Henley Management College

Hypothesis:
Medical Device manufacturer applied or embedded RFID has benefits to Patient Safety over existing Auto-ID technologies, e.g. Bar Codes.

By

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ABSTRACT

The benefits of Radio Frequency Identification (RFID) technology over Bar Codes, for greater patient safety, when used with Medical Devices (MD).

This dissertation evaluates the hypothesis that:

Medical Device manufacturer applied or embedded RFID has benefits to Patient Safety over existing AIDC technologies, e.g. Bar Codes.

The research methodology employed was the inductive, "building theory" (Saunders et al 2003:87) approach; as it is "more flexible" than the deductive approach, "permits changes of research emphasis as the research progresses", is concerned with the particular context and because it is appropriate for "a topic that is new, is exciting much debate and on which there is little existing literature".

The research process was in two stages:
The first stage involved a search and subjective review of recent literature. The output of the review led to formulation of the research hypothesis and questions. However, the distinguishable lack of literature significantly influenced the literature review. The lack of relevant secondary literature sources resulted in primary literature as the predominant literature source.

The fieldwork, in the form of one-to-one interviews with key stakeholders and an on-line Questionnaire of the wider stakeholder community, constituted the second stage of the research process.

Analysis of the data collection established that Patient Safety is the key driver. But the theory that RFID would deliver greater patient safety was not proven and is largely hypothesis.

The conclusions were summarised by rewording the hypothesis into the following statement:

Medical Device Manufacturer applied or embedded RFID should be voluntary. RFID has benefits over existing AIDC technologies, e.g. Bar Codes and has the potential to deliver greater patient safety in the clinical environment. But it should not be seen as a panacea; all AIDC technologies should be considered and piloted, and the most appropriate selected, when attempting to address reported adverse incidents in the most severe "degree of harm" categories (NPSA).

DEDICATION

To my partner Bob and our daughter Kate:
Thank you for your patience, love and support over the last three years.

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- To the 60 people who completed the online questionnaire.

And finally:

- To Henley Management College: A challenging course in a beautiful setting.

Johnson & Johnson

August 31, 2006

Michael P. Rose
Johnson & Johnson Corporate
Vice President, RFID/EPC
Global Value Chain

Subject: Janice Kite – MBA Dissertation Endorsement

Since Johnson & Johnson is the world's most diversified healthcare manufacturing company, our company has keen interest in Janice's research. The Johnson & Johnson Credo states that

> We believe our first responsibility is to the doctors, nurses and patients,
> to mothers and fathers and all others who use our products and services.
> In meeting their needs everything we do must be of high quality.

Clearly, ensuring the patient safety of our medical devices is viewed as a Credo responsibility across our Johnson & Johnson family of companies. The Medical Devices & Diagnostics operating group is the fastest growing and the most technologically sophisticated business unit within Johnson & Johnson.

To date, virtually little has been written on the subject of auto-identification and data capture technologies (AIDC), and the relative potential merits of radiofrequency identification (RFID) over bar codes for providing greater patient safety.

As Janice was preparing to begin her work on her dissertation, I had the pleasure of discussing with Janice her ideas that she was considering for her hypothesis. We agreed that her dissertation would be a vital piece of work that is much needed by the medical device industry.

Janice's dissertation helps Johnson & Johnson and the over all Medical Device industry in several ways:

- Provides a critical compilation of basic research conducted with key stakeholders, thought leaders, standards bodies, and regulators about the merits of RFID and bar codes for greater patient safety.
- Delivers recommendations that can help guide the Medical Device industry's piloting and adoption of AIDC and RFID.
- Provides an appropriately conservative message that properly tempers the industry and regulator's expectations of AIDC and RFID for improving patient safety.
- Provides material that will be reviewed and discussed in various industry forums and internal Johnson & Johnson RFID/AIDC meetings.

Through Janice's independent research and work on this dissertation, she has advanced Johnson & Johnson and the medical devices' understanding of RFID/AIDC and RFID's relationship to patient safety.

Michael P. Rose

Table of Contents

		Page
1. Introduction		**7**
1.1	Healthcare	7
1.2	Medical Devices	7
1.3	Types of Auto-ID Systems	8
1.4	What is RFID?	8
1.5	History	9
1.6	Topic Selection	9
1.7	The Aim of the Dissertation	10
1.8	The Scope of Dissertation	12
1.9	Research Approach	12
1.10	Objectives	14
1.11	Structure of Dissertation	16
2. Literature Review		**17**
2.1	Lack of Secondary Literature Sources	17
2.2	Primary Literature Sources – Limitations	18
2.3	A Review of Relevant Primary Literature Sources	19
2.4	Summary	33
3. Aims and Objectives		**36**
3.1	Aims	36
3.2	Objectives	36
3.3	Research Questions	36
4. Research Design and Methodology		**38**
4.1	Research Philosophy	38
4.2	Research Approach	39
4.3	Research Strategies	40
4.4	Time Horizon	41
4.5	Data Collection Methods	41
4.6	Chapter Summary	42
5. Data Analysis and Results		**43**
5.1	Stakeholder Analysis	43
5.2	Interview Analysis	45
5.3	Questionnaire Analysis	52
6. Discussion, Conclusions and Recommendations		**61**
6.1	Discussion	61
6.2	Conclusions	65

6.3 Recommendations 67
6.4 Limitations of Research 68
7. Reflection – Personal Development 72
7.1 Lessons Learnt 72
7.2 Next Time? 73
7.3 Unexpected Outcomes 73
Bibliography 75
Glossary 81
Appendices 84
A Research Interview – Invitation eMail 84
B Research Interview protocol and questions 85
C Completed Interview – verbatim example 88
D Research Questionnaire – Invitation eMail 91
E Standard Deviation analysis 92
Tables
1 What is 'new' about RFID? Evolution of RFID 11
2 Structure of Dissertation 16
3 Comparison of Bar Code and RFID Technology 29
4 No of incidents: …reported outcome by reported category 31
5 Summary of Themes & Concepts of Key Authors 34
6 Stakeholder classification 43
7 Stakeholder participation (Interviews) 45
8 Stakeholder participation (Questionnaire) 52
9 Spread across stakeholder groups 53
10 Job roles of participants 54
11 Patient Safety Driver categories 55
12 Other Drivers 55
13 The link between Supply Chain and Patient Safety 56
14 Priority – Top 5 Medical Devices 57
15 Top 5 Barriers 58
16 Pilots with Medical Devices 59
Figures
1 The family of Automatic Identification Technologies 21
2 The Research Process 'Onion' 38
3 Stakeholder analysis grid 44

1. Introduction

This chapter provides a high level definition of MDs and Auto-ID systems, information about RFID; why the topic was selected, its significance to the MD market, the aim and scope of the study and the research approach taken.

1.1 Healthcare

Healthcare is an industry where patient safety comes first and "is one of the most regulated industries in the world. In almost every link of the supply chain there are reports to file with government, insurance carriers, manufacturers and quasi government associations concerning each medical device, instrument and supply." (Sokol and Shah, 2004)

This dissertation focuses on the Medical Device (MD) Sector of the Healthcare market. The global MD market is valued at over £126bn (€184bn, $230bn) (Eucomed, 2004), with the US accounting for 43% and Europe 30% of the world market.

It looks at Radio Frequency Identification (RFID), an Auto-ID and Data Capture technology, and considers whether it has benefits to patient safety over existing AIDC technologies, e.g. Bar Codes, when applied to or embedded in MDs.

This introduction provides a high level definition of MDs, a list of AIDC systems, a brief history of RFID and what it is; the reason why the topic was selected, its significance to the MD market, the aim of the study, what is in and out of scope and the research approach taken.

1.2 Medical Devices

The term "Medical device" covers a broad and diverse range of products. The European Union (EU) Medical Devices Directive (93/42/EEC) defines the term to mean:

"...any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means..."

1.3 Types of AIDC Systems

The following are types of AIDC systems (full definitions for each can be found in the glossary):

- "Bar Codes
- Radio Frequency Identification (RFID)
- Optical Character Recognition (OCR)...
- Magnetic Stripe
- Smart Cards..." (Agarwal, 2001)

This dissertation focuses on the first two: Bar Codes and RFID.

1.4 What is RFID?

The wide range of literature and publications available on RFID technology are consistent on what constitutes an RFID system, for the non-technical reader Wyld (2005:16) captures it simply as follows:

"Three elements are necessary for an RFID system to work:

- *Tags*
- *Readers*
- *Software/information processing*

In a nutshell, the technology works like this: The tag is the unique identifier for the item it is attached to. The reader sends out a radio signal, and the tag responds with a signal to identify itself. The reader then converts the radio waves returned from the tag into data that can be passed on to an information processing system to filter, categorize, analyse and enable action based on the identifying information."

1.5 History

RFID has been around for over 60 years (Datta, 2001:2), so generally it would not be considered an "emerging technology". But it "is moving into the healthcare world…" (Arcarese, 2005:1) and therefore, for the MD sector of healthcare, it is an emerging technology.

In the last few years interest in and use of RFID in the fast moving consumer goods (FMCG) supply chain has increased. Datta's table "What is 'new' about RFID? Evolution of RFID" (Table 1) indicates that this began in 1999, with "the hype curve" [Gartner, 1995] being driven in 2005 by US' Wal-Mart and Department of Defense "demanding suppliers use passive RFID".

The initial driver in healthcare came the same year when Florida, then California and Nevada, drafted the "Pedigree" law, due to come into effect in 2007 (Dana Barlow, 2005), aimed at preventing counterfeit drugs entering the pharmaceutical supply chain and at improving patient safety. This law requires pharmaceutical manufacturers, and any subsequent handlers of the "tagged" product, to be able to prove the "Pedigree" of that product.

1.6 Topic selection

RFID is a "hot" topic and there is an assumption that, at some point in the future, MD manufacturers will be requested or required through regulation to tag product in the context of improving Patient Safety (Crotch-Harvey, 2005:10).

However, a cause and effect link between RFID tagged MD and improvement in patient safety has not been tested or proven, the link and benefits are assumed. In addition, there is little, if any, evidence that the technology will work with MDs across both the diverse range of products and environmental situations, e.g. sterilisation processing.

Given the size of the market (1.) and the volume of individual items, the cost of the "three [necessary] elements" (Wyld, 2005) alone, for both manufacturers

and healthcare establishments, is likely to be significant. And it may be that existing AIDC technologies, e.g. Bar Codes, or process efficiency improvements in the healthcare establishments could achieve the desired improvements in patient safety.

The distinguishable lack of tangible evidence in the literature (Chapter 2) confirms that these issues have not been fully researched and therefore, there is potential for RFID to be implemented based on assumptions and ultimately failing to "assist in greater patient safety" (Ibid).

This topic needs to be researched and tested more thoroughly so that all stakeholders can make rational and informed decisions. This dissertation aims to begin this process.

1.7 The Aim of the dissertation

The aim of this dissertation is to attempt to provide an answer to the hypothesis:

"Medical Device manufacturer applied or embedded RFID has benefits to Patient Safety over existing AIDC technologies, e.g. Bar Codes."

It will also begin to fill the literary gap and provide a "vital and relevant" (Rose, 2006) piece of research to the MD market that:

- Increases understanding of the benefits of tagging MD in comparison to existing AIDC technologies (specifically Bar Codes),
- Assists in informing and influencing the national and international public bodies driving this agenda, and
- Assists key stakeholders in the MD industry in identifying which MDs should be priorities for AIDC pilots to deliver greater patient safety.

"What is 'new' about RFID? Evolution of RFID

1940	1950	1960	1970	1980	1990	2000
RFID born out of Radar effort (WWII)	**RFID crawls out**	**Theory of RFID, field trials planned**	**Early adopters implement RFID**	**Commercial RFID endeavours sprout**	**Many RFID standards emerge**	**RFID Hype peaks**
1948: Harry Stockman invents RFID. Publishes paper, "Communication by means of reflected power"	1950: D B Harris patents RFID. "Radio Transmission systems with modulatable passive responder"	1963-1964: R F Harrington advances theory with "Field measurements using active scatterers" and "Theory of loaded scatterers"	1973: Raytheon's "Raytag"	1982: Mikron founded; bought by Phillips	1991 TI creates TIRIS to develop and market RFID	2003: UPC and EAN forced by US retailers to promote EPC
	1952: F L Vemon "Application of the microwave homodyne"	1966: Commercialisation of EAS, 1-bit Electronic Article Surveillance	1975: Los Alamos National Lab (LANL) releases RFID research to public sector, publishes "Short-range radio-telemetry for electronic identification using modulated backscatter"	1987: First RFID road toll collection implemented in Norway	1992-1995: Multi-protocol traffic control and toll collection implemented in Texas, Oklahoma and Georgia (USA)	2005: Wal-Mart and US DoD fuels the hype curve by demanding suppliers use passive RFID and EPC.
	1959: Identification of Friend or Foe (IFF) long-range transponder system reaches breadboard demonstration stage.		1976-1977: LANL RFID spin-offs Identronix and Amtech		1998: David Brock and Sanjay Sarma of MIT publishes an idea: "Internet of Things"	
			1977: RCA develops "Electronic identification system"		1999: Auto-ID Center created at MIT. Retailers drive to standardise EPC	
			1975-1978: Raytheon, Fairchild & RCA develop RFID		Vast number of RFID companies and 'short-sight' enters the market.	

Modified from: Han Pang Huang, National Taiwan University" in Datta (2001)

Table 1

1.8 The Scope of the dissertation

1.8.1 In Scope

- MD market
- AIDC technologies, specifically Bar Codes and RFID, applied to / embedded in MD
- Achieving greater Patient Safety related to MDs

1.8.2 Out of Scope

- Supply chain efficiency applications
- RFID technology per se and its effectiveness
- Physics issues related to RFID with MDs
- Radio Frequency standards
- Data protection / Privacy issues

1.9 Research approach

The research approach taken was a two-stage process. The first stage involved a search and subjective review of recent literature (Chapter 2). The output of the review led to formulation of the research hypothesis (1.6) and questions (3.3). The fieldwork, in the form of one-to-one interviews with key stakeholders and an on-line Questionnaire of the wider stakeholder community, constituted the second stage of the research process. The findings from the research combine to result in the conclusions and recommendations (Chapter 6).

The inductive, "building theory" (Saunders et al 2003:87) approach has been used as it is "more flexible" than the deductive approach, "permits changes of research emphasis as the research progresses", is "particularly concerned with the context in which such events [are] taking place" and because it is appropriate for "a topic that is new, is exciting much debate and on which there is little existing literature"

A stakeholder analysis was undertaken (5.1), to “get a feel of what was going on, so as to understand better the nature of the problem” (Ibid), and a sample number of key stakeholders were selected and invited to take part in a one-to-one interview with the author (5.2). Analysis of the interviews formed the basis for an on-line questionnaire (5.3) that was sent to a full and wide range of stakeholders (circa 270 contacts).

1.10 Objectives

1.10.1 Henley's Objectives

The objectives set by Henley Management College for the dissertation stage of the MBA are outlined as follows:

1. Create a proposal
2. Structure and carry out an investigation which generates new ideas/data
3. Confirm, consolidate and test MBA learning, linking theory to practice
4. Select other appropriate information/data sources
5. Exhibit capability to apply research method(s)
6. Demonstrate critical thinking and insight
7. Design, write and present a dissertation, in which the presentation enhances the contribution to knowledge
8. Undertake retrospective reflection.

1.10.2 Johnson & Johnson's Objectives

Johnson & Johnson (J&J) is the world's most comprehensive and broadly based manufacturer of health care products; the business is structured around three market sectors: Consumer, Pharmaceutical and Medical Device and Diagnostics (MD). In the context of this dissertation (RFID), J&J's objectives are:

- Sustain our Credo
- Increase Customer Satisfaction
- Reduce costs
- Improve productivity, quality and safety

1.10.3 Personal Objectives

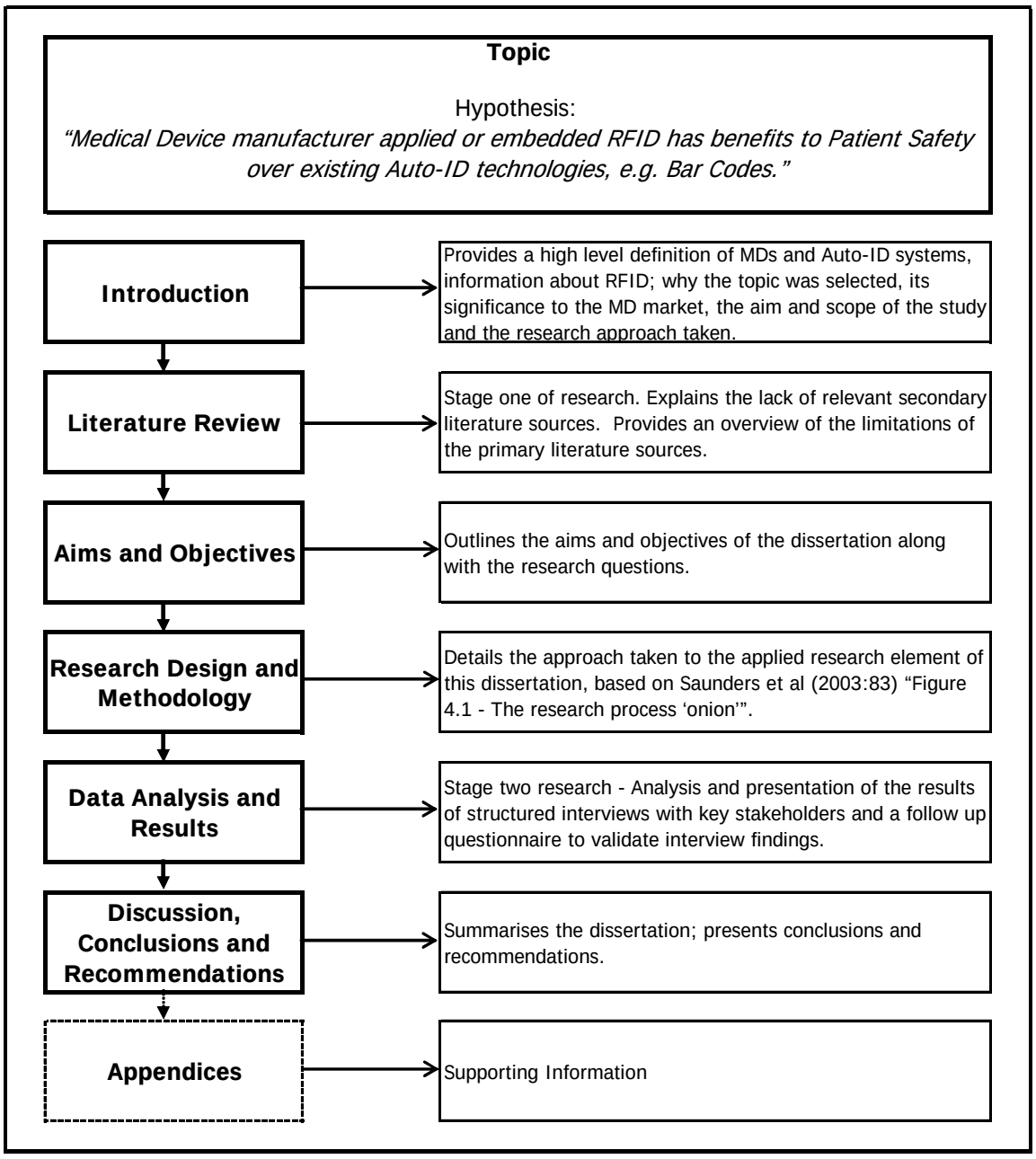
The author has an overall objective of obtaining "A senior European change management leadership role; that is strategic, collaborative, consultative and relationship-building" (Author's development plan, 2006).

A common thread throughout the author's career has been positions at various stages of the extended value chain, with the trend of moving closer to the external/economic customer. The chosen topic continues this thread and is related to an interest in enabling technologies, whilst being directly related to

the strategic eCommerce element of her current role. Undertaking this research should contribute to the broadening of her knowledge and understanding of medical device industry beyond Johnson & Johnson (J&J) and United Kingdom.

The dissertation process will be the first formal opportunity to undertake academic research, developing new skills; and it will also provide opportunity to further develop both internal and external networks and assist the author in achieving her overall objective as outlined above.

1.11 Structure of Dissertation



170 words

Table 2

2. Literature review

This chapter covers stage one of the research. The first section (2.1) explains the lack of relevant secondary literature sources, followed by an overview of the limitations of the primary literature sources - although primary literature is the predominant literature source for this review.

RFID technology has been around for 60 years and there was a wide range of literature available; a Google search returned 270 million items! The search for literature sources was therefore restricted to the time period from 2000 to date.

However, there was a distinguishable lack of literature that was specifically focussed on the adoption and use of RFID with MD, this significantly influenced the literature review, making it somewhat challenging.

2.1 Lack of Secondary Literature Sources

A search specifically for books on RFID produced a range of titles, however, the vast majority were concerned purely with RFID technology itself (out of scope, 1.6.2.), e.g. a recent publication: "RFID Essentials" (Glover & Himanshu (2006)).

Although, at the same time Aelbrecht & McIntyre published "Spychips: How Major Corporations and Government plan to track your every move with RFID", a non-technical publication, the title warning of the potential impact of the use of RFID on individuals, i.e. the collection and use of information about them, commonly termed "Privacy" or "Data Protection". Although privacy concerns and understanding of individual rights have increased over the last few years the book's relevance to this paper was out of scope (1.6.2.). However, despite being out of scope for this work, it is a key concern in healthcare due to the very personal nature of the information collected, held and used; and the topic will require further research even though it is the opinion of one of the interviewees (Torelli, H 2006) that as understanding and use of RFID increases the current high level of concern will lessen.

In an effort to uncover concepts or models that may be relevant and applicable to "an emerging technology in healthcare", the search topic was modified to "emerging technologies". "Wharton on Managing Emerging Technologies" (Day & Schoemaker (2000)) promised to be useful but was written from the perspective of organisations 'developing emerging technologies' to market and sell, as opposed to the perspective of potential users trying to understand whether the emerging technology was relevant and/or useful to their business, products and/or market.

Internet searches of reputable databases (e.g. EBSCO) were more successful and resulted in more than 30 literature items. However, upon review, approximately two thirds of these items were found to be of little or no relevance to this subject, e.g. "RFID in Action" (IDTechEx, 2005) – although it is an interesting collection of RFID case studies, none of them related to MD.

This is contradictory to the view expressed by Saunders et al (2003:51) in "Research Methods for Business Students" which states, "The number of secondary literature sources available to you is expanding rapidly"!

2.2 Primary Literature Sources - Limitations

The sources used for this literature review are, therefore, predominantly primary: reports, white papers, presentations and some government publications.

Even so, of the range of literature sources identified, the majority focused on RFID adoption and implementation in the fast moving consumer goods (FMCG) supply chain (e.g. Agarwal, 2001); and even the more recent literature identified, by including "healthcare" in the search topic, focussed on pharmaceutical supply chain applications, resulting from the US "Pedigree" laws, due to come into effect in 2007 (Dana Barlow, 2005); with a few items on RFID use for tracking patients in hospitals (Law, 2005:5; Anon., CNN.com, 2005), but little specific to applications with MDs. Whilst it is likely that there will be general lessons to learn, from the applications and experiences in FMCG

and Pharmaceutical, the conditions in MD are different and may not universally apply, e.g. sterilisation.

Hefflin (2005) experienced the limitations of literature sources, he says:

"While there is a growing body of peer-reviewed literature related to automatic identification technologies and pharmaceuticals or transfusion safety, there seems to be very few studies in the peer reviewed literature related to applications for automatic identification of medical devices, particularly with relation to patient safety."

2.3 A Review of Relevant Primary Literature Sources

However, there were some literature sources that were relevant and these are reviewed here.

The following sections relate directly to the key attributes of the hypothesis, namely:

- Medical Devices — The market context (2.3.1.)
- Auto ID Technologies — The technology under consideration, specifically Bar Codes and RFID, (2.3.2)
- Patient Safety — The desired outcome (2.3.3)

2.3.1 Medical Devices – The Market Context

As mentioned in the Introduction the term "Medical device" covers a broad and diverse range of products in an industry that "is one of the most regulated industries in the world", resulting in a highly complex market. Two key items of literature assist in understanding this complexity, but in reality they only scratch the surface of the complexity of this market:

A marketing brochure produced by Eucomed (2004), the European Association of the Medical Technology Industry, explains that MDs[1] are "aids for disabled persons, e.g. wheelchair… active and non-active implantable devices, e.g. stent… hip implant… anaesthetic/respiratory equipment… orthopaedic equipment… dental devices… electromedical and imaging equipment, e.g. x-ray… in-vitro diagnostics, e.g. genetic tests… ophthalmic equipment, e.g. contact lenses… surgical instruments, e.g. scalpel, forceps… biotechnological products, e.g. tissue engineered bone… medical disposables, e.g. bandage…"

And, from a regulatory point of view, stated in a survey report for Advamed (the US association representing manufacturers of medical devices, diagnostic products and medical information systems), the Food & Drug Administration (FDA (US)) "reviews MDs based on three "classes" which are risk based":

- Class III devices … "present the highest risk to the user". These types of devices are often those that support or sustain life.
- Class II devices… "present generally lower risk", therefore they are subjected to less rigid scrutiny.
- Class I devices… "present little or no risk to the user and many can be used without medical advice or supervision… [and] are sold in the retail supply chain". (Longe 2004)

The analysis (ibid) indicates the split of medical device products across the three classes to be Class I – 64%, Class II – 34% and Class III – 2%. Although the author would suggest that if percentages were available for each Class related to complexity of products then they would be the reverse, i.e. Class I would be a low percentage as the products are things such as bandages (little complexity) whilst Class III would be a high percentage as the products are those such as coronary stents (http://www.cypherusa.com) "…designed to open up your arteries and keep them open…"

1 NOTE: According to interviewees (Crowley, J., Ferriter, A.) from the FDA, the classification of MD by the European Union and the FDA differ: "[the classification] is similar, it is not the same. There is a lot of overlap, but there are some differences". In the context of this dissertation these differences are assumed to be immaterial.

2.3.2 The Technology - Auto ID

As previously mentioned (2.1) there was a wealth of sources available focused purely on RFID technology and the other AIDC technologies themselves. In the context of this dissertation a low level technical understanding of the technologies being discussed is required and Furness (2005) and Wyld (2005) are the key sources used to provide this for Bar Codes (2.3.2.2) and RFID (2.3.2.3) respectively, as they are easily understandable by the non-technical reader.

2.3.2.1 Types of Auto ID Technologies

Figure 1 below (Wyld, 2005:9) is included as it outlines the range of AIDC systems. For this dissertation, the focus is on RFID and Bar Codes (but full definitions for each of the AIDC systems shown can be found in the glossary):

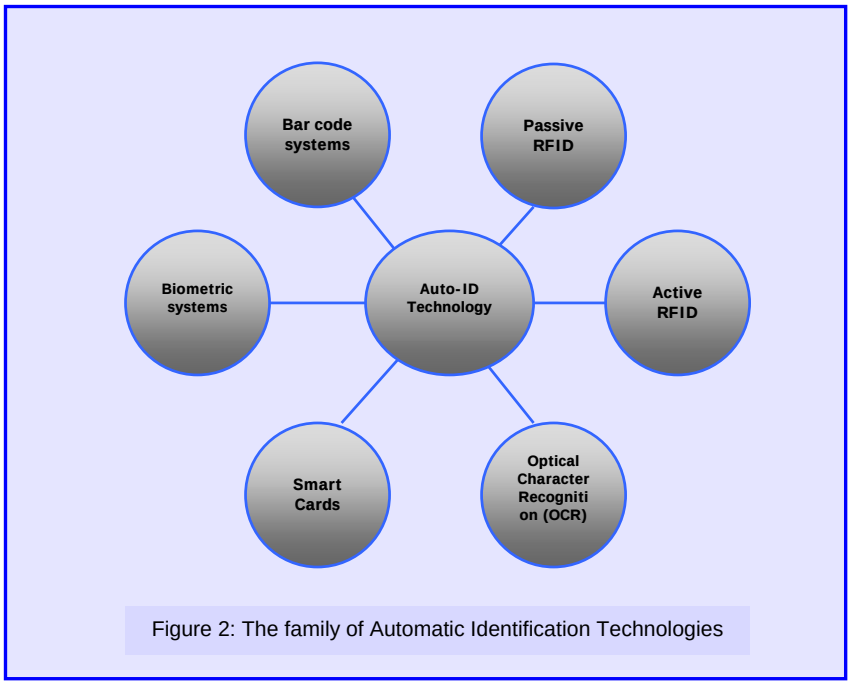


Figure 2: The family of Automatic Identification Technologies

Figure 1 25 Words

2.3.2.2 Bar Codes

Wyld (2005) and Phillips (1997) state that Bar Codes are "ubiquitous" and, empirically, they are visible on most items in every day use. However, this is certainly not true for MDs; the purpose of the Advamed survey (Longe, 2004) was to determine the uses of AIDC Technology across the entire MD supply chain. For Bar Codes, the results showed that 78% of Advamed members are bar coding products (Figure 5:9) but "...there appears to be [a] lack of consistency on the packaging levels... where bar codes are applied. ...less than 45% of unit-of-use products... are bar coded. Thus, currently hospitals considering scanning at bedside... will have to be prepared to apply bar codes to approximately 55% of unit-of-use products." This survey is, at most, two years old and clearly indicates that currently Bar Codes are not 'ubiquitous' in MD.

Wyld outlines the different types of AIDC technologies (Figure 1) and RFID technology is covered extensively, but little space is given to the various types of Bar Codes available; only the linear bar code is depicted (Figure 3:11). Whereas Furness' (2005:17) "Annex 1 The AIDC technologies", provides a comprehensive review of the range of AIDC technologies, including the various types of bar codes, identifying their uses, attributes and limitations. Because of its focus the use examples are specifically healthcare and he states, "Linear bar coding ... is the most widely used AIDC technology in healthcare". "Two-dimensional... codes... can be effectively applied for small items marking" and a specific version of the same (Multi-row bar codes) "...have been trialed on blood packs complementary to and as an alternative to linear bar codes."

From Longe, it could be inferred that if all MD manufacturers used bar codes on all packaging levels this would bring benefits to the organisations using these products, e.g. hospitals, as well as negating the need for the hospitals to apply bar codes themselves. But until the hospitals are being seen to increasingly use the manufacturer's bar code (Flynn, 2005 – 2.3.2.4.); it is unlikely that all MD manufacturers will apply bar codes consistently and at unit of use level.

From a cost perspective they are “inexpensive to implement in a reliable and flexible manner…” (Phillips, 1997:1). But should that lead to manufacturers of MD being encouraged or mandated to use Bar Codes? The US and European MD trade associations, Advamed and Eucomed respectively, appear to have differing general opinions:

"Eucomed recommends that all parties involved in the manufacture of, and use of, medical devices should implement bar code technology to improve patient safety and provide quality data whilst minimising supply chain costs… Applying bar codes to medical devices has a two-fold impact: it increases patient safety and makes the supply chain more efficient for everybody.” (Eucomed, 2004)

Whereas Advamed states that a “Mandatory bar code rule for medical devices will increase cost and complexity for users, with little assurance of improving patient safety.” (Advamed, 2006)

Neither Eucomed nor Advamed provides evidence to support their hypotheses. Hence this dissertation, the particular findings of which should provide evidence either in support of or to contradict either or both hypotheses.

2.3.2.3 RFID

As mentioned above, the vast majority of literature sources were concerned purely with RFID technology itself (2.1) and nothing particular to applications with MDs (2.3); Wyld’s (2005) non-technical definition of RFID was previously covered in the Introduction (1.3). But another source concerned with the technology proved insightful: “A feasibility study of new RFID applications” (Johansen & Storm, 2004).

They suggest that RFID “…technology has matured considerably during the recent years. Development on integrated circuits has boosted research on new RFID tags and readers” it could be assumed this is the reason why “the hype

curve" (Datta, 2001:2) is being experienced in the FMCG and Pharmaceutical supply chains. And, based on their findings, they established "an [RFID] Evaluation Framework" using "suitable parameters... such as:

- Technical selection criteria for the RFID components to be evaluated for an RFID application
- Requirement for standardisation
- Are frequencies within regulated frequency bands – regulatory issues
- Requirements for security features
- The application's impact on consumer [patient] privacy and ethical considerations
- External factors as the price of tags and the number and value of the items to be tagged"

They use 36 'suitable parameters' in total and, in their conclusion, they apply the general "Evaluation Framework" to five particular application examples, e.g. "Asset tracking of important or valuable objects", these are summarised in their Tables 47 and 48 (p. 77-78).

This 'Evaluation Framework' is a comprehensive and potentially powerful tool that is logically structured and useable, and this author would agree with Johansen & Storm that, "by using [their] framework, any organisation will get an insight whether their own new RFID Application will have good prospects of becoming successful in the future". This framework has potential to be used effectively to assess RFID technology's applicability with MDs in particular situations. This view is reinforced in Dana Barlow (2005) where he states "...Technology [choices] should be driven by the applications you are trying to address..."

In relation to cost he continues on to say that "Trying to pin down the actual cost of implementing RFID technology and comparing that cost to implementing

bar code technology can be tricky." Until there are case studies particular to implementing RFID technology with MDs, making comparison with bar codes based on cost is going to be impractical.

2.3.2.4. Comparison: Bar Codes and RFID

Bar codes, although widely used, are not ubiquitous in healthcare and particularly not in MD, despite the general assertion that they are "inexpensive to implement". And for RFID very few examples of use with MDs were identified (5.2.4. and 5.3.4).

Flynn, quoted in Healthcare Purchasing News (Reiner & Sullivan, 2005) suggests that bar codes and RFID are "...not competitive technologies. They're highly complementary." Controversially he goes further to question "A healthcare facility will say they want to use RFID and not bar codes. Well, why? ...What makes healthcare facilities think they can be successful with RFID when they haven't fully adopted bar coding into their operations?"

These comments are reinforced in "Bar Coding's Replacement" (Roark & Miguel (2006)) where they state, "Despite the pervasiveness of bar codes in retail and other industries... healthcare has been the one industry slow to adopt bar code technology... Bar codes presently cost significantly less than RFID tags. In addition, RFID tags require a marked infrastructure investment of [readers] installed every 50 feet in the hospital..."

Although evidence is not presented to support their statement that "Bar codes presently cost significantly less..." the fact that a high percentage of MD manufacturers are bar coding their products (Longe, 2004) and that they could be utilised easily in hospitals equipped with hand-held readers (e.g. Alinco DJ-X3 £70.00 on www.ebay.co.uk!), when compared to the current price of RFID tags ("Expect to pay from US$0.85 to over US$1 per tag" (www.biblio-

tech.com, 2006)) alone (without considering the infrastructure that would be required in the hospital (Wyld, 2005)), this statement is probably true.

But neither article considers why bar codes haven't been fully adopted. Not even Furness' highly critical, yet thorough review of NHS ability to adopt RFID/Auto-ID tech, considers the 'why'.

In addition, there are a number of other issues to be overcome with both technologies, for example:

a. For Bar Codes:

- If present, the issues are mainly to do with the quality of the code itself that can impact effective scanning, e.g. "Bar codes cannot be read if they become dirty or damaged" (Wyld, 2005:12). Even where bar codes are ubiquitous the quality issues are encountered. This lack of quality is unlikely to be tolerated in the risk-averse environment of MD.

b. For RFID:

- Physics issues to be overcome, specifically in relation to MDs. An article on UsingRFID.Com (Anon, 2005) stated, "As we all know, liquids and metals usually interfere with RFID tag operation. ...the problem of tagging metal parts/containers and liquid-filled packages presents a distinct reliability problem... meaning that metallic or liquid contents are usually considered unsuitable or at least critical for RFID labeling." But this comment is most likely related to FMCG not MD and the author would argue, through interaction with RFID providers, their appreciation and detailed understanding of these issues in the MD context is generally lacking.

- Radio Frequencies differ across the world, e.g. “Europe uses 868 MHz for UHF systems and US uses 915 MHz” (Wyld, 2005), although work is progressing on harmonisation.
- Read rates of tags – although “the suppliers of the RFID tags claim they can read 100%… in reality there is a fail rate of between 20-30%” (Interviewee, Jensen, R). To put this in context, a quote in Advamed (2006) powerfully highlights the impact of a 0.1% read rate failure:

"Food for thought: If 99.9% were good enough: There would be a major plane crash every 3 days; 12 babies would be given to the wrong parents each day; There would 37,000 ATM errors every hour (Source: Institute For Healthcare Improvement)”.

The read rate accuracy is critical to healthcare because of the implications, e.g. if a tag on a drug fails and it cannot be confirmed that it is the right drug for that patient, and the drug is administered, the consequences (e.g. wrong drug, wrong dose) could be the death of the patient.

c. For both Bar Codes & RFID:

- Standards, the most widely used is the GS1 System (GS1 is a worldwide network that specialises in cross-sector supply chain standards from bar coding to electronic business communications); but MDs have their own standard, the Health Industry Bar Code (HIBC). Some manufacturers use GS1, others HIBC, a few use both (e.g. J&J). Also, Arcarese (2005) presented evidence that “Some organisations use their own barcodes to put over manufacturer/supplier bar code”. Lack of a single standard makes tracking and traceability extremely difficult across an extended and increasingly global supply chain, from manufacturer to patient bedside.

For the purpose of this dissertation it is assumed, perhaps over optimistically (certainly by RFID providers), that these issues will be overcome in time; e.g. in relation to the physics issue with metal, the UsingRFID.Com article (Op Cit) highlights that "Paxar has come up with its own solution... the idea is to simply use air as a spacer between the tag and the item being tagged... SpaceTag." But the author is assuming that it hasn't yet been tested with a MD!

To summarise the comparisons between Bar Codes and RFID, Table 1 in Hefflin (2005) was taken, adapted and augmented with additional items from other literature sources, resulting in Table 3 below.

But, probably the most succinct analogy to conclude this section is from Argawal (2001:11):

"The race between [RFID] and bar code[s], at the moment, is a little like a contest between a submarine and a bicycle [Bert Moore, June 1999]. The submarine is not much of a threat on dry land, and the bike is not going to be very useful in the ocean. In other words, it is less a contest between technologies than it is a difference between visions..."

Comparison of Bar Code and RFID Technology

Parameter	Bar Code Technology	RFID Technology	RFID benefit over Bar Code (Author's view)	Literature Source
Transmission type	Optical	Radio Frequency; Electromagnetic	Yes: Increased efficiency – e.g. Potentially negating manual intervention and increasing speed.	Hefflin, 2005:Table 1; Johansen & Storm, 2004:5
Position of label/tag compared to reader	Line-of-sight, specific orientation	Non-line-of-site, not typically orientation dependent		Hefflin, 2005:Table1; Wyld, 2005:12; Crotch-Harvey, 2005:6; Johansen & Storm, 2004:5
Read Range (Typical)	Up to a few feet; A few meters	A few inches to 4 feet (passive tags), more than 100 feet (active tags); 10-20m with active tags		Hefflin, 2005:Table 1; Johansen & Storm, 2004:5
Maximum Read Rate	One per scan	Up to 1000 tags per second		Hefflin, 2005:Table 1; Wyld, 2005:12; Crotch-Harvey, 2005:6;
Tracking	Bar codes must be manually tracked for item identification	RFID tags can be automatically tracked, eliminating human error.		Wyld, 2005:12; Crotch-Harvey, 2005:6;
Accuracy	….making human error an issue; Manual scanning; Reduced accuracy	High degree of accuracy; Improved accuracy		Wyld, 2005:12; Crotch-Harvey, 2005:6; Evans & Piechowski, 2005:12;
Resource	*Human required for manual scanning for every read.*	*Real-time, no human resource necessary*		Crotch-Harvey, 2005:6; Agarwal, 2001:11;
Tag programmability During Use	No	Yes, if WORM or read/write	Yes: Increased effectiveness, e.g. more data can be held and updated	Hefflin, 2005:Table 1
Level of ID	Bar codes can only identify the type of item	RFID tags can identify a specific item		Wyld, 2005:12; Agarwal, 2001:10;
Updates	Bar code information cannot be updated; Read only;	Electronic information can be overwritten repeatedly on RFID tags		Wyld, 2005:12; Evans & Piechowski, 2005:12; Agarwal, 2001:11; Johansen & Storm, 2004:5
Data held/capture; volume	*Limited data (type of item);* 1-100 bytes	Tags can potentially contain a greater amount of data; 128-8KB		Agarwal, 2001:11; Johansen & Storm, 2004:5
Anti-collision (ability of reader to read more than one code)	Not possible	Possible	No: Could impact the effectiveness benefits given above.	eJNJ, 2005
Environment	Bar codes cannot be read if they become dirty or damaged; *Considerable susceptibility;*	RFID tags are able to cope with harsh and dirty environments; *Little susceptibility*	Debatable (see 2.3.2.4.)	Wyld, 2005:12; Agarwal, 2001:11; Johansen & Storm, 2004:5
Robustness	Easily damaged	Greater protection		Evans & Piechowski, 2005:12;
Symbologies or Tags appropriate for small items	Yes	Yes	Debatable: French case study (surgical instruments (See 5.2.4.)	Hefflin, 2005:Table 1
Cost	Low cost	Higher cost	Depends on pay back period and other tangible benefits realised.	Evans & Piechowski, 2005:12;

Adapted from Hefflin (2005:Table 1) *Author's italics*

Table 3

2.3.3 Patient Safety – The Desired Outcome

The introduction to this dissertation opened with “Healthcare is an industry where patient safety comes first”, but it was recognised, in the English National Health Service (NHS), that “there [was] no systematic recording… of what goes wrong…” (Crotch-Harvey, 2005) A document published by the NHS in 2001 (“Building a Safer NHS for Patients”) resulted in the establishment of the National Patient Safety Agency (NPSA) (Ibid).

Some of the statistics that are quoted are “Adverse events occur in around 10% of acute admissions, or at a rate of 850,000 per year. Adverse events cost approx £2 billion/year in hospital stay alone… There are 44,000 deaths of which 20,000 could be avoidable…” (Ibid) These statistics illustrate why Patient Safety is a key focus area in healthcare.

This was confirmed as one of the “main points” in a briefing from the NPSA that stated, "The DH [Department of Health] expects patient safety to be the driver of the auto-ID project ("patient safety is the theme that unites it all")” (Ranger & Cousins (NPSA), 2006)

The author made an enquiry to the NPSA (May 2006) with regards to the percentage of adverse incidents related to MDs, in an effort to assess how far down the list of NPSA priorities such product related incidents would be. The NPSA subsequently provided information for December 2005-April 2006 that showed “There were 8849 cleansed incidents relating to medical equipment out of a total of 263,912 reports. This equates to 3.35% of all incidents reported in this time period related to medical devices incident reports” and concluded that “The picture in relation to medical device related reports is showing… a consistent % of the total reports submitted…” (Stevenson, 2006). Given the small percentage quoted, the author has assumed that MD related adverse incidents fall towards the low end of the total of all types of adverse incidents. This assumption is made in relation to a statement in “Right patient – right

care" (NPSA, 2004:2) that cites patient matching errors "form a significant part of the whole range of errors in health care" although no numbers or percentages are provided.

The NPSA categorise incidents by "degree of harm (severity)" (Stevenson, 2006), starting with "No Harm" then Low, Moderate, Severe and Death. For MDs, table 4 below (4, Ibid) shows the two most severe categories ("Severe" and "Death") and the number of reported incidents for each; further analyses in the report states that 21% of the MD incidents relate to "Pump Malfunction" and 20% "...to non-availability of equipment. In the interviews and the questionnaire it will be explored which MDs stakeholders would prioritise to tag and if they correlate with these products and the reasons for the incident.

"...reported outcome by reported category

	Deaths	Severe
Failure of device	9	61
Lack of/unavailability of device	2	29
User Error	0	10
Other	0	2 "

(Table 5, Ibid)

Table 4

Overall, the literature sources concur that Patient Safety is the key driver for embedding in or applying to RFID MDs; it is cited in a high number of them (e.g. Advamed, 2002 & 2006; Arcarese, 2005; Collins, 2005; Crotch-Harvey, 2005; Evans & Piechowski, 2005; Furness, 2005; Hefflin, 2005; Longe, 2004; Morgan, 2005; NPSA, 2004; Range, 2005 & 2006; The Patients Association, 2005; Reiner & Sullivan, 2005). However, it appears that the examples cited are based on an assumption that there is a positive cause and effect link between tagging of MDs and greater patient safety. For example:

“Surgical instruments and other devices must be properly cleaned and packaged between uses. Tags on the instruments and readers on the sterilisation chambers and storage cabinets can validate proper cleaning and help locate needed instruments.” (Reiner & Sullivan, 2005) This example takes no account of the recognised physics issues with RFID, e.g. metal and the various sterilisation processes that ‘fry tags’ (Interviewee: Jensen R.), neither does it explain how tags on chambers and cabinets will “validate proper cleaning”, or how/where a record of the cleaning would be held and subsequently retrieved (6.4.2.).

Other examples make the same assumption and they too provide little explanation of how greater patient safety would actually be achieved, the processes involved and no tangible evidence, real examples or pilots are quoted where RFID has been used with MD. The lack of real examples or pilots is explored through the interviews (5.2.4.) and questionnaire (5.3.4.).

The report of the meeting between the FDA and Advamed (Longe, 2004) introduces an element of reality, albeit referenced to bar codes, “bar coding can provide benefits both for patient safety and for improved supply chain efficiency...” but acknowledges that “...patient safety benefits would be realised less frequently for device use than for drug use."

Arcarese (2005) expands on this by suggesting, “A single identification technology for all devices is probably impossible... Not all devices would benefit to the same extent from a unique identification system in terms of patient safety (e.g. an implant vs. a bandage).”

Whilst neither Longe nor Arcarese provide tangible evidence to support these comments, the comments do indicate an understanding of the diversity and complexity of MDs and their environment in relation to the application of AIDC.

2.4 CHAPTER SUMMARY

The MD market is highly complex, with a broad and diverse range of products. The literature supports the assumption that the key driver for the use of AIDC technologies with MDs is Patient Safety.

Literature related to AIDC technologies, specifically focusing on bar codes and RFID, have been researched and a range of attributes for each compared (Table 3). Whilst it would be difficult to definitively state for each attribute whether RFID has potential benefits over bar codes when used with MD, the author has included a column that indicates where these potential benefits could be realised. In addition, overall, there is broad agreement that both Bar Codes and RFID:

- have their "own set of strengths and disadvantages" (Hefflin, 2005:13);
- are not universally applicable to all MDs or to all applications: "In some cases, one technology may be the preferred solution over the other; in other cases, both technologies may be used in combination to achieve a particular goal." (Ibid)
- the technology selected should address a particular business problem; no AIDC is a panacea, it's "A Tool, Not a 'Magic Bullet' ... it is a technology that is a building block that can be used to construct a solution." (Haldane and Eischents, 2005 (in Wyld, 2005:31))
- technology takes time to implement and reap the benefits: "RFID has the potential to be a revolution in the supply chain, but not yet. Ten years may be a bit aggressive for RFID to be ubiquitous. It will be closer to 15 years – half as much time as it took bar codes" (Boone (in Wyld, 2005:33))

The literature provided a wide range of sources that cited Patient Safety benefits with the use of RFID, but all were based on assumption, no tangible evidence was identified that showed a cause and effect link between RFID use and greater Patient Safety. Numerous examples of possible scenarios were

provided throughout the literature, but case studies and results were lacking. And none of the literature considered why the ubiquitous bar code was not ubiquitous in healthcare; until or unless the 'why' is understood, the same fate may await RFID.

Does the literature provide tangible evidence to answer to the hypothesis?

No, but there are themes and concepts, such as the categories listed in Arcarese (2005), that informed the questions put to key stakeholders in the research interviews and the subsequent on-line questionnaire (Chapter 5). The themes and concepts from key authors are summarised in Table 5.

Summary of Themes and Concepts of Key Authors

Last Name	Initials	Year	Key themes / concepts used / referred to	Contrary views	Dissertation Link
Advamed		2006	Mandatory Bar Codes rule will increase cost and complexity (See Eucomed), Impact of 0.1% read rate failure**, Patient Safety**	Eucomed	Chapter 1: 1.5
Agarwal	V	2001	RFID in FMCG, Analogy - submarine & bike		Chapter 6
Arcarese	J S	2005	"…moving into healthcare world…", Bar code over-labeling, **Patient Safety**, single ID technology for MD "impossible"		Chapter 5: Key driver; Issues
Collins	J	2005	**Patient Safety**		Chapter 5: Key
Crotch-Harvey	T	2005	Recording of what goes wrong - NPSA, Cost of adverse events, **Patient Safety**		Chapter 5: Key driver
Datta	S	2001	Table "What is 'new' about RFID? Evolution of RFID, 'the hype		Chapter 1:1.4
Eucomed		2004	Size of MD market, EU definition of MD	Advamed	Chapter 1:1.1
Furness	A	2005	Definitions and review of AIDC technologies, including Bar Codes and RFID + Comparison of the technologies, **Patient Safety**		Chapter 5: Key driver
Hefflin	B	2005	Limitations of lit., Table comparing bar code technology to RFID technology *(adapted by author)* - strengths and disavantages, **Patient Safety**		Chapter 5: Key driver
Johansen & Storm	T H & O	2004	Defines an evaluation [RFID] Framework, inc. 36 suitable		Chapter 6
Longe	K	2004	FDA Definition of MD, Split of products across 3 classes, Uses of AIDC in MD supply chain, Bar codes not ubiquitous in Healthcare (see Phillips; Wyld), **Patient Safety**, AIDC bring fewer benefits to MD than for pharma.	Phillips; Wyld	Chapter 5: Key driver; Issues. Chapter 6
Morgan	J	2005	**Patient Safety**		Chapter 5: Key
National Patient Safety Agency		2004	Patient and procedure ID key to patient safety improvements, **Patient Safety**		Chapter 5: Key driver
Phillips	J T	1997	Ubiquitous' bar codes (see Longe; Reiner & Sullivan; Roark & Miguel)	Longe; Reiner & Sullivan; Roark & Miguel	
Ranger	C	2005	**Patient Safety**		Chapter 5: Key
Ranger & Cousins	C & D	2006	"**Patient Safety** is the theme that unites it all"		Chapter 5: Key
Reiner & Sullivan	J & M	2005	Bar Codes and RFID are complementary technologies, **Patient Safety**, Surgical instruments	Phillips; Wyld	Chapter 5: Key driver
Roark & Miguel	D C & K	2006	Bar codes not ubiquitous in healthcare (see Phillips; Wyld)	Phillips; Wyld	
Stevenson	E	2006	Report of Adverse Incidents with MDs 05/06, **Patient Safety**		Chapter 5: Key
The Patients Association		2005	**Patient Safety**		Chapter 5: Key driver
Wyld	D C	2005	Non-technical definitions of AIDC technologies, including Bar Codes and RFID + Comparison of the technologies, 'Ubiquitous' bar codes (see Longe; Reiner & Sullivan; Roark & Miguel), issues with AIDC technology: e.g. frequencies, no AIDC is a panacea, 15 years before ubiquitous	Longe; Reiner & Sullivan; Roark & Miguel	Chapter 1. Chapter 5: Issues

Table 5

464 Words

The next chapter will discuss the research approach and detailed methodology used in the fieldwork research. But the following quote from Advamed (2002) concludes this, stage one of the research:

"It is important to note that automatic identification of medical devices is not a panacea to resolve either device-related medical errors or inventory management challenges. All stakeholders - FDA, hospitals, providers, risk managers and manufacturers - must recognise that coding is but one piece of an overall system that requires a commitment to scan products, update code information, and analyse data if benefits are to be realised... Increased patient safety may be attainable for only a subset of medical devices, depending on the nature of the device and its use in a clinical setting."

(Advamed, 2002)

3. Aims and Objectives

This chapter outlines the aims and objectives of the dissertation along with the research questions.

3.1 Aims

In the context that RFID is a "hot" topic in healthcare in relation to Patient Safety (1.6; Crotch-Harvey, 2005:10) ideally, the aim of this dissertation was to definitively prove or disprove the hypothesis outlined in 1.7. However, due to the range and complexity of MDs (Eucomed, 2004; Longe, 2004) and the healthcare market (e.g. Sokol and Shah, 2004), doing so was improbable.

3.2 Objectives

The objectives (1.7) of the dissertation were to:

- Provide the medical industry with a "vital and relevant" (Rose, 2006) piece of research to begin to fill the literary gap (2.1; 2.2; Hefflin, 2005)
- Assist in informing and influencing the public bodies driving this agenda (2.3.3; NPSA, 2001; Ranger & Cousins (NPSA), 2006; Longe, 2004)
- Increase understanding of whether or not tagging MD delivers greater patient safety over existing AIDC (Arcarese, 2005; Hefflin, 2005:13; Longe, 2004; Table 3 in 2.3.2.4), and
- Assist key stakeholders in the MD industry in identifying which MDs should be priorities for AIDC pilots to deliver greater patient safety (2.3.3; NPSA, 2001; Ranger & Cousins (NPSA), 2006).

3.3 Research Questions

The following are the research questions this dissertation aimed to answer:

- The notion of tagging MD to improve patient safety (1.6; Crotch-Harvey, 2005:10), is it theory (definition - Gill & Johnson (1997:178) in Saunders at al (2003:26)) or assumption?
- If theory, are there real examples that demonstrate a positive cause and effect link, e.g. pilots where RFID with MD has been specifically used with a link to greater patient safety? If so,
- Why was RFID used rather than other AIDC technologies, e.g. Bar Codes in this/these context(s)

- Or is it that the technology is “new” to this sector of healthcare, e.g. “hype”, and thus seen as a panacea?

Next, Chapter 4 discusses the research approach and detailed methodology used in the fieldwork research.

4. Research Design and Methodology

This chapter details the approach taken to the applied research element of this dissertation and is based on Saunders et al (2003:83) "Figure 4.1 - The research process 'onion'", recreated below (Figure 2)

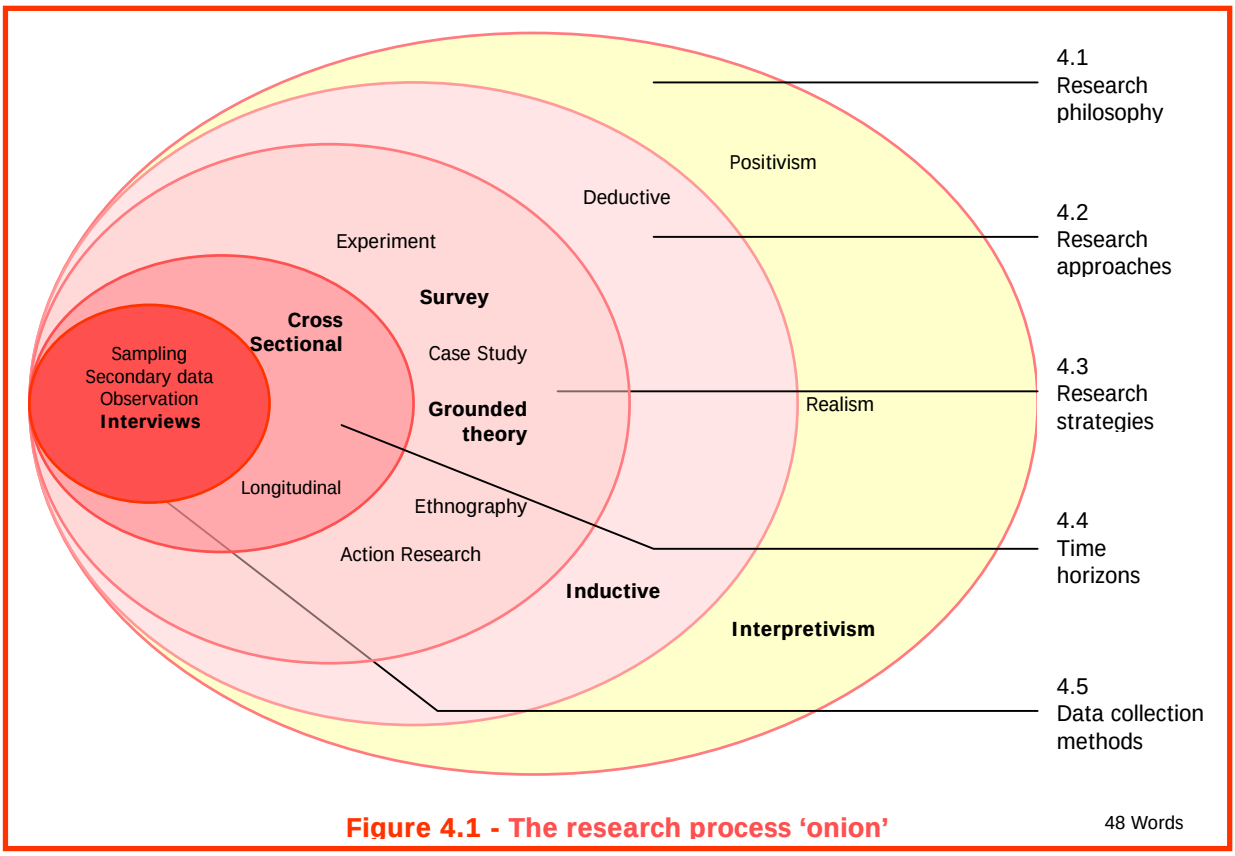


Figure 2

The different "layers" of the research process onion have been numbered in line with the subsequent sections of this is chapter and, within Figure 2, the elements selected have been emboldened:

4.1 Research Philosophy

Saunders et al suggest that the way individuals "unwittingly" think about the development of knowledge affects how an individual will approach doing research. There are three dominant research processes and "All three have an important part to play in business and management research." (Ibid):

- "Positivism" Remenyi et al (1998:33 (in Saunders et al: 84)) state, "the researcher is independent of and neither affects nor is affected by the

subject of the research". This process was not selected, as the author is involved in the topic area as part of her role.

- "Realism" It is suggested that there is "philosophical" overlap between realism and positivism, realism is more focused on social constructs and how they may affect "... the nature of people's views and behaviours". Whilst the human interaction element of technology should be considered (6.4.2), it is not the main focus of this dissertation; this process was not selected either. Therefore:
- "Interpretivism" was the process selected as the one most appropriate due to "the way [the author] think[s] about the development of knowledge" (Ibid:85) and "the necessity to discover what Remenyi et al (1998:35) call "the details of the situation to understand the reality or perhaps a reality working behind them"." Particularly as in this context it will be "necessary to explore the subjective [Patient Safety] meanings motivating people's actions in order to be able to understand these."

4.2 Research Approach

Although Saunders et al believe that making a link between a particular research philosophy and either of the two research approaches, deductive and inductive, "is potentially misleading and of no practical value", they do, in fact, link the deductive approach to positivism and the inductive approach to interpretivism. However, whilst it is acknowledged that this linkage could affect the choice of research approach, here the choice was based on further explanation (Ibid) that this approach is about:

- "building theory" (Ibid:87)

  Throughout the literature (Chapter 2) there is an assumption that tagging MDs will lead to greater patient safety, but a theory has not been formulated to show the cause and effect relationship between RFID technology and patient safety and there is little, if any evidence, of case studies to test this assumption. As well as attempting to build theory on this relationship, this dissertation is also attempting to build theory on advantages of RFID over bar codes.

- "the context in which such events [are] taking place", i.e. the highly complex context of MDs in healthcare

As well as being:

- appropriate to "get a feel of what was going on..."
- "more flexible" than the deductive approach and
- it "permits changes of research emphasis as the research progresses" (4.5)

And finally:

- it is appropriate "into a topic that is new, is exciting much debate and on which there is little existing literature". RFID in MD is relatively new, it is definitely creating debate (or is that "hype"?) and, as evidenced in Chapter 2, there is little literature related to the use of RFID with MD.

However, it was accepted this approach could be more protracted, potentially creating pressure on the overall timeline (4.4).

4.3 Research Strategies

In order to answer the research questions (3.3) the strategy employed continued the inductive, building theory approach, namely "Grounded Theory", the "best example of the inductive approach". It was selected as the most appropriate in this context as it is explorative, "data collection starts without the formation of an initial theoretical framework" and the need "to start... collect[ing] data and then explor[ing] them to see which themes or issues to follow up and concentrate on" (Ibid:93).

Tactically, "multi-methods" (Ibid:99) were employed to provide flexibility as the theory, themes and / or issues emerged (4.5).

Whichever strategy had been employed, there would have been limitations. For the grounded theory approach the key limitations were acknowledged and consideration was given to how they might be mitigated:

- The approach is time consuming due to its iterative nature. The time element was controlled by fixed time periods being planned for each of the data collection tactics.
- Whilst it was a "difficult strategy to follow and may not [have] lead to success for... [the author] who is an inexperienced researcher", the tactics were selected to enable iterative analysis and assessment of "themes... emerging from the data being gathered" to identify "relationships between [the] data and develop[ment] of questions..." to validate these. (Ibid)
- The initial review indicated that there was a gap in the literature available on this research topic, therefore the implication "that little of significance will emerge at the end of the research process" would still provide more information than was already available, thus beginning to address the literature gap. (Ibid)

4.4 Time Horizon

As this research project was part of academic study and time bound, the "cross-sectional" (Ibid) approach was the only option.

4.5 Data collection methods

As mentioned in 4.3, tactically, "multi-methods" (Ibid:99) were employed, for data collection, namely the three principal ways of:

- A search of literature (Chapter 2)
- A series of structured interviews with key stakeholders in the industry who have knowledge and experience of AIDC in healthcare in relation to identifying the key issues and pros and the cons of RFID as a suitable AIDC technology (5.2). (Whilst running focus groups would have been a more efficient use of research time, the impracticality of co-ordinating the key stakeholders, geographically dispersed across Europe and US, into groups to be in one place at one time was impractical.)
- Follow up questionnaire to 271 business contacts/stakeholders to validate Interview findings (5.3).

4.6 Chapter Summary

The philosophy adopted for the applied research element of the dissertation was “Interpretivism”, the approach “Inductive”, the strategy “Grounded Theory” with a ”Cross Sectional” time horizon, using the “multi-method” for data collection, specifically Literature Search, Key Stakeholder Interviews and an on-line Questionnaire.

5. Data Analysis and Results

This chapter analyses and presents the results of the two additional (to the literature review (Chapter 2)) methods of data collection, namely a series of structured interviews with key stakeholders and a follow up questionnaire to validate interview findings.

5.1 Stakeholder Analysis

The first stage Stakeholder Analysis identified 10 inner circle and 15 outer circle groups of stakeholders (Table 6).

Inner Circle		Outer Circle	
MD&D General Operating Council	1	Patients	20
Vice President RFID	2	Healthcare Personnel	21
Global RFID Steering Committee	3	Supply chain partners	22
MD&D Franchises	4	Stockholders	23
Packaging & Labeling employees	5	Federal Drug Administration (FDA), US	24
Research & Dev. Employees	6	European Union (EU)	25
Manufacturing employees	7	Standards Bodies (GS1, HIBCC)	26
Supply Chain/Distribution/Logistics professionals	8	National Patient Safety Agency	27
Regulatory/Compliance/Legal	9	Healthcare Providers (e.g. NHS Trusts)	28
IM (NCS) Employees	10	Medical Device Manufacturers	29
		Pressure groups (Privacy)	30
		Media	31
		Auto-ID Technology Providers	32
		Trade Associations	33
		Academia	34

105 Words

Table 6 - Stakeholder classification

The second stage Stakeholder Analysis plotted these groups on a “power/interest” grid (Figure 3).

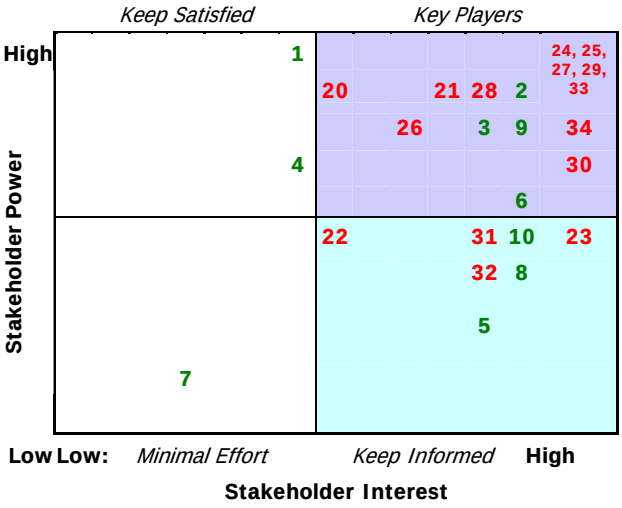


Figure 3 - Stakeholder analysis

46 Words

The author has a wide business network, related in some part to working for J&J but also to participation in various external (to J&J) organisations, e.g. trade associations (Association of British Healthcare Industries (ABHI), Eucomed) and standards bodies (GS1/EPCGlobal). From this network, 287 contacts were identified. 22 "Key Player" contacts were targeted for interview; the remaining key players and the "Keep Informed" contacts were invited to complete the online questionnaire.

Of the stakeholders identified as "Key Players", it was acknowledged that there could be issues with accessibility in four key player groups (20: Patients, 24: FDA, 25: EU and 30: Privacy Groups).

5.2 Interview Analysis

The 22 key players were approached to take part in one-to-one interviews with the author. Contact was made by email (Appendix A) that included an attachment (Appendix B) outlining the research project, the interview protocol (including available dates/times) and the interview questions.

Of these 22, 16 agreed to be interviewed, equating to 73% participation rate. The majority of 'key player' groups participated, including two of the four groups where accessibility was expected to be an issue: 24: FDA, 25: EU. Therefore, the only groups missing were 20: Patients and 30: Privacy Groups (Table 7).

Statistically, standard deviation analysis (Appendix E) showed the participation rate to be highly representative, being two standard deviations away from the mean and thus accounting for roughly 95% of the interview population. However, in terms of Confidence Level, 16 participants could only be considered as "moderately positive" (Hopkins, 2001) and thus the results were not necessarily generalisable to the wider MD population; this confidence level could be interpreted as a weakness of this stage of the research; the questionnaire (5.3) provided a higher Confidence Level.

Category Ref.		Spread of Stakeholder Interviewees	Count	%age of Total
Inner	1 to 10	J&J Internal contacts	5	31.3%
O	29	Medical Device Manufacturers	1	6.3%
	28	Healthcare Provider (e.g. NHS Trusts)	1	6.3%
U	26	Standards bodies	3	18.8%
	33	Trade Associations	1	6.3%
T	24	Federal Drug Administration	3	18.8%
	25	European Union (EU)	1	6.3%
E	27	National Patient Safety Agency	1	6.3%
	20	Patients	0	0.0%
R	21	Healthcare Personnel	0	0.0%
		Total	**16**	100.0%
		Participation Rate:	**22**	**73%**

83 Words

Table 7- Stakeholder participation (Interviews)

The high participation rate was assumed to be because of the author's business network.

The purpose of the interviews was to:

1. Establish the level of understanding and knowledge of RFID in the key stakeholder groups
2. Establish if Patient Safety is the key driver for using RFID with MD
3. Establish which MDs the stakeholder community would target for RFID tagging, why and what barriers they foresee with doing so, and
4. Find out if there are pilots being undertaken with these MDs

All the interviews were done via the telephone due to geographic dispersion and related time-differences. All the interviewees agreed to the interview being recorded. An example of a fully transcribed interview is shown in Appendix C.

5.2.1 Establish the level of understanding and knowledge (u/k) of RFID in the key stakeholder groups

Low (no u/k)	Medium (some u/k)	High (Expert)	Total
	6 (38%)	10 (63%)	16

All the interviewees ranked themselves in either the medium or high range for level of understanding and knowledge of RFID. From this ranking it was assumed that they have sufficient understanding and knowledge to provide relevant answers to the remaining questions.

5.2.2 Establish if Patient Safety is the key driver for using RFID with MDs

Yes	One of them	No	Not sure	Total
7 (44%)	8 (50%)		1 (6%)	16

Whilst there may be an element of "yes" being the politically correct answer to this question, as suggested by 2 (13%) of interviewees, the number of positive responses ("Yes" + "One of them" = Total 15 (94%)) indicates that Patient Safety is a KEY driver, but it was not seen as the only driver; of the 8 who answered "one of them", 5 (31% of total) cited "**supply chain efficiency**", as

in the extended value chain (Porter, 1985) (upstream from manufacturer, downstream to point of care) as the other key driver. FDA and NPSA cited patient safety as their primary driver.

In relation to both of these drivers, the interviewees provided examples of numerous issues they believed could be addressed through RFID tagging of MDs.

5.2.2.1 Patient Safety Issues

The issues provided in relation to Patient Safety have been grouped into three categories: Suitability, Authenticity and Availability. These categories were derived by the author, rather than adopting "'in vivo' codes" (Saunders et al, 2003:399) given by interviewees in an effort to avoid readers of this analysis interpreting in vivo codes "according to their prior understanding of such theoretical concepts rather than the particular meaning now being placed on such terms". These categories also relate to key themes and issues emerging from the follow up online questionnaire (5.3):

- **Suitability**, i.e. suitable for use. e.g. if a surgical instrument, is:
  - Re-useable: information about when/where/how the item was decontaminated (Datta, 2001) could be written to the tag and read before re-use, with a record being written to that patient's electronic patient record (EPR), if required.
  - Single use: having this fact held on the tag so that when it's used it is recorded and if an attempt is made to re-use the instrument an alert communication is generated and recorded. OR
  - Control or watch expiration dates of products – the tags alerting if the product has expired
  - Avoiding medical errors, e.g. "being able to know if a product contains latex before you administer, if the patient is latex sensitive" - interaction between patient record or patient RFID wristband and product RFID.

- **Authenticity**
  - Anti-counterfeit - the RFID tag confirms it is the said product, avoiding inferior product being used on the patient, which could have an impact on patient safety.

However, Neumann and Weinstein (2006) caution that RFID tags are “useful as identifiers but not as authenticators...” due to “...a wide range of proven abuses... Tags may be counterfeited, cloned (duplicated), swapped, damaged, intentionally disabled (in some cases even remotely), or otherwise misused.”

- **Availability**, e.g.
  - Location: Being able to identify an RFID tagged asset, e.g. an Infusion Pump, on a computer generated map and locate it when it is required to provide treatment to a patient, impacting patient safety. Roark and Miguel (2006) recognise this: "The struggle in any hospital is that items such as infusion pumps... are often lost in crevices or closets of large hospital buildings. In addition, these movable pieces of equipment are considered scarce resources to the hospital personnel that need them. This leads to hording of equipment...", if it can’t be located it's not available for patient treatment, impacting patient safety
  - Anti-theft: An RFID tag emitting an alert communication if it is taken from a defined area (Such a process is employed in a number of hospital maternity wards to prevent baby abduction (Warden, 2006)) - if stolen it's not available for patient treatment, impacting patient safety.

5.2.2.2 Supply Chain Issues

The issues provided in relation to supply chain efficiency were:

- Tracking: “Monitor ‘shelf life’, ‘expiry date’, ‘Out of stock’” - one interviewee stated “some clinicians do see an ‘out of stock’ as a clinical adverse event. If they substitute or improvise, there is potential harm to the patient”.

- Tracing: e.g. Product recalls, FDA cited this as “one of three primary patient safety objectives”, from manufacturer to patients electronic record and vice versa.

5.2.3 Establish which MDs the stakeholder community would target for RFID tagging, why and what barriers they foresee with doing so

(Question: Do you think RFID tagging is applicable to ALL medical device products?)

Yes	No	Total
3 (in theory) (19%)	13 (81%)	16

The majority of interviewees did not think RFID tagging was applicable to ALL medical device products. Consistently, the product area cited that should not be tagged, mainly for economic reasons (i.e. cost of tag compared to cost of item), was “disposables” (e.g. bandages, syringes, consumables).

The top five MDs cited that should be tagged were *(“Why” relates to categories defined above):*

	Why
8 Assets - e.g. Infusion Pumps, defibrillators, Patient monitoring equipment	Availability & High value
6 Surgical instruments	Suitability
7 Orthopaedic Implants	) Supply chain:
5 Stents (implants)	) Track and
3 Cardiac implants	) Trace

There is some correlation with this top five and the reasons for tagging them with the NPSA data (Stevenson, 2006) (2.3.3), e.g. “...to non-availability of equipment.

The barriers provided, in descending priority, were:

- **Technology/physics issues** related to MDs. Although it was stated that these were out of scope, it was the key barrier given by all the stakeholder groups. This was closely followed by:

- The **cost of implementation** due to the financial constraints of the healthcare providers/hospitals, particularly related to ability to invest in infrastructure (readers/antenna etc.) and
- **Culture**, related to technology adoption and use.

25% of interviewees gave the next two barriers:

- **Privacy**/data protection concerns ("spy tags") and
- Lack of global **standards**, related to data capture/storage/management and radio spectrum (the frequencies used vary across the globe).

To validate the top five MDs, the categories and the barriers given, they were included in the questionnaire (5.3).

5.2.4 Find out if there are pilots being undertaken with these MDs

During the course of the interviews seven pilots were mentioned:

- Two by French hospitals related to marking of instruments, the author was already aware of these (Vincent (2006), Talon (2006)),
- Two by MD manufacturers and One by US hospital related to supply chain efficiency and inventory management,
- One by an MD manufacturer related to counterfeit prevention of sterilisation chemicals and
- One by hospital in US "trying to develop the Operating Room (OR) of the future and part of that is being able to identify what is brought into the OR".

All of these pilots are work in progress and evidence of success (or failure) is not yet available. Although one MD manufacturer stated that their supply chain pilot was "very successful" in achieving its purpose, namely gaining experience with RFID and identifying tangible benefits and limitations.

However, there is evidence that the perceived technology/physics barriers mentioned earlier are being experienced in reality in these pilots:

- "Tags applied during manufacturing... before sterilisation… sterilisation "fried" the tags"
- "Read rate of the tags - tag suppliers claim 100% but experienced fail rate of 20-30%"
- "Alignment of packages to avoid 'collision'"

Given the size of the market and the diverse range of MD products, this number of pilots was judged to be insignificant and it would therefore be inappropriate to draw any major conclusions.

5.2.5 Interview Analysis Summary

This second data collection method achieved a high participation rate (73%) across the majority of "key player" stakeholder groups. The interviewees had medium to high knowledge & understanding of RFID and saw the key drivers for adoption with MDs as Patient Safety AND value chain efficiency. However, they did not believe that RFID tagging was applicable to all MDs, particularly consumable type products; high value items with related expiry, maintenance and/or use/re-use issues were seen as the priorities - there was some correlation between these and the products in the higher percentage categories of "...reported outcome by reported category" (2.3.3.).

There was consistency of views with regards to the key issues and barriers. The issues, for patient safety related to Suitability, Authenticity, Availability, for the value chain they related to tracking and tracing. The barriers related primarily to physics issues with the technology when used with MDs followed closely by the cost of implementation and the culture, particularly in clinical environments. Privacy and standards were mentioned but were not seen as key barriers. Potentially the barriers could be the reason why there are so few pilots underway. Those that are underway are incomplete and case studies of success or failure are not yet available.

5.3 Questionnaire Analysis

Of the original 287 contacts identified, 271 (287 less 16 interviewees) were invited by email (Appendix D) to complete the online questionnaire. 26 emails failed, e.g. incorrect email addresses, leaving a total of 245 potential participants (Table 8).

Category Ref.		Spread of Stakeholder Contacts	Count	%age of Total
Inner	1 to 10	J&J Internal contacts	69	24.0%
	29	Medical Device Manufacturers	132	46.0%
	28	Healthcare Provider (e.g. NHS Trusts)	25	8.7%
	26	Standards bodies	19	6.6%
O	33	Trade Associations	15	5.2%
	24	Federal Drug Administration	8	2.8%
U	32	Auto-ID Technology Providers	7	2.4%
	34	Academia	5	1.7%
T	22	Supply Chain/Distribution/Logistics Professionals	2	0.7%
	25	European Union (EU)	2	0.7%
E	27	National Patient Safety Agency	2	0.7%
	23	Stockholders	1	0.3%
R	20	Patients	0	0.0%
	21	Healthcare Personnel	0	0.0%
	30	Pressure Groups (e.g. Privacy)	0	0.0%
	31	Media	0	0.0%
		Total	**287**	**100.0%**

Invited for Survey (Total Stakeholders less Interviewees)	**271**	
Failed/undelivered/Declined eMails	**26**	**9.6%**
Balance of invitees	**245**	**90.4%**
No. who participated (as %age of total invited)	**58**	**21.4%**
No. who participated (as %age of "Balance of Invitees")		**23.7%**

Table 8 - Stakeholder participation (Questionnaire)

147 Words

The questionnaire was open for two weeks and 58 stakeholders completed it, equating to 21.4% of the total invited and 23.7% of the balance (after failed email delivery) of invitees.

Statistically, consistent with the interviews, standard deviation analysis (Appendix E) indicated that the participation rate is highly representative, being two standard deviations away from the mean and thus accounting for roughly 95% of the invited population. In terms of Confidence Level, 245 participants

could be considered as “definitely large” (Hopkins, 2001), providing a much higher Confidence Level than the interviews, and thus the results were could be taken as the generally view of the wider MD population.

Table 9 shows the spread of the participants across the targeted stakeholder groups, with the MD manufacturers the dominant group (58.6%).

Type of Organisation	Participation	
	Count	%age of Total
Medical Device Manufacturer	34	58.6%
Healthcare Provider (e.g. Hospital)	6	10.3%
Standards Body	6	10.3%
Technology Provider	4	6.9%
Trade Association	3	5.2%
Government Body	2	3.4%
Distributor	1	1.7%
Academia	1	1.7%
Regulatory Body	1	1.7%
Total	**58**	**100%**

48 Words

Table 9 - Spread across stakeholder groups

Table 10 shows the job roles of the participants. In line with RFID being an emerging technology in healthcare, the highest participation group was from Research or Technical areas (43.1%) with Supply Chain coming next highest (15.5%).

Type of Role	Participation	
	Count	%age of Total
Research / Technical	25	43.1%
Supply Chain & Logistics	9	15.5%
Product / Marketing / Brand Management	5	8.6%
Sales / Business Development	5	8.6%
Clinical	3	5.2%
Executive / General Management	2	3.4%
Programme Management (Government)	2	3.4%
No Response	2	3.4%
Academic	1	1.7%
Legal	1	1.7%
Packaging	1	1.7%
Programme Management (Industry)	1	1.7%
Regulatory	1	1.7%
Total	**58**	**100%**

71 Words

Table 10 - Job roles of participants

5.3.1 Establish the level of understanding and knowledge (u/k) of RFID in the key stakeholder groups

Consistent with the results of the interviews, the most common rankings of questionnaire participants were either medium (58.6%) or high (39.7%) level of understanding and knowledge of RFID. Therefore, the same assumption was made, as with the Interviewees, that the questionnaire participants have sufficient understanding and knowledge to provide relevant answers to the remaining questions.

5.3.2 Establish if Patient Safety is the key driver for using RFID with MD

A higher percentage (77.6%) of the participants said that Patient Safety was the KEY driver compared to 44% of the interviewees.

Those who answered “yes” were asked “Why do you think Patient Safety is the KEY driver for applying or embedding RFID to Medical Devices?” and the three categories (Suitability, Authenticity and Availability) were given as options,

along with an “other” free text option. They were permitted to select more than one category. Table 11 shows the results and the ranking of the three categories along with the “other” reasons given. “Suitability” was the modal category with 80%. The “other” reasons were all related to the extended value chain (28.9%); again consistent with the 31% of interviewees who cited supply chain as the other key driver.

Why do you think Patient Safety is the KEY driver for applying or embedding RFID to Medical Devices?		Participation		
		Count	%age of Total	%age of 45 " Yes' "
Suitability (i.e. it is fit for purpose, e.g. the multi-use instrument is clean and sterile or the product is within expiry period)		36	35.6%	80.0%
Authenticity (i.e. Anti-counterfeit - the RFID tag confirms it is the said product, avoiding inferior product being used on the patient)		28	27.7%	62.2%
Availability (i.e. Being able to identify an RFID tagged asset, e.g. an Infusion Pump, on a computer-generated map and locate it when it is required)		24	23.8%	53.3%
Other: Revenue	2	13	12.9%	28.9%
Other: Efficiency	**7**			
Other: Effectiveness	**4**			
(Note: More than one answer could be selected)	**Total**	**101**	**100%**	

129 Words

Table 11 - Patient Safety Driver Categories

The 22.4% who answered “no” were asked, “If Patient Safety is NOT the key driver for applying or embedding RFID to Medical Devices, what do you think is/are the key driver(s)?” They were permitted to select more than one category. 100% gave the extended value chain as the other key driver (Table 12), with a number of other drivers, continuing the consistency with the interviewees.

If Patient Safety is NOT the key driver for applying or embedding RFID to Medical Devices, what do you think is/are the key driver(s)?		Participation		
		Count	%age of Total	%age of 13 "No"
Supply Chain Efficiency (from manufacture to point of care)		13	22.4%	100.0%
Financial		6	10.3%	46.2%
Preventative healthcare		4	6.9%	30.8%
Product Innovation		2	3.4%	15.4%
(Note: More than one answer could be selected)	**Total**	**25**	**43.1%**	

70 Words

Table 12 - Other Driver

In order to assess if the participants saw a cause and effect link between the two key drivers (Patient Safety and Supply Chain Efficiency), they were asked, "Do you think that utilising RFID to improve the medical device supply chain (from manufacturer to point of care) will result in greater patient safety?" About 20% answered "yes" (6.9%) or "possibly" (13.8%), one answered "no", but the majority (77.6%) did not answer the question. Given the high percentage that declined to answer the question, it is not possible to assess if there is a cause and effect link between the two key drivers.

However, those who answered "yes" or "possibly" were asked a further question to understand their reasons for thinking there was a cause and effect link between the two key drivers: "Please explain how you see an improved medical device supply chain leading to greater patient safety." Their verbatim (sic) responses, with the author's interpretation and linking to patient safety and supply chain categories, are shown in Table 13. Interestingly, one respondent (penultimate) gave examples of the link but concludes, "...there is no direct relationship."

Please explain how you see an improved medical device supply chain leading to greater patient safety.	Drivers	
	Patient Safety	Supply chain efficiency
Reduce counterfeits. Assure proper handling while in the	Authenticity	Track and Trace
Expedited Recalls Product Authentication	Authenticity	Track and Trace
Reduces the risk of adulterated or counterfeit product from entering the legitimate supply chain	Authenticity	Track and Trace
understanding where the devices are and how they are performing on a systematic basis is key to appreciating the population based impact of these devices	Availability	Track and Trace
Improving accuracy of inventory and shipments and therefore reducing errors in product shipments. Speeding delivery of supplies. Improving control over the supply chain, meaning that the correct inventories are in the right place at the right time. Improving kitting and Consignment control. Improving receiving accuracy at the customer	Availability	Track and Trace
more visibility of the product pipeline,	Availability	Track
By ensuring the device is delivered to the right patient	Availability	Track
better supply chain management together with inventory management will give the hospital the information to do the right things and will not further make mistakes. But nevertheless unskilled people are round the world the biggest issues for mistakes. Education in the supply chain and inventory management is mandatory to increase via a indirectly patient safety. But there is no direct relationship.		Track and Trace
standard product identification from factory to patient		Track

238 Words

Table 13 - The link between Supply Chain and Patient Safety

5.3.3 Establish which MDs the stakeholder community would target for RFID tagging and what barriers they foresee with doing so

5.3.3.1 Priority product groups

The participants were advised that from the initial research interviews 5 medical device product groups were prioritised for RFID tagging / pilot. They were asked "What order of priority would [they] give to each of these medical device product groups?" and they were asked to rank Highest, High, Medium high, Medium, Low (per product group); using an ordinal scale where Highest = 5 down to Low = 1. The results were a count of the individual ranking scores for each product group.

Comparison of the results from the interviews and questionnaire (Table 14) show a minor difference of opinion for Assets, ranked first by interviewees and second by questionnaire participants. But a major difference of opinion for Cardiac Implants, the interviewees ranked them as fifth priority, the questionnaire participants ranked them first! Both audiences ranked Stents as forth priority. As MD manufacturers made up the majority of the questionnaire participants, it could be assumed that the ranking was influenced by the products they manufacture, but it could also be assumed that there is broad agreement that these are the top 5 product groups to consider for pilots.

5 medical device product groups were prioritised to be targeted for RFID tagging / pilot	Ranking	
	Interviews	Questionnnaire
Assets (e.g. Infusion Pumps, Defibrillators, Patient Monitoring Equipment)	1	2
Orthopaedic Implants (e.g. hips, knees)	2	3
Surgical Instruments (e.g. forceps, scalpels)	3	5
Stents	4	4
Cardiac Implants (e.g. Pacemakers)	5	1

Table 14 - Priority - Top 5 Medical Devices

51 Words

5.3.3.2 Barriers

The participants were advised, from the initial research interviews, what top 5 barriers were cited to adoption of RFID with MDs. They were asked to rank them "Most Significant, Significant, Moderate, Least Significant (per barrier

type)"; using an ordinal scale where Most Significant = 4 down to Least Significant = 1. The results were a count of the individual ranking scores for each barrier type.

Comparison of the results from the interviews and the questionnaire (Table 15), show agreement that the technology/physics issues are the top barrier to adoption and finance/cost is the second highest. It could be assumed that these are considered immediate barriers to adoption that need addressing; as is the need to address Standards, this barrier changed by two rank points, the questionnaire participants ranking it higher than the interviewees. The difference in ranking of Culture and Privacy was negligible and, if the assumption of immediacy is correct, it could follow that these barriers would need to be tackled later / after technology, cost and standards issues.

top 5 barriers for adoption of RFID with Medical Devices.	Ranking	
	Interviews	Questionnnaire
Technology / Physics barriers (e.g. lack of performance of RFID with liquids, metals, coping with sterilisation, multiply frequencies, interference)	1	1
Financial status of healthcare providers / Cost of implementation	2	2
Culture - suspicion of new technology / resistance to change	3	4
Privacy / Data security and/or protection	4	5
Lack of Standards - frequency, data	5	3

73 Words

Table 15 - Top 5 Barriers

5.3.4 Find out if there are pilots being undertaken with these MDs

50% (29) of the participants stated they were aware, or could give examples of, real trials or pilots of RFID applied or embedded with medical devices. The analysis of the responses (Table 16) showed that, of the examples given, 17 were related to MD specifically, whilst the other 12 were not.

Analysis of 17 MD related pilots showed that both the Patient Safety (PS) and Supply Chain (SC) categories (5.3.3.2.) were given as “key successes”, i.e. Availability (PS), Track & Trace (SC) and Cost/Financial (SC). The technical/physics issues were the barriers cited, in line with initial research.

Description of pilot	Results?					
	Total	Successful	Not success	Not available / Pilot continuing	Key Successes	Barriers cited
Assets	4	2		2	Availability (both); Cost savings (1)	
Surgical Instruments	4	1	1	2	Improvements to: Reader (Technical); Track and Trace; User satisfaction; "Proved that RFID was as easy to use a bar codes but much more useful"	Physics issues; Read rate; "The RFID's are too big and preparation of the instruments is too costly"
Patient levels (blood, glucose) Monitoring (3 MD)	4	2		2	Availability, Tag reading	
Orthopaedic Implants	3			3		
Stents	3	1		2	Read rate/accuracy	
Blood	**2**	**1**		**1**		
Hospital / Op Room enablement (not MDs)	**2**			**2**		
Pharma	**2**		**1**	**1**		**Read rate**
No response	**5**			**5**		
Totals	**29**	**7**	**2**	**20**		
Medical Device Totals	**17**	**5**	**1**	**11**		

131 Words

Table 16 – Pilots with Medical Devices

Interestingly, four of the five suggested target product groups (5.3.3.1.) were the focus of the pilots; the only product group where there were no pilots mentioned were cardiac implants – in line with the view of the interviewee community, who ranked it as fifth priority product group.

5.3.5 Questionnaire Analysis Summary

This third and final data collection method again achieved a high participation rate (21.4%/23.7%) across the majority of “key player” and “keep informed” stakeholder groups.

Broadly the data was consistent with the data collected from both the literature review (Chapter 2) and the interviews:

- The participants had medium to high knowledge & understanding of RFID

- They saw the key drivers for adoption with MDs as Patient Safety AND value chain efficiency and the reasons why (e.g. suitability, track and trace) were ranked in a similar way
- They agreed that RFID tagging was not applicable to all MDs
- The ranking of the barriers were similar
- Although there were some differences with the ranking of the top 5 product groups to focus upon, 4 of the 5 product groups were covered in the ongoing pilots, although cardiac implants were missing (possibly supporting the view of the interviewees, who ranked them fifth priority), and
- The example pilots are mainly incomplete, although there is some evidence that the successful pilots are addressing some of the reasons for the patient safety and supply chain driver focus, e.g. availability, track and trace, but equally the barriers, e.g. technology, physics, were also experienced.

The analysis and results of the interviews and questionnaires and the literature review informed the conclusions and recommendations, presented in detail in the next chapter.

6. Discussion, Conclusions and Recommendations

This chapter discusses the findings of the research, draws a number of conclusions and presents recommendations on how the healthcare industry could progress adoption of AIDC with Medical Devices to facilitate greater patient safety. It also comments on areas not covered in this dissertation that warrant further research.

6.1 Discussion

As outlined in 3.1, the ideal aim of this dissertation was to definitively prove or disprove the hypothesis:

"Medical Device manufacturer applied or embedded RFID has benefits to Patient Safety over existing AIDC technologies, e.g. Bar Codes."

However, it was anticipated that, due to the range and complexity of MDs, as cited in Eucomed, 2004 and Longe, 2004, and the complexity of the healthcare market, as cited in Sokol and Shah, 2004, doing so was improbable.

The author believes this to be the case; the hypothesis has not been definitively proven or disproved, but a number of conclusions and recommendations can be drawn based on the research findings. These conclusions and recommendations relate to the different elements of the hypothesis; therefore, the following discussion focuses on each element separately.

6.1.1 "…RFID has benefits to Patient Safety…"

The data collected via the interviews and the online questionnaire confirmed the assumption identified in a range of the literature sources, e.g. as cited in Eucomed, 2004, that patient safety is a key driver for adopting RFID with MDs; although it is not the only driver (supply [value] chain efficiency was the other consistently cited). Indeed, "Tracing" was cited by FDA "as one of three primary patient safety objectives" (5.2.2.2.). The patient safety element of the hypothesis is therefore discussed first.

The English NPSA have stated "It is important to link the supply chain and the patient; if [they] use technology to identify devices then that makes a much more effective system. If it is more effective and efficient it is likely to be safer for the patient." (Ranger, 2005)

Although the data collected confirms patient safety as a key driver (5.2.2.), does it also support the theory that applied or embedded RFID will lead to greater patient safety?

The author would argue that it does not; the cause and effect link is essentially still based on hypothesis. The minor successes of the few MD case studies mentioned in the research interview and Questionnaire relate to supply chain efficiency improvements or technology improvements (5.3.4.), they have not progressed through the chain to the patient and, thus, patient safety benefits are not mentioned or considered and a link, therefore, is not established.

Although intuitively, in some situations, the use of RFID with medical devices could deliver greater patient safety (e.g. to address the 20% of incidents related "...to non-availability of equipment" quoted in NPSA, 2006 (2.3.3)), until there are a sufficient number of case studies with MDs across the extended supply chain to the point of care, that prove greater patient safety as a key success, the statement "RFID has benefits to greater patient safety" will largely remain an assumption.

6.1.2 "Medical Device manufacturer applied or embedded RFID..."

In regards to the opening element of the hypothesis, assuming the statement "RFID has benefits to greater patient safety" is proven through pilots and case studies, would MD manufacturers be requested to voluntarily tag MDs or would they be required (mandated) to do so through regulation?

Based on the experience with bar codes in healthcare highlighted by Flynn, quoted in Healthcare Purchasing News (Reiner & Sullivan (2005), 2.3.2.2.), the author would suggest that it should be voluntary.

Whilst MD manufacturers may make a commercial decision to invest in and adopt RFID to increase the efficiency of their supply chain (5.3.2.), their control or influence over the supply chain ends at the point of delivery, e.g. at the healthcare facility. For a healthcare facility to reap the benefits of manufacturer applied or embedded RFID, they would require a technical infrastructure (1.3), processes and trained resource to be in place and working efficiently, i.e. fully adopted into their operations - this would require a significant financial and operational investment in each facility (Roark & Miguel (2006), 2.3.2.4.).

To mandate MD manufacturers to tag would require a deliverable guarantee that the MD supply chain would be fully extended downstream into each healthcare facility, to the point of care/the patient. But a comment taken from the summary of the Harrop report (in Anon, UsingRFID.Com (2006)) indicates that the "...primary impediments to rollout of RFID in healthcare are limited budgets, inertia, lack of education, high cost of many RFID systems..."; the author would argue that such a guarantee to MD manufacturers is, therefore unlikely to be deliverable.

Whether voluntary or mandatory, without the technical infrastructure, processes and trained resource operational in the healthcare facility, MD manufacturer applied or embedded RFID, or any AIDC, will deliver little, if any, improvements to either the healthcare facility's internal supply chain or to patient safety. The experience with Bar Codes is a case in point (Furness, 2005 (2.3.2.4.)).

6.1.3 "...RFID has benefits... over existing AIDC technologies, e.g. Bar Codes."

The author would suggest that RFID has some benefits over existing AIDC technologies, e.g. Bar Codes, but they are limited. The benefits are discussed in the literature review and subsequently summarised in Table 3 (2.3.2.4.).

But it is generally believed that these benefits are not universal, i.e. not realisable for all classes of MDs or for all products within the classes. In addition to the infrastructure requirements (1.3) and related financial costs (Roark & Miguel (2006), 2.3.2.4.) that could be barriers to adoption,

- It may not be economically viable to undertake item-level tagging for "disposables" (bandages, syringes, consumables (Interviews, 5.2.3.)) because the cost of a tag may be the same or more than the cost of the item.
- There are known issues with RFID technology, e.g. read rate of tags (Interviews, 5.2.4.) and, particularly for MDs, physics issues (e.g. metal, liquid, sterilisation (UsingRFID.Com (Anon, 2005), 2.3.2.4.)
- Radio Frequency standards are not global (Wyld, 2005 (2.3.2.4.b.))

The author would also argue that there are unrealised opportunities in healthcare with Bar Codes or other AIDC technologies that may lead to greater patient safety. As previously mentioned Bar Codes are not ubiquitous in healthcare facilities, and in some cases they have their own type of bar code and over-label that of the manufacturer. Flynn's comment (2.3.2.4) sums up the situation: "What makes healthcare facilities think they can be successful with RFID when they haven't fully adopted bar coding into their operations?"

6.2. Conclusions

In answer to the research questions stated in 3.3, the following conclusions have been drawn from the foregoing research, analysis and discussion:

a. Patient Safety is the KEY driver for using RFID with MD (e.g. Ranger & Cousins (NPSA), 2006 (2.3.3); Interviews (5.2.2); Questionnaire (5.3.2), 6.1.1.

b. There have been insufficient pilots and resulting case studies to definitively prove that applying or embedding RFID to MDs will deliver greater patient safety. The theory is largely still based on assumption (Ranger & Cousins (NPSA), 2006, (2.3.3); Vincent (2006), Talon (2006) (5.2.4); Questionnaire (5.3.4); 6.3.1.).

c. Whilst RFID has benefits over other AIDC technologies, they are not universally realisable or applicable to all MDs (Arcarese, 2005 (2.3.3), Interviews (5.2.3), 6.1.3.).

d. There are barriers to be overcome with RFID technology (UsingRFID.Com, Anon, 2005 (2.3.2.4.b); Interviewee, Jensen, R (5.2.4); Questionnaire (5.3.3.2); 6.1.3.).

e. There is potential, in healthcare facilities, to derive benefits through a more tactical, widespread and efficient use of other AIDC technologies that are already used by MD manufacturers (78% of Advamed members are bar coding products (Longe, 2004, (2.3.2.4); 6.1.3.).

The hypothesis has not been proved or disproved, but it can be reworded into a statement based on the research and findings of this dissertation, as follows:

Medical Device Manufacturer applied or embedded RFID should be voluntary. RFID has benefits over existing AIDC technologies, e.g. Bar Codes and has the potential to deliver greater patient safety in the clinical environment. But it should not be seen as a panacea; all AIDC technologies should be considered and piloted, and the most appropriate selected, when attempting to address reported adverse incidents in the most severe "degree of harm" categories (NPSA).

The author would also conclude that the research, above conclusions and statement address the objectives outlined in 3.2, namely:

- It provides the medical industry with a piece of research that begins to fill the literary gap,
- It can assist in informing and influencing the public bodies driving this agenda,
- It has increased understanding of whether or not tagging MD delivers greater patient safety over existing AIDC, and
- It suggests to key stakeholders in the MD industry that products with high percentages of reported adverse incidents in the most severe "degree of harm" categories of "severe" or "death" should be prioritised for AIDC pilots.

6.3 Recommendations

In summary, the following are recommendations to the MD industry.

6.3.1 Pilots

Although there have been insufficient pilots and resulting case studies, it is recommended that, to develop the theory (i.e. RFID has benefits to Patient Safety) it should be tested "through subsequent data collection and analysis" (Saunders et al, 2003), i.e. through pilots and published case studies.

"This means looking past the disappointing results, limited functionality and modest initial applications to anticipate the possibilities." (Day & Schoemaker, 2000:38) Because: "Successful adaptation to the vagaries of emerging technologies requires a willingness to experiment and an (sic) openness to learn from the inevitable failures and setbacks." (Ibid:43)

The author would commend Johansen & Storm's "Evaluation Framework" (2.3.2.3) and recommend that it be used to assess RFID technology's applicability with MDs and the likelihood of success in particular situations.

6.3.2 Priorities

The analysis of the interviews and questionnaire provided a list of the top five MDs suggested as priorities for RFID tagging (5.3.3.1: Table 14). These may very well be the MDs to focus the pilots upon, but it is recommended that these should be correlated with country data on reported adverse incidents related to MDs, such as that provided by the English NPSA (2.3.3). Focusing on those related to highest percentage of reported adverse incidents should increase the likelihood of establishing a tangible cause and effect link to patient safety.

6.3.3 Just RFID?

The pilots should not just focus on RFID with MDs; it is recommended that RFID be tested in parallel with (an)other AIDC technologies. This parallel testing is important to facilitate comparison of the benefits or limitations of each AIDC with a particular MD in a given clinical setting and concurrently increase the use of the range of AIDC in healthcare.

This is to ensure that we don't "…loose sight of all [AIDC] solutions. In some applications traditional bar codes and data matrix are equally as efficient and reliable as RFID. The mix of technologies with a seamless interaction between them will allow for a greater deployment in the medium to long term. This implies that both barcodes and RFID dependent applications must be developed in a consistent manner so that both can be used and complement each other." (Questionnaire respondent: B. Kernan), or more succinctly, that we "Tag where it makes sense" (Questionnaire respondent: U. Kreysa).

6.3.4 Participants

To ensure that the pilots test the extended value chain linking it through to the point of care/patient, it is recommended that they involve key stakeholder groups. Such as, but not limited to country or regional:

- government health departments
- healthcare regulatory agencies, e.g. English NPSA, US FDA
- clinicians
- supply chain (supplier and healthcare provider)
- standards bodies, e.g. GS1 or HIBCC
- Trade Associations, e.g. ABHI, Eucomed, Advamed
- Patients or patient organisations and
- Technology providers

6.4 Limitations of research

There are three particular areas that the author would suggest require further research:

6.4.1 Adverse Incidents with MDs

Although this has been included here, it has only been considered at a high level and suggested as a selection criterion for piloting AIDC with MDs. It is suggested that more detailed research and analysis be undertaken in this area at the country level; although it is acknowledged that this may already be taking place at the next level in the English NPSA.

6.4.2 Data Capture element of AIDC

This dissertation has focused on the application of **A**utomatic **I**dentification of MDs linked to patient safety; it has not considered or touched upon the **D**ata **C**apture element of the AIDC technology.

One interviewee (T. Aelbrecht) explains: "RFID is a pure identification technology, it's to communicate and identify a particular item; the information about that item is on a back end system..."

Although the data capture, repository (i.e. Information System(s) and software) and the data analysis have not been covered, a database or linked databases to record events is an intrinsic part of an AIDC system. The author is aware that GS1 is working upon this area (i.e. Global Data Synchronisation Network (GDSN)), but she would suggest that two related areas need further exploration:

a. Electronic Patient Records (EPR)

The first is particular to healthcare, namely that to link the supply chain to the patient, EPRs are fundamental to a healthcare AIDC system - EPR is the healthcare providers DC element of their AIDC system. Are EPRs ubiquitous? What are the implications if they are not?

b. The human element

If an objective of an AIDC system is to generate alerts, e.g. a tagged garment leaving a retail outlet, or in healthcare that the right drug is being administered to the right patient, then an alert generated by the

AIDC system will require a response and/or an action, more than likely, by a human being! What if they don't take action? What steps could be taken to make it more likely that they will take action? Etc.

6.4.3 Out of Scope

In the introduction, in an effort to focus the area of research, the areas that would be both in and out of scope were listed (1.7). The areas in scope have been widely covered in the foregoing text and there has been, as a result of data collection results, some scope-creep into the "out of scope" areas of Supply chain efficiency applications, RFID technology per se and its effectiveness and Physics issues related to RFID with MDs, but not in sufficient breadth or depth. However, it is anticipated that these areas will be within the scope of the recommended pilots (6.3.1) and thus they will begin to be explored more thoroughly.

With regards to Radio Frequency standards it is assumed that the various regional/country regulatory bodies are undertaking work in this area and that they will eventually agree and establish a global Radio Frequency standard.

But the one out of scope area that merits further, expansive research is that of Data protection / Privacy. Not just with regards to the deployment of RFID with MDs, but in any industry where RFID is deployed. Privacy with RFID is a highly emotive subject, as evidenced by the title of Aelbrecht & McIntyre book "Spychips: How Major Corporations and Government plan to track your every move with RFID" (2.1) and should be researched and addressed thoroughly and objectively.

CONCLUSION

Medical Device Manufacturer applied or embedded RFID should be voluntary.

RFID has benefits over existing AIDC technologies, e.g. Bar Codes and has the potential to deliver greater patient safety in the clinical environment. But it should not be seen as a panacea; all AIDC technologies should be considered and piloted, and the most appropriate selected, when attempting to address reported adverse incidents in the most severe "degree of harm" categories (NPSA).

7. Reflection – Personal Development

A common thread throughout my career has been positions at various stages of the extended value chain, with the trend over time of moving closer to the external/economic customer. My current role (UK eBusiness Manager), taken up in 2001, was newly created and focused on ensuring the organisation was well positioned to seize the opportunities offered by the internet, both internally (efficiency) and externally (effectiveness).

The policies, processes, solutions and trained resource are now embedded within the organisation, achieving my vision of "eBusiness = Business". The dissertation, therefore, coincided with the need to consider "what next", both organizationally for eBusiness and career-wise for me.

From a career perspective the topic related both to the thread of the extended value chain and to the strategic eCommerce element of my current role. Personally the dissertation provided an ideal opportunity to combine a long held interest in enabling technologies (that began when the first word-processor was shown on the BBC programme "Tomorrow's World" (circa 1980)) with the first opportunity to undertake academic research.

7.1 Lessons Learnt

As the first formal opportunity to undertake academic research the dissertation process, whilst challenging, facilitated the development of new skills particularly in information gathering, assimilation and interpretation, through the literature review, and new knowledge in regards to the multi-dimensional nature of research (the research process "Onion").

Additionally, the dissertation process broadened my knowledge and understanding of the medical device industry beyond Johnson & Johnson (J&J) and United Kingdom and my knowledge of Auto-ID technologies. This knowledge is already being called upon internally and by both the UK (ABHI) and European (Eucomed) trade associations through my membership of their eBusiness groups.

However, the process also highlighted lack of knowledge and understanding of statistical analysis and tools. Whilst comprehensive use was not necessarily critical, due to the qualitative nature of the research, the tools used (Standard Deviation and Confidence Levels (5.2, 5.3)) proved challenging to understand and were thus conservatively applied! With regards to the "moderately positive" (Hopkins, 2001) confidence level for the interview stage of the research, perhaps a longer timescale would provide the opportunity to increase the number of interview participants, thus improving it.

7.2 Next Time?

Overwhelmingly, rather than avoiding the area, the key thing I would do differently if I were to undertake a research project again, would be to attend at least one, probably more than one, statistical workshop and devote more time to understanding and applying the most appropriate statistical analysis techniques and tools.

7.3 Unexpected outcomes

From an industry perspective the recommendation (6.3.2.) to focus on products related to the highest percentage of reported adverse incidents, to increase the likelihood of establishing a tangible cause and effect link to patient safety, was not an expected outcome. But, it seems so obvious now and will hopefully be heeded by the MD industry.

From a career perspective, as a hot topic, it has generated much interest amongst medical device stakeholders and has resulted in extension of my business network and invitations to present my research and findings at various upcoming industry forums and conferences, as well as the possibility of my work being cited in another research project just started between GS1 and a US University.

Optimistically, the extended network and the interest in the topic in this particular market context will provide career opportunities that continue the common thread of my career in the extended value chain with my ongoing interest enabling technologies.

The three years committed to the Henley MBA has been time-consuming, enjoyable, frustrating, challenging and rewarding – the knowledge and experienced will be well used!

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BIBLIOGRAPHY

Abrahamsen, C. Washington taps into healthcare technology (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=16293711, 2005.

Advamed. A Position paper on Automatic Identification for Medical Devices (Online). Available http://www.advamed.org/publicdocs/auto_id_devices.pdf, 2002.

Advamed. (Presentation) Food for Thought, 2006.

Aegate. (Presentation) Industry Update, March 2006.

Aelbrecht, K. & McIntyre, L., 2006. Spychips: How major corporations and Government plan to track your every move with RFID. US: Nelson (Thomas) Publishers.

Agarwal, V. 2001. Assessing the benefits of Auto-ID Technology in the Consumer Goods Industry, Manufacturing Engineering Masters Project. Cambridge UK: Cambridge University Auto-ID Centre.

Anon. Everything with Chips (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=20874208, 2006.

Anon. Innovating Surgical Workflow (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=19538913, 2006.

Anon. FDA Okays Implanted Chip for Health Care (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=15615179, 2005.

Anon. Patient Safety: The Culture Connection (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=15512646 2005.

Anon. Human 'chipping' takes off (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=11866187, 2003.

Anon. Report forecasts RFID's future in healthcare (Online). Available http://www.usingrfid.com/news/read.asp?lc=t95421cx704zy&version=printable, 2006.
Anon. Paxar's air trick gets around metal and liquid issues (Online). Available www.usingrfid.com/news/read.asp?lc=a993831x464zy&version=printable, 2005.

Anon. Military Medical Centre Installs RFID System (Online). Available http://www.rfidinternational.com/news.php?action=full_news&NewsID=168, 2006.

Arcarese, J. S. Report on Meeting to Discuss Unique Device Identification (Online). Available http://www.fda.gov/cdrh/ocd/uidevices061405.html, 2005

Barthel, H. 2006. Press Release: A Consortium of 31 global organisations supported by the European Commission launches a three-year project in RFID application research and development (by eMail). GS1 Europe.

Bouwen, J. 2006. RFID - Discussion Document (by eMail). Eucomed, Brussels.

Cambridge Consultants. Cambridge Consultants Matching Report - Section 3 - Recommendations (Online). Available www.npsa.nhs.uk/site/media/documents/812_cambridge%20consultants%20report%20section%203.pdf, 2004.

Chignell et al, M. Survey shows rising RFID Interest (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=19538929, 2006.

CNN.com. Wrist tags may stop drug errors (Online). Available http://www.cnn.com/2005/TECH/08/10/spark.wristband/index.html, 2005.

Cochran, M. (Presentation) RFID for Rigid Packaging. UK RFID Interest Group Meeting. Bracknell, UK. 2006.

Collins, J. Healthcare see safety in RFID (Online). Available http://www.rfidjournal.com/article/articleview/2005/1/1/, 2005.

Crotch-Harvey, T. Report of the HealthTag Task Force of the EBS Working Group of Eucomed (Online). Available http://www.eucomed.be/docs/HealthTag%20Reportfinal.pdf, 2005.

Crowell, A. & McCollum, T. The RFID Revolution (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=14670214, 2004.

Da Silva, S. J. (Presentation) From RFID to the INTERNET of Things - Towards a network of tomorrow. EU Commission, Brussels, Belgium. 2006.

Dana Barlow, R. Auto ID Tug-of-War: Bar coding vs. RFID (Online). Available http://www.hpnonline.com/inside/June%2005/0506Cover.html, 2005.

Datta, S. RFID.... An incomplete story (Online). Available http://supplychain.mit.edu/innovation, 2001.

Day, G.S. & Schoemaker, P.J.J. 2000. Wharton on Managing Emerging Technologies. John Wiley & Sons Inc.

Dzwil, E. 2006. RE: Dissertation Hypothesis. (eMail). J&J. 2006.
eHealth Insider. Europe making progress to eHospitals (Online). Available www.e-health-insider.com/news/item.cfm?ID=1097&displayMode=print, 2005.

eHealth Insider. PA calls for electronic tracking of medical devices (Online). Available http://www.e-health-insider.com/news/item.cfm?ID=1089, 2005.

eJNJ. Radio Frequency Identification (RFID) Executive Briefing. J&J Internal document. 2005.

Elliott, M. Bar Codes are forever (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=16288781, 2005.

EU Commission. RFID Consultation (Online). Available http://www.rfidconsultation.eu, 2006.

EU Commission. 2006. RFID Frequently Asked questions (FAQs), Issued at an EU Commission consultation event. Brussels, Belgium.

Eucomed. 2004. Eucomed Position paper on Bar Coding for Medical Devices. Trade Association Position Paper. Brussels, Belgium.

Eucomed. 2005. Medical Technology Brief. Trade Association Brief. Brussels Belgium.

European Union. RFID Consultation (Online). Available http://rfidconsultation.eu/docs/ficheiros/framework_paper_applications_final_version_sw.pdf, 2006.

Evans, N D & Piechowski, R. RFID in Healthcare - 2005 Survey Results Summary (Online). Available http://event.on24.com/event/18413/1/documents/slidepdf/bearingpoint_rfid_in_healthcare_survey_results_(12-05)_final.pdf, 2005.

Fanberg, H. The RFID Revolution (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=14331009, 2004.

Furness, A. 2005. Exploiting the Power of Identification. DTI - Management Overview. UK.

Gannon, B. (Presentation) Towards a RFID policy for Europe. J&J internal. 2006.

Gartner. The Hype Curve (Online). Available www.gartner.com. 1995.

Glover, B. & Himanshu, B. 2006. RFID Essentials. O'Reilly.

Gonzalez, L. EC Workshops: "From RFID to the Internet of Things" (Online). Available http://www.rfidinternational.com/news.php?action=full_news&NewsID=149, 2006.

GS1. 2006. European Adoption Programme. GS1's internal newsletter for GS1 member organisations (MOs). May 2006.

Hay, C. 2004. Auto-identification technologies. ABHI Newsletter “Focus”. Jul-04, 20. Healthcare Industry Task Force (HITF). 2004. Better healthcare through partnership: A programme for Action. Department of Health, Best Practice Guide. November 2004.

Hefflin, B. White Paper: Automatic Identification of Medical Devices, Final Version (Online). Available http://www.fda.gov/cdrh/ocd/ecritask4.pdf, 2005.

Hopkins, W. G. Hopkins: A new view of statistics, http://sportsci.org/resource/stats/generalize.html, 2001.

IDTechEx. 2005. RFID in Action. Journal - RFID in Action. June 2006.

Institute for Safe Medication Practices. The "Five Rights" (Online). Available http://www.ismp.org/Newsletters/acutecare/articles/19990407.asp, 1999.

Janz, B., Pitts, M. & Otondo, R.F. Information Systems and healthcare II: Back to the future with RFID: Lessons Learned - Some old, some new (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=17557171, 2005.

Jenkins, J. & Hay, C. 2004. Automated Tracking of Medical Devices in Europe, Outline proposal for a Proof of Concept Pilot and Demonstration of Best Practice. (eMail). 2006.
Johansen, T.H. & Storm, O. A Feasibility study of new RFID Applications (Online). Available http://student.grm.hia.no/master/ikt04/ikt6400/g10/files/Report.pdf, 2004

Kreysa, U. GS1 HUG - Work Teams. (eMail). May 2006.

Kreysa, U. The Global Healthcare User Group (GS1 HUG). HUG eNewsletter. 31st May 2006.

Law, J. A Women's hospital of the future (Online). Available http://www.rwh.org.au/emplibrary/quality_rwh/CPR_June2005.pdf#xml=http://www.rwh.org.au/cgi-bin/texis/webinator/search4/pdfhi.txt?query=%22A+Women%27s+Hospital+of+the+future%22&pr=rwhmelb_ext&prox=page&rorder=500&rprox=500&rdfreq=500&rwfreq=500&rlead=500&, 2005.

Longe, K. Automatic Identification in the Medical Device Supply Chain - A Survey Report (Online). Available http://www.advamed.org/publicdocs/auto_id_survey.pdf, 2004.

Longworth, L. 2006. The Changing UK Market for Medical Devices; ABHI's Annual Conference: Book of presentations. London.

Malone, R. RFID - It's more than price! (Online). Available www.forbes.com/2005/12/12/rfid-reliability-data-cx_rm_1212rfid_print.html, 2005.

Medwell, G. AIDC & RFID Pilot. (eMail). 31st May 2006.

Morgan, J. (Presentation) The Safe & Secure Supply Chain. EPCGlobal Conference and Exhibition. 7th June 2005. London.

National Patient Safety Agency (NPSA). 2004. Right patient - right care. NPSA, UK.

National Patient Safety Agency (NPSA). 2004. Action to prevent mismatching patients with care - Press release (attachment to Ref. 22). 26th March 2006. NPSA, London.

Neumann, P.G. & Weinstein, L. Risks of RFID (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=20725041, 2006.

Oehlmann, H. UIM - The Unique Identification Mark. Eurodata Council (DIN). (eMail - Sent by member of EPCGlobal HUG Sub-team (Instruments & Implants). 2006.

Phillips, J.T. Betting on Bar Codes (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=2474, 1997.

Porter, M.E. 2005. Competitive Advantage: Creating and Sustaining Superior Performance. Free Press.

Ranger, C. RFID Futures. 2005. (eMail response to Author) 26th March 2006.

Ranger, C. & Cousins, D. Auto-ID and data capture technologies in the NHS - Reaping the benefits, NPSA - Briefing document. (eMail to author) 26th March 2006.

Reiner, J. & Sullivan, M. HEALTHCARE Purchasing News (Online). Available http://www.hpnonline.com/inside/june%2005/0506newsmaker.html, 2005 .

Roark, D.C. & Miguel, K. Bar Coding's Replacement? (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=20019022, 2006.

Rose, M. 2006. RE: MBA Dissertation - Proposal. (eMail response to Author). 13th February 2006.

Saunders, M., Lewis, P. & Thornhill, A. 2003. Research Methods for Business Students. Pearson Education Ltd, Harlow.

Scott, R. 2005. Achieving real EPC Labeling Compliance - Planning your pilot. The GS1 UK EPC Global Conference and Exhibition, 7th June 2005, London.

Sensmeier, J. Here and now: Healthcare's Top 10 IT Breakthroughs (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=18369482, 2005.

Shorecliff Communications. RFID Applications (Online). Available http://www.shorecliffcommunications.com/RFID06Fall/default.asp?showid=R033&info, 2006.

Sokol, B., & Shah, S. 2004. The Future of RFID to the Healthcare Industry.Patni Computer Systems Ltd - Working Paper.

Standeford, D. 2005. Electronic product codes and RFIDs raise privacy fears and lead to code of conduct. Privacy Laws & Business UK Newsletter. 9th October 2005.

Stevenson, E. 2005. Report: Infusion Device Project - Evaluation of Impact of Safer Practice Notice 1. NPSA, London. December 2005.

Stevenson, E. 2006. Commentary on incidents with medical device report from NRLS. Briefing document. NPSA, London. 25th May 2006.

Swetnam, D. 2004. Writing your Dissertation. How to books Ltd:Oxford.

Talon, D. (Presentation) Practical application of traceability on surgical instrument level with RFID to GS1 Healthcare User Group (HUG). Bichat-Claude Bernard Hospital, France. 30th May 2006.

The Patients Association. Tracking medical Devices and the Implications for Patient Safety (Online). Available http://www.patients-association.org.uk/onlinewebmanager/downloads/Tracking%20and%20Tracing.doc, 2005.

van Hasselt, C. When bar codes aren't good enough (Online). Available http://search.epnet.com/login.aspx?direct=true&db=buh&an=15594445, 2005.

Vincent, F. (Presentation) Traceability of surgical instrument at unit level - Experience at HEGP. GS1 Healthcare User Group (HUG). Hopital Europeen Georges Pompidou (HEGP), Paris, France. 30th May 2006.

Walhburg, J. et al. 2006. Performance Management in Health Care - Improving patient outcomes: an integrated approach. Routledge Health Management Series, UK.

Warden, S. (Presentation) RFID in Healthcare. RFID Centre, Bracknell. 15th June 2006.

White, A. White Paper: Radio Frequency Identification (RFID) Why Reusable Asset Tracking is the place to start. (eMail to Author). 2005.

Wyld, D.C. RFID: The Right Frequency for Government (Online). Available http://www.businessofgovernment.org/main/publications/grant_reports/details/index.asp?GID=232, 2005.

WEBSITES:

www.advamed.com
http://www.rwh.org.au
http://www.eucomed.be
http://www.ecri.org/
http://www.fda.gov/
http://www.bearingpoint.com
http://www.aimuk.org/
http://www.zebra.com/id/zebra/na/en/index/campaigns/emea_healthcare_-0/emea_healthcare_-.html
http://www.idtechex.com
http://www.gs1.org
http://whatis.techtarget.com
http://www.ebay.co.uk
http://www.biblio-tech.com

GLOSSARY (1 of 3)

Term	Defintion[2]
	A
ABHI	Association of British Healthcare Industries
Active Tag	A type of RFID tag that has its own power supply (battery or external power) and, when interrogated by a reader, emits its own signal… greater read distances than passive tags… (Wyld, 2005)
Antenna	Conductive elements designed to radiate and/or receive radio energy. As part of an RFID system, antennas radiate or receive radio energy to/from the RFID tags and the reader. (Wyld, 2005)
Anti-Collision	A general term encompassing the means of preventing radio waves from one device interfering with radio waves from another. Anti-collision algorithms enable readers to read more than one tag in the same reader's field. (Wyld, 2005)
Auto-ID	Automatic Identification is a broad term given to a host of technologies that are used to help machines identify objects or persons. It is often coupled with Automated data capture. (e.g. *Bar Code, Smart labels, Voice Recognition, OCR, RFID*) (Furness, 2005) (See AIDC)
AIDC	Automatic Identification and Data Capture
	B
Bar Code	A type of automatic identification technology (See also *Auto-ID, Smart Cards, Voice Recognition, OCR, RFID*) (CNN.com, 2005)
	Linear Bar Code: Ubiquitous. Vertical black lines, white spaces of varying widths plus numbers. In widespread use since early 1970s. (Furness, 2005)
	Two-Dimensional Bar Code: Includes Multi-row bar codes, Matrix bar codes and composite codes (Furness, 2005)
	Multi-Row Bar Codes: exploit the principle of linear bar code symbols but feature cleverly constructed rows capable of containing over two thousand characters in some cases. Include features to support error detection and correction so that even damaged symbols can be read. (Furness, 2005)
Bit/s	Binary bits per second (digital systems)
	C
	D
DH	Department of Health (UK)
	E
EMC	Electro-magnetic compatibility - EU directive: everything to do with interference to other equipment
EPC	Electronic Product Code – A unique number, stored in the chip on an RFID tag, which identifies an item in the supply chain, allowing for tracking of that item. (Wyld, 2005)
EPR	Electronic Patient Record
EU	European Union
	F
FMCG	Fast Moving Consumer Goods
Frequency	The number of repetitions of a complete wave within one second. For example, 1Hz equals one complete waveform in one second; 1KHz equals 1,000 waves in a second. RFID tags use low, high, and ultra-high and microwave frequencies. All frequencies have their own advantages and disadvantages that make tem ore suitable for some applications than for others. (Wyld, 2005)
	G
GS1	Worldwide GS1 network, which specialises in cross-sector supply chain standards from bar coding to electronic business communications.
GDSN	GS1's programme: Global Data Synchronisation Network

GLOSSARY (2 of 3)

<table>
<tr><th colspan="2">H</th></tr>
<tr><td>HIBCC & HIBC</td><td>HIBCC is the Health Industry Business Communications Council, the primary standard-setting and educational organization for bar coding in the world of healthcare. We were founded in 1983 by a consortium of national trade associations specifically to develop an approach to labeling that would fulfill the unique requirements of our industry. The Health Industry Bar Code (HIBC) Standard is the result of that effort.</td></tr>
<tr><th colspan="2">I</th></tr>
<tr><td>Identifier</td><td>A number or some other form of assigning identity to an item. Using in conjunction with a data carrier. (Furness, 2005)</td></tr>
<tr><th colspan="2">L</th></tr>
<tr><td>-Level tagging</td><td>As in: Item-, Case-, Carton- or Pallet-level tagging.
<table>
<tr><th>Level</th><th>Use</th><th>Application</th></tr>
<tr><td>Item</td><td>Consumer Units</td><td>Products and Individual items</td></tr>
<tr><td>Case or Carton</td><td>Traded Units</td><td>Boxes/Packaging/Product carriers</td></tr>
<tr><td>Pallet</td><td>Distribution Unit</td><td>Pallets/Trucks</td></tr>
</table></td></tr>
<tr><th colspan="2">M</th></tr>
<tr><td>MD</td><td>Medical Device:
Definition of the European Union Medical Devices Directive (93/42/EEC):
“...any instrument, apparatus, appliance, material or other article, whether used alone on in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
Diagnosis, prevention, monitoring, treatment or alleviation of disease
Diagnosis, monitoring, treatment or alleviation of or compensation for an injury or handicap
Investigation, replacement or modification of the anatomy or of a physiological process
Control of conception
And which down not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.”</td></tr>
<tr><th colspan="2">N</th></tr>
<tr><td>NPSA</td><td>National Patient Safety Agency</td></tr>
<tr><th colspan="2">O</th></tr>
<tr><td>OCR</td><td>Optical Character Recognition: data is in human readable form. Systems are capable of high speed, accurate recognition, handling multiple fonts and distorted characters. (Furness, 2005)</td></tr>
<tr><th colspan="2">P</th></tr>
<tr><td>Passive Tag</td><td>A type of RFID tag that does not have its own power supply. Instead, the tag draws power from the reader, which sends out electromagnetic waves that induce a current in the tag’s antenna. Without an onboard power source, passive tags have a lesser-read range than active tags. However, they cost less than active tags and have an unlimited life span. (Wyld, 2005)</td></tr>
<tr><th colspan="2">R</th></tr>
<tr><td>R&TTE</td><td>Radio & telecommunications terminal equipment. EU Directive: deals with the single market and product requirements on telecoms and radio products including RFID.</td></tr>
</table>

GLOSSARY (3 of 3)

Reader (or Interrogator)	A device that communicates with RFID tags. The reader has one or more antennas that emit radio waves and receive signals back from the tag. Readers may have a digital display to relay information to the operator and may transmit data on to an organisation's computer network infrastructure. Readers can be either fixed or portable, and today they are beginning to be integrated into other electronic devices such as PDAs (Personal digital assistants) and cell phones, and even into objects such as pens. (Wyld, 2005)
RFID	Radio Frequency Identification. A wireless technology that is used to uniquely identify an object, animal or person. RFID is coming into increasing use in industry as an alternative to the bar code. The advantage of RFID is that it does not require direct contact or line-of-sight.
S	
T	
Tag	The unique identifier for the item it is attached to
Track / Tracking	"Involves controlling the shipping and receiving process for medical devices, as well as managing assets and inventories within healthcare facilities" (Hefflin, 2005) "...The capability to track the path of a specified unit of a healthcare product through the supply chain as it moves between organisations - from manufacturers to distributors to hospitals to patients. Products are tracked routinely for obsolescence, inventory management, potential recall and logistical purposes..." (Jenkins & Hay, 2004)
Trace / Tracing / Traceability	"Relates to building a history - an audit trail - for manufacturing, shipping and receiving medical devices, as well; as the use of devices and supplies in patient care." (Hefflin, 2005) "... The capability to identify the origin of a particular unit and/or batch of product and its location within the supply chain (including the hospital) by reference to records held upstream in the supply chain. Products are traced for purposes such as product recall, investigating complaints, and product servicing and repair..." (Jenkins & Hay, 2004)
W	
W.O.R.M. Tag	Write Once Read Many – A tag that is designed to be written or programmed once and then read many times throughout its life, without the ability to be updated or modified. (Wyld, 2005)

2. Some of the definitions in this glossary have been taken from or are based on definitions suggested by Whatis.com, a leading online ICT encyclopaedia and learning centre. See http://whatis.techtarget.com. Other definitions indicate specific references.

APPENDIX A

Research Interview - Invitation eMail

From: Kite, Janice [MEDGB]
Sent: 30 May 2006 18:29
Subject: MBA Dissertation (RFID) - Interview

Hello

I am in the final stage of study (the Dissertation) for a Master of Business Administration (MBA) qualification with Henley Management College in the UK. The dissertation focuses on Radio Frequency IDentification (RFID) with Medical Devices, an area, I have assumed, is of interest to you due to your participation in RFID related teams, workgroups, organisations etc., that I too participate in. And I would like to request your assistance in my research.

The hypothesis this research will be attempting to provide an answer to is:

> *"Medical Device manufacturer applied or embedded RFID has benefits to Patient Safety over existing AIDC technologies, e.g. Bar Codes."*

The Dissertation is not J&J focused and will be in the public domain. The research is in two parts:

The first part being interviews with key stakeholders in the medical device industry, the second part being a questionnaire, developed from the data collected in the first part and sent to a wider audience (200+).

As key stakeholders, I would very much appreciate your time to be interviewed (max. 60 minutes). This can either be face to face or over the telephone. I have attached a document that outlines the interview approach, dates/times available to be interviewed and the questions that will be asked.

The dissertation will include acknowledgement of your assistance and you will receive a copy. I very much hope you are able to take part in my research and would appreciate your reply by **Friday 9th June.**

Thank you and regards
Janice

Janice Kite
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Johnson & Johnson Medical Devices & Diagnostics
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Mobile: 07785 516 010 *Email*: jkite@medgb.jnj.com
Website: www.jnjgateway.com

APPENDIX B (1 of 3)

RESEARCH INTERVIEW

Hypothesis: Medical Device manufacturer applied or embedded RFID has benefits to Patient Safety over existing AIDC technologies, e.g. Bar Codes.

Radio Frequency Identification (RFID), an AIDC technology, has been around for over 60 years (Datta, 2001:2), so generally it would not be considered an "emerging technology". For the Medical Device (MD) sector of healthcare it "is moving into the healthcare world as well" (Arcarese, 2005:1); therefore, for this sector, it is an emerging technology.

In the last few years interest in and use of RFID in the fast moving consumer goods (FMCG) supply chain has increased. Datta's table "RFID: Still 'new' after 60 years?" indicates that this began in 1999, with "the hype curve" being driven in 2005 by US' Wal-Mart and Department of Defense "demanding suppliers use passive RFID". The driver in healthcare came the same year when Florida, then California and Nevada, drafted the 'Pedigree' law, due to come into effect in 2007 (Dana Barlow, 2005), aimed at preventing counterfeit drugs entering the pharmaceutical supply chain and at improving patient safety. This law requires pharmaceutical manufacturers, and any subsequent handlers of the 'tagged' product, to be able to prove the 'Pedigree' of that product.

There is an assumption that, at some point in the future, MD manufacturers will be requested to tag product in the context of improving Patient Safety (Crotch-Harvey, 2005:10). However, a direct link between RFID tagged MD and improvement in patient safety has not been tested or proven, the link and benefits are assumed.

The following four items are mentioned to provide a common level of understanding for all interviewees:

Types of Auto-Identification systems: (Agarwal, 2001)
- Bar Codes
- Radio Frequency Identification (RFID)
- Optical Character Recognition (OCR)
- Machine Vision
- Magnetic Stripe
- Smart Cards
- Touch memory
- Voice Data Entry
- Radio Frequency Data Communications (RFDC)

Definition of Medical Device:
"'Medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;" *(European Union Medical Devices Directive (93/42/EEC))*

In Scope of Research:
- AIDC applied to / embedded in Medical Devices
- Medical Device market and applications
- Improving Patient Safety related to Medical Devices

Out of Scope of Research:
- RFID Technology - Type of Tags; Tag read rates; Tag prices; Physics issues related to use of RFID tags with medical devices (liquid, metal, temperature, sterilisation) - **It is assumed all issues related to RFID technology will be overcome in due course.**
- Consumer Package Good (CPG) and Fast Moving Consumer Goods (FMCG) market and applications
- Pharmaceutical market and applications
- Business Case / Costs/Savings of implementation
- Supply chain applications (raw material procurement to economic customer delivery)

APPENDIX B (2 of 3)

INTERVIEW PROTOCOL

Purpose: Research for Master of Business Administration (MBA) Dissertation
The dissertation will be generally applicable to the Medical Device industry and will not be specific to any one organisation.

Duration: Maximum 60 minutes

Method: Face-to-Face or telephone

Information capture: Tape recorder - with permission of interviewee

Prior to interview: MBA Student will provide interviewee with this document 2 working days in advance of the scheduled interview data/time.

During the interview:- The interviewee can decline to answer any questions where their answer may be commercially sensitive. Alternatively:
- Some or all the information provided can be kept confidential or anonymous.

After the interview: **-** A transcript of the interview can be provided to the interviewee upon request.
- The information captured during the interview will be used to develop an on-line questionnaire to the wider stakeholder community AND used in the final dissertation itself.
- Final dissertation will be available (Nov. '06) to all participants in the research.

Available Dates & Times:

Session No.	Day	Date	Time (BST; CET -1)	Select all suitable sessions
1	Tuesday	6th June 2006	15:30 - 16:30	Booked
2	Monday	12th June 2006	10:30 - 11:30	
3			13:30 - 14:30	
4			15:00 - 16:00	
5	Tuesday	13th June 2006	13:30 - 14:30	
6			16:00 - 17:00	
7	Wednesday	14th June 2006	09:00 - 10:00	
8			12:30 - 13:30	
9			15:00 - 16:00	
10	Friday	16th June 2006	09:30 - 10:30	
11			11:00 - 12:00	
12			13:30 - 14:30	
13			15:00 - 16:00	
14	Tuesday	20th June 2006	09:30 - 10:30	
15			14:30 - 15:30	
16			16:00 - 17:00	
17	Thursday	22nd June 2006	10:30 - 11:30	
18			13:30 - 14:30	
19			15:00 -16:00	
20	Friday	23rd June 2006	09:30 - 10:30	
21			11:00 - 12:00	
None of the above, please contact me				

Interviewee details:

Name:		**Organisation:**	
Role:		**Tel. No.:**	
eMail:		**Stakeholder class:**	
Date of interview:		**Time of interview:**	

APPENDIX B (3 of 3)

INTERVIEW QUESTIONS

1. Prior to reading the information given above, what was your level of understanding or knowledge of RFID? Please rank low, medium or high

2. Do you agree that improving patient safety is the key driver for applying or embedding RFID to Medical Devices?

3. If yes, what key patient safety issues would RFID tagged products address?

4. If not, why not? And what other drivers do you think there are?

5. The broad definition of Medical Devices provided earlier covers a wide and diverse range of products. Do you think RFID tagging is applicable to ALL medical device products?

6. If yes, why?

7. If not, which are the top five medical device products that should be RFID tagged? And why?

8. The following are some of the reported advantages of RFID over other AIDC systems, e.g. Bar Codes: Tracking; Traceability; Anti-Counterfeit; No line of sight; Expiration alert; Use indication; Scan at distance.

   Are there medical device products in addition to those you have just given that would realise advantages?

9. If yes, what are they and advantages are there?

10. From your perspective as *[an MD manufacturer; a healthcare provider; a patient; a standards body; a Regulatory body; a Government body; a stakeholder - delete not applicable],* if RFID tagging of medical devices does correlate to greater patient safety, what key barriers do you think there are to moving the approach forward?

11. Please rank the level of use of AIDC technologies in your organisation. The ranking is:

    Not applicable; non-user, ex-user, potential user, first-time user, regular user (Kotler, 2003)

12. Are you aware, or can you give examples of, real trials or pilots of RFID applied or embedded with medical devices?

13. How successful was/were the pilot(s)?

14. What were the key successes?

15. What were the key barriers?

16. Is there any additional information that you would like to provide before we conclude the interview?

Thank you for your time and the information you have provided.

APPENDIX C (1 of 3)

INTERVIEW: Medical Device Manufacturer

INTERVIEW QUESTIONS / *Responses*

1. Prior to reading the information given above, what was your level of understanding or knowledge of RFID? Please rank low (no knowledge/understanding), medium or high

I would say an expert as I have worked in the MD industry for 14 years and have a related academic background

2. Do you agree that improving patient safety is the key driver for applying or embedding RFID to Medical Devices?

I know what the politically correct answer would be to that - a clear 'Yes' but I can't see companies working together unless they can see supply chain efficiencies out of it as well. So it's true in some case for some devices you will see patient safety as the key driver, if you look it on a global scale it will be supply chain efficiency as the drivers. Things we do manufacturer we already use RFID in house. So far the RFID tags we need to use have been so expensive that it doesn't compete with what you can do with manual labour and bar codes and regarding patient safety the devices we are dealing with they are still perfectly traceable - with the current processes in place we are still able to manage everything we do. We don't gain much more by applying RFID to them. But we could do things more efficiently, but that's not patient safety, it means savings or headcount reduction and may be speeding up identify where our inventories are.

3. If yes, what key patient safety issues would RFID tagged products address?

4. If not, why not? And what other drivers do you think there are?

5. The broad definition of Medical Devices provided earlier covers a wide and diverse range of products. Do you think RFID tagging is applicable to ALL medical device products?

That depends in the end if you are willing to apply to all, of course you could do that, but the reasons for doing so would be very limited for many of those medical devices. Because we have some consumables that it does not make sense to tag. You also have medical devices like syringes - it would be very limited what could be done here.

6. If yes, why?

7. If not, which are the top five medical device products that should be RFID tagged? And why?

I would always say that, in relation to patient safety, what we are talking about medical devices, we have several in our company that certainly would be high priority for RFID tags. That means critical devices where you have temperature ranges that need to be kept to very strictly; we have also things we implant in patients where, if you had the RFID embedded, you would always be able to identify what devices are implanted in the patient - by serial number, even by taking an x-ray of the patient. They are plenty of those devices that are very particular and usually very costly.

8. The following are some of the reported advantages of RFID over other Auto-ID systems, e.g. Bar Codes. Are there medical device products in addition to those you have just given that would realise advantages? Tracking; Traceability; Anti-Counterfeit; No line of site; Expiration alert; Use indication.

What in addition to those you have already mentioned.

Most of the products in our company would benefit from RFID tags - all the MDs manufactured within our group, they qualify for RFID. They have advantages over existing auto-ID, the business case for MD manufacturers is pretty straight forward: we need to scan our things as they move through the warehouse, if you ship 30k items through your warehouse, that's a lot of scans! Even with the best people in the world, scanning still takes several seconds, the bar code needs to be scanned and you need a person to do that; and items need to be taken out and individually scanned and put back - several times; whereas if you have RFID tags and readers in the shelves you can check stock even without leaving your desk. There are lots of advantages to using RFID tags and we should not forget that! Also further, there are many more things like 'demand planning' you can optimise more than

you can do today. You don't know the needs of the hospital until you get there, consider this… if you knew exactly what, in real-time, when they use any MD you can automatically supply to them.

So you're pushing inventory rather than them pulling it? Yes
We spend millions trying to improve our supply chain, but it stops when the box is dropped at the hospital. And if you could optimise the last few steps in the chain then we have the ripple effect back to our own manufacturing and warehouse and then we can optimise further - these last few steps in the chain there are some many blocks in the road, we need to have higher levels of inventory of everything we supply. If we could see real time that today they use 2, tomorrow 3, then we can ship 5. The biggest savings with RFID are in the hospitals themselves. However, they have so strict tight budgets and very low staffing levels to be able to put the process in place.

Another thing, even if we supply product with tags we need to somehow ensure one standards - That is a problem with bar codes, there is not a unique standard that everyone has agreed on, so it makes it a challenge for the hospital to have one system - they need to optimise their own internal systems. SO I certainly encourage that we agree on a global standard. Otherwise a hospital will not agree to have 10 different standards running in parallel depending on what product has been supplied that they need to track.

9. If yes, what are they and in what way?

10. From your perspective as *an MD manufacturer* if RFID tagging of medical devices does correlate to greater patient safety, what key barriers do you think there are to moving the approach forward?

Hospital capability - the readers put up in the hospital departments. Also devices are being used in cardiology, radiology and they are not too happy having radio frequency put up. Suspicion about new technology and the disruption of that in the clinical world. Tight budgets. They are late adaptors of anything new.

11. Please rank the level of use of Auto-ID technologies in your organisation. The ranking is: *Not applicable; non-user, ex-user, potential user, first-time user, regular user* (Kotler, 2003)

We use Auto-ID in everything we do - Regular user

12. Are you aware, or can you give examples of, real trials or pilots of RFID applied or embedded with medical devices?

Yes, we have a pilot ourselves. Tag products to trial in our own manufacturing and also in customer locations.

13. How successful was/were the pilot(s)?

Very successful for the purpose they were set up - that was mainly for us to get some experience of RFID also to try to further identify where we can get benefits out of using it. And also we have identified some limitations.

14. What were the key successes?

To gain experience and to try to identify where further benefits could be derived from using RFID

15. What were the key barriers?

Limitations and barriers: Sterile and sit in sterile packaging e.g. implants. The problem is we need to apply the ID tag already at the manu. point those products are then brought over to a place where we sterilise and some of those sterilisation processes are simply killing the RFID tags - the electronics are getting fried. Another thing is that the RFID tags, the suppliers of the RFID tags claim they can read 100% etc., but in reality there is a fail rate of between 20-30%. And that is also to do with the reality out in the clinical environment, the nurses they don't always have the time to put up the boxes of the clinical devices nice side by side and all the labels to the same side and down - we need to deal with

reality, we have to work in the environment where our MDs are - what we have seen is that some of the tops of boxes are facing each other then the tags inside the boxes are so close and tight that you will not be able to read both tags. So that means you will get wrong numbers of inventory - and there would be many more than 2 devices, so they could be losing track of many more. And today this is not competing, we do six sigma in our organisation, if we only accept vv few errors = if RFID creates only 10% of errors, that is far from being acceptable in six sigma terms. On top of 20-30% read rate failure the situation is even worse. So far RFID is not near any competition with bar codes.

16. Is there any additional information that you would like to provide before we conclude the interview?

I wish that everybody would come more together and work together to make this a success we could get to market better. It is not a question of if, but when - there are some physical barriers.
GS1 assisting in the collaboration - but they need to do more. The last meetings have had nothing on RFID - they have been focused on retail and pharma.

What do you think the timescale is for having RFID widely used and available in MD?

Even retail is only active using pallet tags - they are very expensive. It would not be economical to tag MDs with actives tags and MDs end their lives in the hospital that is the tags are killed. To apply active tags in this situation the prices of the products would have to rise accordingly and that doesn't make sense. We need to have passive tags so reliable that we can apply them and they need to be cheaper <5c each. But the RFID antennas and tags need to be so reliable that we get as close to 100% read rate. We might see university hospitals installing, otherwise that is a showstopper. That is reality. Some hospital will be willing to trial things and we will work with them and need to see some positives coming out of it first. We need experience, we need to start some activities - What is good about GS1 was the ability to sit down and agree standards to all our benefits - proprietary / proliferation of tags and standards would be a definite barrier to adoption. We see the number of bar codes stands (>=15) - bar codes are not ubiquitous. That shouldn't stop us exploring the next step - there will always be early adopter and late adopters. RFID will only be useful on a large scale

Thank you for your time and the information you have provided.

APPENDIX D

Research Interview - Questionnaire Invitation eMail

From: Kite, Janice [MEDGB]
Sent: 10 July 2006 16:27
Subject: RFID & Medical Devices - Research Questionnaire

Hello

I am in the final stage of study (the Dissertation) for a Master of Business Administration (MBA) qualification with Henley Management College in the UK. The dissertation focuses on Radio Frequency IDentification (RFID) with Medical Devices, an area, I have assumed, is of interest to you due to your participation in RFID related teams, workgroups, organisations etc. And I would like to request your assistance in my research by taking part in a short on-line questionnaire. It should take no more than **10 minutes** to complete the questionnaire.

The hypothesis this research will be attempting to provide an answer to is:

Medical Device manufacturer applied or embedded RFID has benefits to Patient Safety over existing Auto-ID technologies, e.g. Bar Codes.

The dissertation will be generally applicable to the Medical Device industry and not be specific to any one organisation.

This link will take you to the questionnaire:
http://www.surveymonkey.com/s.asp?u=459112339451

The questionnaire is anonymous, unless you choose to provide your details. It will remain open for two weeks up to and including **Sunday 23rd July 2006.**

Whilst comprehensive completion of the questionnaire would be invaluable, you may skip questions that you are unable to answer and decline to answer any questions where the answer may be commercially sensitive. Please also feel free to forward it to colleagues or contacts that have interest or expertise in this topic.

A copy of the final dissertation will be available (Nov. '06) to those whom request it (at the end of the questionnaire).

Thank you for your time and assistance
Best regards
Janice
Janice Kite
UK E-Business Manager
Johnson & Johnson Medical Devices & Diagnostics
The Braccans, London Road, Bracknell, Berkshire, RG12 2AT
Direct: +44 (0) 1344 864 392 Fax: +44 (0) 1344 319 424
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Website: www.jnjgateway.com

APPENDIX E

Interviews - Standard Deviation

Score	Mean	deviation from mean	Squared deviation		
5	0	5	25	3SD	-3.13
1	0	1	1	2SD	-1.56
1	0	1	1	1SD	0.02
3	0	3	9	**Mean**	1.6
1	0	1	1	1SD	3.18
3	0	3	9	2SD	4.76
1	0	1	1	3SD	6.33
1	0	1	1		
0	0	0	0		
0	0	0	0		
Mean	**1.6**				
Sum of squared deviations			**48.00**		
Square root (sum of squared deviations / (N-1))				**5.33**	
Standard deviation				**1.58**	

Questionnaire - Standard Deviation

Score	Mean	deviation from mean	Squared deviation		
69	17.94	51.06	2607.38	3SD	-87.13
132	17.94	114.06	13010.25	2SD	-52.11
25	17.94	7.06	49.88	1SD	-17.09
19	17.94	1.06	1.13	**Mean**	17.94
15	17.94	-2.94	8.63	1SD	52.96
8	17.94	-9.94	98.75	2SD	87.98
7	17.94	-10.94	119.63	3SD	123.01
5	17.94	-12.94	167.38		
2	17.94	-15.94	254.00		
2	17.94	-15.94	254.00		
2	17.94	-15.94	254.00		
1	17.94	-16.94	286.88		
0	17.94	-17.94	321.75		
0	17.94	-17.94	321.75		
0	17.94	-17.94	321.75		
0	17.94	-17.94	321.75		
Mean	**17.94**				
Sum of squared deviations			**18398.94**		
Square root (sum of squared deviations / (N-1))				**1226.60**	
Standard deviation				**35.02**	

192 words