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An exploratory study of reverse exchange systems used for medical devices in the UK National Health Service (NHS)

Abstract:

Purpose

This study aims to provide insights into the scale and use of Information Communication Technology (ICT) in managing medical devices in the NHS, with a focus on Reverse Exchange (RE) systems, as part of the broader Reverse Logistics (RL) systems, within which medical devices are returned and exchanged.

Design/Methodology/Approach

Two case studies were conducted with NHS Hospital Trusts, while another was built upon secondary resources. Primary findings were triangulated with information collected from the NHS Trusts' reports, direct observation and a preliminary round of consultations with 12 healthcare professionals working in other NHS Trusts or Integrated Equipment Community Services.

Findings

The findings suggest that the sophistication of ICT implementation increases with the risks and value associated with medical devices. Operational attributes are derived from ICT implementations which can positively impact on RE performance. The forces that drive the adoption of ICT in the NHS include pressure from government, business partners and patients, competitive pressure, perceived benefits, organisation size, top management support and the availability of sufficient resources. **Obstacles are mainly centred around the lack of sufficient resource.**

Research limitations/implications

Although the Trusts that participated in this research are representative of different regions, the generalisation of the study results may be limited by the size of the sample organisations, so the results can only provide insights into the research problem. As this work is exploratory in nature, there is insufficient data on which to form definitive recommendations.

Practical implications

NHS Trusts may use the 6 operational attributes identified and verified by the case studies to benchmark their ICT implementation for device management. The actual and potential benefits of ICT implementation could inform technology development and encourage the uptake of ICT in healthcare. Governmental bodies can utilise this information to develop directives to actively drive ICT adoption in device management and the associated RE system. A well-considered training programme is needed to improve staff ICT skills in order to fully realise the potential of ICT systems which support the effective RE of medical devices.

Originality/value

The results suggest that ICT supported reverse exchange of medical devices backs up the supply chain reduces capital costs and medical risks and, facilitates the redeployment of funds to frontline medical treatment.

Key words

Reverse Exchanges, ICT, NHS, Reverse Logistics, and Healthcare

1. Introduction

Medical devices are issued to medical units and patients/carers to be used for therapy, monitoring, rehabilitation and care. Reverse exchange (RE) of medical devices can be defined as occurring when products are returned to source for exchange or final recovery due to product replacement (based on patient needs changing), product maintenance (the functionality of the product parts need to be checked or repaired) or obsolescence (product reaches its natural end of life). A systematic approach to investigating this phenomenon is the reverse logistics (RL) system, which retrieves the product from the end user for the purposes of capturing value or proper disposal (Van Hoek, 1999). The concept of RE is novel within the supply chain (SC) and, for the purpose of this study, is considered to be a sub set of the wider concept of RL.

NHS organisations are under pressure to make unprecedented efficiency savings of £15-20bn between 2011 and 2015 (The Nicholson Challenge) (Parliament UK, 2010). With an estimated spend of £4.6 billion of the NHS budget on medical devices and consumables, and an annual spend of £50 million on high value devices (value of device exceeds £5000) (NHSBSA, 2012), there is a greater need for NHS to be stringent in their efficient and effective use of existing assets. Enhancing the safety of medical devices by improving their traceability also forms part of the remit of the Medicines and Healthcare Products Regulatory Agency (MHRA) (MHRA, 2015).

Only a limited number of studies have investigated the RL system in the NHS (Ritchie et al., 2000; Xie and Breen 2012, 2014), and their findings indicate that RL delivers an economic benefit of cost minimisation and also results in extensive impacts on both human health and the environment (Li and Olorunniwo, 2008).

Research findings showed that ICT is a necessary component to improve RL related operational attributes, such as tracking/monitoring returns and handling return operations (Daugherty et al., 2005); ICT facilitated information sharing, and collaboration with other entities within the SC (Olorunniwo and Li, 2010); all of these can positively impact both economic and service quality-related RL performance. While our initial consultations with 12 healthcare professionals show that ICT has been implemented by Medical Equipment Libraries (MEL) in hospital Trusts or Integrated Community Equipment Service to record medical devices, there is little or no research on how or why ICT is implemented in managing RE of medical devices.

This research therefore aims to gain insights into the scale and use of ICT specific to managing RE of medical devices in the NHS, by means of exploratory case studies. This study focuses on high risk implantable medical devices (devices that support or sustain human life) and valuable medical devices (each device costs more than £1000). According to NHSBSA (2012) and MHRA guidance (2015), we estimate these two categories of devices account for at least £1 billion of NHS expenditure on medical devices. Specifically, the paper examines:

- How has ICT been implemented to manage the RE of high risk or valuable medical devices?
- Why ICT is adopted to manage the RE?
- What are the barriers to wider ICT adoption?

Having a clear understanding of the answers to these questions will undoubtedly be helpful in informing strategic and tactical decision-making processes on information system design for medical devices exchange systems.

2. Literature Review

2.1 Reverse Logistics

Owing to the high asset values involved and the potential impacts on customer service (Daugherty et al., 2005), organisations need the capability to handle RL activities, including product returns, remanufacturing, source reduction, material substitution, and waste management (Rogers and Tibben-Lembke, 1999). RL is so information intensive that organisations must also develop capabilities to process RL related data and strategically apply the information gathered to streamline processes and support Collaborative Planning Forecasting and Replenishment (CPFR). A successful RL system can enhance competitiveness, profit, and customer satisfaction (Li and Olorunniwo, 2008). It also delivers positive impacts on health and the environment, helping companies create and sustain an environmentally friendly corporate image (Murphy and Poist, 2003). As such, Stock et al. (2002) claim that RL should not be viewed as a costly normal operations process, but should be seen as an opportunity to build competitive advantage.

Such sentiments have promoted further research on RL systems and practices. The research conducted on RL can be classified into seven categories (Xie and Breen, 2014): i) concepts of RL (Rogers and Tibben-Lembke, 2001; Stock et al., 2002); ii) quantitative models to enhance RL system (Fleischmann et al., 1997; Yu and Wu, 2010); iii) research dealing with more specific logistical issues (remanufacturing, distribution, etc.) (Andel 1997); iv) the applications of RL in different industrial sectors, such as packaging materials (Gonzalez-Torre et al. 2004), bottling or glass (González-Torre and Adenso-Díaz, 2006), pallets, cardboard boxes (Breen, 2006); v) the capability, effectiveness and performance of a RL system (Genchev et al., 2011); (vi) the drivers and the obstacles of a RL system (Rogers and Tibben-Lembke, 1999; Alvarez Gil et al., 2007); and (vii) how ICT influences and facilitates the operation of an RL system (Daugherty et al., 2005; Olorunniwo and Li, 2010).

Depending on the size, the nature of products, resources and constraints, companies implement RL for different purposes across a wide range of industry sectors. The automobile industry implemented RL to recapture used materials from returned automobiles (Lebreton and Tuma, 2006), the electronics industry implemented RL to comply with government regulations (such as Waste Electrical and Electronic Equipment (WEEE)) and to reduce waste (Lau and Wang, 2009), and most industries recycle packing materials, bottles or glass via their RL systems for effective resource use and reduction (González-Torre and Adenso-Díaz, 2006). An RL system is proposed for the effective disposal of waste medicines, in order to increase environmental protection and economic savings and to respond to safety considerations (Xie and Breen, 2012). Unlike RL in industrial settings, where it is regarded as an effective competitive tool (Chan and Chan, 2008), RE (under the umbrella of the RL) is a must have element in the SC for high risk or high value medical devices. These devices may need to be exchanged for replacement, maintenance, repair or proper disposal; the absence of such an RE system may result in faulty devices being issued to patients and adverse incidents.

The drivers influencing RL implementations can be summarised as: 1) external factors, such as environmental legislation (Nnorom and Osibanjo, 2008), public awareness and concerns

on the environment (Lau and Wang, 2009), and support of SC partners (Rogers and Tibben-Lembke, 1999); and 2) internal factors, such as organisational strategies on the environment (Knemeyar et al., 2002), extended producer responsibility (Khetriwal et al., 2009), economic benefits (Liu et al., 2008), and improved customer service (Wu and Cheng, 2006). There are also many obstacles to RL implementation. Lack of systems and technologies, for example ICT technologies, and shortage of personnel and financial resources are identified to be the most common barriers (Rogers and Tibben-Lembke, 1999). As a result, category vii) how ICT influences and facilitates the operation of a RL system, has received much attention and is widely discussed in literature (Closs and Savitskie, 2003; Daugherty et al., 2002; Daugherty et al., 2005; Olorunniwo and Li, 2010).

2.2 ICT implementations in reverse logistics

The growth in ICT has transformed the operational management of many business sectors including SC and logistics. SC and logistics operations are inter-regional and global; as such the efficiency of communication and management of information flows becomes critical, resulting in a greater need for effective ICT implementation (Nguyen, 2013). ICT offers a solution that enables organisations to improve operational attributes; for example, instantaneous information sharing and processing, and speedy communication. ICT can help SC partners achieve efficient coordination and integration of all the logistics activities. In a highly competitive business environment, the use of ICT has been vital for improving logistics performance (Sundarraj and Talluri, 2003), and differentiating and diversifying service (Evangelista and Sweeney, 2006). Whilst exploring the task-technology fit, Huscroft et al (2012) commented that ICT is a key enabler of logistics performance, but that most systems are forward and not reverse focused. However, the RL environment is characterised by uncertainty of return volumes, frequency and sources and thus has a greater need to use ICT to accurately track items and rapidly process enquiries/information.

ICT has been identified and validated to be one of the key constructs that underpins SCM research (Chen and Paulraj, 2002). ICT systemises the forward and reverse flow of products and materials across the SC, and has the potential to facilitate collaborative planning among SC partners by sharing information on demand forecasts and production schedules that dictate SC activities (Karoway, 1997). The concept of Collaborative Planning Forecasting and Replenishment (CPFR) is one that has been adopted within SCs to improve stock production and management involving small scale or mass collaboration (Holmström et al, 2002). The role of ICT systems in supporting CPFR is critical in reducing overstocking, increasing time savings, delivering increased transparency of real time data within the SC and enhancing buyer-supplier relationships (Kolozyc, 1998). This can have a positive impact on the RL system leading to a reduction in the return of stock for redistribution or safe disposal.

The benefits brought about by ICT lead to a greater use of ICT systems across all the logistics functions, including RL (Patterson et al., 2003). When applied in RL, ICT execution systems, such as inventory/transportation management systems, can improve RL operational attributes, for example, efficient tracking and effective planning (Li and Olorunniwo, 2010), which improves labour productivity, resource utilisation, increases asset recovery, and reduces inventory buffers and obsolescence (Garcia-Dastugue and Lambert, 2003). All of these improve the economic performance of an RL system. ICT communication systems, such as EDI (Electronic Data Interexchange) and RFID (Radio Frequency Identification), enhance efficiency by providing access to real-time information (Radstaak and Ketelaar, 1998) and allowing rapid information exchange (Li and Olorunniwo, 2010) regarding the location of

returns, inventory levels, shipment status, and reprocessing requirements. ICT also improves communications with SC partners, integrates information across the SC, and improves responsiveness to customers. High levels of ICT capability make transitions smooth and transparent for customers and, therefore, are the key enablers for RL service excellence (Kent and Mentzer, 2003).

Based on the review above, the operational attributes derived from ICT implementation in a SC (encompassing an RL system) can be summarised:

- 1) Storing information and enhancing information visibility
- 2) Streamlining processes and reducing workload
- 3) Improving communications among SC partners
- 4) Efficient information sharing and processing across the SC
- 5) Supporting CPFR
- 6) Enabling efficient tracking and effective planning

The positive impacts of these operational attributes on RL performance and service excellence have been observed in both retail and healthcare RL (Yundt, 2002). Advanced forms of ICT such as RFID have proved invaluable when utilised in outbound and reverse logistics. RFID has enabled greater functionality and responsiveness within RL due to its timely capture and retrieval of real-time data relating to product lines, manufacturer, storage, dates of sale, the consumer, and improved information on the returns leading to higher return rates and customer satisfaction (Kim and Glock, 2014).

RFID designed primarily for patient monitoring and management also inform logistics providers and inventory managers of actual and anticipated needs in the community. This is not only in terms of the forward supply of medicines and devices needed for facilitating care but also the potential return of unused, redundant or waste/recyclable items back up the SC. Hospitals have been trialling RFID for the tracking and management of reverse flows in the SC. Mun and Kantrowitz (2008) suggested that as much as 40% of staff time could be spent looking for equipment such as pumps and wheelchairs, which could be alleviated through a tag based asset tracking system. Non-return of rental or leased equipment related to patient care can also be a significant source of cost as hospital management systems are often not designed to track external assets brought in for a limited period. This has led to hospitals making direct appeals to patients to return equipment such as nebulisers or compressors that may be stored on a 'just-in-case' basis. RFID can help identify when these devices are no longer being operated and also give an indication of their operating status to ensure their timely return.

In an RE system the effective return of products in a timely fashion is tantamount to success especially where the product is destined for refurbishment and redistribution (Breen, 2006). However, there is less published material on the RE of medical devices in this service and no research outputs which comment on the role of ICT facilitating RE.

2.3 Drivers of ICT adoption

Although ICT adoption is considered as a key enabler to improve organisational operational attributes that lead to improved logistics economic performance and service levels, organisations face various challenges in adopting ICT. The challenges can be addressed by identifying various factors that influence organisations' decisions regarding ICT adoption (Lin, 2014). Research on factors affecting organisational decisions to adopt ICT systems has

been undertaken using various theoretical frameworks (see Table 1), such as institutional theory (Teo et al., 2003), Diffusion of Innovation (DOI) method (Russell and Hoag, 2004), Technology Acceptance Model (Venkatesh and Davis, 2000), and Technology-Organisation-Environment framework (TOE) (Kuan and Chau, 2000).

Among these models, TOE is the most commonly used framework, describing that an organisation's adoption and implementation of ICT is influenced by (Tornatzky and Fleisher 1990): (1) the Technological context, which refers to perceived technological benefits brought about by innovation; (2) the Organisational context, which refers to characteristics and resources of the organisation, including the size, top management support, financial resources, human resources, amount of slack resources; and (3) the Environmental context, which refers to the organisational sector and its interaction with business partners, government and competitors.

Using a TOE framework, Kuan and Chau (2000) examined six factors affecting EDI adoption in small businesses, including perceived direct and indirect benefits, perceived financial costs and technical competence, and perceived industry and government pressure. Their findings revealed that these factors correlate positively with the intention of EDI adoption. Similar findings were reported in Zhu et al.(2006) and Hsu et al. (2006), where perceived benefits, organisational readiness (such as technological competence, organisational size, financial commitment), and external pressure (competition and regulatory requirements) are important antecedents of e-business adoption. Based on a survey study, Teo et al. (2009) developed a perception based TOE framework incorporating six factors (perceived benefits, perceived costs, firm size, top management support, information sharing culture, and business partner influence) as important influencing factors to e-procurement adoption. The aforementioned review investigated the factors affecting ICT adoption within one organisation. Lin (2014) investigated the determinants of e-SCM adoption across an organisation and its trading partners. In contrast with stand-alone technologies, e-SCM must be co-adopted by multiple organisations. Research findings indicated that organisations with certain perceived benefits, financial ability, top management support, absorptive capacity, and competitive pressure are more likely to adopt e-SCM.

Insert Table 1 here

2.4 Reverse Exchanges of medical devices

RE is a type of RL activity, and can be classified into to five types according to the reasons as to why medical devices are returned and the ways they are processed.

RE-1 Product Exchange: A patient with an implanted device can, post review from a medical professional, be referred back to clinic to exchange their medical device for an alternative product. This decision is based on factors such as lack of rehabilitation or patient health deterioration. When several patients with the same implanted device have similar symptoms or there is a lack of rehabilitation or health deterioration, an alert on the device is sent to the clinic and devices are recalled for exchange.

RE-2 Manufacturer recall: The manufacturer's recall of a device takes precedence over other considerations. If implanted devices are recalled, they need to be tracked to identify the patients with the implanted devices, and the patients need to be contacted for appropriate actions. In this scenario, the Medical Device Coordinator or the consultant discusses action

plans with the manufacturer on the best method for recovery. Under the guidance of the manufacturer, implanted devices may need to be removed and exchanged, or be adjusted, repaired, or monitored.

RE-3 Faulty devices: Faulty devices are repaired on-site before being replaced. If the device is no longer serviceable, beyond economic repair, or spare parts are no longer available, the device is returned to the Medical Equipment Library (MEL) and decommissioned; a replacement is issued and installed at requested premises if it is in stock, or a new order is made. If the faulty item cannot be repaired on site, it is returned and repaired at the manufacturer or a third party repair facility. If it cannot be repaired, the manufacturer will issue a new one if the unit is still within the warranty period.

RE-4 Regular Maintenance: Medical devices are subject to routine inspection and maintenance. If medical devices are returned for maintenance, the user will be issued a replacement device to ensure the continuity of using the device.

RE-5 End-of-life return: When a device reaches its End-of-Life, the device is deemed not reusable, and is called to be returned and decommissioned. At this stage, the manufacturer is usually contacted for information on decommissioning, and for advice on any environmental, disposal, recycling or structural requirements; a replacement device will be issued to the user.

3. Theoretical framework and research methodologies

3.1 Theoretical framework

Research relating to ICT adoption for RL has confirmed the ICT adoption-operational attributes-RL performance relationship in a range of industry sectors (Daugherty et al., 2005; Olorunniwo and Li, 2010). This research examines this relationship in a healthcare setting. Drawing on preliminary interviews with 12 healthcare professionals, combined with a literature review and theoretical perspectives relating to TOE, this study hypothesises that the TOE framework is appropriate for studying ICT adoption by NHS trusts as ICT is driven by the perceived benefits brought about by ICT innovation itself, enabled by organisational readiness, and influenced by environmental factors, especially the situations of suppliers, patients, competitors, government and regulators.

Grounded in the ICT adoption-operational attributes-performance relationship and TOE as discussed above, this study presents the research model shown in Figure 1. We shall examine if operational attributes 1)-6) as listed in Section 2.2 are gained through ICT adoption, and if these attributes are translated into performance improvement (economic benefits and service excellence). The framework hypothesises that ICT adoption creates a network structure that permits the collection and sharing of quality data on REs (Christiaanse and Kumar, 2000). ICT provides ubiquitous computing and communication aids to streamline processes and enhance traceability of products and people (Razavi et al., 2007) while also facilitating electronic transactions and communication in various forms between the SC partners and supporting CPFR (Chen and Paulraj, 2002). In addition, ICT processes involve the processing and analysis of large volumes of data, making operational processes more efficient, thereby enhancing productivity with fewer personnel and thus saving costs. The outcomes from deploying ICT is improvements in both economic performance and service level of a RE system.

The research model also incorporates technological, organisational, and environmental contexts as important determinants of ICT adoption. Each of these three contexts is discussed below. Based on its applicability, we adapt the TOE framework to the healthcare domain, and start with an environmental context which presents an informative backdrop for the other two contexts.

Environmental context

The environment presents both opportunities and challenges for ICT adoption. In an SC context, ICT adoption is influenced by requirements imposed by government, regulatory bodies, customers and business partners (Kuan and Chau, 2001; Nguyen, 2013).

To reduce increasing healthcare costs, governmental bodies increasingly encourages or forces NHS trusts to adopt more cost-effective procedures. The NHS is challenged by the government to become paperless by 2018 to cut billions from expenditure and improve its service (DoH, 2013). This directive has driven the rolling out of electronic patient records across Hospital Trusts (NHS, 2015). Under the same directive, MHRA requires Hospital Trusts to improve traceability of medical devices (MHRA, 2015), and communicate about adverse incidents to patients, the public and healthcare professionals. One way of doing this is through ICT implementation. Patients expect better quality of care, shorter waiting times, better service and less waste produced in healthcare. With their enhanced awareness of the functionalities of ICT and its wide use in other sectors, they may be more empowered in their role as a patient and engage more effectively with high level ICT solutions such as electronic health records, results retrieval, and direct contact with NHS professionals e.g. e-mail consultations (Car and Sheikh, 2004).

Business partner influence is a key influencing factor for the successful adoption of ICT (Tummala et al., 2006). Accordingly, ICT facilitates organisations in communicating with business partners, and building buyer–supplier relationship (Lin, 2014). NHS trusts work with thousands of suppliers with the aim of delivering best value for money, quality and sustainability. ICT adoption creates inter-organisational links that can enable NHS trusts and their business partners to streamline business processes, increase visibility, reduce uncertainty and lead times, and achieve long-term benefits (Mustaffa and Potter, 2009).

Furthermore, competitive pressure drives organisations to seek competitive advantage by adopting innovation or computerisation (Dasgupta, 1999). Competitive pressure imposes the threat of losing competitive advantage, which can force organisations to adopt e-business (Lin and Lin, 2008), e-SCM (Lin, 2014), and cloud computing (Low et al., 2011). Although the majority of NHS Trusts are in the public sector, there is considerable competition among the Trusts and between Trusts and private healthcare providers. If Trusts are not competitive enough, the NHS may reduce the number of Trusts. Consequently, many Trusts are seeking ways to enhance competitiveness, and ICT application becomes a response to rivalry among healthcare providers.

Technological context

The main focus of the technological context is on how perceived technological benefits influence the adoption decision. DOI theory claims that the perceived ICT benefits affect adoption (Russell and Hoag, 2004). In Kuan and Chau (2000), perceived technical benefits are classified as strategic and operational benefits. Strategic benefits relate to improved organisational image, improved competitiveness, improved customer service and improved

relationships with business partners, while operational benefits are characterised as being more effective, more efficient, more accurate, and being more economical.

ICT is applied in the healthcare sector to improve information management, access to health services, quality of care, continuity of services, cost containment (Gagnon et al, 2009), and health promotion (Haluza and Jungwirth, 2015). ICT can also improve the quality of care by maintaining accurate records of patients and devices, enhancing their traceability and increasing their availability (Xie and Breen, 2012). ICTs such as barcodes, QR codes and RFID tags (Parnaby and Towill, 2009) can be used to enhance situational awareness and provide greater visibility of staff/product interaction for security purposes.

All of the above could reduce instances of medication errors and enhance staff/device availability, thus reducing treatment delays. These benefits potentially minimise care costs and legal ramifications, and help improve organisational competitiveness and public image.

Organisational Context

The adoption of ICT can only be successful when the perceived benefits can be achieved within the organisational context.

Organisation size is an influencing factor on an organisation's adoption of ICT. Larger organisations are more inclined to adopt ICT as they have more resources and greater ability to implement the project (Frambach and Schillewaert, 2002). NHS trusts considered in this research are large service sector organisations, in terms of both employee headcount and value added. Therefore, they could have more resources to invest in ICT adoption and staff training. However, the NHS is under pressure to make unprecedented efficiency savings, which means funds available for ICT investment may be limited.

Top management support is crucial in enhancing the incorporation of ICT into business processes (Ragu-Nathan et al., 2004) and in reinforcing the degree of commitment of all employees to the implementation (Lee and Kim, 2007). Introduction of a modern ICT-enabled healthcare system has become a national priority for government, with leadership coming from the top management in the Department of Health (DoH, 2012). This is in line with the concept that applying ICT to manage RE of medical devices also requires top management support.

Sufficient organisational resources (financial resources, human resources, technical knowledge etc.) are also major predictors of IT adoption. ICT adoption is essentially an investment decision, which requires large financial investment and has a long term effect on organisational operations (Nguyen, 2013). The levels of ICT expertise existing within an organisation influence the levels of ICT utilisation. ICT users' technical knowledge, training, attitudes and intention toward IT, and engagement in the adoption process impact ICT adoption (Caldeira and Ward, 2003). For an NHS trust, an appropriate resource base is a critical factor for investing in ICT and implementing and integrating ICT into the trusts, as well as making use of the full potential of ICT systems. The healthcare sector prioritises medical treatment and patients, and the perception is that this sector generally lacks proficient in-house ICT skills. The effective use of ICT in Trusts requires good users training; therefore, only when an NHS organisation has a sufficient amount of requisite resources can they be deemed ready for adopting and using ICTs.

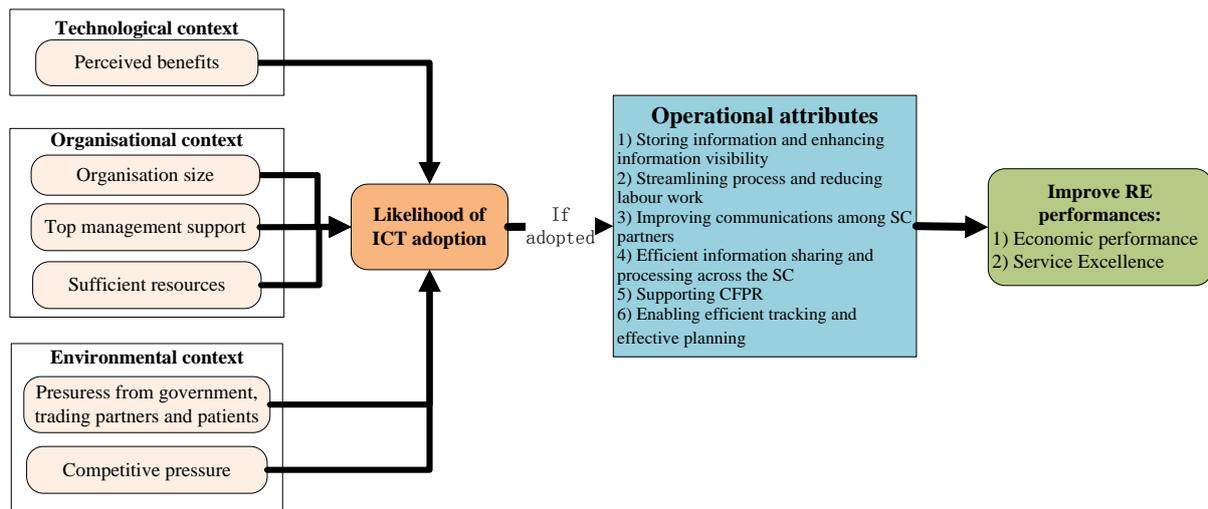


Figure 1. Research model

3.2 Research methodologies

An initial consultation with 12 healthcare professionals was conducted in the form of a questionnaire as the preliminary research, in order to obtain an initial understanding of ICT use in RE of medical devices. Further to this, two primary case studies were conducted to collect more insightful data and information on research questions.

3.2.1 Questionnaire design

Questionnaires have advantages in that they are cheap and do not require much effort from questioners in design and administration. The standardised answers make it simple to compile data. A questionnaire consisting of factual questions and open ended questions was designed (see Appendix 1). To help the respondents contextualise the subsequent questions, questions were grouped in two themed sections. Section one focuses on devices provided to patients subject to return/exchange after a variable period of time, as well as the process of how they are returned. In Section two, respondents were asked “whether”, “why”, “what” and “how” ICT facilitates managing returns, and for recommendations on further improvement.

Since MEL services and medical departments issue medical devices and manage REs, professionals from these departments were found to be the most appropriate respondents to receive the questionnaires. A purposive sampling strategy was adopted to choose respondents (Saunders M. *et al.*, 2009). We administered questionnaires to 12 healthcare professionals (see Table 2) from September 2014 to April 2015 through email, by telephone and face to face, **in order to obtain an initial understanding on the research questions from a wider context.**

Insert Table 2 here.

3.2.2 Case studies

The case study has been recognised as being particularly useful for examining the how and why questions (Yin, 2013). The adoption of a quality case study methodology is also justified by our aim to establish the specific context of the study in the healthcare setting. Since there has been limited evidence of research undertaken which investigates the use of

ICT in managing medical device RE, a quality approach, such as a case study, becomes suitable for preliminary in-depth investigation of this problem and enables us to gain deeper knowledge of this specific context (Walsham, 1995).

We carried out two case studies with two NHS Hospital Trusts in the UK. Since differences of opinion are often related to professional roles and responsibilities undertaken, multiple interviewees were chosen to address all the research questions, and to enhance the validity of research by resolving the discrepancies among interviewees. Although interviewees in the two primary case studies do not have identical roles, they represent multiple perspectives of the research area, and collectively contribute to all aspects of the research problem. Considering the trade-off between efficiency and richness of data, we conducted three interviews in each case study.

Case study 1 was conducted with the Oncology department of a Hospital Trust in Greater London over the period of July to December 2014, investigating how ICT is used to manage RE of high value medical devices such as infusion pumps. Interviews were held with the three interviewees (see Table 3). Case study 2 was based in an NHS Hospital Trust in the East of England from May to July 2015, aiming at replicating the observations. Apart from the direct observations of ICT applications in managing high risk medical devices such as coronary stents, we also conducted interviews with three interviewees (see Table 3). In addition, a mini case study was also constructed to demonstrate the application of RFID in a Hospital Trust in the East of England, by drawing information from the RFID provider's company white papers (see Table 3).

Case selection criteria:

A case study can generate a holistic picture of ICT implementation. Multiple cases can increase external validity, and help guard against observer bias. A convenient sampling method was followed in choosing case hospitals where access was likely to be easy. Within the samples we then selected cases based on criteria:

- 1) The NHS Trust has implemented ICT to manage RE of medical devices.
- 2) The Hospital Trust adopted ICT functions in managing at least one of either high risk or high value medical devices. In each case, we focus on one type of medical device.
- 3) The ICT implementation altered how medical devices are managed, controlled and tracked in some obvious way, and there is clear evidence for performance improvement.

Research instruments and protocols:

Primary data in case research is collected from structured face to face interviews, personal observations, informal conversations, and reviews of literature and archival sources. Before the formal interviews, a cover letter was emailed to the targeted interviewees, explaining the purpose of this RE research. This was followed up with phone conversations with interviewees to answer enquiries and provide clarifications.

Interview questions were developed based on the questionnaire used in the preliminary research, and were altered to suit the case context. In Case 1, the questions were pilot tested in informal discussions with the IT lead and the Head Nurse, and were revised based on their suggestions and inputs. In Case 2, the interview questions were changed to relate to the cardiology setting and revised based on discussions with the Cardiology Consultant and the Medical and Biological Engineer. The revised questionnaires were then used in the face to face in-depth interviews. In Case 2, a tour of the Catheterisation Laboratory was arranged,

which allowed the researchers to make a visual check on areas of interest such as ICT adoption, degree of healthcare work empowerment and training, and the level of implementation compared with other industry settings.

Case 3 was built using a secondary data collection method, with data collected from white papers and websites of companies that provide ICT solutions to healthcare organisations (Stawarski and Phillips, 2008).

Data collection:

The interviews started with broad, open-ended questions as to whether ICT has been used to purchase and manage medical devices. We then explored specific and detailed topics, including areas of applications, operational attributes gained from ICT use, impacts on performances, and drivers of implementations (See Appendix 1). To facilitate cross-case comparisons, secondary data were obtained from strategy reports published by selected Trusts, white papers of RFID providers and websites. This approach enhanced the reliability of our data, and facilitated the collation of much additional valuable data (McCutcheon and Meredith 1993).

Insert Table 3 here.

4. Scale and use of ICTs in NHS specific to manage Reverse Exchanges

In this Section, we examine current and planned ICT use in three NHS Hospital Trusts (Trusts 1, 2 and 13) through case studies. The RE system does not exist alone, but is part of a closed loop SC. Therefore, these case studies help draw a picture of ICT use in both forward and reverse logistics, and highlight any discrepancies. Drawing from findings from the case studies, the operational attributes derived from ICT implementation and their impacts on RE performance are compared in Table 4.

Insert Table 4 here.

Case study 1: NHS Hospital Trust 1

NHS Hospital Trust 1 is in Greater London, and provides a full range of hospital services for local communities. Our research focuses on the RE of infusion pumps used in the Oncology department, in terms of procurement, inventory management, tracking, collection and exchange within the hospital Trust.

As a pioneer and leader in ICT implementation, Trust 1 has widely implemented and integrated ICT systems to manage medical devices within the hospital environment. Trust 1 has implemented ICT for external and internal process integration, which is necessary to realise efficiency gains and improve the quality of healthcare (Closs and Savitskie, 2003).

E-procurement system

Trust 1 needs to procure a large variety of medical devices including infusion pumps, thus E-procurement has been adopted to source them. E-procurement has not only produced significant overall cost savings in purchasing, but also is thought to be able to facilitate returning infusion pumps to suppliers in response to manufacturers' recalls, or when the device becomes faulty.

The case analysis revealed that the purchasing of medical devices is complex, involving decisions on direct replacement and acquiring new models or specific types of device. The E-procurement system is well integrated with the E-inventory system which captures inventory data. Based on demand and lead time, reorder points are setup in the E-inventory, and an electronic order is automatically generated and placed in E-procurement as stock falls under the reorder level.

E-inventory management

The Trust uses an intranet to share documents, or to perform collaborative work. For example, when new pumps are needed, the ward staff member completes an electronic order form and emails it to the MEL placing the order.

The MEL uses the E-inventory System to maintain accurate records, detailing all the activities and inputs relating to infusion pumps. Infusion pumps are labelled with barcodes, which contain information about manufacturers, product codes, and expiry dates. Some of the infusion pumps are issued to the Oncology department and become their assets. Others are loaned to other departments for a certain period. A record of the medical device issued or on loan is maintained in the E-inventory System to ensure regular maintenance or return of equipment. The expected life cycle of an infusion pump is held in the system. To avoid stockouts, a relatively high safety stock level is maintained for infusion pumps.

E-supply chain management

E-SCM software has been used by Trust 1, to facilitate CPFR of the medical devices. Specific to infusion pumps, E-SCM coordinates and integrates product and information flows within the Trust, and between the Trust and its suppliers. The safety stock level is also lowered to reduce the holding cost while still meeting the needs.

Reverse exchanges of infusion pumps

As depicted in Figure 3, there are four types of RE of infusion pumps between the Oncology department and the MEL. For RE-2, 4 and 5, the MEL uses E-inventory to identify the users who borrowed the device and contacts them via email or telephone. Collection is arranged by the MEL and appropriate reprocessing takes place. If a device reaches its end of life, the device is removed from the E-inventory system, and sent to a designated site for proper disposal. Although the E-inventory helps identify the immediate users of pumps, the inter-departmental infusion pump loans, for example from Oncology to Cardiology, are not recorded or tracked by any ICT system.

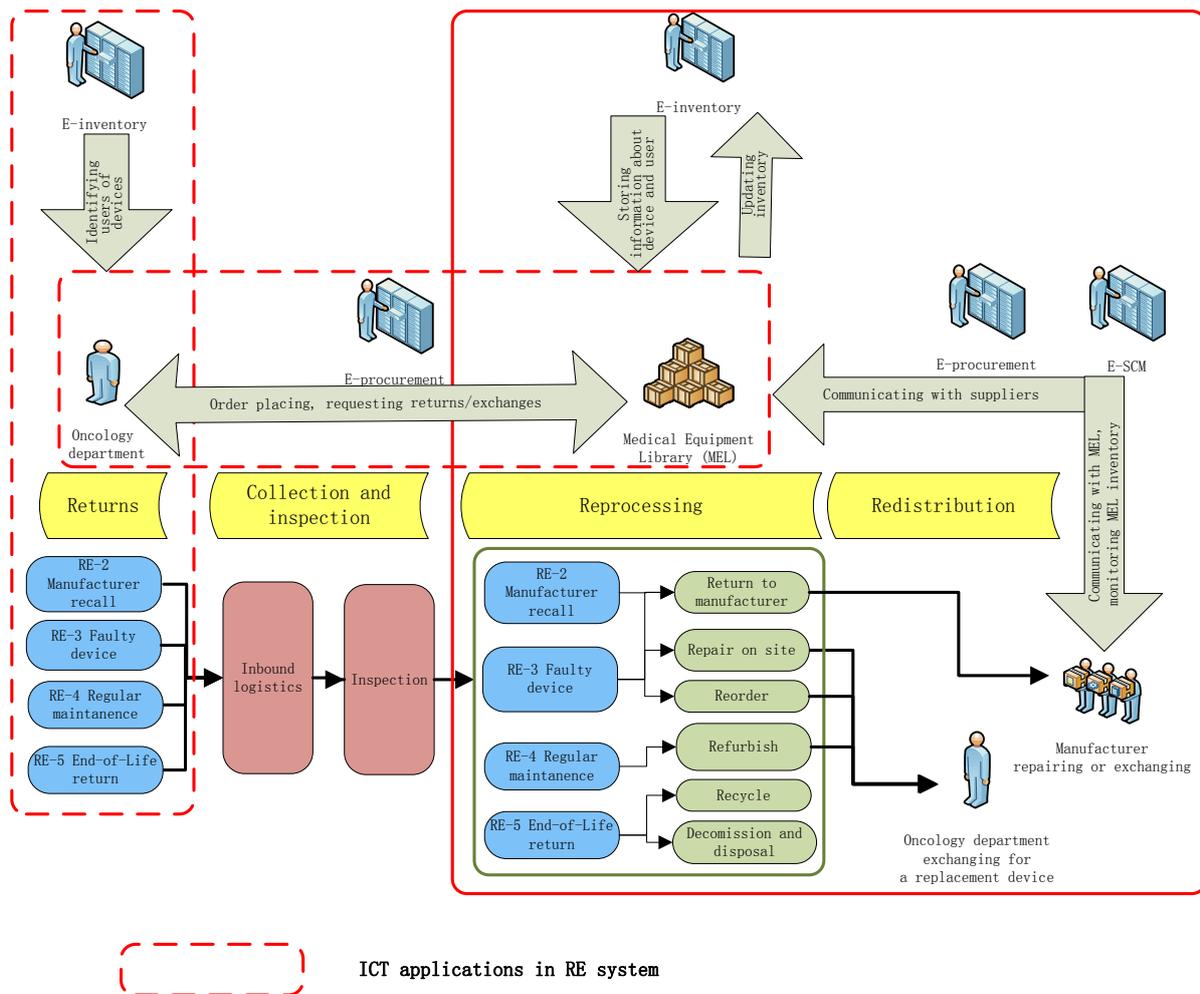


Figure 3 Reverse exchange of infusion pumps between Oncology Department and MEL

Case study 2: NHS Hospital Trust 2

NHS Hospital Trust 2 provides an extensive range of acute medical services in Essex. Our research was carried out with the Cardiology Department, which provides specialist treatment and care for people with heart problems.

The Trust has implemented a core enterprise level IT infrastructure which provides content management, document management and collaboration and workflow capabilities. In 2010, the Trust launched a new IT strategy, aiming to advance its ICT systems to enhance efficiency and reduce costs.

E-procurement system

Within the Cardiology Department, nearly 2000 coronary stents are ordered every two years using the E-Procurement system, with an e-order being sent to the two main suppliers by the central MEL. The E-procurement system is similar to the one used in Case 1, allowing the MEL to record suppliers' information and recall pertinent device data when manufacturer recalls are instigated, or when devices become faulty.

E-asset management system (equivalent to the E-inventory system in Case 1)

Each coronary stent comes with a barcode, and detailed information about it is recorded in the E-asset management system, including batch number, lot number, manufacturer,

medication on the stent, expiry date, etc. When the MEL receives the stents, they are delivered to the Cardiology Department and stored there. The E-asset management system also has planning functionality which supports CPFR among the MEL, the Cardiology department and suppliers, based on historical usage, returns or losses.

E-clinical system

Coronary stents are stored, managed and used by the Cardiology Department, the MEL having little involvement with them after dispatch. The stents are recorded in the E-asset management system, to which the Head of the Catheterisation Laboratory has access. When a stent is implanted in a patient, the information about the stent is also recorded under the patient's e-record which is a part of the E-clinical system. The information is manually entered, and includes all the information about the stent recorded in the E-asset system, for example, time of implantation, and the identity of the surgeon.

Reverse exchanges of coronary stents

As shown in Figure 4, the REs of coronary stents are usually RE-1 and RE-2, but not RE-5, as stents' lifecycles are long if there is no medical or manufacturing failure. If there is a manufacturer recall of a batch of stents (RE-2), a search is conducted in the clinical system to identify patients with stents from that batch, and patients are called back for an appropriate action which is guided by manufacturers, such as replacement, or monitoring of their health. If a group of patients with the same implanted device experience similar symptoms of discomfort or lack of rehabilitation or health deterioration (RE-1), the E-clinical system is also searched to identify other patients who have stents from the same batch, and patients are called back for stent replacement. The MEL and manufacturers are updated about the stents in question, and appropriate processes take place, supported by E-procurement and E-asset systems, such as replacement with new stents or changing suppliers, etc. Inventory information of replaced and new stents is also updated in E-asset system. In these circumstances, the E-clinical system is helpful in identifying the patients and locating the stents; however, the clinical system is not designed for storing information about the device, neither does it have a search function to identify the patients or locate the device, so it takes time to search for patients with the stents in question. In addition, information on the stent is complicated, and is input manually to the system, so there are errors or missing information.

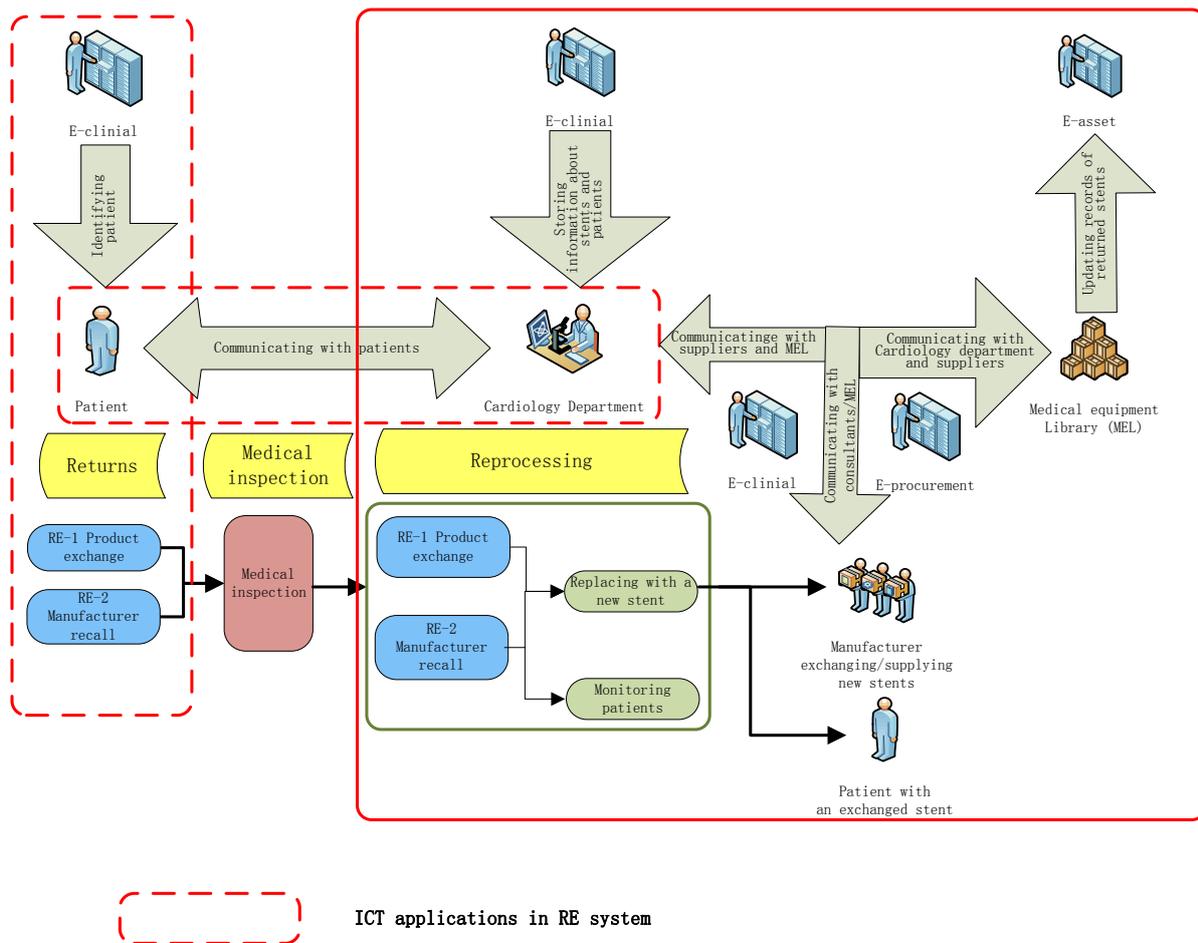


Figure 4 Reverse exchange of stents between Cardiology Department and patients

Case study 3: NHS hospital Trust 13 (Booth *et al.*, 2014)

NHS Hospital Trust 13 established an ICT infrastructure similar to those in Cases 1 and 2, facilitating document management and information sharing and enhancing communication. The MEL in the Trust needs to manage nearly 26,000 medical devices, which has been a constant challenge. The MEL also needs to manage cleaning, statutory maintenance and repairs of medical devices, and is responsible for returning assets upon manufacturers' recalls. It is therefore vital to know the location of medical devices that can be moved around a busy hospital environment, coupled with hundreds of staff vying for their use.

RFID system

The RFID system has been installed in the MEL of the Trust to effectively track and trace high volumes of mobile medical devices. The system uses fixed and portable Personal Digital Assistant (PDA) readers to track tagged devices. The active RFID tags are attached to medical devices such as infusion pumps, scanners or ECG monitors and they transmit their unique identities every few seconds. As the devices move around the hospital, they are automatically tracked by fixed point readers. As soon as a device is detected, the central equipment database is updated. Alternatively, devices are detected when a medical engineer carrying a PDA moves through the hospital. This data can be uploaded to the main database using either local WiFi or a USB connection to a local PC workstation.

Reverse exchanges of medical devices

Mobile medical devices are loaned from the MEL to medical departments, and exchanged for the reasons listed as REs 1-5. Collection is arranged by the MEL if special dismantling/handling procedures are required or, alternately, devices are returned to the MEL by departments.

5. Discussion of findings

5.1 Operational attributes derived from ICT implementations

The findings in Table 4 suggest that all three Trusts studied have implemented ICT in certain areas but on different scales; this indicates a general wide application of ICT in managing RE of medical devices. However, clearly there are areas to be improved in each case. Operational attributes achieved under ICT Implementations can be summarised as below:

Attributes 1): Information storage

Trusts 1 and 2 have implemented ICT in similar areas, and achieved similar operational attributes 1)-5). Trusts have autonomy to choose their own ICT systems and suppliers, as the systems selected must meet individual needs and be compatible with existing systems. Both Trusts adopted ICT to achieve attributes 1), and 4). Key information held on medical devices includes but is not limited to: inventory levels/returns/losses, fill rate, forecasts, cost, manufacturers, life cycles, maintenance and usage. The information is shared and exchanged with medical departments to enhance operational efficiency in RE (e.g., locating device, maintenance, reducing underutilisation and losses of devices) (Olorunniwo and Li, 2010). However, in neither case is ICT implemented to effectively plan RE activities. The scale of RE activities is regarded as being small in both cases; therefore, the ICTs are adopted in a reactive manner to respond to the need for a more efficient system to record and locate devices, rather than effectively plan and execute daily RE activities.

Attribute 2): Streamlining processes

In all three cases, ICT implementation streamlines processes and reduces costs relating to labour, device losses, capital investment in new devices or additional inventory, and operations of managing and maintaining devices. Operational attributes usually support each other, i.e., an improvement in one attribute would lead to enhancement in others. As such, the extent to which a process is streamlined depends on other operational attributes derived from ICT; for example, the level of communications among medical departments, and the ability of real time tracking and tracing. In relation to the RE processes, Trust 13 reported the highest level of streamlining due to the adoption of RFID, followed by Trust 1 (adoption of E-SCM) and Trust 2.

Attribute 3): Communication with SC partners

Although ICT implementation in Trust 2 uses E-clinical and E-asset systems to improve the communications among departments, with suppliers and with patients, Trust 1 is the only trust that has implemented E-SCM, which reflects the various degrees of strategic significance Trusts have placed on the SC and ICT's application to it. Comparable to developments in the industrial sector which widely acknowledged that ICT can play a significant role in improving SCs, Trust 1 has showcased this in the healthcare sector (Schneller et al., 2006).

Attributes 4) and 5): Information sharing, processing and supporting CPFR

Both Trusts 1 and 2 reported that they share information with suppliers to improve collaboration and coordination in forward logistics, and reduce costs (e.g., reducing inventory buffers, underutilised capacity, obsolescence) (Garcia-Dastugue and Lambert, 2003). The only RE related information processed is the number and types of returns/exchanges, and this analysis is communicated to suppliers to identify causes and develop suitable actions. More advanced applications not observed are: **i)** relating device return/exchange to a past loan so that returns/exchanges can be forecast; **ii)** data mining information about users to whom devices are supplied, including demand, supply, returns and exchanges of infusion pumps to discover patterns (de Brito and Dekker, 2004); **iii)** discovering the association between the number of return/exchanges and incident rates with suppliers and thus evaluating suppliers. All of these advanced applications help CPFR, assist in scheduling operations, influencing users' behaviour in returns/exchanges, and informing procurement decisions.

However, the lack of real time tracking on the infusion pumps in Trust 1 means that the information needed for applications **i)** and **ii)** is inaccurate; therefore, advanced information processing cannot be conducted effectively.

Real time tracking on coronary stents used in Trust 2 does not bring much benefit to the Trust. The information storing and sharing provided by the E-asset management system increases the department's ability to identify and communicate with patients, leading to a reduced number of incidents caused by faulty stents and delivering a better quality of care. While information sharing and storing have helped achieve better healthcare performance, it does not add much value to applications **ii)** and **iii)**, monitoring impacts of implanted stents on patients and decision making on sourcing stents. Effective analysis and presentation of information held on stents and patients can discover patterns and knowledge about stents, manufacturers, and incident patterns associated with stent types and manufacturers. Common characteristics can also be identified for patient groups who discover problems with implanted stents. Accumulated knowledge and experience can then be developed into a knowledge database on stents and patients, and shared with other NHS Trusts. This database will not only help consultants and managers of the MEL make informed decisions on sourcing, but also increase active interaction with suppliers and patients to improve quality of care (Harper, 2002).

Although in Trust 13 rich data has been collected and analysed in relation to the benefits brought by RFID, including the increased number of medical devices supplied and increased movement and utilisation of medical devices, we are not able to comment on the level of information analysis as primary research was not conducted.

Attribute 6): Real time tracking and tracing

Although ICT has been implemented to improve coordination in the forward logistics in Case 1, it is not implemented to a large extent in the RL or RE environment. Trust 1 can access historical information on stock levels and returns/exchanges, but there is a high uncertainty in return/exchange volume and frequency due to lack of real time tracking. This makes the coordination of RL or RE complex, characterised by uncertainty in operations of handling returns (maintenance, repair, recycling) and inaccuracy in CPFR of returns/exchanges, and thus less timely processing. Due to lack of real time tracking and the high likelihood of ownership change upon departure from the MEL, a number of devices get lost and then become obsolete, which results in high underutilisation of medical devices.

To overcome the problems caused by lack of real time tracking, Trust 13 in Case 3 has implemented RFID to track and trace mobile devices in a hospital environment. Among the three cases, Trust 13 is the only Trust that has implemented RFID; this is in contrast with industrial settings where RFID is more mature and is used to track and trace products, and is regarded as a tool that has enabled greater functionality and responsiveness within RL due to its timely capture and retrieval of real-time information (Wyld, 2006). This discrepancy reflects the view that the NHS may still be focusing more on implementing enterprise-type ICT to streamline business processes, improve efficiencies and communications, rather than on enhancing traceability of devices in the RL system. In addition, Trusts are traditionally very backward in adopting new technologies (Booth et al., 2014). To improve competitiveness, they are compelled to improve quality of care and be cost conscious; therefore, trusts' prioritised aim is to provide the best quality of medical treatment, with monitoring and tracking medical devices lower down their agenda. Tagging and tracking medical devices offers many benefits such as regular maintenance and frequent auditing of devices, as well as informed decision making and reduced risk based on accurate, up to date and comprehensive data, all of which would minimise the circulation of potentially dangerous, unsuitable or unmaintained devices, and ultimately improve quality of care and reduce costs. Case 3 has reported an improved quality of care and reduced costs.

Despite the numerous benefits delivered by RFID, the high set up cost and the skills required to operate the system prohibit widespread implementation. Trust 13 implemented RFID as a pilot project to manage 4000 mobile devices, using spare budget from other projects. Their decision was informed by data from preceding RFID projects conducted by the provider, in particular that capital savings as a result of RFID implementation were in excess of initial investment, enabling clients to reduce capital expenditure. The success of the RFID project in Case 3 by Trust 13 has been shared as good practice with many NHS Hospital Trusts, which is why the business case of RFID is under review in Trust 2.

Because of the different focuses and emphases, the three Case Trusts implemented ICTs in different areas, with different operational attributes achieved. However, apart from the RFID implementation in Trust 13, there is no dedicated ICT system for managing RL or RE of medical devices. Trusts 1 and 2 both use functions of ICTs implemented for forward logistics/medical treatment to identify and track devices in the RL and RE systems.

5.2 Impacts on performances of Reverse Exchange system

The ICT applications make positive impacts on economic performances and service excellence of the RE systems (see Table 4).

Case study 1:

As presented in Table 4, the integration of E-procurement, E-inventory, and E-integrated SC has made a positive impact on the both economic performance and service excellence of the RE system. The MEL has been able to speedily identify obsolete, end-of-life and unnecessary stock of infusion pumps, allowing the Trust to realise significant savings and reduce the rate of incidents caused by outdated pumps. Consequently, the efficiency and effectiveness of the RE system are improved and economic saving is achieved, leading to better patient service and satisfaction from healthcare professionals. Since there is no ICT system for individual real time tracking and tracing of pumps, they still go missing and a considerable amount of time is spent searching for them. There is a potential to further improve the positive impacts.

Case study 2:

The integration of E-procurement, E-asset management, and E-clinical systems allows the Trust and the Cardiology Department to locate patients with problematic stents swiftly, provides more timely communications with both patients and manufacturers, and allows greater control over implanted stents. The information provided is also more accurate in the streamlined processes. All of these help the Trust achieve economic savings and provide quicker and better service to their patients (see Table 4). With the E-asset management system, the MEL can easily identify which devices (non-implantable) are coming to the end of their life and inform the clinical team, improving overall communication and timely action. However, information on stents and patients is still manually input to the E-clinical system, so there are still errors or outdated information about patients and implanted stents. This results in great difficulty in finding patients with problematic stents.

Case study 3:

Since adopting RFID to track mobile medical devices, the MEL has been able to supply a significantly increased number of units, for example the number of infusion pumps supplied has increased from 1057 to 3326 units. As a direct result of efficient and effective device management, the tracking ability of the department has also improved sharply, with more than four times the number of devices (6333 devices) tracked by March 2013 compared with January 2011. Along with increased tracking ability, use and uptake of devices is increased, and, in turn, greater value is being obtained from the investment made in each device, minimising the rate of unnecessary out of use and underutilisation. After the introduction of RFID, approximately 45% of devices are now returned to the MEL, while the pre-RFID figure was 6%. The director of the MEL estimates that the first year capital savings as a result of RFID are well in excess of £100,000. RFID implementation also improves quality of care by ensuring stock availability, regular cleaning and maintenance, and reducing delays in issuing devices. Risk management on medical devices is improved by RFID, which enables more frequent and speedy audit and regulatory compliance through correct maintenance. All the benefits above not only improve service to patients, but also improve the MEL's intelligence, performance and staff satisfaction (see Table 4).

6. Drivers and challenges of ICT adoption in managing medical devices

6.1 Drivers for ICT adoption

Drivers for ICT adoption are compared for Trusts 1 and 2 in Table 5, and are analysed below under environmental, technical and organisational contexts.

6.1.1 Environmental context

- ***Requirements imposed by government and regulatory bodies***

The main driver of ICT adoption in managing medical devices is compliance with directives from the NHS or other professional bodies such as MHRA. The National Programme for IT (NPfIT) launched in 2002 mandates NHS trusts to initiate ICT reform and operate effectively within this legislative framework. When the MHRA made it a requirement to improve the safety of medical devices, many Trusts introduced ICT Systems to manage them (MHRA 2015).

- ***Requirements from trading partners***

Maximising the impact of ICT requires the active involvement of every party in the healthcare SC (Liddell et al., 2008). Only when a platform such as E-SCM is available, can

the Trusts share retrieved knowledge with other parties to make informed and improved decisions. It is also a requirement from business partners to have higher visibility of inventory and more information on demand. For these reasons, Trust 1 implemented an E-integrated SC to enhance inventory visibility across the chain and improve collaborations among SC partners.

- ***Requirements from patients***

Despite patient expectation being reported as one of driving forces on ICT adoption (de Luisignan et al, 2014), neither Trust 1 or 2 agree this is a driving factor that influenced their adoption of ICTs in managing RE of medical devices. In fact, they point out that patients care about the quality of medical treatment they receive and the safety of medical devices used on them, but have little understanding of, or interest in knowing, which ICT has been implemented to manage or track medical devices. Even in the case of coronary stents, patients focus on the quality and duration of the stent, and the way they can communicate with consultants after the surgery; therefore, e-communication becomes an expectation from patients as a means of post-surgical review or check.

- ***Competitive pressure***

The NHS's intention to close some hospital Trusts in order to centralise care has put underperforming or uncompetitive Trusts at risk. Both Trusts 1 and 2 are under pressure to cope with an imminent financial squeeze in the NHS and deliver better quality and more accessible treatment for patients; ICT use plays an important role in achieving these objectives. Trust 1 has been a pioneer in ICT adoption, enabling it to maintain its competitive position in all aspects of modern healthcare and build up a strong reputation in the market. However, the competitive pressure on managing medical devices is so minor that it does not drive Trust 1 to prioritise it or to tailor build a dedicated ICT system for it.

In contrast, the ICT development in Trust 2 has fallen behind other trusts, which has put pressure on the Trust to deploy new cutting edge clinical and non-clinical systems to enhance its performance and increase efficiency. The Cardiology department is one of the best specialist departments in the country and plays a critical role in building up the reputation of Trust 2 in the market. Exchanges of stents are almost unavoidable and significant technical support is required to locate and track the recipients of stents; any mistake or incident could damage Trust 2's public image. These pressures drive the ICT adoption in the Cardiology department, but the focus is on the forward logistics of managing stents rather than the RE of them. The ICT implementation for the forward logistics has the functionality that allows the Trust to locate stents once there is a need to take them back.

6.1.2 Technological context

- ***Perceived benefits***

Under pressure to cut costs and improve efficiency, the NHS have focussed their efforts on improving activities that add value and decreasing or eliminating activities that do not (Aptel and Pourjalali, 2001). Inventory management and logistics of medical devices do not represent the core mission for the NHS, but have drawn attention and investment as they affect service levels and costs (Baffo *et al.*, 2009). Technical enablers such as ICT are being deployed by Trusts 1 and 2 to streamline processes, enhance their ability to manage medical devices and reduce errors, and, therefore, to improve efficiency and effectiveness. Both Trusts agree that ICT systems help ensure that medical devices are available, clean and fit for use, which is one factor influencing their adoptions of ICT to improve patient care.

6.1.3 Organisational context

- ***Organisation size***

Organisational size proves to be a factor affecting ICT adoption by the Trusts. Case Trusts 1 and 13 are bigger and more advanced, having greater resources available to adopt more advanced ICT on a larger scale, such as E-SCM and RFID. The sophistication of systems depends on the type and variety of medical devices being managed.

- ***Top management support***

Top management's support to lead or innovate, and to become competitive has a strong influence on the pace of adopting ICT, and on the scale of implementation. Benefiting from the high level of commitment from the senior management team in Trust 1 and strong financial resources, the implementation of ICT systems across Trust 1 has always been emphasised and prioritised in order to achieve competitiveness in patient care, organisational efficiency and effectiveness. Trust 2 had relied on national programmes (such as NPfIT) to modernise their ICT solutions, and this has placed them significantly behind some other local Trusts. Having realised that the old system could not fulfil their requirements, Trust 2 invested heavily to introduce ICT to key areas to enhance its competitiveness. Trust 13 had strong support from senior management to make innovative changes to how they managed medical devices and, therefore, introduced RFID to automate the tracking of medical devices and change working practices.

Insert Table 5 here

6.2 Barriers to ICT adoption

6.2.1 Organisational context

- ***Sufficient resources***

The absence of drivers becomes a barrier to ICT adoption (see Table 6). Both Trusts 1 and 2 agree that lack of sufficient resources (financial resources, human resources and technical knowledge) are the major barriers to adopting new, innovative and advanced system such as RFID. Organisationally, the NHS is a large, complicated and multi-tier organisation, within which decision making is characteristically lengthy and challenging. The implementation of RFID in the healthcare sector is still in its infancy. Although solid evidence on the benefits of using RFID to track and manage mobile medical devices in a hospital environment is now available, providing justification of a business case for adopting RFID in NHS Hospital Trusts, there is still little sector-specific cost-and-benefit analysis relating to developing RFID for managing medical devices. Trusts 1 and 2 share the same views on NHS resistance to rolling out RFID to manage medical devices, as it is less critical than using other ICT based approaches to support health and social care, especially as the cost of tagging low cost devices may exceed the cost of the device. However, financial help from the suppliers of technologies will present an affordable route for Trusts with a limited budget to launch trials or adopt RFID on high value or high risk devices.

Neither Trust 1 or 2 has sufficient resources to fund a dedicated system for the RE system of managing medical devices, although both feel the current system is underfunded and under prioritised. According to both Trusts, the RE system is a small portion of their operations, and does not bring enough economic benefit to the trust to justify the resource allocation. However, a more advanced and dedicated ICT system could save up to 40% labour time

(Mun and Kantrowitz, 2008) and enhance the return rate (from 6% to 45%) and utilisation (Case study 13); these savings would potentially be substantial enough to initiate a dedicated ICT system for RE activities. Furthermore, direct economic benefits are not the sole outcome of RL activities (Olorunniwo and Li, 2010); customer service, quality of care, retention of staff and sustainable development can be improved through an ICT enabled RE system, which, in turn, enhances the Trust's reputation and competitiveness, this being particularly beneficial to Trust 2.

RE is complex, and needs significant technical support, for example handling small and frequent shipments, tracking returns and processing exchanges. Both Trusts 1 and 2 admit that finding, and also retaining, the right ICT experts is harder in the healthcare sector, and that the ICT knowledge of current hospital staff needs to be increased to operate the ICT systems or manipulate data/information stored in the systems (see Table 6), which is one reason why there is no dedicated ICT system developed for the RE. This may help create a positive macro environment to promote staff development in using ICT tools and facilitate the development of ICT implementation. In Trusts 1 and 2, ICT training is currently routed through a third party provider, but both Trusts said their IT departments will endeavour to enhance the levels of training given and to assist with any future crucial upgrades.

- ***Top management support***

A lack of commitment from the senior management team was the reason for the slow and inadequate ICT implementation in Trust 2. Senior management did not have a great understanding of the benefits brought by ICT, and relied on national programmes to modernise the ICT systems in the Trust. Only in 2007 did Trust 2 gain the senior management team's buy in on making significant investment in ICT development, and in 2010 they developed an ICT strategy which was critical for the launch and success of the ICT implementations to manage coronary stents. Trust 2 realised that they needed to enhance their knowledge of the benefits of ICT, recognised that investment in ICT might require relatively long timescales for payback, and, therefore, made transitional funding available for ICT adoption and staff training (Hung et al., 2010).

Insert Table 6 here.

6.3 Improvement recommendations and practical implications

While the TOE framework explains the different factors that influenced ICT adoption at the Trust level, factors such as patient expectations are not considered as a driving factor by either Trust.

Furthermore, it appears that the major barriers to ICT adoption in the NHS are a lack of sufficient resources, in particular financial limitations, and also of staff ICT skills. The barriers are common to almost every surveyed Trust in the preliminary research suggesting that they might be issues of the sector.

For long-term sustainable development and competitiveness, however, the governmental bodies and NHS need to make investment in introducing and upgrading ICT applications designed to manage medical devices; NHS Hospital Trusts are subject to an NHS driven economic framework, operate under NHS guidance, and are still relying on central planning to instigate change. To expedite development of ICT in managing RLs and REs of medical devices, the government and NHS can play the role of coordinator or facilitator by stipulating

directives or regulations on introducing ICTs to track medical devices, ensure safety of devices, reduce incidents and enhance utilisation.

Financial considerations comprise investment, benefits, and cost. **An important issue to consider when deciding to invest in ICT is the context, and whether ICT investment can improve operational attributes.** Implementing ICT for the management of medical devices needs heavy upfront investment but, on the other hand, a large number of operational attributes can be sustained by the system, including reduced labour time, improved efficiency and enhanced effectiveness. Extending the use of ICT to RLs and REs of medical devices can improve the utilisation of medical devices, reduce waste and achieve better quality of care in the long run. This may give a Trust a sustainable competitive advantage.

At Trust level the importance of ICT in a Trust's organisational strategy plays a significant role in determining the ICT system adopted to facilitate forward logistics and RE. Well informed and appropriate ICT implementations enable more effective delivery of high calibre services to the public, and, therefore, enhance the reputation of the Trust in the eyes of both staff and the public. As the case studies reveal, the Trusts which see ICT as a strategic tool to gain long-term benefit (e.g. Trusts 1 and 13) and have a desire to lead and innovate will adopt totally different approaches from those that do not. Trust 1 believes that demonstrating capability in a strong and vibrant healthcare ICT area helps the Trust achieve a leadership position in healthcare ICT and attract further healthcare ICT investments.

Both the NHS and Trusts need to recognise that, without appropriate and relevant ICT skills, ICT systems can never be implemented successfully and the full power of such systems can never be fully exploited for RE purpose. It is essential there is a corporate understanding of, and commitment to, the staff development required to sustain the Trust's information needs. To an extent, a culture change is required within the NHS to train staff to perform high level data analysis, to enable the true value of information to be fully understood by staff, and to make informed decisions based on data. Through building a strong healthcare analytics capability, both government and NHS will be better positioned to measure and forecast demands on healthcare, and respond accordingly.

7. Conclusions and limitations of research

While research on the impacts of ICT on RL performance has been growing, the extant research into ICT application in a RE system is minimal. Therefore, this paper, although exploratory in nature, has broken new ground and provided a structure and basis for further research on the application of ICT in healthcare RE systems in particular and on RE systems in general. Recognising the potential economic savings and improvements in patient care, this study, through case study analysis and comparison, has added to this body of knowledge and has produced key outputs which deliver knowledge/impact to both academia and practice.

The key outputs of this study are as follows:

- 1. An initial set of 6 operational attributes have been identified as a result of ICT implementation in managing medical devices. These are information storage, streamlining processes, communication with SC partners, information sharing and processing, supporting CPFR, and real time tracking and tracing.**

2. **RFID was perceived to be the only ICT implementation dedicated to the RL and RE of medical devices, as demonstrated in Trust 13. Both Trusts 1 and 2 believe their RE systems are underfunded, and not prioritised. Findings from this research may help support discussions and justify investment decisions to implement ICT for RE systems.**
3. **A set of drivers and obstacles are formulated, and can be subsequently utilised within the NHS to influence decision making on investment in introducing and upgrading ICT applications for the management of medical devices. The key drivers of ICT adoption to manage medical devices are identified as environmental factors (pressures from government, business partners and patients, competitive pressure), technological factors (perceived benefits), and organisational factors (organisation size, top management support and sufficient resources). Obstacles are mainly centred around the lack of sufficient resources (financial resources, human resources and technical knowledge) and an under appreciation of the benefits of introducing such ICT applications.**

This research enriches the knowledge on the linkage between ICT application and derived operational attributes. Our results show that integrating ICT into the main operational processes can help to improve the effectiveness and efficiency of medical device management. Information sharing has been observed between departments at local Trust level, as well as with external suppliers, although the extent to which information is shared varies with Trusts. Effective and transparent information sharing improves SC visibility, fostering collaboration between partners to deliver increased operational efficiency, reduce costs, and move towards hugely improved customer service, all leading to improved RE performance. The ultimate goal of the device manager or coordinator must be to eventually achieve a position where a Trust can conduct CPFR with strategic device suppliers, and implement a fully integrated RL processes for manufacturing scheduling, distribution and inventory management. Achieving this goal requires trust building and joint strategic planning between the NHS and its business partners. We hope that Trusts will utilise the operational attributes as a basis for benchmarking and good practice development in ICT implementation for device management.

Healthcare organisations face challenges such as acquiring proficiency in understanding and interpreting clinical information so as to attain knowledge and make informed decisions. As for managing medical devices, device managers or coordinators make health or wellbeing related decisions whilst attempting to deal with large amounts of data. **Making use of the data processing and analysis functions of ICT would help staff develop a profound understanding of the demand, supply, returns, utilisation, performance and evaluation of medical devices, leading to informed decision making and the creation of value in both tangible and intangible terms. To enable this, further training needs to be provided by the NHS to improve the ability and competence of staff to perform effective and accurate data analysis.**

These findings add to the current understanding of drivers and obstacles of ICT adoption in a healthcare setting. The findings of the case studies have helped identify the relative influence of these factors on ICT adoption by Trusts to manage medical

devices, with a focus on RE. Unlike in industrial sectors, where companies have autonomy to make investments on ICT implementation, Trusts rely on the governmental bodies and NHS as facilitators to encourage and enable ICT implementation for the management of medical device. In this regard, a set of improvement measures have been proposed on the assumption that an appropriate nationwide directive can be formulated as a long term strategy to drive ICT implementation for device management and the associated RE system. In the short term if government cannot mandate the implementation of ICT for Trusts, it can lead in the creation of a culture that actively encourages, supports and enables the adoption of ICT. Research into this aspect is underdeveloped, and this exploratory study provides insights into the use of ICT in managing the RE of medical devices, which is essential to enhance the understanding of RE in the healthcare sector, as well as to inform technology design and development.

This research also sheds light on which approach should be adopted by Trusts to implement ICT. Based on the discussions with interviewees from Trusts 1 and 2, it is found that the decision making process did involve many strategic considerations, such as legal concerns, strategic significance, reputation, competitiveness and customer service. Trusts implement innovation as a long term strategy to sharpen competition and decrease costs, and utilise ICT to establish or maintain reputation and competitiveness.

To end on a positive note, all indications in this study suggest that, whilst the technical hardware may not be in place or utilised effectively, there is an awareness and a desire among NHS staff to utilise technology to develop the RE system and deliver a more efficient and effective service.

Benefits brought by ICT do not always outweigh the costs and risks, but significant benefits could be achieved for patients, for the tax paying public, for healthcare professionals and for the NHS if the potential of ICT is fully realised. As with all case studies, the limitation of this research lies in the fact that only two primary case studies were investigated and, therefore, generalisation of the findings has to be cautious. The impacts of ICT use demonstrated by the case studies are associated with specific ICT implementations for specific devices, which are essentially unique and internal to the individual organisations. While the examples cited are selective and the analysis incomplete, they do provide the scope needed to review the underpinning concepts about ICT implementation to manage RE of medical devices in NHS.

8. Future research

To enhance generalisability, appropriate future research will be conducted on a large-scale empirical study to survey more hospitals in the UK and globally for comparison. Further research is also proposed to carry out an audit in Trust 2, and investigate the benefit of using ICTs in tracking coronary stents in a quantitative manner. The research will also be extended to cover other high value and high risk devices, and attempt to investigate how ICTs are implemented to assist CPFR of these devices.

As this research is exploratory in nature, there is insufficient data on which to form definitive recommendations. In order to fully understand the benefits, implications and return on investment of ICT implementation with regard to RE of medical devices, further deeper

analysis of costs and benefits, both economic and patient service related, would need to be undertaken at both local and national levels. Only once that further research is done should policy recommendations be developed.

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Table 1: Theories for ICT adoption

Theories	Authors	Methodologies
Institutional Theory	Teo et al., 2003	Field survey
Diffusion of Innovation	Russell and Hoag, 2004	Case studies
Technology Acceptance Model	Venkatesh and Davis, 2000	Longitudinal Field Studies
Technology-Organisation-Environment framework	Kuan and Chau, 2000; Zhu et al.2006; Hsu et al., 2006; Teo et al., 2009; Lin 2014;	Field survey

Table 2: Respondents to questionnaire

Respondents	Role	Healthcare organisation	Location
1	Medical Device Manager	NHS hospital Trust 1	Greater London
2	Head of Catheterization Laboratory	NHS hospital Trust 2	East England
3	IT lead	NHS hospital Trust 3	East England
4	Medical Devices Coordinator	Integrated Community Equipment Service 4	Greater London
5	Medical Devices Coordinator	Integrated Community Equipment Service 5	West England
6	Medical Device Manager	Integrated Community Equipment Service 6	West England
7	Head of Therapy/Physiotherapy	NHS hospital Trust 7	North England
8	Medical Devices Coordinator	NHS hospital Trust 8	North England
9	Medical Devices Manger	Integrated Community Equipment Service 9	Scotland
10	Joint Equipment Loans Service Manager	Northumberland Community Service 10	North England
11	Service Manager	Integrated Community Equipment Service 11	North England
12	Head of Supply Chain	NHS Hospital Trust 12	West England

Table 3: Interviewees and secondary resources for case studies

Interviewees	Role	Healthcare organisation	Location
1	Medical Device Manager	Case study 1: NHS hospital Trust 1	Greater London
13	IT lead		
14	Head Nurse		
2	Head of Catheterization Laboratory	Case study 2: NHS hospital Trust 2	East England
15	Cardiologist Consultant		
16	Medical and Biological Engineer		
Secondary resources		Healthcare organisation	Location
Whitepaper of RFID provider, and mini case studies		Case study 3: NHS hospital Trust 13	East England

Table 4: The scale of ICT use to manage medical devices in the case hospital Trusts

ICT adoptions	Healthcare organisations		
	NHS hospital Trust 1	NHS hospital Trust 2	NHS hospital Trust 13
ICT infrastructure	√	√	√
E-procurement	√ E-procurement system	√ E-procurement system	Unknown
Document management and information sharing	√	√	√
Inventory management of medical devices	√ E-inventory system	√ E-asset management system, E-clinical system	Unknown
Real time tracking medical devices	×	×	√ RFID
E-integrated supply chain management	√ E-SCM	×	×
Operational attributes gained from ICT implementations			
1) Storing information and enhancing information visibility about medical devices, and users	√	√	√
2) Streamlining process and reducing labour work	√	√	√
3)-A Improving communications with suppliers e.g., communications with suppliers on inventory visibility, orders, advance notification about returns/exchanges, reasons and actions	√	√	Unknown
3)-B Improving communications with patients	√	√	Unknown
4)-A Sharing inventory and order information with suppliers	√	√	√
4)-B Sharing product information with users (life cycle, maintenance dates, etc.)	√	√	Unknown
4)-C Analysis and processing of information	√ Limited (analysis on the number of returns/exchanges)	√ Limited (analysis on the number of exchanges, impacts on patients)	√
5) Supporting CPFR	√ Limited (MEL and suppliers collaboratively replenish inventory based on historical usage, losses and safety stock)	√ Limited (MEL, Cardiology department and suppliers collaboratively replenish inventory based on historical usage and safety stock)	Unknown
6) Real time tracking and tracing medical device	×	×	√
Impacts of ICT on RE performances			
1) Economic performance			
<i>Enhanced return rate, audit and maintenance</i>	×	×	√
<i>Enhanced movement and utilisation</i>	×	×	√
<i>Reduced incident rate</i>	√ Limited	√ Limited	√
<i>Streamlined process and increased efficiency</i>	√ Limited	√ Limited	√
<i>Reduced labour time and device losses</i>	×	×	√
2) Service Excellence			
<i>Improved quality of care</i>	√ Limited	√ Limited	√
<i>satisfaction from healthcare professionals</i>	√ Limited	√ Limited	√

Table 5 Drivers of ICT adoptions

Drivers	Case Trust 1	Case Trust 2
Environmental factors		
Requirements from government and trading partners	√	√
Competitive pressure	√	√
Organisational factors		
Organisation size	√	×
Top management support	√	√
Technological factors		
Perceived benefits	√	√
<i>Economic benefits</i>	√	√
<i>Improving efficiency and effectiveness</i>	√	√
<i>Improving quality of care</i>	√	√
<i>Improving competitiveness</i>	√	√

Table 6 Barriers to ICT adoptions

Barriers	Case Trust 1	Case Trust 2
Organisational factors		
Organisational obstacle	√	√
Lack of sufficient resources	√	√
<i>Financial obstacles</i>	√	√
<i>Staff low ICT skills</i>	√	√
Low commitment from senior management team	×	√

Appendix 1 Preliminary questionnaire with 12 healthcare professionals

Product/Process

Can you please list any medical device that you are aware of that is provided to patients and is subject to return/exchange after a period of time?

Can you briefly summarise the reason(s) why patients receive these devices?

Can you briefly summarise the following:

1. How does the patient receive the device?
2. How does the patient return the device?

Is the patient told when they have to return the device? If yes when are they told this information?

If the device is not returned can you briefly summarise the next steps taken by the hospital/dept.

ICT solutions/facilitation

Is there a database held of all device exchanges? If yes is this known software/package or designed by the department?

Are you aware of any alternative ICT solutions that could be used?

Can you comment on how much ICT solutions are used to facilitate the allocation, delivery, tracking and return of these devices?

10% 30% 50% 70% 100%

Can you comment on how ICT support the task of allocation, delivery, tracking and return of these devices?

Do you think that SMART technologies or other well used solutions such as the following could be used to improve this process? Can you please indicate your views in the table below.

Improvement option	Yes	No	Other comments?
Smart phone app			
Dedicated website with track and trace functionality			
RFID chipping			
QR codes			

Why are these ICT solutions adopted?

Have you any other comments on the current design/improvement of this process?

Appendix 2 Interview questions with Case Trust 1

1. Has an Information Communication Technology (ICT) System been implemented to purchase, manage or track infusion pumps? If so, what systems are in place? E.g., E-procurement, electronic inventory system, online database, RFID.
2. Can you briefly summarise the reason(s) why infusion pumps are returned/exchanged?
3. Is there an ICT system implemented solely for the return/exchange of medical devices (including infusion pumps)?
4. If ICT systems have been used to manage infusion pumps, or to manage return/exchange of infusion pumps, what benefits are brought by them? For example,
 - Store information and enhance access to information
 - Enable information sharing among departments
 - Enable information sharing with external business partners, such as suppliers, manufacturers
 - Facilitate data processing, and integration to other systems (such as inventory system)
 - Improve communication among departments, and with patients
 - Improve communication with external business partners, such as suppliers, manufacturers
 - Facilitate inventory planning, forecasting and replenishment (if so, has this been done collaboratively with other departments, or with suppliers?)
 - Enable efficient tracking
 - Enable effective planning for return/exchange
 - Enable integration with the whole supply chain
 - Other benefits
5. Please indicate the impacts the ICT implementations have on your Trust related to handling of returns/exchanges of infusion pumps. For example,
 - Recovery of assets (Higher return rate, reduced losses, and higher utilisation)
 - Improved labour productivity
 - Reduced errors and waste
 - Reduced inventory investment
 - Economic savings
 - Improved quality of care (Higher stock availability, regular cleaning and maintenance, and reduced delays in issuing devices)
 - Other impacts
6. Please explain the factors driving the ICT adoption to manage infusion pumps? For example,
 - Pressures from NHS, patients, suppliers, etc.
 - Perceived benefits (improved efficiencies, reduced labour time and cost, etc.)
 - To be more competitive
 - Instructions from senior management
 - Other factors
7. What are the obstacles to the ICT adoption to manage infusion pumps?