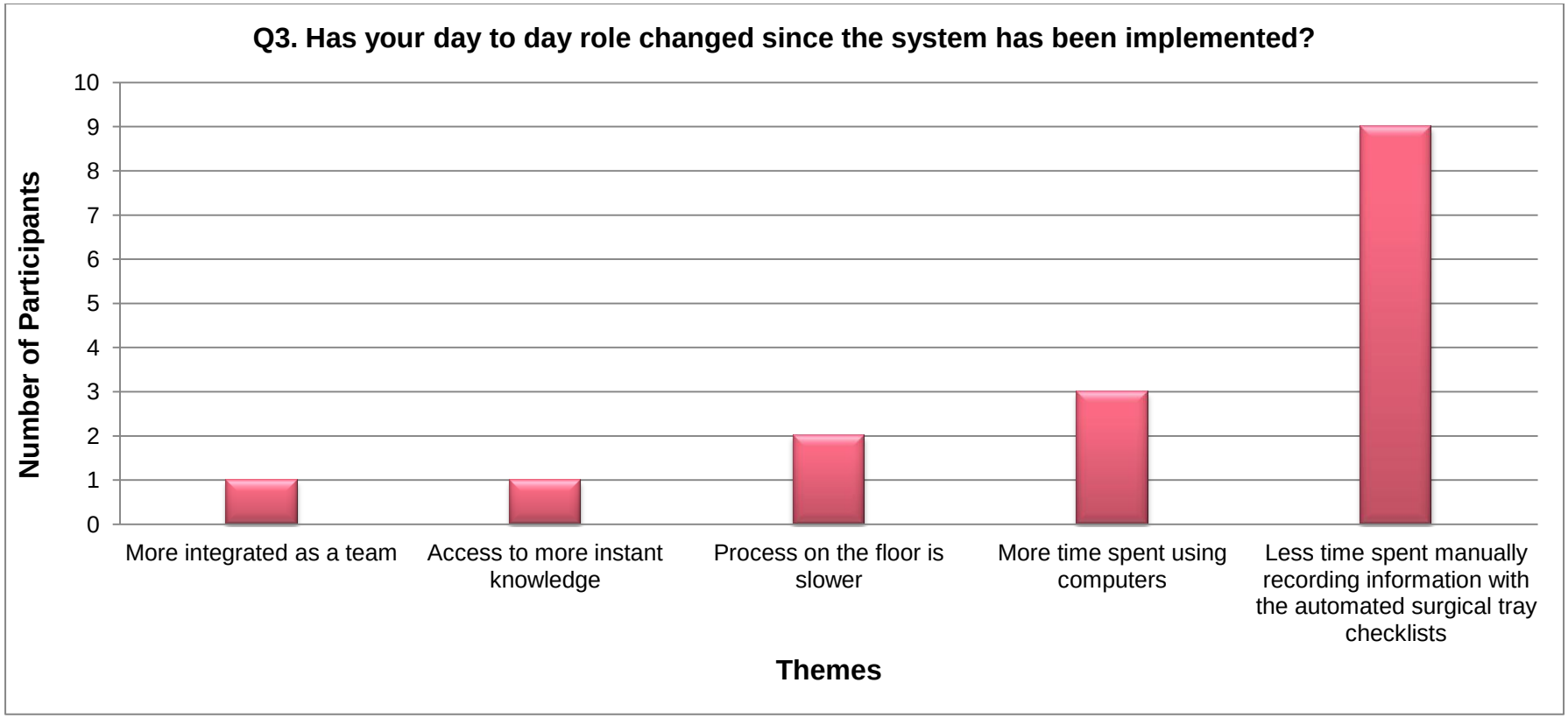

Figure 4.7; Interview responses for Q3. Has your day to day role changed since the system has been implemented?

The biggest change in their day to day identified was less administration work. In particular, when the staff are completing the check on the items in the surgical tray, before the system was implemented they had to search through a filing cabinet to find the appropriate checklist for the surgical tray, which could take up to 5 minutes each time. If only one copy of the checklist is in the filing cabinet, the technicians had to photocopy the checklist, which took additional time. If there were any changes to the surgical set, i.e., an instrument is gone for repair, then a new checklist would need to be created. With the traceability system, when the GS1 barcode on the surgical tray is scanned, a checklist for the surgical tray is automatically generated and printed. This checklist incorporates any changes that have been made to the set. Nine participants stated that this reduced the time spent manually recording information. Three participants stated that more time is spent using computers and two participants said that the process is slower on the floor. Other changes identified were that the team is more integrated and they have access to more instant information.

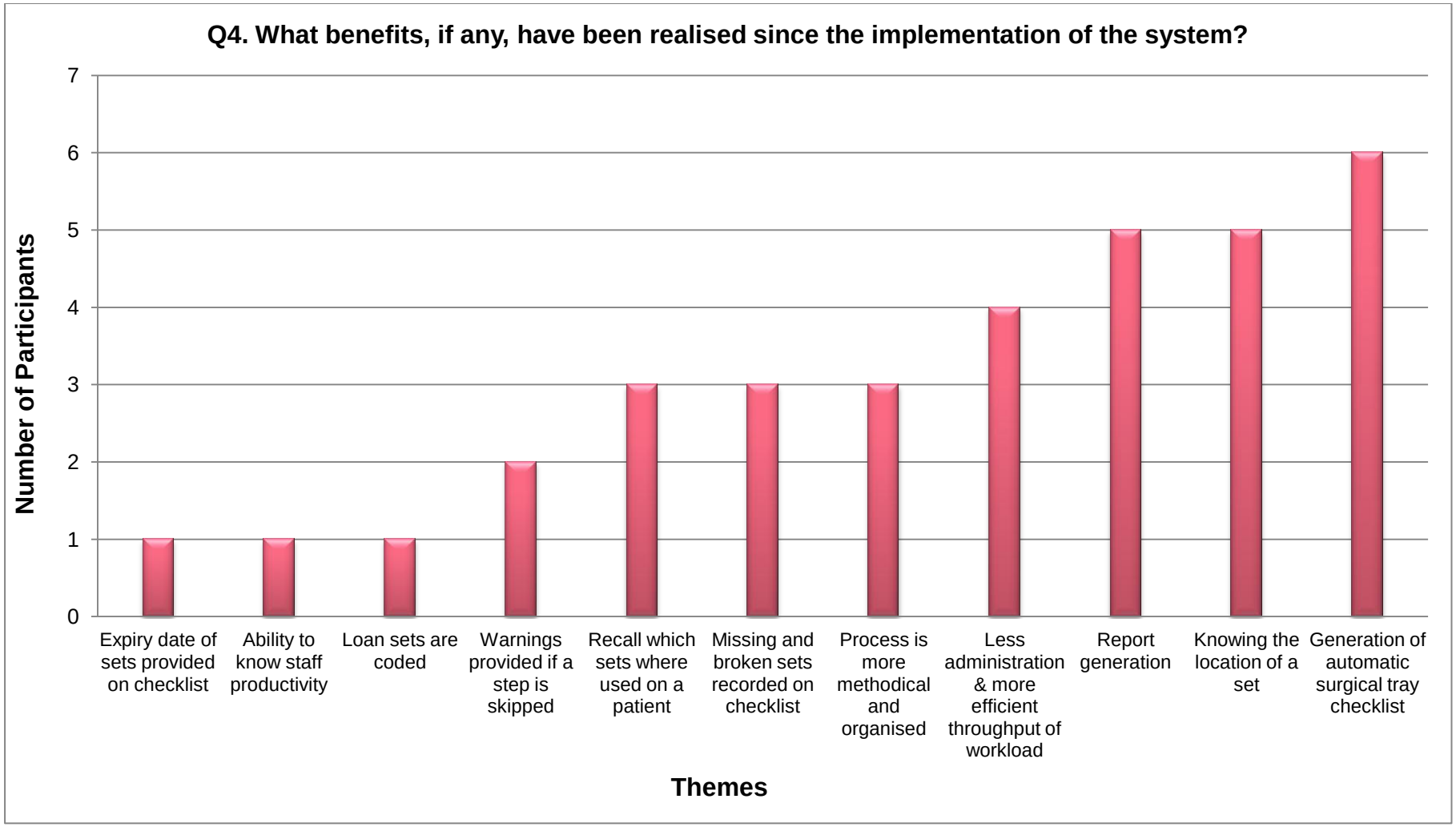

Figure 4.8; Interview responses for Q4. What benefits, if any, have been realised since the implementation of the system?

The benefits identified by the majority of participants included less administration work, more efficient throughput of workload, knowing the location of sets and the automatic generation of surgical tray checklists. Other benefits identified include linking sets to patients, knowing if instruments are being repaired and a more methodical and organised workflow. Benefits mentioned once included knowing the expiry of sets, better visibility of staff productivity and integrating loan sets seamlessly into the CDU process.

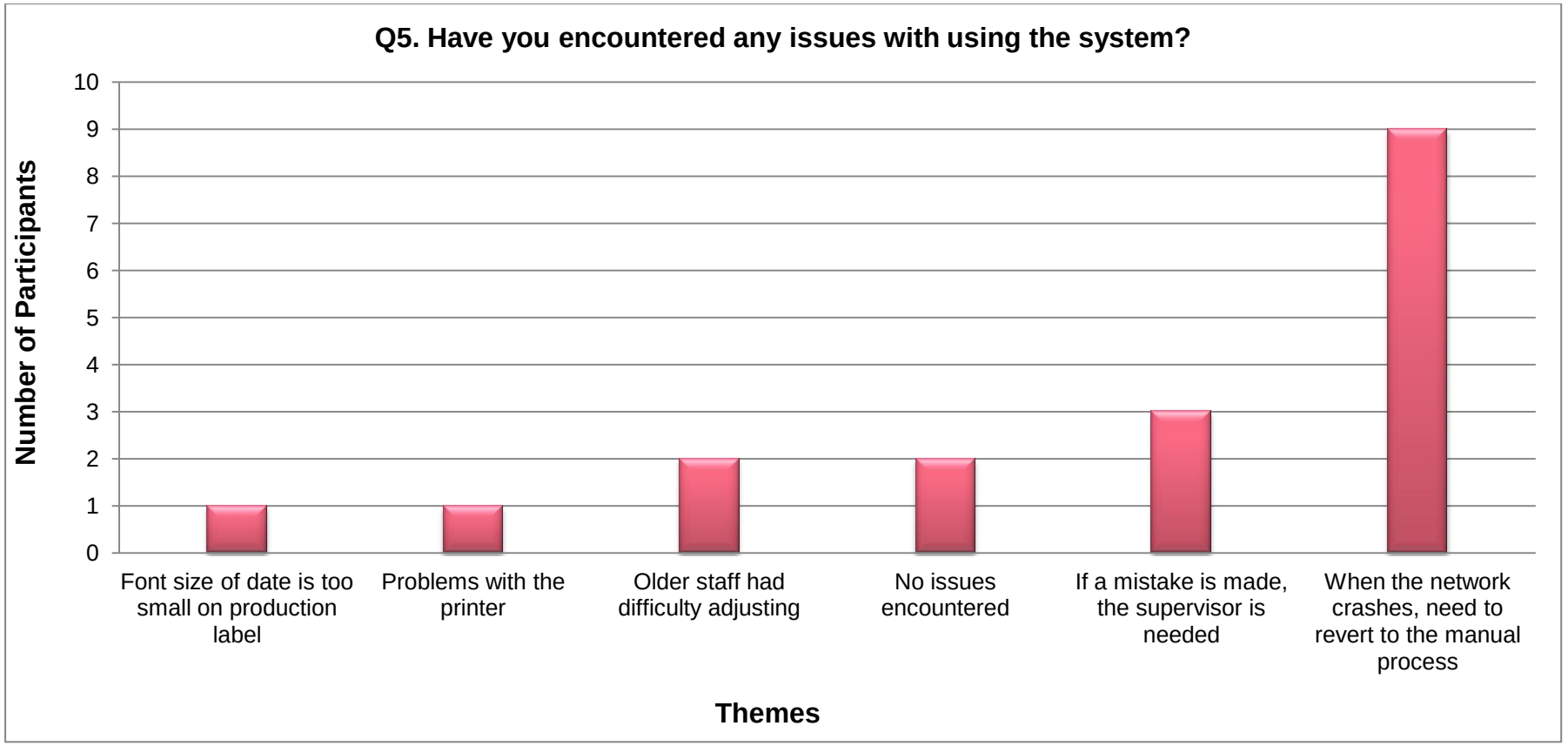

Figure 4.9; Interview responses for Q5. Have you encountered any issues with using the system?

The biggest issue emerging is in relation to the server crashing. Nine participants mentioned this. When the server crashes, it happens for approximately one to two hours, during which time the staff have to revert back to the manual process. The general impression was that staff get frustrated by this. Another issue mentioned by three people was if the wrong washer is scanned, the supervisor needs to be called to remedy this. Two people stated the older staff found it difficult at the start and that the older staff did not like the change of dynamics as they would have been considered the experts prior to the system being implemented. One person stated that the font size of the date on the production label needs to be larger and another person stated that they had difficulties using the printer. Two participants encountered no issues using the system.

Some of the themes identified were expected and some were new themes. These are outlined below.

Expected Themes:

- Change management for the staff
- Learning how to use the system was a challenge
- More time spent using computers each day
- Report generation
- Recall which sets where used on a patient
- Knowing the location of a set
- Less administration and more efficient throughput of workload
- Process is more methodical and organised
- Loan sets are coded making it easier to trace them

New Themes:

- Barcoding the surgical sets and transferring data was a challenge to implementing the system
- Less time spent manually recording information with the automated surgical tray checklists
- Process on the floor is slower
- More integrated as a team
- Warnings provided if a step is skipped
- Expiry date of sets provided on checklist
- Ability to know staff productivity
- Older staff had difficulty adjusting
- If a mistake is made, the supervisor is needed
- When the network crashes, need to revert to the manual process

The interview responses from the staff working the CDUs depicted a positive picture of the traceability solution in place for surgical trays. Overall the CDU staff found the system easy to use, with some staff members noting that the training and the user manual were helpful at the beginning of implementation. The main challenge to implementing the system was the barcoding of the surgical instruments with MS1 and GS1 barcodes and uploading the contents of each surgical tray. In St. James Hospital, 6-8 months was spent barcoding surgical trays before the system Go-Live date. The main challenge was the time it took for staff to do this in addition to their daily tasks. Other challenges noted were change management and learning how to use the system.

In general, there is not a huge change to the day to day role of the employees as the decontamination process itself remains the same. However, nine employees stated that they have less administration work to do throughout the day mainly due to the fact that the system automatically prints the surgical tray checklists and the production labels. See Appendix E for images of the surgical tray checklists and the production labels. These checklists are used to confirm that all the required instruments are in the surgical tray. The production labels are attached to the sterilisation paper in which the surgical sets are wrapped. Two employees stated that the system slows down the process on the floor and that more time is spent using computers.

A number of benefits were identified as a result of the implementation of the system:-

- The traceability system has reduced the amount of administration work carried out by technicians in both Tullamore Hospital and St James Hospital. Prior to the implementation of the traceability system, the technicians had to search through large filing cabinets to find the checklists for the surgical sets. This could take approximately 10 minutes to find each one. With the traceability system in place, the technicians simply scan the GS1 barcode on the surgical set and a checklist is automatically printed for them. The automatic generation of the surgical tray checklist was noted by 64% of participants interviewed as a benefit of the system.

- If there is an emergency surgical procedure needed, the surgical sets would need to be found quickly for this so that the patient could undergo surgery as soon as possible. Specific surgical sets are required for different surgeries. Hospitals are fast paced and there is no time for error especially in a situation where an emergency operation needs to take place. These are life and death situations. There is no time for delay. The longer it takes to locate a surgical set, the longer the delay in starting surgery and the repercussions of this could be dramatic for the patient's outcome. With the traceability system, the location of the surgical sets is known instantly as the set is tracked through each stage of the CDU and if the surgical set has been dispatched to another department, this is also recorded. The interviews reaffirmed that knowing the location of surgical set is a proven benefit of the system.

- The traceability system allows instruments to be tracked through each stage of the decontamination process. In doing so, through reporting the hospital can now confirm that the

sets have been fully decontaminated. See Appendix F for sample reports produced by the traceability system. The IMS monitors the washer cycle by viewing the washer's controller and conducting a comparison on the critical parameters, providing assurance that they are within the acceptable tolerances. The IMS system linked to the autoclave will send a message to the tracking software to confirm if the required parameters for complete sterilisation were achieved.

- Loan sets that are borrowed from other hospitals and commercial lenders can be tracked without difficulty. As the details of the loan set are stored in the MS1 server, the tracking systems are reading their information from this MS1 server and can recognise the loan sets as one of their own sets. This allows the technicians to easily trace the loan set through the CDU without having to manually trace the set. In cases where patients with CJD have used the set, the background of the hospital that the set had been used in and the patients that the set had been used on is all recorded and traceable. Loan sets can be loaned from hospital to hospital in different countries and without the traceability system it would become quite difficult to trace the loan sets. Only one participant mentioned this as a benefit in the interviews. This is most likely because the benefits of the loan sets have not been fully realised yet.

In order to appreciate the potential financial benefits of the traceability system for surgical trays, a simple financial was developed.

4.6 Financial Model of Cost Benefits

Using data from various sources a simple financial model was developed to illustrate the potential cost benefits of a traceability solution for surgical trays in a hospital. The model is designed to give a broad indication of the potential savings.

SSIs contribute to the levels of morbidity and mortality in Irish hospitals. SSIs are one of the most common HAIs and SSIs can have a severe impact on the patient both personally and financially. A patient may have prolonged pain, immobility, increased length of stay, additional surgery and a loss of income if they contract an SSI. SSIs can also impact hospitals financially with additional resources, medicines and follow up visits required.

The Hospital Infection Society in a 2006 survey found that in Ireland 4.6% of patients who had undergone a surgical procedure contracted an SSI. The NHS (2008) found that at least 5% of patients in the UK contract an SSI after surgery and that SSIs account for 20% of HAIs.

The HSE survey conducted in 2006 identified the rate of HAIs in Irish hospitals. The survey found that out of total population of 7518 patients, 4.9% of the patients contracted a HAI and 1.1% of the patients contracted an SSI. This is illustrated in Table 4.3 below.

	Regional / Tertiary Hospital	General Hospital	Specialist Hospital	Total
Total Survey Population (# of patients)	3512	3654	352	7518
HAI	210 (6%)	152 (4.2%)	7 (2%)	369 (4.9%)
SSI	50 (1.4%)	32 (0.9%)	1 (0.3%)	83 (1.1%)
SSI as a % of HAIs	23.8%	21%	14%	22.5%

Table 4.3; A survey of the amount of Hospital Acquired Infections and SSIs in Irish hospitals (*pp. 24*) – Health Service Executive (HSE, 2006)

This HSE survey also provided a breakdown of the rate of the most common HAIs in Irish hospitals, which identified that alongside Urinary Tract Infections (UTIs), SSIs are the largest cause of HAIs in Irish hospitals. These results are illustrated in Figure 4.10 below.

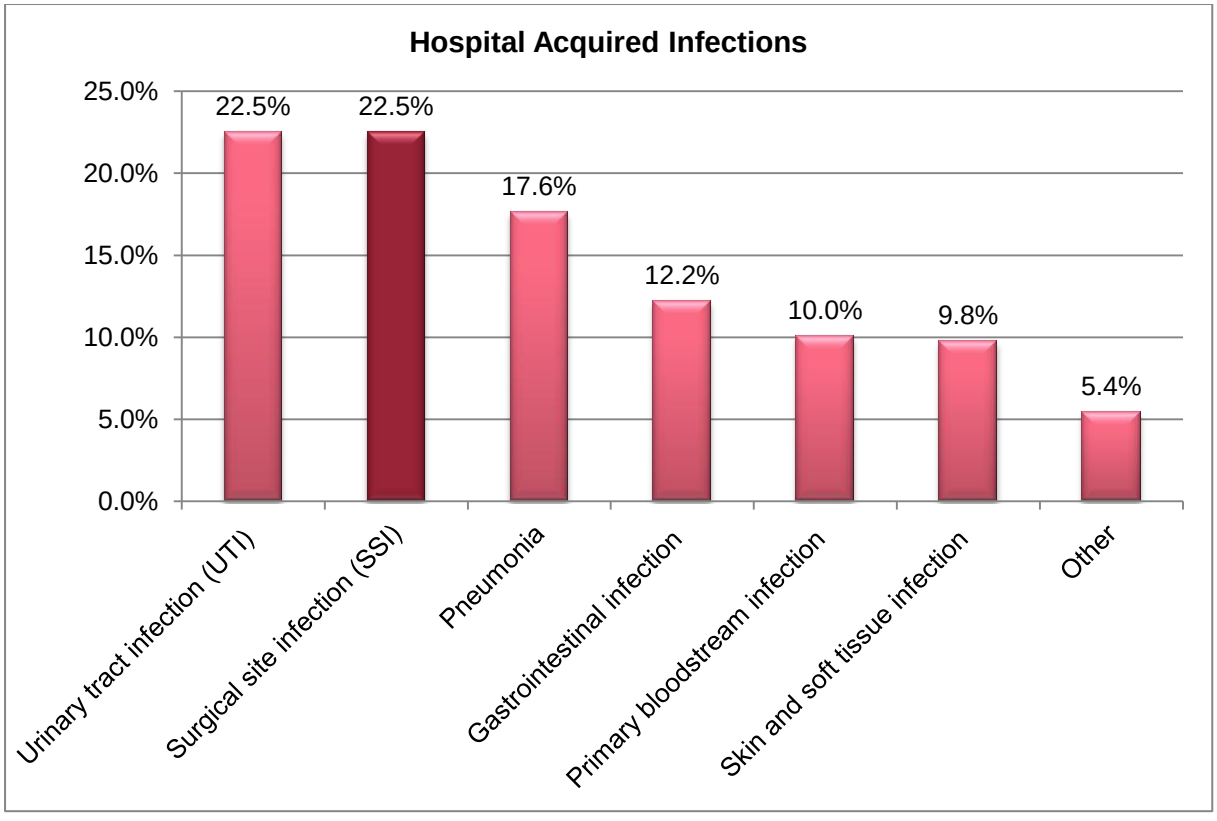

Figure 4.10; A breakdown of the most common Hospital Acquired Infections in Irish hospitals – Health Service Executive (HSE, 2006, p.24)

There is limited information relating to the cost of treating SSIs in Ireland. The *American Journal of Infection* (De Lissovoy *et al.,* 2009, p.394) published the following information illustrating the breakdown of additional bed days and additional costs for treating patients in the USA who contract SSIs following various surgeries (See Table 4.4). The cost was converted from US$ to Euro (US$1 = €0.7949).

Surgery Category:	Additional bed days:	Additional cost *(Euro):*
Neurologic	10.9	€20,650
Cardiovascular	13.7	€29,913
Colorectal	8.9	€14,317
Skin, subcutaneous, tissue, and breast	5.7	€5,367
Gastrointestinal	10	€16,609
Orthopaedic	9.5	€12,065
Obstetric and gynaecologic	6	€11,139
Average	**9.2**	**€15,723**

Table 4.4; Additional bed days and additional cost for a patient with an SSI – American Journal of Infection Control. (De Lissovoy *et al.,* 2009, p.394)

Figures from various sources were utilised to develop the financial model. The number of surgeries 14,000 is based on the number of surgeries carried out in St James Hospital each year. The rate of SSIs 1.1% for patients undergoing surgical procedures is from the HSE (2006). The figures for the additional bed days and additional cost for a hospital to treat a patient who contracts a SSI is taken from a study in the USA in the American Journal of Infection in 2008.

The model illustrates that the additional cost for a hospital in which 14,000 surgeries are undertaken annually, such as St. James Hospital, Dublin, to treat all SSIs is nearly €2.5 million and that an additional 1,380 bed days are required for the treatment of SSIs each year (See Figure 4.11).

Data Description:	Figure:	Source:
Number of surgeries each year:	14,000	St James Hospital, Dublin, Ireland
Rate of SSIs for all patients:	1.1%	(HSE, 2006)
Average additional bed days for a patient with a SSI:	9	(De Lissovoy et al., 2009, p.394)
Average additional cost to treat a patient with a SSI:	€ 15,723	(De Lissovoy et al., 2009, p.394)

Model for the potential savings for one hospital: Cost of treating all patients with SSIs each year:	
Data Description:	**Figure:**
Number of surgeries each year:	14,000
Number of SSIs in the hospital each year:	154
Number of additional bed days required for patients with SSI each year:	1386
Additional cost for the hospital each year:	€ 2,421,342

Figure 4.11; Simple financial model to illustrate the additional cost for a hospital each year to treat all SSIs

Scenarios were developed to illustrate the cost savings for a hospital if a traceability system for surgical instruments is implemented (See figure 4.12 below). Four scenarios were created to illustrate the potential cost savings of treating SSIs which are directly associated with surgical instruments. The four scenarios identify the potential cost of treating SSIs if 33%, 20%, 10% and 5% of the infections are associated with surgical instruments. Even if only 5% of the SSIs are associated with surgical instruments, there is still a potential cost saving of over €120,000 per year for the hospital. The other benefit realised is the reduction of the number of bed days required for patients.

Scenario 1: **If one third of all Surgical Site Infections are related to the surgical instruments**		
Additional cost for the hospital each year:	€	799,043
Additional bed days required each year:		457

Scenario 2: **If 20 % of the Surgical Site Infections are related to the surgical instruments**		
Additional cost for the hospital each year:	€	484,268
Additional bed days required each year:		277

Scenario 3: **If 10 % of the Surgical Site Infections are related to the surgical instruments**		
Additional cost for the hospital each year:	€	242,134
Additional bed days required each year:		139

Scenario 4: **If 5 % of the Surgical Site Infections are related to the surgical instruments**		
Additional cost for the hospital each year:	€	121,067
Additional bed days required each year:		69

Figure 4.12; Simple financial model to illustrate the various scenarios of the additional cost and bed days required for hospitals each year to treat SSIs which are related to the surgical instruments

Figure 4.13 below illustrates the potential savings of the traceability system for a hospital undertaking 14,000 surgeries each year, assuming all SSIs are eliminated. These figures are derived from the financial model above.

- If 33% of SSIs are related to the surgical instruments, this could save nearly €800,000 each year for the hospital.
- If 20% of the SSIs are related to surgical instruments, this could save almost €500,000 each year.
- If 10% of the SSIs are related to surgical instruments, this could save almost €250,000 each year.
- If 5% of the SSIs are related to surgical instruments, this could save over €100,000 each year.

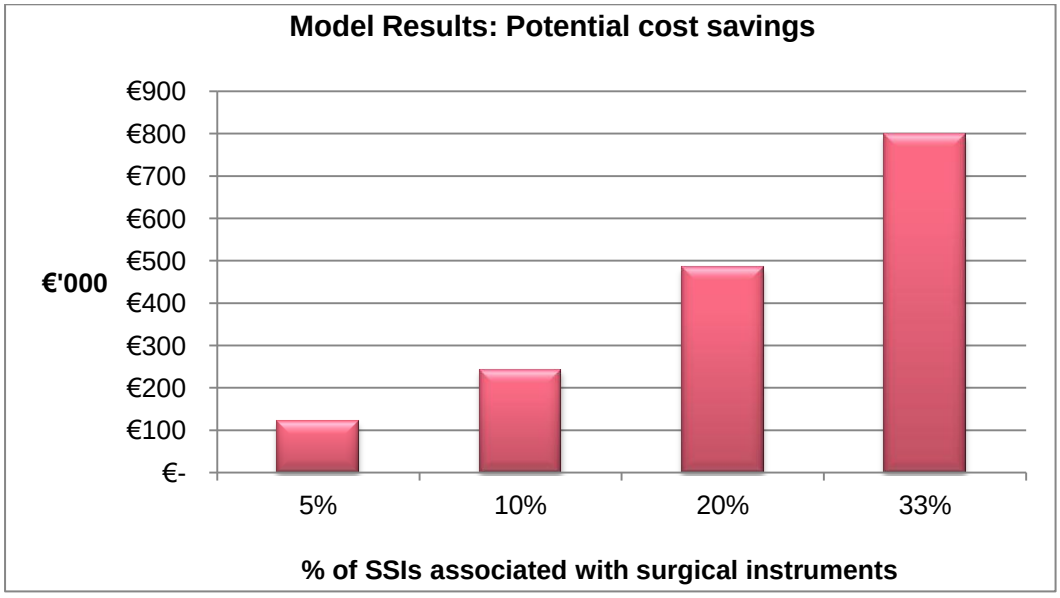

Figure 4.13; Potential savings attributable to the traceability system if SSIs associated with surgical instruments could be eliminated.

Figure 4.14 below illustrates the potential increase of bed days for other patients where the hospital conducts 14,000 surgeries each year. These figures are derived from the financial model above.

- If 33% of SSIs are related to the surgical instruments, this could make over 450 bed days available for other patients each year.

- If 20% of the SSIs are related to surgical instruments, this could make over 250 bed days available for other patients each year.
- If 10% of the SSIs are related to surgical instruments, this could make over 100 bed days available for other patients each year.
- If 5% of the SSIs are related to surgical instruments, this could make over 50 bed days available for other patients each year.

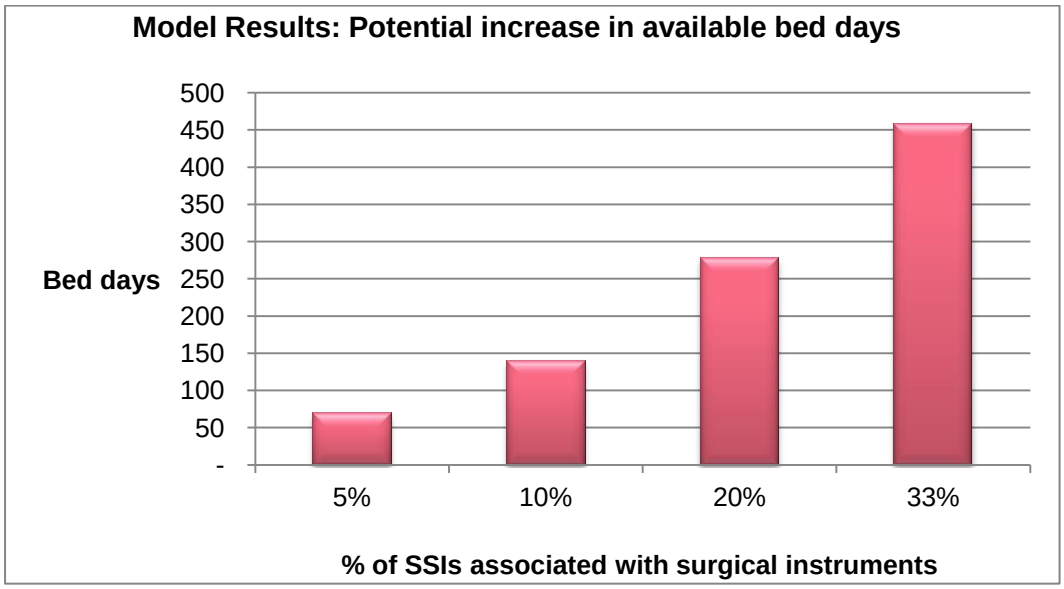

Figure 4.14; Potential increase in available bed days attributable to the traceability system if SSIs associated with surgical instruments could be eliminated.

The actual cost of implementing a traceability system will vary depending on the size of the hospitals and how many surgical instrument they process etc. Approximate cost of the traceability solution for surgical trays for one of the larger pilot hospitals below:

Traceability System Components:	Cost:	
Local project manager (1 year)	€	35,000
Enablement works (network cabling)	€	10,000
Hard ware (PCs)	€	6,000
Calibration costs (IMS)	€	5,000
Miscellaneous	€	1,000
Total (Approximate)	**€**	**57,000**

Table 4.5; Approximate cost of the traceability system for surgical trays in one of the large pilot hospitals in Ireland

Of the eight pilot hospitals, four of these hospitals are large and four are small. The cost for implementing the solution in the smaller hospitals was estimated to be half that of the larger hospitals. The figures were then extrapolated to give an average cost of implementing the system in each hospital. See table below:

Size:	Pilot Hospital:	Approximate Cost:
Large	Beaumont Hospital	€ 57,000
Large	Kerry General Hospital	€ 57,000
Small	Mullingar Hospital (Half the cost)	€ 28,500
Small	Portlaoise Hospital (Half the cost)	€ 28,500
Large	St James Hospital	€ 57,000
Large	Tallaght Hospital	€ 57,000
Small	Tullamore Hospital (Half the cost)	€ 28,500
Small	Waterford Hospital (Half the cost)	€ 28,500
	Total	**€ 342,000**
	Average cost per hospital:	**€ 42,750**

Table 4.6; Approximate cost for implementing the traceability system for surgical trays in one hospital

The cost benefits analysis of the traceability system is summarised below for each of the four SSI surgical instrument incident rates. The return on investment is calculated by subtracting the cost of the traceability system for the hospital each year. The cost for a project manager of approximately €35,000 is not included after year 1. The estimated running cost of the system after year 1 is €7,750 per year.

Year:	Scenario 1: Cost of treatment for SSIs 33%	Return on Investment:
End of year 1:	€799,043	€756,293
End of year 2:	€1,598,086	€1,590,336
End of year 3:	€2,397,129	€2,389,379
End of year 4:	€3,196,172	€3,188,422
End of year 5:	€3,995,215	€3,987,465

Year:	Scenario 3: Cost of treatment for SSIs 10%	Return on Investment:
End of year 1:	€242,134	€199,384
End of year 2:	€484,268	€476,518
End of year 3:	€726,402	€718,652
End of year 4:	€968,536	€960,786
End of year 5:	€1,210,670	€1,202,920

Year:	Scenario 2: Cost of treatment for SSIs 20%	Return on Investment:
End of year 1:	€484,268	€441,518
End of year 2:	€968,536	€960,786
End of year 3:	€1,452,804	€1,445,054
End of year 4:	€1,937,072	€1,929,322
End of year 5:	€2,421,340	€2,413,590

Year:	Scenario 4: Cost of treatment for SSIs 5%	Return on Investment:
End of year 1:	€121,067	€78,317
End of year 2:	€242,134	€234,384
End of year 3:	€363,201	€355,451
End of year 4:	€484,268	€476,518
End of year 5:	€605,335	€597,585

Figure 4.15; Potential cost savings of implementing the traceability system over five years

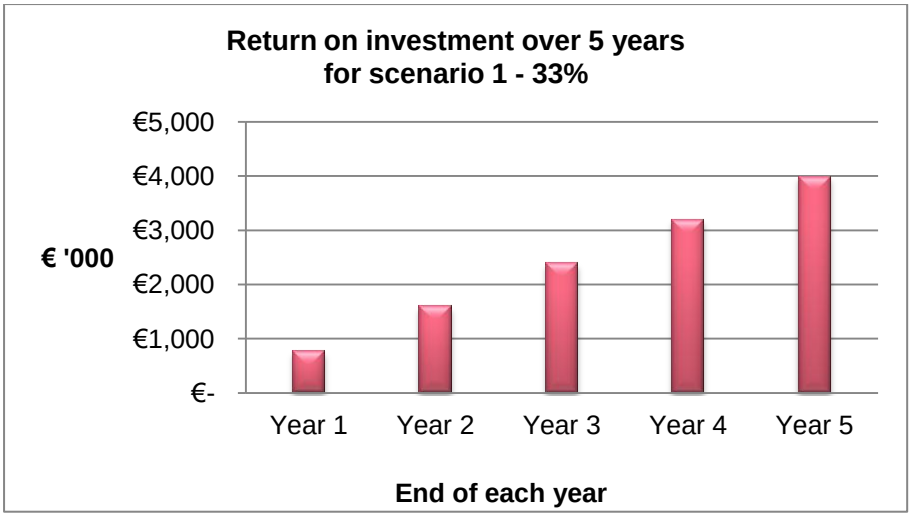

Figure 4.16; Potential return on investment over 5 years for scenario 1

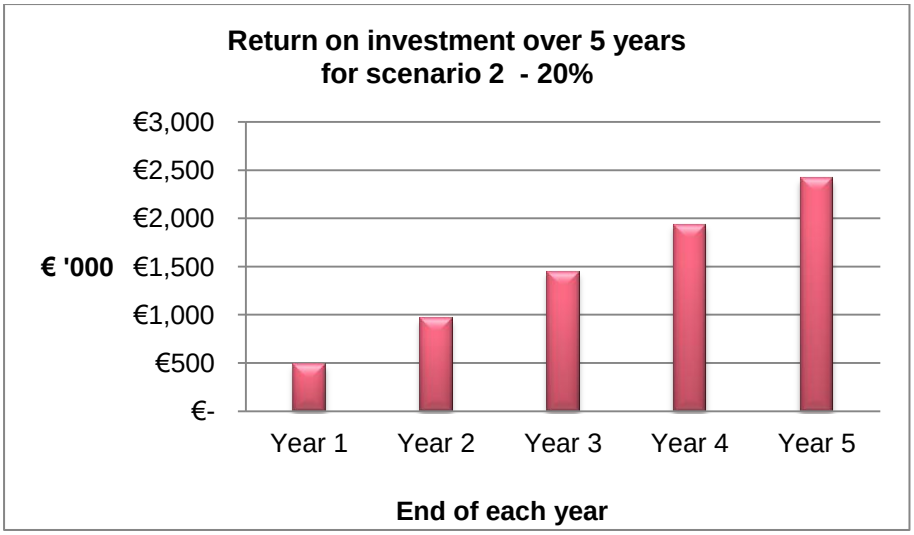

Figure 4.17; Potential return on investment over 5 years for scenario 2

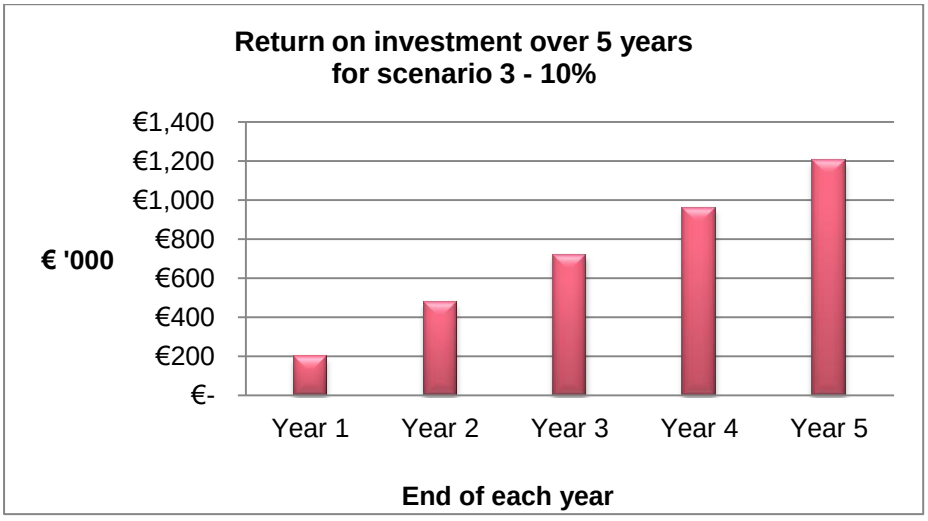

Figure 4.18; Potential return on investment over 5 years for scenario 3

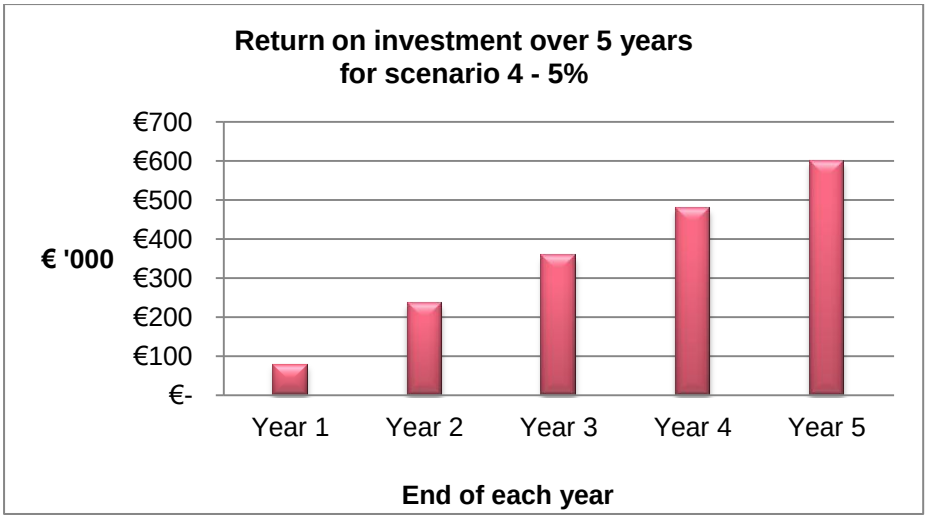

Figure 4.19; Potential return on investment over 5 years for scenario 4

From the above table and graphs it is apparent that, if the system costs approximately €42,750 to implement, potential savings of over €750,000 would be realised by the end of year 1 for Scenario 1 (where 33% of SSIs are associated with surgical instruments) and potential savings of over €75,000 would be realised by the end of year 1 in scenario 4 (where 5% of SSIs are associated with surgical instruments).

In addition to these potential cost savings and increased availability of bed days for the hospital. The patient would also benefit financially. If the average amount of additional bed days required to treat an SSI is nine days then the patient would not lose an additional nine days income for these days. The intangible benefits for a patient not contracting an SSI are also a crucial factor to be considered. Patients will suffer more pain, stress, further surgery and additional medication and treatment.

Chapter 5. Discussion and Conclusions

The focus of this dissertation was to answer the research question:

What are the potential benefits of a traceability solution for surgical trays in the Irish health service?

The subsidiary questions to be answered for this dissertation were:

- What are the benefits of traceability solutions in the other industries (e.g., Food and Pharmaceutical industries)?
- Why is the decontamination process of surgical devices important?
- What is the impact of SSIs for hospitals and patients?
- What benefits, if any, have been realised since the implementation of the traceability solution in St James Hospital and Tullamore Hospital?
- What were the challenges, if any, to the implementation of the traceability solution in St James Hospital and Tullamore Hospital?

This dissertation examined the potential benefits of a traceability solution for surgical trays in the Irish health service through literature review, interviews with stakeholders and CDU staff and through the development of a financial model. Two of the eight hospitals in Ireland which took part in the pilot phase of the nationally funded traceability solution for surgical trays were the case studies for this research. The objective of this dissertation was to provide a framework to assist hospitals in evaluating the economic viability of implementing a traceability solution for surgical trays. The approach taken to achieve this objective was to identify the potential benefits, the challenges involved to implement the system and the potential cost benefit of implementing such a system.

An extensive literature review was conducted to review literature on traceability systems, decontamination processes, HAIs and SSIs.

Through the literature review, research case studies and a financial model the following benefits of the system were noted:-

From the literature review, it can be concluded that there are numerous benefits of traceability systems. Traceability systems benefit the food industry by providing information about the origin of a food product to customers. A benefit realised in the pharmaceutical industry was the reduction of counterfeit medicines in the pharmaceutical supply chain. Traceability systems can have similar benefits across different industries. As traceability systems give assurance to the food and pharmaceutical

industries that their products are being monitored and checked through the supply chain, traceability systems give assurance to hospital managers that the decontamination process for surgical instruments is completed. Two case studies were reviewed where a hospital in France and in Manchester implemented traceability systems for surgical instruments. The benefits realised from these hospitals indicated that the traceability solution allowed surgical instruments to be traced back to patients, helped the hospital to manage the inventory of their surgical instruments, allowed surgical instruments to be located more easily and facilitated the process of confirming that all surgical instruments were in each surgical tray. Literature available on decontamination standards was reviewed. It was identified from the literature that hospitals do not always follow the recommended standards for CDUs. Implementing a traceability solution in CDUs would guarantee compliance with the recommended standards. Traceability systems for surgical trays would also prevent any steps being missed in the decontamination process. Cross contamination is a serious problem which can be benefitted by traceability systems for surgical trays as they would allow the hospital to know which patients might be affected by the cross contamination and which instruments need to be destroyed.

From the research case studies, a number of benefits were provided by the CDU staff. The traceability system ensures that instruments are tracked at each stage of the decontamination process which provides hospitals with assurance that the sets have been fully decontaminated. The traceability system has reduced the amount of administration work carried out by technicians in both Tullamore Hospital and St James Hospital. A manual task of searching for surgical tray checklists is now automated as the surgical tray checklists are automatically printed when the technicians scan the GS1 barcode on the surgical set. With the traceability system, the CDU can find out the location of the surgical sets instantly. Loan sets which are borrowed from other hospitals and commercial lenders can be tracked without difficulty with the traceability system. The traceability system has a reporting function which allows the CDU manager to confirm that surgical sets were decontaminated correctly. The reports can show that the IMS recorded that the washers and autoclaves completed the washing and sterilisation processes. Reporting generation was mentioned by five participants as a benefit of the system.

It has been acknowledged that monitoring the level of infection control in a hospital is a good indicator of the level of patient care in the hospital. HAIs are a huge problem today, with more than 1.4 million patients worldwide having a HAI at any time. Hospitals HAI can result additional bed days for patients and an additional cost for the patient, from loss of income, and an additional cost to hospitals, for treating the patient. SSIs cause approximately 20% - 30% HAIs and can increase the length of stay for patients from 7 days to 19.5 days. The financial model illustrated that for one hospital to treat all patients with SSI's would cost approximately €2.5 million each year. If 5% of SSIs are associated with surgical instruments, a traceability solution for surgical trays would eliminate the possibility of 5% of SSIs in the hospital, saving the hospital €120,000 each year. A traceability system for surgical trays costs approximately €42,750 to implement. The return on investment for the system would be almost €80,000 after the first year of implementation and nearly €250,000 after the second year of implementation. In conclusion, the evidence found through literature review, case study research and

a financial model strongly supports the implementation of a traceability solution for surgical trays in Irish hospitals.

Through the research case studies the following challenges to implementation of the traceability system were noted:-

The biggest challenge to implementing the traceability system was the marking of the surgical instruments with MS1 and GS1 barcodes. In St. James Hospital, 6-8 months was spent marking surgical trays. The main challenge for staff was completing the marking of the surgical trays in addition to their daily tasks. Other challenges noted were change management and taking time to learn how to use the system.

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Appendices

Appendix A: GS1 Standards

Barcodes and RFID tags

Barcodes are machine readable symbols which sometimes hold information related to the product that is attached. Radio Frequency Identification (RFID) tags are used for tracking and tracing. Unlike barcodes, they do need not to be visible, and can be embedded into items. RFID tags contain electronic information which is read by an RFID reader.

DataMatrix 2D barcodes are barcodes with 2 dimensions and can be attached to surgical instruments by micropercusion or laser etching or by a keydot label. According to Nicolaos *et al.,* (2010) in operating theatres and CDUs, RFID tags and DataMatrix 2D barcodes are used. See Figure A1 below for the different types of 2D barcodes.

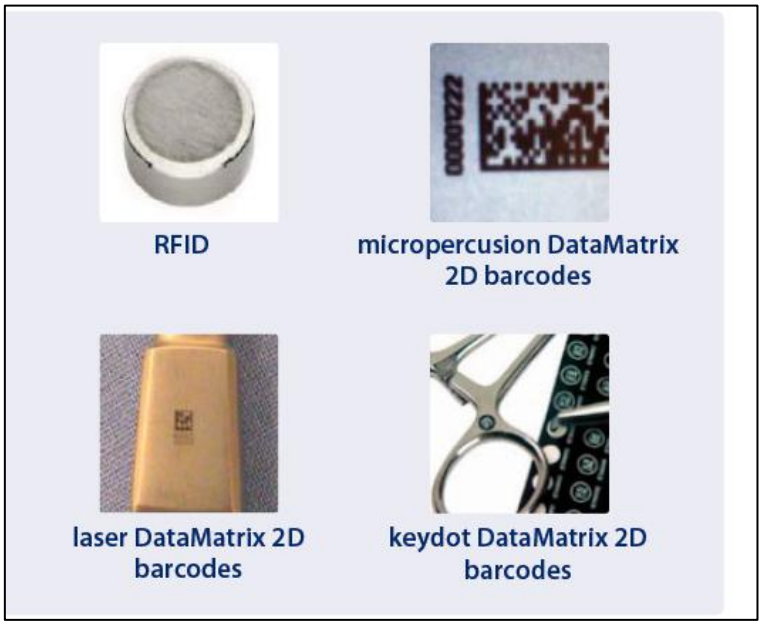


Figure A1; Different tags (Nicolaos *et al.,* 2010)

DataMatrix 2D barcodes link the surgical instruments/trays to a data file in a software application. The barcode is scanned by a 2D barcode reader. The Keydot DataMatrix 2D barcode is convenient as it gives more control to the decontamination manager in hospitals for marking the surgical instruments.

No training is required for marking instruments with a KeyDot as it is very simple and easy to apply them to instruments.

Figure A2; KeyDot DataMatrix 2D barcodes (KeySurgical, 2012)

"I just hope that bar coding doesn't remain in everyone's peripheral vision but comes sharply into focus." (GS1, 2011a)

Figure A3; Scanning the DataMatrix 2D barcode on a surgical instrument (Nicolaos *et al.,* 2010)

GS1 Data Carriers and identification Keys

The GS1 standards for both barcodes[6] and RFID[7] tags specify the correct use and application for the family of GS1 Identifiers and data carriers. GS1 data carriers (bar codes and RFID tags) hold GS1 identification keys and sometimes application information. All GS1 identification keys have an Application Identifier[8] (AI) which allows for additional information to be linked to the keys and concatenated in the same symbol. A Global Location Number (GLN) is a GS1 identification number which is used to identify physical locations. The Global Trade Item Number (GTIN) is the GS1 key for unique trade item identification. Other GS1 identification Keys include:

- SSCC – Serial Shipping Container Code
- GRAI – Global Returnable Asset Identifier
- GIAI – Global Individual Asset Identifier
- GSRN – Global Service Relation Number
- GDTI – Global Document Type Identifier
- GSIN – Global Shipment Identification Number
- GINC – Global Identification Number for Consignment

The use of application identifiers and defined Identification keys is one of the primary reasons why GS1 Standards are preferred over proprietary systems. Users know how to decode and use the information that is encoded in a symbol. For example if the application identifier 17 is used the technology and software that scans and decodes the barcode will know it is about to read an expiry date in the format of YYMMDD, it can then send that information to an application such as a point of sale unit in a shop and prevent a sale if the date is expired. Of course another fundamental reason is that the identification keys are globally unique thus enabling interoperable traceability.

The GS1 system utilises the following data carriers listed below:

- The EAN/UPC bar codes
- ITF-14 bar codes
- GS1-128 barcodes
- GS1 Databar
- Data Matrix ISO version ECC 200
- GS1 QR Code Bar Code

[6] The GS1 Standards for barcodes Application Identifiers and identification Keys are found in the GS1 General Specification V12
[7] The GS1 Standards for RFID related specifications can be found in the Tag Data Standard v. 1.6 (2011 September 9)
[8] An application identifier is a set of defined identifiers used to define the information that will be carried and transmitted when a barcode is scanneed.Each AI has a two, three, or four digit numeric Prefix in front of the data to tell what the data means. For example, the AI for SSCC is (00) and for GTIN it is (01) GS1-128, RSS, GS1 DataMatrix, and Composite Component can carry AIs.

The International Organisation for Standardisation (ISO) releases standards for bar code symbology and RFID specifications. This is a two way collaborative process. Specifications submitted and then published by ISO include EAN/UPC bar code symbology specifically ISO/IEC 15420 and UHF Gen 2 protocol (RFID) ISO/IEC 18000-6 type C. On the other hand GS1 adopts existing ISO standards such as Data Matrix bar code symbology, ISO/IEC 16022.

GS1 system standards aim to be completely compatible with the related published national, regional and international symbology standards.

The GS1-128 barcode is a subset of a more general code-128 as defined in ISO/IEC 15417:2007 Information technology. Automatic identification and data capture techniques - Code 128 bar code symbology specification. Similarly, the GS1 Data matrix is a subset of the Data Matrix bar code symbology specified in ISO/IEC 16022.

The difference between them is that the the Function 1 Symbol Character (FNC1) is encoded in the first position of the data and enables scanners to process the information according to the GS1 System Rules. Its second function is to act as a group separator between certain application identifiers to allow concatenation of different application Identifiers.

The GS1-128 barcodes provide a high level of security in comparison with non-standardised barcodes. They are used to mark the medical instrument trays.

Figure A4 illustrates the structure of the GS1-128 bar code (containing an SSCC) which is structured as follows:

- Left Quiet Zone
- Data
- A Symbol Check Character
- The Stop Character
- Right Quiet Zone

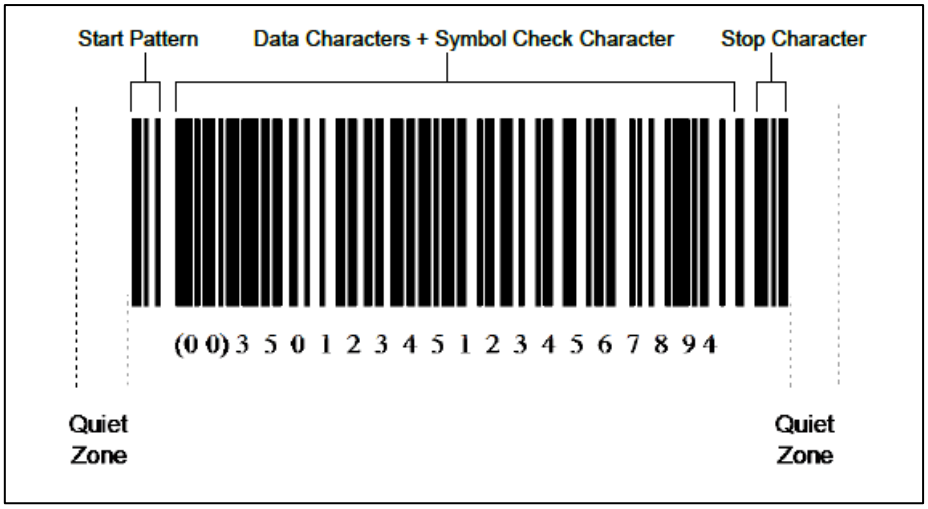


Figure A4; General Format of a GS1-128 Bar Code, (GS1 General Specifications, 2012)

The GS1 data matrix Data Matrix is a matrix (2D or two-dimensional) bar code which may be printed as a square or rectangular symbol made up of individual dots or squares. As described above the use of the function 1 differentiates it from the ISO/IEC 16022 specification in that it indicates that the symbol should be processed according to the GS1 System Rules.

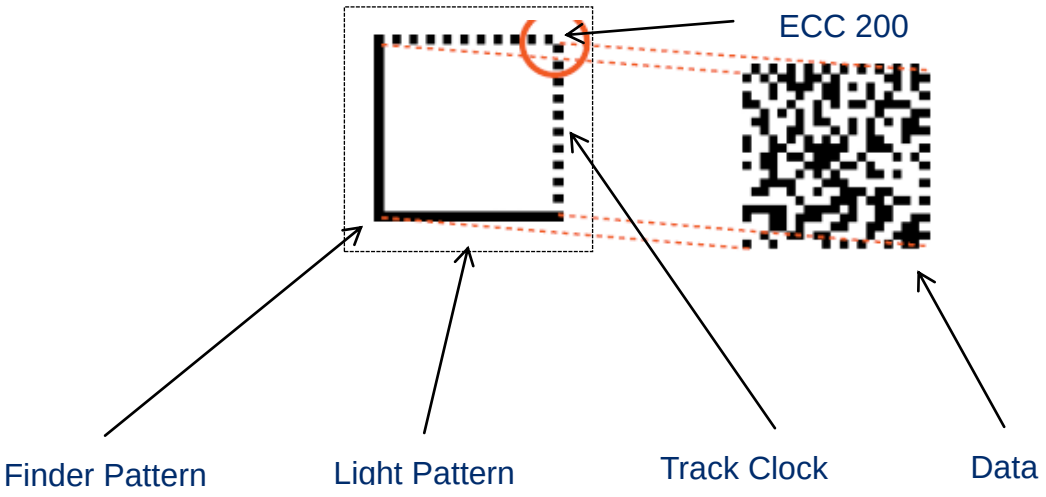


Figure A5; General Format of a GS1-128 Bar Code, (GS1 General Specifications, 2012)

Figure A5 illustrates the structure of the GS1-Data Matrix bar code which is structured as follows:

- Finder Pattern - used to specify the orientation and structure of the symbol
- Data
- Track Clock

- Light pattern

- Reed Solomon error correction is integral to the symbol data and allows for the data encoded to be read by a scanner even after it has been damaged.

A key application of the GS1 system is scanning trade items at the Point-of-Sale (POS). A trade item is essentially a product where pre-defined data about the item needs to read at some point along the supply chain (e.g., the price of a retail product in a clothes shop). Trade items are divided into three different groups depending on the application and the sector in which they belong to:

- General Retail Consumer Trade Items
  These trade items use omnidirectional linear bar codes which are read by retail POS scanners or linear hand held scanners.
- Regulated Healthcare Retail Consumer Trade Items
  These trade items use 2D Matrix symbols which are read by hospital pharmacies or distribution centres.
- Non-Retail Trade Items
  These trade items are typically used in mixed scanned places (e.g., laser and image based).

Small medical instruments and surgical instruments are non-retail trade items. GS1 (2012) state that the preferred marking method for manufactures of surgical instruments is with GTIN (01) and AI (21) serial numbers. The Data Matrix symbol should be used for marking single medical instruments. However, it is recognised that for a hospital to retrospectively mark instruments and trays the GIAI or GRAI may be used. When a hospital becomes a member of GS1, they are assigned a GCP (Global co Prefix). The GCP forms part of the unique identification keys used to identify items such as surgical instrument trays.

Element String

An Element String is the combination of a GS1 Application Identifier and a GS1 Application Identifier Data Field.

Automatic processing of Element Strings in business applications requires information about the type of transaction to which the transferred data refers. Element Strings can be carried by GS1-128, GS1 DataBar Symbology, GS1 Composite, and GS1 DataMatrix and GS1 QR Code Symbols.

When a pre-defined length GS1 Key and attributes are encoded together, the GS1 Key should appear before the attributes. In most cases pre-defined length element strings should be followed by non pre-defined element strings. The sequence of pre-defined and non pre-defined element strings should be at the discretion of the brand owner.

GS1 Application Identifiers in Numerical Order

Notes: The first position indicates the length (number of digits) of the GS1 Application Identifier. The following value refers to the format of the data content. The following convention is applied:

N numeric digit

X any character in figure 7.12 - 1

N3 3 numeric digits, fixed length

N..3 up to 3 numeric digits

X..3 up to 3 characters in figure 7.12 - 1

**: If only year and month are available, DD must be filled with two zeroes.

***: The fourth digit of this GS1 Application Identifier indicates the implied decimal point position.

Example:

- 3100 Net weight in kg without a decimal point
- 3102 Net weight in kg with two decimal points

FNC1: All GS1 Application Identifiers indicated with (FNC1) are defined as of variable length and shall be delimited unless this Element String is the last one to be encoded in the symbol. The delimiter shall be a Function 1 Symbol Character in GS1-128 Symbology, GS1 DataBar Expanded Versions and GS1 Composite Symbology and should be a Function 1 Symbol Character in GS1 DataMatrix and GS1 QR Code Symbology.

AI	Data Content	Format*	FNC1 Required	Data Title
00	SSCC (Serial Shipping Container Code)	N2+N18		SSCC
01	Global Trade Item Number (GTIN)	N2+N14		GTIN
02	GTIN of Contained Trade Items	N2+N14		CONTENT
10	Batch or Lot Number	N2+X..20	(FNC1)	BATCH/LOT
11 (**)	Production Date (YYMMDD)	N2+N6		PROD DATE
12 (**)	Due Date (YYMMDD)	N2+N6		DUE DATE
13 (**)	Packaging Date (YYMMDD)	N2+N6		PACK DATE
15 (**)	Best Before Date (YYMMDD)	N2+N6		BEST BEFORE or SELL BY
17 (**)	Expiration Date (YYMMDD)	N2+N6		USE BY OR EXPIRY
20	Variant Number	N2+N2		VARIANT
21	Serial Number	N2+X..20	(FNC1)	SERIAL
22	Secondary Data Fields	N2+X..29	(FNC1)	QTY /DATE /BATCH

AI	Data Content	Format*	FNC1 Required	Data Title
240	Additional Item Identification	N3+X..30	(FNC1)	ADDITIONAL ID
241	Customer Part Number	N3+X..30	(FNC1)	CUST. PART NO.
242	Made-to-Order Variation Number	N3+N..6	(FNC1)	MTO VARIANT
250	Secondary Serial Number	N3+X..30	(FNC1)	SECONDARY SERIAL
251	Reference to Source Entity	N3+X..30	(FNC1)	REF. TO SOURCE
253	Global Document Type Identifier (GDTI)	N3+N13+X..17	(FNC1)	GDTI
254	GLN Extension Component	N3+X..20	(FNC1)	GLN EXTENSION COMPONENT
30	Count of Items (Variable Measure Trade Item)	N2+N..8	(FNC1)	VAR. COUNT
310 (***)	Net weight, kilograms (Variable Measure Trade Item)	N4+N6		NET WEIGHT (kg)
311 (***)	Length or first dimension, metres (Variable Measure Trade Item)	N4+N6		LENGTH (m)
312 (***)	Width, diameter, or second dimension, metres (Variable Measure Trade Item)	N4+N6		WIDTH (m)
313 (***)	Depth, thickness, height, or third dimension, metres (Variable Measure Trade Item)	N4+N6		HEIGHT (m)
314 (***)	Area, square metres (Variable Measure Trade Item)	N4+N6		AREA (m^2)
315 (***)	Net volume, litres (Variable Measure Trade Item)	N4+N6		NET VOLUME (l)
316 (***)	Net volume, cubic metres (Variable Measure Trade Item)	N4+N6		NET VOLUME (m^3)
320 (***)	Net weight, pounds (Variable Measure Trade Item)	N4+N6		NET WEIGHT (lb)
321 (***)	Length or first dimension, inches (Variable Measure Trade Item)	N4+N6		LENGTH (i)
322 (***)	Length or first dimension, feet (Variable Measure Trade Item)	N4+N6		LENGTH (f)
323 (***)	Length or first dimension, yards (Variable Measure Trade Item)	N4+N6		LENGTH (y)

AI	Data Content	Format*	FNC1 Required	Data Title
324 (***)	Width, diameter, or second dimension, inches (Variable Measure Trade Item)	N4+N6		WIDTH (i)
325 (***)	Width, diameter, or second dimension, feet (Variable Measure Trade Item)	N4+N6		WIDTH (f)
326 (***)	Width, diameter, or second dimension, yards (Variable Measure Trade Item	N4+N6		WIDTH (y)
327 (***)	Depth, thickness, height, or third dimension, inches (Variable Measure Trade Item)	N4+N6		HEIGHT (i)
328 (***)	Depth, thickness, height, or third dimension, feet (Variable Measure Trade Item)	N4+N6		HEIGHT (f)
329 (***)	Depth, thickness, height, or third dimension, yards (Variable Measure Trade Item)	N4+N6		HEIGHT (y)
330 (***)	Logistic weight, kilograms	N4+N6		GROSS WEIGHT (kg)
331 (***)	Length or first dimension, metres	N4+N6		LENGTH (m), log
332 (***)	Width, diameter, or second dimension, metres	N4+N6		WIDTH (m), log
333 (***)	Depth, thickness, height, or third dimension, metres	N4+N6		HEIGHT (m), log
334 (***)	Area, square metres	N4+N6		AREA (m^2), log
335 (***)	Logistic volume, litres	N4+N6		VOLUME (l), log
336 (***)	Logistic volume, cubic metres	N4+N6		VOLUME (m^3), log
337 (***)	Kilograms per square metre	N4+N6		KG PER m^2
340 (***)	Logistic weight, pounds	N4+N6		GROSS WEIGHT (lb)
341 (***)	Length or first dimension, inches	N4+N6		LENGTH (i), log
342 (***)	Length or first dimension, feet	N4+N6		LENGTH (f), log
343 (***)	Length or first dimension, yards	N4+N6		LENGTH (y), log
344 (***)	Width, diameter, or second dimension, inches	N4+N6		WIDTH (i), log
345 (***)	Width, diameter, or second dimension, feet	N4+N6		WIDTH (f), log

AI	Data Content	Format*	FNC1 Required	Data Title
346 (***)	Width, diameter, or second dimension, yard	N4+N6		WIDTH (y), log
347 (***)	Depth, thickness, height, or third dimension, inches	N4+N6		HEIGHT (i), log
348 (***)	Depth, thickness, height, or third dimension, feet	N4+N6		HEIGHT (f), log
349 (***)	Depth, thickness, height, or third dimension, yards	N4+N6		HEIGHT (y), log
350 (***)	Area, square inches (Variable Measure Trade Item)	N4+N6		AREA (i^2)
351 (***)	Area, square feet (Variable Measure Trade Item)	N4+N6		AREA (f^2)
352 (***)	Area, square yards (Variable Measure Trade Item)	N4+N6		AREA (y^2)
353 (***)	Area, square inches	N4+N6		AREA (i^2), log
354 (***)	Area, square feet	N4+N6		AREA (f^2), log
355 (***)	Area, square yards	N4+N6		AREA (y^2), log
356 (***)	Net weight, troy ounces (Variable Measure Trade Item)	N4+N6		NET WEIGHT (t)
357 (***)	Net weight (or volume), ounces (Variable Measure Trade Item)	N4+N6		NET VOLUME (oz)
360 (***)	Net volume, quarts (Variable Measure Trade Item)	N4+N6		NET VOLUME (q)
361 (***)	Net volume, gallons U.S. (Variable Measure Trade Item)	N4+N6		NET VOLUME (g)
362 (***)	Logistic volume, quarts	N4+N6		VOLUME (q), log
363 (***)	Logistic volume, gallons U.S.	N4+N6		VOLUME (g), log
364 (***)	Net volume, cubic inches (Variable Measure Trade Item)	N4+N6		VOLUME (i^3)
365 (***)	Net volume, cubic feet (Variable Measure Trade Item)	N4+N6		VOLUME (f^3)
366 (***)	Net volume, cubic yards (Variable Measure Trade Item)	N4+N6		VOLUME (y^3)
367 (***)	Logistic volume, cubic inches	N4+N6		VOLUME (i^3), log

AI	Data Content	Format*	FNC1 Required	Data Title
368 (***)	Logistic volume, cubic feet	N4+N6		VOLUME (f^3), log
369 (***)	Logistic volume, cubic yards	N4+N6		VOLUME (y^3), log
37	Count of Trade Items	N2+N..8	(FNC1)	COUNT
390 (***)	Applicable Amount Payable, local currency	N4+N..15	(FNC1)	AMOUNT
391 (***)	Applicable Amount Payable with ISO Currency Code	N4+N3+N..15	(FNC1)	AMOUNT
392 (***)	Applicable Amount Payable, single monetary area (Variable Measure Trade Item)	N4+N..15	(FNC1)	PRICE
393 (***)	Applicable Amount Payable with ISO Currency Code (Variable Measure Trade Item)	N4+N3+N..15	(FNC1)	PRICE
400	Customer's Purchase Order Number	N3+X..30	(FNC1)	ORDER NUMBER
401	Global Identification Number for Consignment (GINC)	N3+X..30	(FNC1)	GINC
402	Global Shipment Identification Number (GSIN)	N3+N17	(FNC1)	GSIN
403	Routing Code	N3+X..30	(FNC1)	ROUTE
410	Ship to - Deliver to Global Location Number	N3+N13		SHIP TO LOC
411	Bill to - Invoice to Global Location Number	N3+N13		BILL TO
412	Purchased from Global Location Number	N3+N13		PURCHASE FROM
413	Ship for - Deliver for - Forward to Global Location Number	N3+N13		SHIP FOR LOC
414	Identification of a Physical Location - Global Location Number	N3+N13		LOC No
415	Global Location Number of the Invoicing Party	N3+N13		PAY TO
420	Ship to - Deliver to Postal Code Within a Single Postal Authority	N3+X..20	(FNC1)	SHIP TO POST

AI	Data Content	Format*	FNC1 Required	Data Title
421	Ship to - Deliver to Postal Code with ISO Country Code	N3+N3+X..9	(FNC1)	SHIP TO POST
422	Country of Origin of a Trade Item	N3+N3	(FNC1)	ORIGIN
423	Country of Initial Processing	N3+N3+N..12	(FNC1)	COUNTRY - INITIAL PROCESS.
424	Country of Processing	N3+N3	(FNC1)	COUNTRY - PROCESS.
425	Country of Disassembly	N3+N3	(FNC1)	COUNTRY - DISASSEMBLY
426	Country Covering full Process Chain	N3+N3	(FNC1)	COUNTRY – FULL PROCESS
7001	NATO Stock Number (NSN)	N4+N13	(FNC1)	NSN
7002	UN/ECE Meat Carcasses and Cuts Classification	N4+X..30	(FNC1)	MEAT CUT
7003	Expiration Date and Time	N4+N10	(FNC1)	EXPIRY TIME
7004	Active Potency	N4+N..4	(FNC1)	ACTIVE POTENCY
703s	Approval Number of Processor with ISO Country Code	N4+N3+X..27	(FNC1)	PROCESSOR # s
8001	Roll Products (Width, Length, Core Diameter, Direction, Splices)	N4+N14	(FNC1)	DIMENSIONS
8002	Cellular Mobile Telephone Identifier	N4+X..20	(FNC1)	CMT No
8003	Global Returnable Asset Identifier (GRAI)	N4+N14+X..16	(FNC1)	GRAI
8004	Global Individual Asset Identifier (GIAI)	N4+X..30	(FNC1)	GIAI
8005	Price Per Unit of Measure	N4+N6	(FNC1)	PRICE PER UNIT
8006	Identification of the Components of a Trade Item	N4+N14+N2+N2	(FNC1)	GCTIN
8007	International Bank Account Number (IBAN)	N4+X..30	(FNC1)	IBAN
8008	Date and Time of Production	N4+N8+N..4	(FNC1)	PROD TIME
8018	Global Service Relation Number (GSRN)	N4+N18	(FNC1)	GSRN
8020	Payment Slip Reference Number	N4+X..25	(FNC1)	REF No

AI	Data Content	Format*	FNC1 Required	Data Title
8100	GS1-128 Coupon Extended Code	N4+N6	(FNC1)	-
8101	GS1-128 Coupon Extended Code	N4+N1+N5+N4	(FNC1)	-
8102	GS1-128 Coupon Extended Code	N4+N1+N1	(FNC1)	-
8110	Coupon Code Identification for Use in North America	N4+X..70	(FNC1)	-
8200	Extended Packaging URL	N4+X..70	(FNC1)	PRODUCT URL
90	Information Mutually Agreed Between Trading Partners	N2+X..30	(FNC1)	INTERNAL
91 to 99	Company Internal Information	N2+X..30	(FNC1)	INTERNAL

Figure A6; GS1 Application Identifiers in Numerical Order

Appendix B: Ethics

Ethics Approval from Trinity College Dublin

Alana McMahon
TCD MSc Candidate: Health Informatics
PwC Advisory Consulting
One Spencer Dock
North Wall Quay
Dublin 1

Trinity College Dublin
School of Computer Science and Statistics
O'Reilly Institute
University of Dublin
Dublin 2, Ireland

Dr. Carl Vogel, FTCD
Director of Research
Telephone: 353 1 608 1538
Facsimile: 353 1 677 2204
e-mail: vogel@scss.tcd.ie

Ref: Research Ethics Application

June 6, 2012

Dear Ms. McMahon,

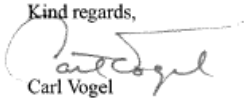
I write on behalf of the Research Ethics Committee of the School of Computer Science and Statistics in connection with your application for research ethics approval for a project entitled "Standardised Approach for Traceability of Surgical Trays".

On May 22, 2012, we wrote to you via email to express the approval of the revised application that you submitted.

The purpose of this letter is to confirm the same via post, as per your request.

We wish you every success in your research.

Kind regards,



Carl Vogel

cc: Committee Files

Consent form for the interview participants.

Consent Form

Trinity College Dublin
INFORMED CONSENT FORM

This research contributes to an MSc in Health Informatics at TCD

LEAD RESEARCHERS: Alana McMahon, Mobile: 087 6130285, Email: mcmaho a6@tcd.ie

BACKGROUND OF RESEARCH: The research contributes to an MSc in Health Informatics at TCD The purpose of the research is to identify the benefits, if any, of the traceability solutions which have been implemented in the decontamination units at St James Hospital and Tullamore Hospital.
PROCEDURES OF THIS STUDY: Information gathered from the interviews will be included in the final dissertation for an MSc in Health Informatics at TCD.
PUBLICATION: The research will be published in the researcher's dissertation for an MSc in Health Informatics at TCD and the research could be presented at the GS1 global forum and at the ISQua conference in October 2012.

Individual results will be aggregated anonymously and research reported on aggregate results.

DECLARATION:

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I understand that I may stop electronic recordings at any time, and that I may at any time, even subsequent to my participation have such recordings destroyed (except in situations such as above).
- I understand that, subject to the constraints above, no recordings will be replayed in any public forum or made available to any audience other than the current researchers/research team.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- I have received a copy of this agreement.

Information sheet for the interview participants

Information Sheet

Trinity College Dublin
INFORMED CONSENT FORM

This research contributes to an MSc in Health Informatics at Trinity College Dublin

LEAD RESEARCHER: Alana McMahon, Mobile: 087 6130285, Email: mcmaho a6@tcd.ie

BACKGROUND OF RESEARCH: The research contributes to an MSc in Health Informatics at TCD. The purpose of the research is to identify the benefits, if any, of the traceability solutions which have been implemented in the decontamination units at St James Hospital and Tullamore Hospital.
PROCEDURES OF THIS STUDY: Information gathered from the interviews will be included in the final dissertation for an MSc in Health Informatics at TCD.
PUBLICATION: The research will be published in the researcher's dissertation for an MSc in Health Informatics at TCD and the research could be presented at the GS1 global forum and at the ISQua conference in October 2012.
SELECTION PROCESS: CDU staff members who utilise the traceability solution in the decontamination units of the hospitals will take part in the survey. The participants will be selected at random.
RESEARCH PARTICIPATION: Participation in this research is voluntary; participants have the right to withdraw and to omit individual responses without penalty.
EXPECTED DURATION OF INVOLVEMENT IN RESEARCH: Involvement by participants is only required for a face-to-face interview which will be carried out at their hospital site.
ANTICIPATED RISKS/BENEFITS TO PARTICIPANTS: An anticipated benefit to the participants is that if they have recommendations for improvement for the traceability solution, these could be taken into consideration by hospital management. There are no anticipated risks to participants.
PROVISIONS FOR DEBRIEFING AFTER PARTICIPATION: Once all interviews have been carried out in both hospitals, a general summary of the interview responses will be provided to the participants.
ANONYMITY OF RESEARCH FINDINGS:
Individual responses will be aggregated anonymously and research will be reported and presented on aggregate responses.
DIRECT QUOTATIONS: Some direct quotations may be included in the dissertation to emphasise a particular point; however the participant's name will remain anonymous.

PARTICIPANT'S NAME:

Interview questions for the semi structured interviews with the CDU staff

Interview Questions

- The interview will be semi-structured and the following questions will be asked to the participants:

Questions for Decontamination unit staff members and for surgical nurses:

- Is the traceability system for surgical trays easy to use?
- Have there been any challenges to implementing the system?
- Has your day to day role changed since the system has been implemented?
- What benefits, if any, have been realised since the implementation of the system?
- Have you encountered any issues with using the system?

Appendix C: CDUs

Surgical Instrument Sets – St. James Hospital, Dublin, Ireland.

Washers / Disinfectors – St. James Hospital, Dublin, Ireland.

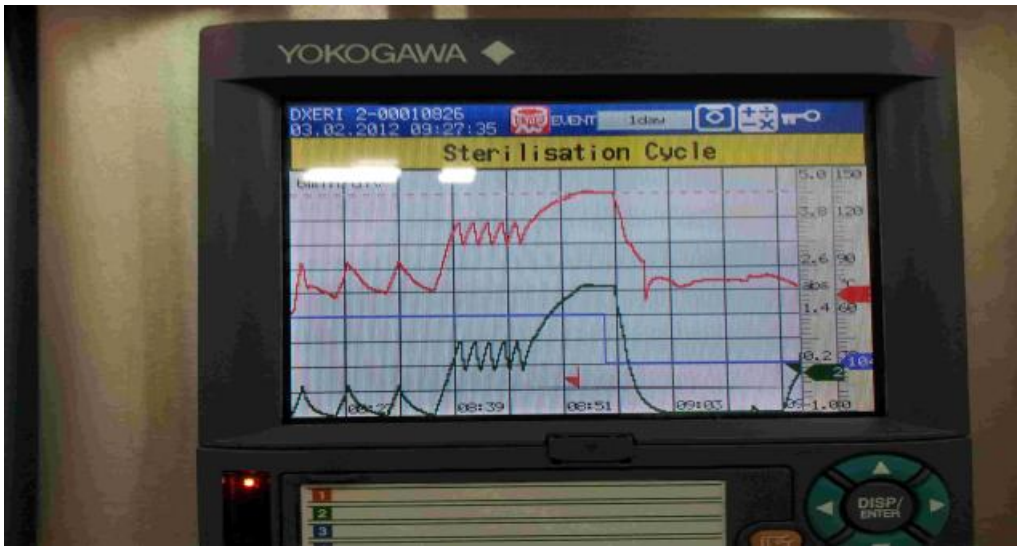
Clean room - work in progress – St. James Hospital, Dublin, Ireland.

Porous load steam sterilisers – St. James Hospital, Dublin, Ireland.

Sterile Goods Store – St. James Hospital, Dublin, Ireland.

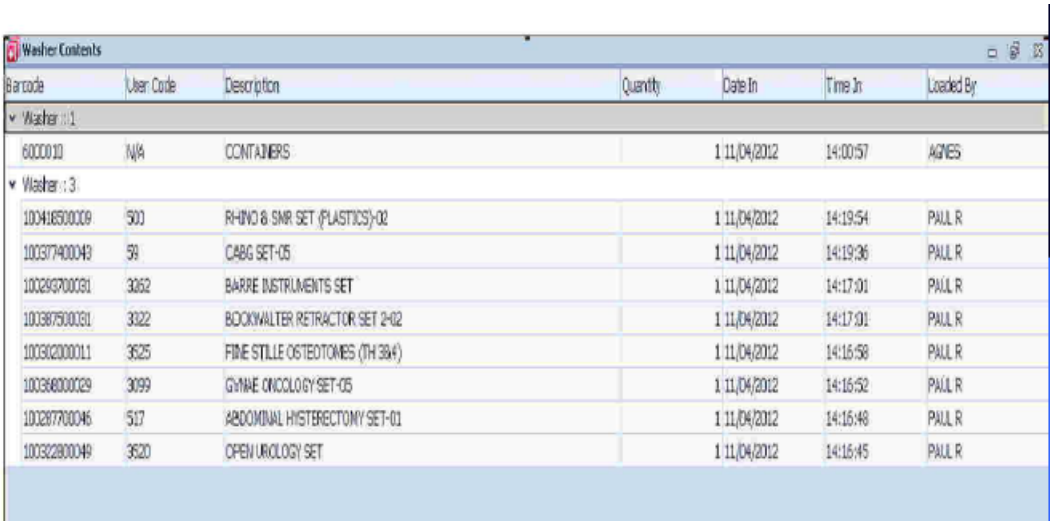
Tracking stations

Appendix D: As-Is and To-Be in the CDUs



Dataloggers

Tracking Instruments Before – Manual Check



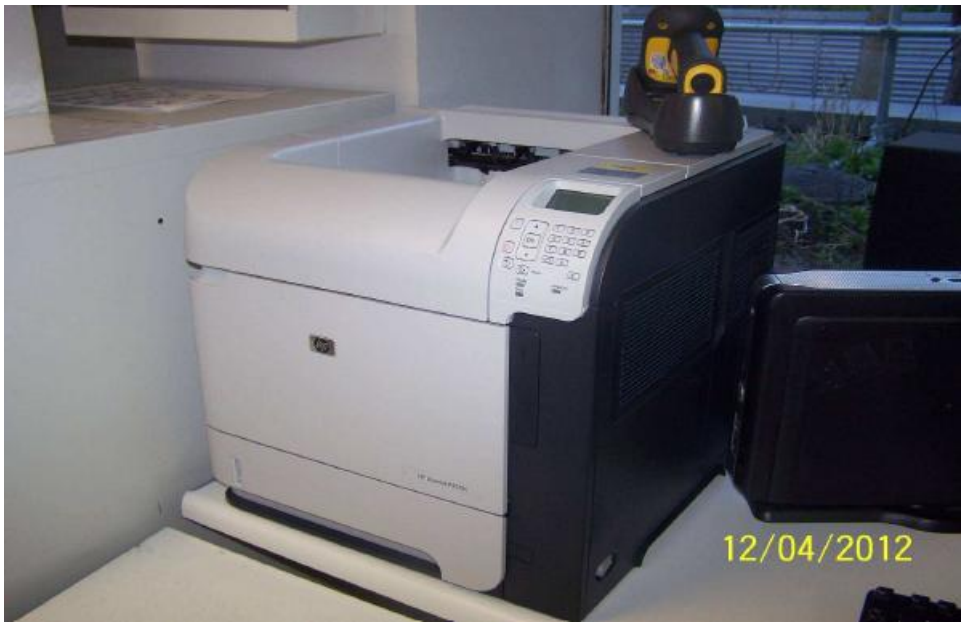
Washer Contents

Barcode	User Code	Description	Quantity	Date In	Time In	Loaded By
Washer : : 1						
6000010	N/A	CONTAINERS	1	11/04/2012	14:00:57	AGNES
Washer : : 3						
100416500009	500	RHINO & SMR SET (PLASTICS)-02	1	11/04/2012	14:19:54	PAUL R
100377400043	59	CABG SET-05	1	11/04/2012	14:19:36	PAUL R
100293700031	3052	BARRE INSTRUMENTS SET	1	11/04/2012	14:17:01	PAUL R
100387500031	3022	BOOKWALTER RETRACTOR SET 2-02	1	11/04/2012	14:17:01	PAUL R
100312000011	3625	FINE STILLE OSTEOTOMES (TH 394)	1	11/04/2012	14:16:58	PAUL R
100368000029	3099	GYNAE ONCOLOGY SET-05	1	11/04/2012	14:16:52	PAUL R
100287700046	517	ABDOMINAL HYSTERECTOMY SET-01	1	11/04/2012	14:16:48	PAUL R
100322800049	3620	OPEN UROLOGY SET	1	11/04/2012	14:16:45	PAUL R

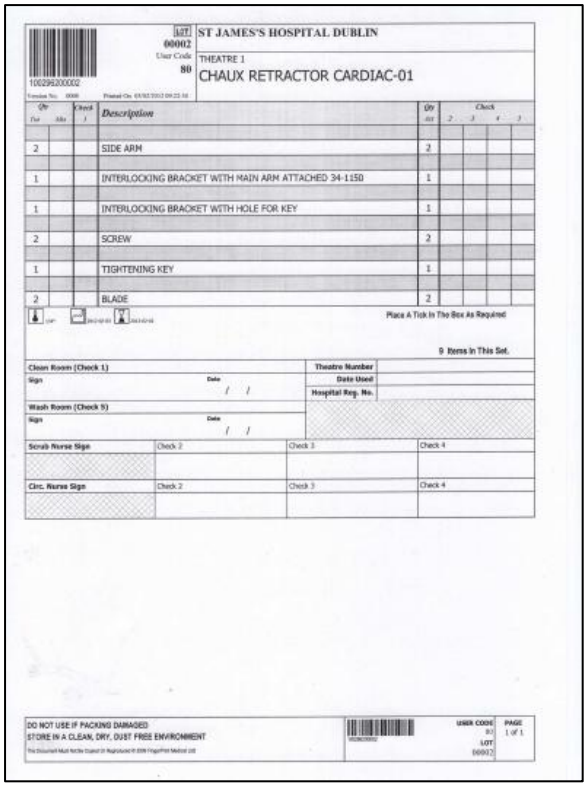
Tracking Instruments After – Information available electronically & post event

Instrument Set Lists Before – paper based

Instrument Set Lists Before – Hard to find the right version



Instrument Set Lists After – Electronic, file is printed when tray is scanned. No need to search. And there is certainty of document version.



ST JAMES'S HOSPITAL DUBLIN

LOT 00002 | User Code 80

THEATRE 1

CHAUX RETRACTOR CARDIAC-01

Qty Out	Qty Abs	Check 1	Description	Qty Set	Check 2	Check 3	Check 4	Check 5
2			SIDE ARM	2				
1			INTERLOCKING BRACKET WITH MAIN ARM ATTACHED 34-1150	1				
1			INTERLOCKING BRACKET WITH HOLE FOR KEY	1				
2			SCREW	2				
1			TIGHTENING KEY	1				
2			BLADE	2				

Place A Tick In The Box As Required

9 Items In This Set.

Clean Room (Check 1)	Theatre Number
Sign / Date / /	Date Used
	Hospital Reg. No.
Wash Room (Check 5)	
Sign / Date / /	

Scrub Nurse Sign	Check 2	Check 3	Check 4
Circ. Nurse Sign	Check 2	Check 3	Check 4

DO NOT USE IF PACKING DAMAGED
STORE IN A CLEAN, DRY, DUST FREE ENVIRONMENT

USER CODE 80 | LOT 00002 | PAGE 1 of 1

Set List printed automatically

CHAUX RETRACTOR CARDIAC-01

THEATRE 1

Tracker Ref: 1002962

2

8004539702199910009 28

Duplicate Label Tracker Ref: 1002962

ST JAMES'S HOSPITAL DUBLIN

THEATRE 1

CHAUX RETRACTOR CARDIAC-01

ID 1002962

LOT 00002

2012-02-03 2013-02-02

CHAUX RETRACTOR CARDIAC-01

ID 1002962 LOT 00002 USER CODE 80

CHAUX RETRACTOR CARDIAC-01

ID - 1002962 LOT - 00002

UC - 80

Version 0

Category

STEAM

BROWN WHEN PROCESSED

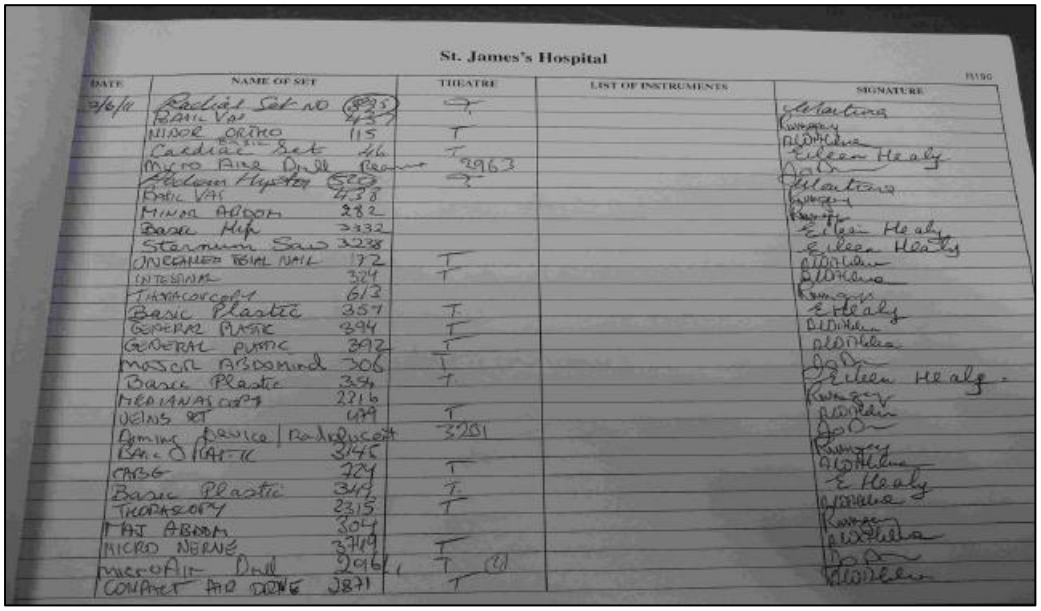
Reorder code FPH001

Tel: +44 (0) 1494 338 742

DO NOT USE IF PACKAGING IS DAMAGED OR OPEN

STORE IN A CLEAN DUST FREE ENVIRONMENT

Label for set list printed automatically



St. James's Hospital

DATE	NAME OF SET	THEATRE	LIST OF INSTRUMENTS	SIGNATURE
3/6/12	Radial Set NO	T		
	BASIC VAS	T		
	MINOR ORTHO	T		
	Cardiac Set	T		
	Micro Air Drill	T		
	Abdom Hysterectomy	T		
	BASIC VAS	T		
	MINOR ABDOM	T		
	Basic Hip	T		
	Sternum Saw	T		
	UNREAMED TIBIAL NAIL	T		
	INTERNAL	T		
	THORACOTOMY	T		
	Basic Plastic	T		
	GENERAL PLASTIC	T		
	GENERAL PLASTIC	T		
	MASSOL ABDOMINAL	T		
	Basic Plastic	T		
	MEDIANASTOMY	T		
	VEINS SET	T		
	Ophthalmic Device Radiosurgery	T		
	BASIC PLASTIC	T		
	CABG	T		
	Basic Plastic	T		
	THORACOTOMY	T		
	LAP ABDOM	T		
	MICRO NERVE	T		
	MICRO AIR DRILL	T		
	COMPACT AIR DRIVE	T		

Process log before, paper based.

From : 05/04/2012
To : 05/04/2012

ST JAMES'S HOSPITAL DUBLIN

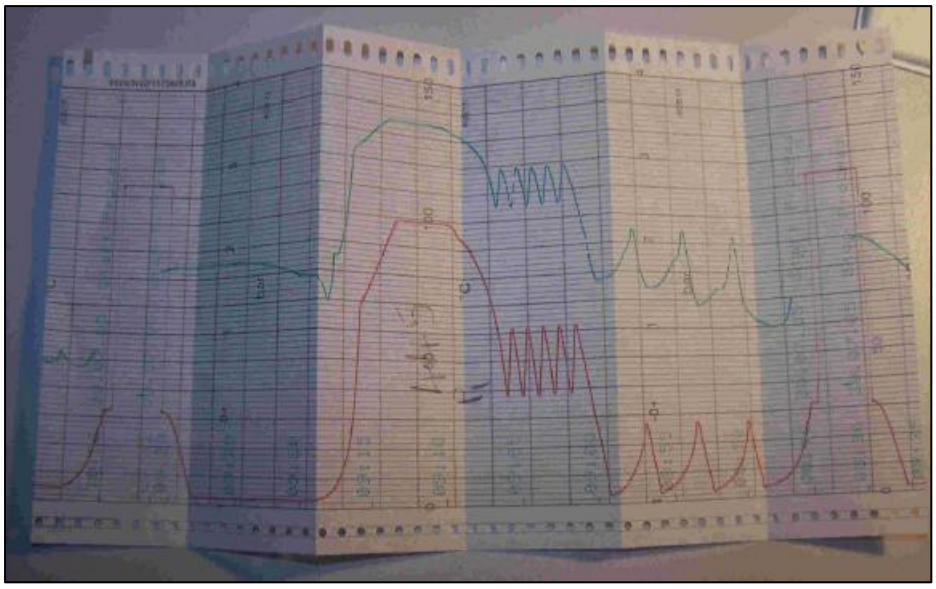
01:Packing Detail

Unknown Type

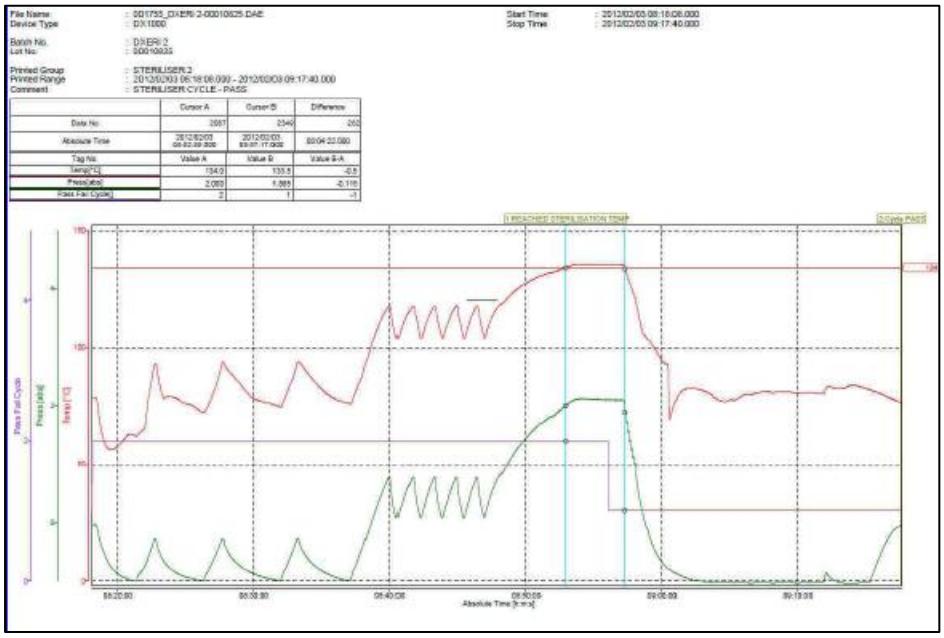
Barcode	UserCode	Operator	Date In	Time In	Description
10039870004	531	EILEEN H	05/04/2012	08:13:31	GYNAE LAPAROSCOPY SET-01
10045840001	2772	LINDA R	05/04/2012	08:54:05	30° LENS 4MM WOLF 433424 DSC
10045790001	2130	LINDA R	05/04/2012	09:01:13	0° LENS 4MM WOLF 427581 DSC
10045850001	2781	LINDA R	05/04/2012	09:05:31	30° LENS 4MM WOLF 433413 DSC
10046050002	4030	LINDA R	05/04/2012	09:08:52	HYSTEROSCOPE & SHEATH 5000193167 DSC
10030360008	2609	EILEEN H	05/04/2012	10:41:07	GENERAL LAPAROSCOPY SET NEW-01
10045510002	3768	LINDA R	05/04/2012	10:44:50	0° LENS 10MM WOLF 5000171714 DSC
10037540007	2938	PAUL R	05/04/2012	11:42:50	GENERAL LAPAROSCOPY SET NEW-06
10045250002	3195	ANTHONY C	05/04/2012	12:11:05	0° LENS 5.3MM WOLF 468796
10045490000	3177	LINDA R	05/04/2012	14:15:57	30° LENS 10MM WOLF 436023 DSC
10047570002	6024	LINDA R	05/04/2012	14:16:29	0° LENS 5MM STORZ 1127861 DSC
10037520007	2936	DOROTA S	05/04/2012	14:31:34	GENERAL LAPAROSCOPY SET NEW-04
10032100000	2393	JOSEPHINE D	05/04/2012	17:12:41	NEPHROSCOPE
10045300004	3194	DEIRDRE C	05/04/2012	17:29:14	30° LENS 10MM WOLF 457074
10045240000	3304	DEIRDRE C	05/04/2012	17:33:15	0° LENS 5MM STORZ 9306001
10041690002	3889	JOSEPHINE D	05/04/2012	17:36:06	URETEROSCOPE STRAIGHT TH 10 & 11-04
10045320004	3677	DEIRDRE C	05/04/2012	17:38:59	30° LENS 10MM WOLF 5000145118
10032820001	879	JOSEPHINE D	05/04/2012	17:42:33	WOLF LITHOCLAST FULL SET
10046550003	6000	DEIRDRE C	05/04/2012	17:44:08	30° LENS 4MM ACMI 739453
10045310004	3676	DEIRDRE C	05/04/2012	17:48:29	30° LENS 10MM WOLF 5000145117

Number Of Items : 20

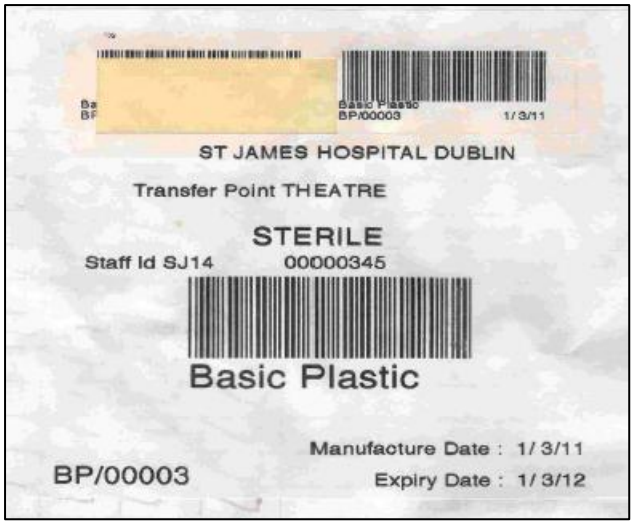
Process log after, electronic and legible, post-event – can be retrieved at a touch of a button



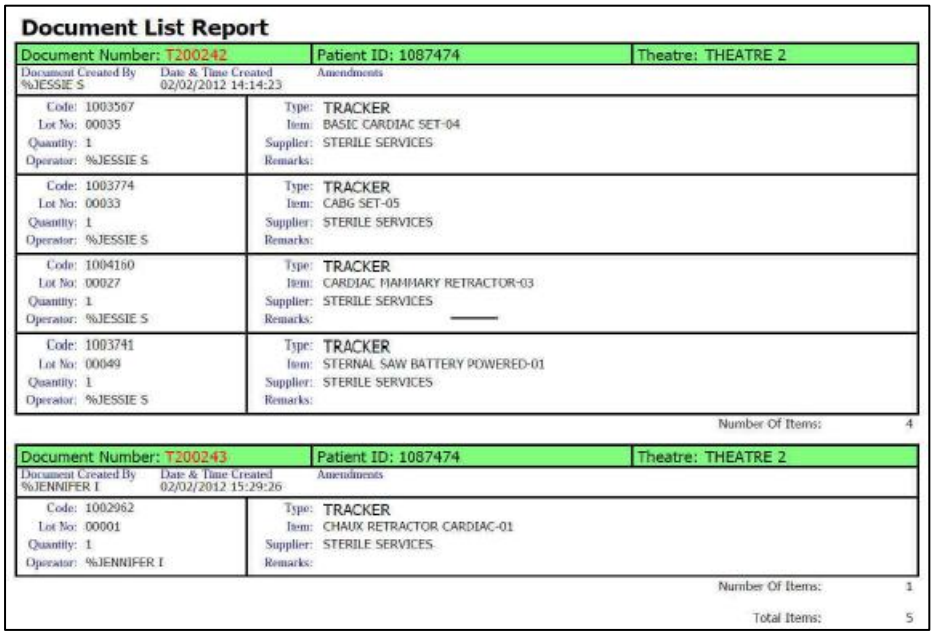
Steriliser cycle record before – paper based & subject to deterioration over time.



Steriliser record after – electronic, post-event – can be retrieved at the touch of a button



Tracking in theatres before – paper based.



Document List Report

Document Number: T200242	Patient ID: 1087474	Theatre: THEATRE 2
Document Created By: %JESSIE S	Date & Time Created: 02/02/2012 14:14:23	Amendments

Code: 1003567 Lot No: 00035 Quantity: 1 Operator: %JESSIE S	Type: TRACKER Item: BASIC CARDIAC SET-04 Supplier: STERILE SERVICES Remarks:
Code: 1003774 Lot No: 00033 Quantity: 1 Operator: %JESSIE S	Type: TRACKER Item: CABG SET-05 Supplier: STERILE SERVICES Remarks:
Code: 1004160 Lot No: 00027 Quantity: 1 Operator: %JESSIE S	Type: TRACKER Item: CARDIAC MAMMARY RETRACTOR-03 Supplier: STERILE SERVICES Remarks:
Code: 1003741 Lot No: 00049 Quantity: 1 Operator: %JESSIE S	Type: TRACKER Item: STERNAL SAW BATTERY POWERED-01 Supplier: STERILE SERVICES Remarks:

Number Of Items: 4

Document Number: T200243	Patient ID: 1087474	Theatre: THEATRE 2
Document Created By: %JENNIFER I	Date & Time Created: 02/02/2012 15:29:26	Amendments

Code: 1002962 Lot No: 00001 Quantity: 1 Operator: %JENNIFER I	Type: TRACKER Item: CHAUX RETRACTOR CARDIAC-01 Supplier: STERILE SERVICES Remarks:

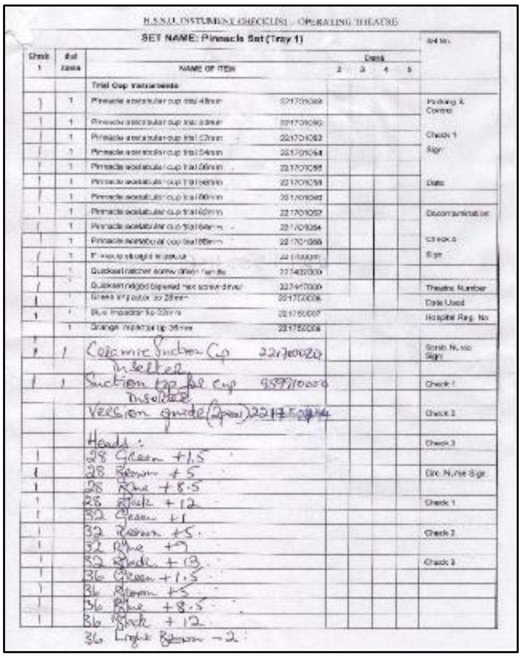
Number Of Items: 1

Total Items: 5

Tracking in theatres after – electronic, post –event – can be retrieved at the touch of a button, linked to instrument tracking system.

Loan Sets

The big challenge. Shared among hospitals, traceability is very challenging



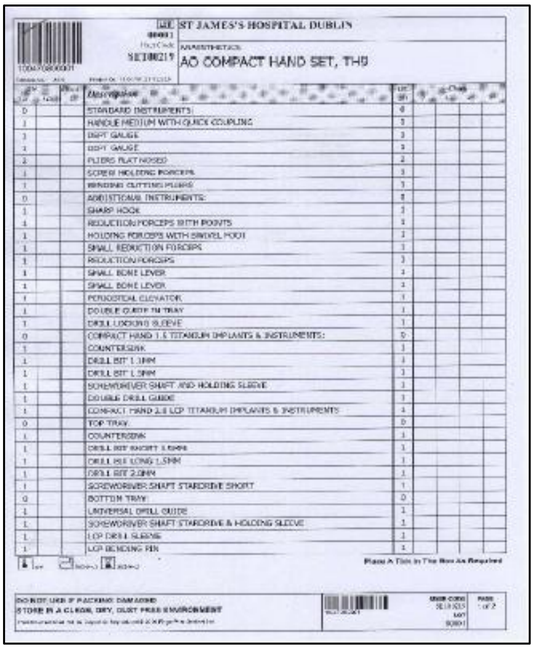
H.S.S.U. INSTRUMENT CHECKLIST – OPERATING THEATRE

SET NAME: Pinnacle Set (Tray 1)

Check 1	Std items	NAME OF ITEM		Check 2	Check 3	Check 4	Check 5
		Trial Cup Instruments					
1	1	Pinnacle acetabular cup trial 48mm	[illegible]				
1	1	Pinnacle acetabular cup trial 50mm	22170[illegible]				
1	1	Pinnacle acetabular cup trial 52mm	22170[illegible]				
1	1	Pinnacle acetabular cup trial 54mm	22170[illegible]				
1	1	Pinnacle acetabular cup trial 56mm	22170[illegible]				
1	1	Pinnacle acetabular cup trial 58mm	22170[illegible]				
1	1	Pinnacle acetabular cup trial 60mm	22170[illegible]				
1	1	Pinnacle acetabular cup trial 62mm	22170[illegible]				
1	1	Pinnacle acetabular cup trial 64mm	22170[illegible]				
1	1	Pinnacle acetabular cup trial 66mm	22170[illegible]				
1	1	[illegible] straight impactor	[illegible]				
1	1	Quickset ratchet screw driver handle	[illegible]				
1	1	Quickset ridged tapered hex screw driver	[illegible]				
1	1	Green impactor tip 28mm	[illegible]				
1	1	Blue impactor tip 32mm	[illegible]				
	1	Orange impactor tip 36mm	[illegible]				
1	1	Ceramic Suction Cup Inserter	22170002[illegible]				
1	1	Suction tip for cup Inserter	9597100[illegible]				
		Version guide (2 piece) 2217[illegible]					
		Heads:					
1		28 Green +1.5					
1		28 Brown +5					
1		28 Blue +8.5					
1		28 Black +12					
1		32 Green +1					
1		32 Brown +5					
1		32 Blue +9					
1		32 Black +13					
1		36 Green +1.5					
1		36 Brown +5					
1		36 Blue +8.5					
1		36 Black +12					
		36 Light Brown −2					

Set No.
Packing & Control
Check 1
Sign
Date
Decontamination
Check 2
Sign
Theatre Number
Date Used
Hospital Reg. No.
Scrub Nurse Sign
Check 1
Check 2
Check 3
Circ. Nurse Sign
Check 1
Check 2
Check 3

Loan set checklists – before



ST JAMES'S HOSPITAL DUBLIN

ANAESTHETICS

SET00219 AO COMPACT HAND SET, TH9

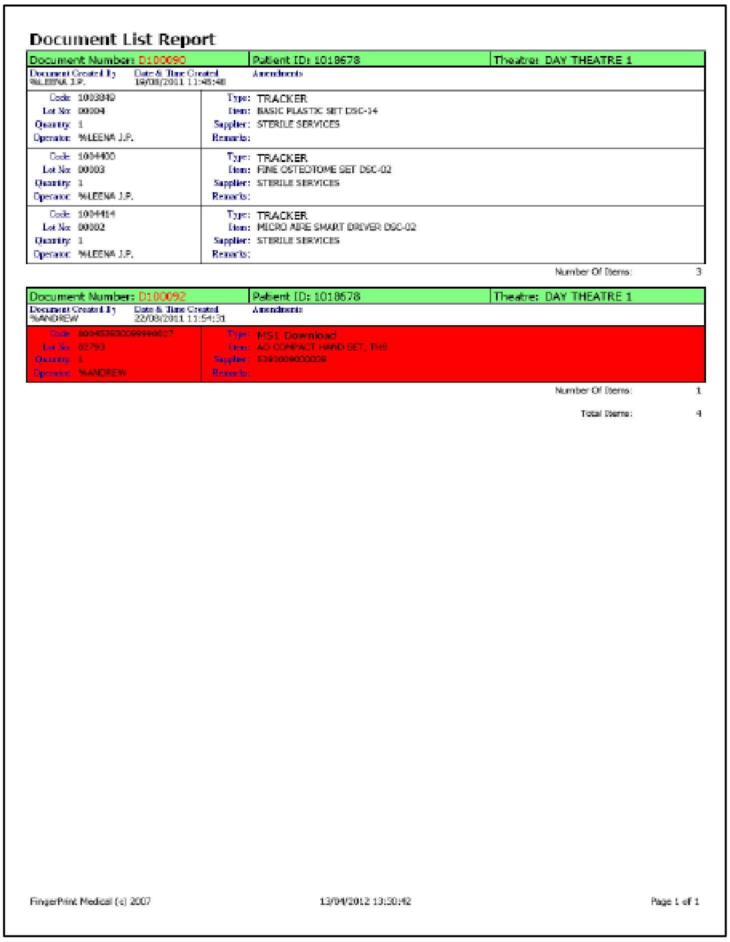
Qty			Description	Qty		Check		
0			STANDARD INSTRUMENTS:	0				
1			HANDLE MEDIUM WITH QUICK COUPLING	1				
1			DEPT GAUGE	1				
1			DEPT GAUGE	1				
2			PLIERS FLAT NOSED	2				
1			SCREW HOLDING FORCEPS	1				
1			BENDING CUTTING PLIERS	1				
0			ADDITIONAL INSTRUMENTS:	0				
1			SHARP HOOK	1				
1			REDUCTION FORCEPS WITH POINTS	1				
1			HOLDING FORCEPS WITH SWIVEL FOOT	1				
1			SMALL REDUCTION FORCEPS	1				
1			REDUCTION FORCEPS	1				
1			SMALL BONE LEVER	1				
1			SMALL BONE LEVER	1				
1			PERIOSTEAL ELEVATOR	1				
1			DOUBLE GUIDE IN TRAY	1				
1			DRILL LOCKING SLEEVE	1				
0			COMPACT HAND 1.5 TITANIUM IMPLANTS & INSTRUMENTS:	0				
1			COUNTERSINK	1				
1			DRILL BIT 1.1MM	1				
1			DRILL BIT 1.5MM	1				
1			SCREWDRIVER SHAFT AND HOLDING SLEEVE	1				
1			DOUBLE DRILL GUIDE	1				
1			COMPACT HAND 2.0 LCP TITANIUM IMPLANTS & INSTRUMENTS	1				
0			TOP TRAY:	0				
1			COUNTERSINK	1				
1			DRILL BIT SHORT 1.5MM	1				
1			DRILL BIT LONG 1.5MM	1				
1			DRILL BIT 2.0MM	1				
1			SCREWDRIVER SHAFT STARDRIVE SHORT	1				
0			BOTTOM TRAY:	0				
1			UNIVERSAL DRILL GUIDE	1				
1			SCREWDRIVER SHAFT STARDRIVE & HOLDING SLEEVE	1				
1			LCP DRILL SLEEVE	1				
1			LCP BENDING PIN	1				

Place A Tick In The Box As Required

DO NOT USE IF PACKING DAMAGED
STORE IN A CLEAN, DRY, DUST FREE ENVIRONMENT

PAGE 1 of 2

Loan set checklists after – electronic, fully legible, up to date



Document List Report

Document Number: D100090	Patient ID: 1018678	Theatre: DAY THEATRE 1
Document Created By %LEENA J.P.	Date & Time Created 19/08/2011 11:45:48	Amendments

Code: 1003949 Lot No: 00004 Quantity: 1 Operator: %LEENA J.P.	Type: TRACKER Item: BASIC PLASTIC SET DSC-14 Supplier: STERILE SERVICES Remarks:
Code: 1004400 Lot No: 00003 Quantity: 1 Operator: %LEENA J.P.	Type: TRACKER Item: FINE OSTEOTOME SET DSC-02 Supplier: STERILE SERVICES Remarks:
Code: 1004414 Lot No: 00002 Quantity: 1 Operator: %LEENA J.P.	Type: TRACKER Item: MICRO AIRE SMART DRIVER DSC-02 Supplier: STERILE SERVICES Remarks:

Number Of Items: 3

Document Number: D100092	Patient ID: 1018678	Theatre: DAY THEATRE 1
Document Created By %ANDREW	Date & Time Created 22/08/2011 11:54:31	Amendments

Code: [illegible] Lot No: 02793 Quantity: 1 Operator: %ANDREW	Type: MSL Download Item: AO COMPACT HAND SET, TH9 Supplier: [illegible] Remarks:

Number Of Items: 1

Total Items: 4

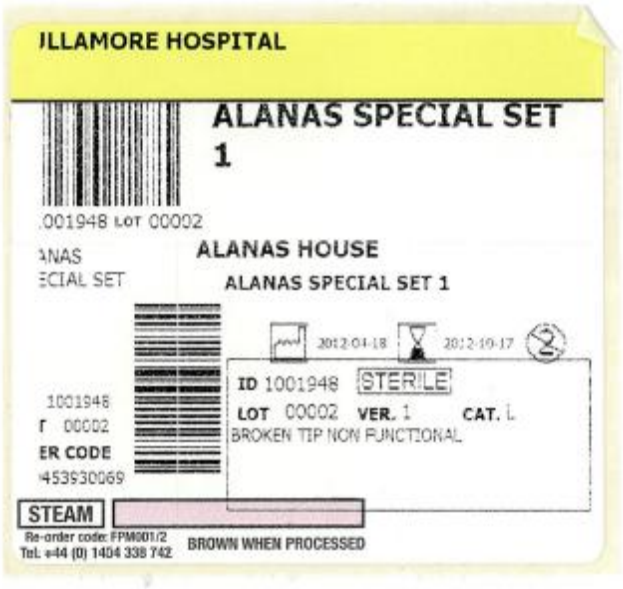
FingerPrint Medical (c) 2007 13/04/2012 13:30:42 Page 1 of 1

Loan set tracking in theatres

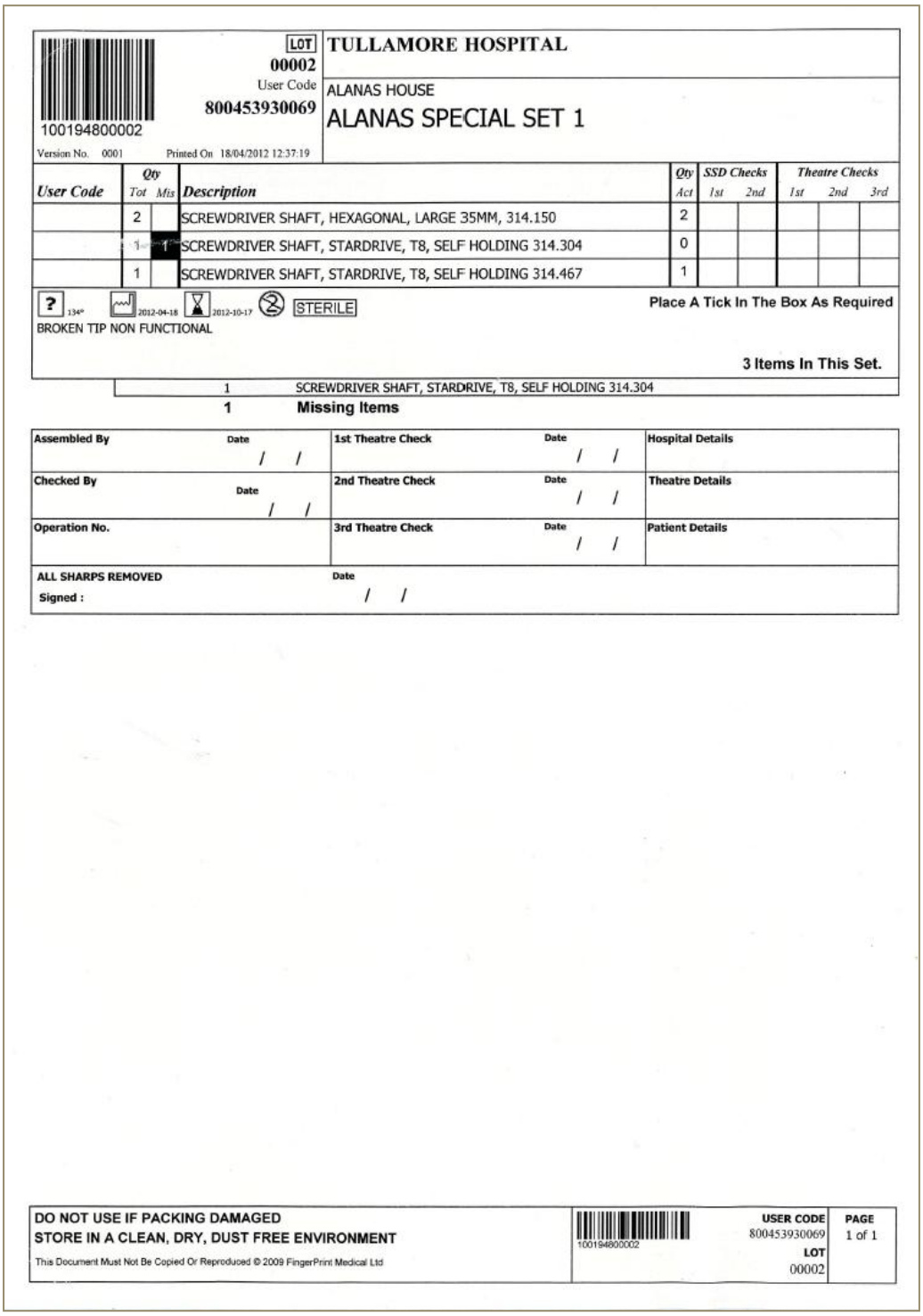
Appendix E: Surgical Tray Checklists and Production Labels

Identification tag for the surgical containers which has the MS1 and GS1 barcode.

Production Labels


ILLAMORE HOSPITAL
ALANAS SPECIAL SET 1
.001948 LOT 00002
ALANAS HOUSE
ALANAS SPECIAL SET 1
2012-04-18
2012-10-17
ID 1001948 STERILE
LOT 00002 VER. 1 CAT. L
BROKEN TIP NON FUNCTIONAL
STEAM
Re-order code: FPM901/2
Tel. +44 (0) 1404 338 742
BROWN WHEN PROCESSED

Surgical Tray Checklists



LOT 00002
User Code 800453930069
100194800002
Version No. 0001 Printed On 18/04/2012 12:37:19

TULLAMORE HOSPITAL

ALANAS HOUSE

ALANAS SPECIAL SET 1

User Code	Qty Tot	Qty Mis	Description	Qty Act	SSD Checks 1st	SSD Checks 2nd	Theatre Checks 1st	Theatre Checks 2nd	Theatre Checks 3rd
	2		SCREWDRIVER SHAFT, HEXAGONAL, LARGE 35MM, 314.150	2					
	1	1	SCREWDRIVER SHAFT, STARDRIVE, T8, SELF HOLDING 314.304	0					
	1		SCREWDRIVER SHAFT, STARDRIVE, T8, SELF HOLDING 314.467	1					

? 134° 2012-04-18 2012-10-17 STERILE

BROKEN TIP NON FUNCTIONAL

Place A Tick In The Box As Required

3 Items In This Set.

1 SCREWDRIVER SHAFT, STARDRIVE, T8, SELF HOLDING 314.304

1 Missing Items

Assembled By	**Date** / /	**1st Theatre Check**	**Date** / /	**Hospital Details**	
Checked By	**Date** / /	**2nd Theatre Check**	**Date** / /	**Theatre Details**	
Operation No.		**3rd Theatre Check**	**Date** / /	**Patient Details**	
ALL SHARPS REMOVED	**Date**				
Signed :	/ /				

DO NOT USE IF PACKING DAMAGED
STORE IN A CLEAN, DRY, DUST FREE ENVIRONMENT

100194800002

USER CODE 800453930069
LOT 00002
PAGE 1 of 1

100194800001

LOT 00001

User Code 800453930069

Version No. 0001 Printed On 18/04/2012 12:34:52

TULLAMORE HOSPITAL

ALANAS HOUSE

ALANAS SPECIAL SET 1

User Code	Qty Tot	Qty Mis	Description	Qty Act	SSD Checks 1st	SSD Checks 2nd	Theatre Checks 1st	Theatre Checks 2nd	Theatre Checks 3rd
	2		SCREWDRIVER SHAFT, HEXAGONAL, LARGE 35MM, 314.150	2					
	1		SCREWDRIVER SHAFT, STARDRIVE, T8, SELF HOLDING 314.304	1					
	1		SCREWDRIVER SHAFT, STARDRIVE, T8, SELF HOLDING 314.467	1					

? 134° 2012-04-18 2012-10-17 STERILE

Place A Tick In The Box As Required

4 Items In This Set.

Assembled By Date / /	**1st Theatre Check** Date / /	**Hospital Details**
Checked By Date / /	**2nd Theatre Check** Date / /	**Theatre Details**
Operation No.	**3rd Theatre Check** Date / /	**Patient Details**

ALL SHARPS REMOVED Date / /

Signed :

DO NOT USE IF PACKING DAMAGED
STORE IN A CLEAN, DRY, DUST FREE ENVIRONMENT

100194800001

USER CODE 800453930069
LOT 00001

PAGE 1 of 1

Appendix F: Sample Reports

From : 02/02/2012
To : 02/02/2012

ST JAMES'S HOSPITAL DUBLIN

Washer Report Washer Report Washer Report Washer Report Washer Report Washer Report Washer Report Washer Report

01:Machine Detailed Report

Machine No. 5

Code	User Code	Description	Cycle Rack	Qty	LoadedBy Date In	Time In	Unloaded By DateOut	Time Out
1004160	1943	CARDIAC MAMMARY RETRACTOR-03	9484	1	RAJAN D 02/02/2012	17:15:50	SEAMUS L 02/02/2012	18:35:30
1002962	80	CHAUX RETRACTOR CARDIAC-01	9484	1	RAJAN D 02/02/2012	17:15:48	SEAMUS L 02/02/2012	18:35:31
1003611	132	BASIC ORTHOPAEDIC SET-10	9484	1	RAJAN D 02/02/2012	17:20:39	SEAMUS L 02/02/2012	18:35:31
1004137	3719	SELLORS RETRACTOR, CARDIAC-03	9484	1	RAJAN D 02/02/2012	17:15:44	SEAMUS L 02/02/2012	18:35:31
1003695	252	THORACOTOMY SET-07	9484	1	RAJAN D 02/02/2012	17:15:39	SEAMUS L 02/02/2012	18:35:31
1002981	2867	COMPACT AIR DRIVE, 23009	9484	1	RAJAN D 02/02/2012	17:15:20	SEAMUS L 02/02/2012	18:35:31
1003174	2964	MICRO AIRE DRILL REAMER SET NO 4	9484	1	RAJAN D 02/02/2012	17:16:10	SEAMUS L 02/02/2012	18:35:32
1003248	3717	SELLORS RETRACTOR, CARDIAC-01	9484	1	RAJAN D 02/02/2012	17:15:56	SEAMUS L 02/02/2012	18:35:32
				8				

Machine detailed report

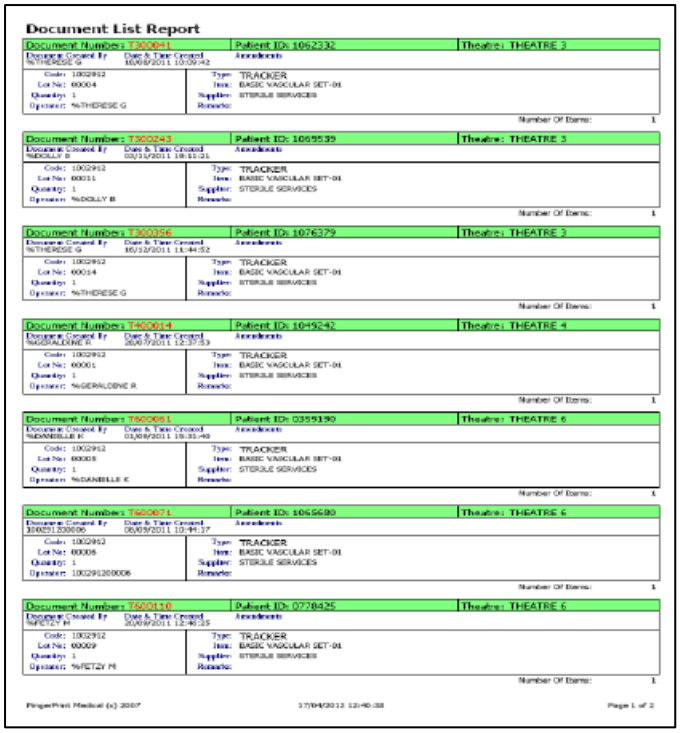
From : 01/02/2012
To : 03/02/2012

ST JAMES'S HOSPITAL DUBLIN

Audit Report

Date	Time	Code	Operator	Description	Machine	Cycle	Status
02/02/2012	18:22:15	10029620000 1	PAUL R	CHAUX RETRACTOR CARDIAC-01	0	0	DIRTY RETURNS
02/02/2012	17:15:48	10029620000 1	RAJAN D	CHAUX RETRACTOR CARDIAC-01	5	9484	WASHER LOAD
02/02/2012	18:35:31	10029620000 1	SEAMUS L	CHAUX RETRACTOR CARDIAC-01	5	9484	WASHER UNLOADED
02/02/2012	18:59:34	10029620000 2	SUSAN O B	CHAUX RETRACTOR CARDIAC-01	0	0	PACKING 1st SCAN
03/02/2012	08:18:22	10029620000 2	DEIRDRE C	CHAUX RETRACTOR CARDIAC-01	2	10826	AUTOCLAVE LOAD
03/02/2012	09:35:09	10029620000 2	DEIRDRE C	CHAUX RETRACTOR CARDIAC-01	2	10826	AUTOCLAVE UNLOAD
03/02/2012	09:35:09	10029620000 2	DEIRDRE C	CHAUX RETRACTOR CARDIAC-01	2	10826	ISSUED OFFSITE

Audit Report



Document List Report

Remote diagnosis – enabled with new tracking system