HUG

Master of Business Administration (MBA) Research Dissertation

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The global language of business

www.gs1.org

Hypothesis

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

Assume it’s true...

Great research topic!

Research Questions...

- Fact, theory or assumption: tagging MDs WILL improve patient safety?
- Has it been piloted with MDs?
- Will it work?
  - Is RFID technology stable enough?
    - Physics issues: metal, liquid, sterilisation
    - Frequency standards: vary globally
  - Identification standards: developing?
- Will it be accepted?
  - Privacy ‘spy tags’
- Does RFID have benefits over existing Auto-ID technologies?

Objectives

- 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

Research

- Literature Review
- 1:1 Interviews of key stakeholder groups
- On-line questionnaire wider stakeholder groups

Literature Research

Google it!

- Databases: EBSCO, ProQuest, GoogleScholar
- Keywords: "RFID" – 107m
  RFID+Medical Devices+2005 – 1.8m
- Sources: Focus on Journals and preview text – 1k
- Results? Majority
  - Identifying patients
  - Future looking: 'potential' 'opportunity'
- Limitations: Lack of literature sources

- Reviewed circa 100 items of literature
  - 42 relevant
- ZERO containing tangible evidence that tagging MD improved patient safety!

Stakeholder Interviews

22 Approached

Medical Device Manufacturers
Trade Associations
Standards Bodies (GS1, EPCGlobal)
EU
FDA
UK National Patient Safety Agency
Legal / Policy
UK NHS Trust

Two groups – no participation:
Patients
Privacy groups

Stakeholder Interviews

16 Participants - 73% Participation Rate

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 foresaw with doing so

4. Find out if there are pilots being undertaken with these MDs

Stakeholder Interviews

Results

Level of understanding and knowledge of RFID in the key stakeholder groups

(low = none : high = expert)

83% medium to high

Assumed they were sufficiently well informed to answers to the remaining questions!

Stakeholder Interviews

Results

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

94% Yes / A Key driver

of which

36% Supply Chain Efficiency

Examples related to a point or sub-process within the extended supply chain

- **Availability:** Being able to identify an RFID tagged asset, e.g. an infusion pump, and locate when required
- **Suitability:** It is fit for purpose, e.g. the multi-use instrument is clean and sterile or the product is within expiry period.
- **Authenticity:** Anti-counterfeit – the RFID tag confirms it is the said product, avoiding inferior product being used on the patient

Improving overall supply chain efficiency could result in greater Patient Safety

Stakeholder Interviews

Results

Establish which MDs the stakeholder community would target for RFID tagging, why and…

The top 5 MDs that should be tagged:

MD	WHY
Assets - e.g. Infusion Pumps	Availability & High value
Surgical instruments	Suitability & High value
Orthopaedic Implants	Supply chain & High value
Stents (implants)	Supply chain & High value
Cardiac implants	Supply chain & High value

Stakeholder Interviews

Results

…what barriers they foresaw with doing so

TOP 5:

Technology/physics issues with MD

Cost of implementation particularly due to the financial constraints/health of the healthcare providers/hospitals

Culture - technology adoption and use *(Bar Codes are not ubiquitous in healthcare)*

Privacy/data protection concerns ('spy tags')

Lack of global standards

- data capture/storage/management and
- radio spectrum (the frequencies used vary across the globe).

Stakeholder Interviews

Results

Find out if there are pilots being undertaken with MDs

5 pilots were mentioned:

- 2 French hospitals: marking of instruments
- 2 MD manufacturers: supply chain efficiency
- 1 MD manufacturer: counterfeit prevention of sterilisation chemicals

All work in progress, evidence of success is not yet available

But…

Stakeholder Interviews

Results

...evidence of technology / physics barriers being experienced in reality

Tags applied during the manufacturing process... before sterilisation... sterilisation 'fried' the tags

Read rate - tag suppliers claim 100% experienced fail rate of 20-30%

- manipulation of antenna and/or positioning of tags

Alignment of packages on shelves to avoid tag 'collision'

Given the size of the market and the diverse range of MD products, this is an insignificant number of pilots and it would be inappropriate to draw major conclusions from them

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Stakeholder Interviews

Summary

High stakeholder participation Rate (73%)

Stakeholders are well informed

Patient Safety is the KEY driver for using RFID with MD

Improving extended supply chain – a tactical way to achieve it

"Linking the supply chain with the patient" *Chris Ranger, NPSA*

The top 5 MDs that should be tagged:

- Assets
- Orthopaedic Implants
- Cardiac implants
- Surgical instruments
- Stents

TOP 5 barriers:

- Technology/physics
- Privacy ('spy tags')
- Culture - technology adoption and use
- Cost of implementation
- Lack of global standards

Pilots - insignificant number of pilots to draw major conclusions

Further Research

Stakeholder Questionnaire

The purpose of the survey was to validate the interview results with a wider stakeholder audience

On-line Survey – www.surveymonkey.com

Stakeholder Questionnaire

23.7% Response Rate

- 271 invited
- 26 failed email addresses – 245 potential
- Open for two weeks
- 58 respondents = 23.7%
- Statistically high response rate
- Average response rate for on-line surveys

Stakeholder Questionnaire

23.7 % Response Rate

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%**

Medical Device Manufacturers were the predominant stakeholder group – 58.6% (34 of 58)

Stakeholder Questionnaire

23.7 % Response Rate

Level of understanding / knowledge of RFID

Common with the results of the interviews:

Medium (58.6%) or High (39.7%)

Consistent assumption:

Sufficient understanding and knowledge to provide relevant answers to the remaining questions

Stakeholder Questionnaire

23.7 % Response Rate

Is Patient Safety the KEY driver for using RFID with MDs?

77.6% - YES

Higher than interviewees (44%)

Why is it the key driver?

Suitability 80% (35.6% of total respondents)

It is fit for purpose, e.g. the multi-use instrument is clean and sterile or the product is within expiry period.

Authenticity 62.2% (27.7%)

Anti-counterfeit – the RFID tag confirms it is the said product, avoiding inferior product being used on the patient

Availability 53.3% (23.8%)

Being able to identify an RFID tagged asset, e.g. an infusion pump, and locate when required

Stakeholder Questionnaire

23.7 % Response Rate

Is Patient Safety the KEY driver for using RFID with MDs?

22.4% - NO

What is the key driver? Could give more than one category

100% Supply chain efficiency (from manufacturer to point of care)

46.2% Financial

30.8% Preventative healthcare

15.4% Product innovation

Stakeholder Questionnaire

23.7 % Response Rate

"Supply Chain efficiency" anticipated as high response

Cause and effect link to Patient Safety?

Do you think that utilising RFID to improve the supply chain will result in greater patient safety?

13.8%	Possibly
6.9%	Yes
<2%	No
77.6%	Did not answer!

It could be assumed that they could not explain the linkage!

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Stakeholder Questionnaire

To "Yes" / "Possibly" respondents

How do you see improved supply chain leading to greater patient safety?

Free text responses analysed
Corresponded to cited Drivers:

Patient Safety

- Authenticity (Anti-counterfeit – the RFID tag confirms it is the said product, avoiding inferior product being used on the patient)
- Availability (Being able to identify an RFID tagged asset, e.g. an infusion pump, and locate when required)

Supply chain efficiency

- Track
- Traceability

So, a few could make a cause and effect link – in theory

Stakeholder Questionnaire

23.7 % Response Rate

Rank the 5 target product groups prioritised to be tagged

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

Slight difference of opinion (Assets & Orthopaedic implants)

Reversal of ranking for Cardiac implants

Stakeholder Questionnaire

23.7 % Response Rate

Rank the top 5 Barriers to adoption of RFID with MDs

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

Very similar!

Tech issues / Finance / Standards – immediacy? Need addressing now?

Culture / Privacy – later?

Stakeholder Questionnaire

23.7 % Response Rate

- Similarities between interviews and questionnaire
- A few could make a cause and effect link – in theory…
- But largely Possibilities and Assumptions

OR is there tangible evidence?

Stakeholder Questionnaire

23.7 % Response Rate

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**		

Stakeholder Questionnaire

23.7 % Response Rate

Are there pilots being undertaken with MDs?

50% (29) gave examples

Analysis:

- 12 NOT related to MDs
- 17 related to MDS

Successes?

- Availability
- Track & Trace
- Cost/Financial

Barriers?

- Technical / Physics issues

4 of top 5 target product groups involved (not Cardiac Implants)

ALL are work in progress – no published case studies

Stakeholder Questionnaire
SUMMARY

- High participation rate
- Consistent with data from literature review and interviews
- Medium/high knowledge & understanding of RFID
- Key drivers: Patient Safety AND Supply chain efficiency
- Reasons why (e.g. suitability, track and trace) ranked in a similar way
- RFID tagging is not applicable to all MDs
- Ranking of top 5 target product groups similar
- 4 of these covered in the ongoing pilots (not cardiac implants)
- Ranking of the barriers similar
- Pilots are work in progress, but some evidence of:
  - addressing some “reasons”
  - Barriers encountered

Conclusions

In answer to the research questions the following conclusions have been drawn:

a. Patient Safety is the KEY driver for using RFID with MD

b. There have been insufficient pilots and resulting in 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.

c. Whilst RFID has benefits over other AIDC technologies, they are not universally realisable or applicable to all MDs

d. There are barriers to be overcome with RFID technology

e. There is potential to derive benefits through a more tactical, widespread and efficient use of other AIDC technologies that are already used by MD manufacturers

Conclusions

Hypothesis:

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

Proven?

No! The hypothesis has not been definitively proven

or disproved

Objectives

The research project has met the objectives:

- It provides the medical industry with a piece of research that begins to fill the literary gap
- It could 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

Recommendations

"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)"

Involve key stakeholder groups in pilots. 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

Limitations of Research

Further research topics

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

1. Adverse Incidents with MDs – as a criteria for pilots
2. Data Capture element of AI*DC*
3. Data protection / Privacy

Opportunities for GS1 HUG™?

Publication of Dissertation

If I pass!

mid October

If you want a copy...

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