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Policy options for Radio Frequency Identification (RFID) application in healthcare; a prospective view

Final report (D5)

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Prepared for the European Commission Directorate General for Information Society and Media



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This is the final report of the study: *Policy options for Radio Frequency Identification (RFID)* application in healthcare (or RFID&Health study). Its primary objective is to generate robust policy recommendations for the European Commission. It builds on all previous research done within the study (literature review, interviews, Delphi survey, case studies, Scenario analysis and gaming workshop), and refers to other reports published before for further evidence, where relevant.

This report adds a prospective angle to allow developing policies to support the roll out of RFID and similar technologies to benefit the quality and efficiency of care delivery. Through the use of scenarios we considered the robustness of potentially relevant policies against different ways the future can work out, taking into account the major uncertainties in the way RFID and the provision of healthcare may develop. The scenarios are also stand alone deliverables and can be used by parties interested in reviewing the future of care.

This report mainly focuses on the current market situation, the prospective views on how the future may look; what possible policy issues this generates and how the European Commission may address these.

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Glossary

| COTS | Commercial off-the-shelf products, i.e. not customised to specific clients | | | | | |
|------------|--|--|--|--|--|--|
| DataMatrix | Two-dimensional matrix barcode consisting of black and white "cells" or modules arranged in either a square or rectangular pattern. The information to be encoded can be text or raw data. | | | | | |
| eID | Electronic Identity | | | | | |
| eIDM | Electronic Identity Management | | | | | |
| FTTH | Fibre to the home, term for any broadband network architecture that uses optical fibre to replace all or part of the usual metal local loop used for last mile telecommunications to the home | | | | | |
| GDP | Gross Domestic Product is the market value of all final goods and services made within the borders of a nation in a year | | | | | |
| GP | General Practitioner | | | | | |
| GPS | Global Positioning System, a global navigation satellite system (GNSS) that allow GPS receivers to determine their current location, the time, and their velocity | | | | | |
| Hype cycle | A hype cycle is a graphic representation of the maturity, adoption and business application of specific technologies (Gartner) | | | | | |
| ICT | Information and communication technologies, an umbrella term that covers all advanced technologies in manipulating and communicating information. | | | | | |
| ISM | Industrial, scientific and medical (ISM) radio bands were originally reserved internationally for the use of RF electromagnetic fields for industrial, scientific and medical purposes other than communications. In general, communications equipment must accept any interference generated by ISM equipment. It is now widely in use for RFID applications. | | | | | |

| MAC | Medical Alert Chip", invented by the project team, standardised throughout Europe. The MAC only stores key medical information like allergies and heavy medicine use, to support the delivery of care in case of incidents | | | | | |
|-------|--|--|--|--|--|--|
| РРР | Public Private Partnership: collaboration between public and private sector organisations with a mutual objective | | | | | |
| PTL | Patient Throughput and Logistics management | | | | | |
| RFID | Radio-frequency identification, use of an object ("tag") applied to or incorporated into a product, animal, or person for the purpose of identification and tracking using radio waves | | | | | |
| ROI | Return On Investment is the ratio of money gained or lost on an investment relative to the amount of money invested. | | | | | |
| RTD | Research and Technology Development, as so called, sponsored by the European Framework Programmes | | | | | |
| RTLS | Real-time location systems, often used in combination with wireless sensor networks | | | | | |
| SMEs | Small and Medium-Sized Enterprises | | | | | |
| STORK | Large scale pilot in the ICT-PSP (ICT Policy Support Programme), under the CIP (Competitiveness and Innovation Programme), and co-funded by EU. It aims at implementing an EU wide interoperable system for recognition of eID and authentication that will enable businesses, citizens and government employees to use their national electronic identities in any Member State. It also pilots trans-border eGovernment identity services and learn from practice on how to roll out such services, and to experience what benefits and challenges an EU wide interoperability system for recognition of eID will bring. | | | | | |
| SWOT | Strength, Weaknesses, Opportunities and Threats, as dimensions that are considered for analysis of competitiveness | | | | | |

Objectives

The main objective of this report is to take all the analysis of the study of the most promising RFID applications in healthcare and derive a useful set of policy recommendations for the European Commission. The ultimate objectives being:

- *1.* the improvement of the quality and efficiency of care through the use of information and communication technologies, notably RFID
- *2.* the strengthening of the EU RFID industry's ability to capture the opportunities for deploying RFID in healthcare

The first objective aims at policies to support an effective deployment ICT in care delivery environments, to improve healthcare by increasing quality of care and patient safety, making healthcare more efficient. This can only be achieved within the right regulatory, organisational and technical environment, taking account of the rights of patients and staff and providing for the right infrastructures, frequencies, financing mechanisms etc.

The second objective looks at the RFID technology as an economic opportunity for EU industry. Following the Aho report¹, innovation and industry support should not only be supply based but must also focus on market and pull factors. Healthcare is a promising market for RFID technology and thus has the potential to create a European niche for suppliers of RFID equipment and underlying software.

Therefore this report looks at policies to establish the right conditions required for effective and responsible deployment of RFID in healthcare, as well as market support mechanisms to stimulate the European RFID & health industry.

What is RFID?

RFID is Radio-frequency identification, in which an object ("tag") is applied to or incorporated into a product, animal, or person to facilitate identification and tracking using radio waves. Applications might include tracking assets within a hospital, reducing medical error by matching patients to procedures and drugs, and tracking patients (e.g. in dementia)

Approach

¹Creating an Innovative Europe Report of the Independent Expert Group on R&D and Innovation appointed following the Hampton Court Summit and chaired by Mr. Esko Aho

This study applied a number of research approaches in a sequential manner: systematic review of literature; Delphi expert survey; semi-structured interviews; case studies and scenario analysis. To determine effective future policies experts were asked to engage with 3 future scenarios in a gaming workshop. This included a role play of stakeholders and applying the technique of 'foresight through virtual hindsight'. The scenarios provide three different future contexts that can be used by interested parties to scope market opportunities and threats, and to form views on evolving healthcare environments. These are not predictions but instruments to help policy development and support decision makers in dealing with uncertainty.

General market review and outlook

RFID is still a relatively young market with good growth potential. More mature application can be found in retail logistics where RFID has proven its value and successful implementations have led to a realistic understanding of capabilities and hence to adoption by mainstream users. As a general trend across sectors, innovation rather than cost reduction has become the driver for RFID adoption. In particular, aggressive technology adopters are reaching out for RFID-enabled solutions to boost competitiveness of their businesses, and investment decisions often favour closed-loop systems² that show robust returns on investment. Market projections for RFID in healthcare have been overly optimistic. Strong growth is expected in particular for item-level tagging of drugs (outside the scope of this study³) and for active RFID applications combining environments and technologies (e.g. RFID+sensor, RFID+GPS). In addition, interest in palliative care, home care and preventive care applications, including tele-homecare applications is expected to further develop.

Europe is trailing the US on most economic indicators relating to RFID. Of the total RFID revenues in 2007 North America covers 65%, followed by Europe (23%). After an initial phase dominated by pilots in many domains, Europe is now entering a second round of adoption and expected to enter significant upturn in RFID activity by 2010 as it explores and adopts new standards and takes advantage of the latest tag and reader technology. Also, other regions are catching up, and strong take-up is expected for 2012 in particular in Asia/Pacific and Japan, Latin America, the Middle East and Latin America.

The current picture of the supplier market is that chip producer, assembler markets and suppliers of real-time tracking applications are already highly consolidated and concentrated, as most Small and Medium-Sized Enterprises (SMEs) have been acquired and merged into bigger entities, making RFID an add-on – one of many complementary and/or competing technologies in the product portfolio of larger companies. Mergers and acquisition indicate that RFID markets, in particular markets for RTLS, are undergoing a shakeout phase, giving a brief window of opportunity for European firms to secure a foothold.

It is not immediately clear that fast and widespread adoption of a homogeneous RFID approach (especially passive systems) is *necessarily* desirable from either the economic or

² Dedicated application within a defined context

³ Explicitly excluded by DG INFO from the scope of this study, as this is the domain of DG Enterprise.

healthcare perspective. The fragmented EU markets are likely to develop different deployment trajectories, favouring different applications and technologies, following from differences in rules, funding mechanisms, and healthcare strategies. This diversity is important and valuable as it holds the potential for innovative discovery and product development as the technology and the applications are still not fully mature.

Current status of RFID deployment in healthcare

The overall picture of the potential of RFID in healthcare is nuanced: there seem to be many arguments in favour of a wide RFID roll-out, though health care providers do not care about the technology, but about costs and functionalities. As such RFID is just one among other ID technologies (2D barcodes, DataMatrix). Most RFID applications are found in hospital logistics and operational management. However it turns out that in Europe the reasons for investing in RFID mostly concern the quality of care and not so much a reduction of costs (which seems to be driving the application in the US). The applications are mostly specific and bespoke, and not integrated in wider IT systems, thus presenting a very fragmented picture.

For now RFID applications are rarely integrated in the overall ICT environment of the hospital, let alone in a wider a context of outbound eHealth solutions. In Europe they still seem geared to address specific issues, without a view on capturing the overall benefit of the information that is generated, for monitoring and management purposes. This potential thus remains largely untapped.

Most promising applications are: tracking of assets, tracking and identification of patients, and automatic data collection and transfer. The further development and roll out of these still meet with certain technical, organizational, cultural and other impediments (actual barriers as well as uncertainties). Moreover, there are important organisational factors that have to be taken into account for successful implementation of RFID.

This section draws on the findings in the previous report of this study: *Study on the requirements and options for Radio Frequency Identification (RFID) application in healthcare (Final report).* For a detailed discussion of the most promising RFID applications in healthcare; barriers, drivers, enablers and uncertainties, as well as success and failure factors we refer to this report.

Future contexts and possible policy issues

Three scenarios were developed to allow a forward looking discussion on necessary policies.

Scenario 1: The *private care society* is very well equipped with RFID to monitor and manage health issues, in a local context. Everybody has his or her RFID reader at hand, coupled with the mobile phone. RFID data and medical records are with the patient, who is in control. Whereas she or he cannot change critical health data without co-authorization of a medical professional, she or he can read the data and add "personal remarks". Medical professionals need to have permission from the patient to read the data, which are protected by a patient-owned pin. However, in case of emergency access to the chip can be obtained using specific equipment that will require strict ex-post justification for its use. In this society, health is seen as something that needs to be protected by actively signaling health risks (prevention). For those recovering from health incidents and treatment RFID supported equipment can help to keep track of recovery progress and

suggest specific action when required following a signal from (implanted) body sensors. This is a society with confidence in RFID and new technologies in general, with a strong European system of regulation effectively enforced at the national level. For those in regular work, with employer contributions to health insurance, it is a world of steady increase in number and quality of treatments. However, few incentives exist to ensure that these benefits are spread to marginalized groups and more collective public health interventions aimed at benefiting the whole of society are often difficult to deliver. Few incentives exist to integrate health care with related services (social care, diet and exercise support, healthy workplaces and so forth) although the technology to do so is available. A small but vocal minority is hostile to high technology solutions to what they see as ill-health created by a spiritual malaise.

Scenario 2: The central care society is truly measuring and bringing together all medical data of its citizens, in order to be able to prevent health incidents by actively informing citizens about health risks. Also, in case of accidents as well as in cases where continuous health care assistance is needed, linking all data has proven to be effective and useful. The public value that is created through preventive care and life style support (lowering of healthcare costs, fitter people, less social exclusion etc) puts pressure on (and may even demand from) people to conform and follow up on healthcare recommendations. RFID enabled sensors will report compliance issues to the medic responsible for the health of that specific citizen. The costs of the system are covered by savings of the healthcare system as a whole. This cost saving potential provides an incentive to implement RFID. The coercive aspect to this has led to some resistance and refusal to participate in RFID-enable health care and has led to people being excluded from the main healthcare system and provided with a more basic service. Such people tend not to adopt a more 'natural' or 'holistic' approach to healthcare; instead they suffer poor levels of health status and health care. Particular anger has been expressed by those who object to data being collected in one sector (health) being made available to elsewhere (e.g. in food marketing, alcohol retail etc). Regulations exist at the European level but Member States have tended to give these very different interpretations through national regulation.

Scenario 3: The Incident Care Society (ICS) world is a world we could not have imagined to have developed a decade ago. Overall, this society is one where medical care is provided on a very basic level, with little emphasis on preventive care. In addition, advances have been made in better handling of emergencies, and incidents. It is here where RFID makes a difference as rapid identification of people in emergencies and accidents and their specific medical needs is available, and integrated in the incident handling activity supported by the "Medical Alert Chip" (MAC), which is standardised throughout Europe. The MAC only stores key medical information like allergies and heavy medicine use, to support the delivery of care in case of incidents. In this world, resources and incentive to innovate focus narrowly on specific health treatments and interventions such as elective surgery, accidents and emergency, short term ill-health. This leaves chronic conditions, long-term multifactoral health problems, and mental health care and other long term interventions under-funded, though through the MAC platform new services like monitoring medication are being considered. Care is provided in a largely low-tech environment. This has reinforced a division between the 'occasionally unwell' and the 'long-term sick' with older, poorer and non-employed people tending to be in the latter category. The European level has attempted to limit this trend but with little success and indeed European regulations intended to benefit excluded groups have been blamed for hampering improvements.

Issues emerging across scenarios

Policies and vision: a particular vision on healthcare in Europe should be leading in the developing RFID policies. RFID is obviously only a small part of the whole tech investment. Also, discussions should focus on functionalities and not on a specific technology. Information technology is likely to be an increasingly important component in the delivery of affordable healthcare for all. Yet there are also considerable risks that need to be addressed; like possible public resistance, privacy and security concerns, spectrum access and management. In dealing with these lessons should be drawn from other sectors and countries. In Japan, a major foresight study is on the way to picture Japan in 2025 (including health). In the health domain, it particularly looks at personal care in home environments and its implications for healthcare and the pharmaceutical industry.

Technology issues: Many problems can be solved with other ID technologies (barcodes, 2D barcodes, DataMatrix, etc) and do not necessarily require RFID. Affordable 2D barcodes and DataMatrix printers have very recently been brought to the market. RFID applications in healthcare in use today are often fragmented and not coherently embedded in existing infrastructures. A better understanding is required on how tags communicate with existing technologies and how to implement RFID in a barcode infrastructures.

Functionalities: When considering to invest in RFID, the potential improvement in the quality of care should be assessed as well as the potential for efficiency increases (cost reductions). The real challenge lies in evaluating quality improvements, in particular when no (or insufficient) data exists on the status quo, and hence no benchmark to compare to. In doing so RFID needs to be clearly distinguished as a therapeutic device versus RFID as an identification device, as they have different benefits and concerns.

Risks: Any cost-benefit analysis on any RFID system should consider the requirements for and costs of the back-up system and try to evaluate the risk of system failure. In the health care sector, system failure can be fatal.

Recommendations for DG INFSO

- 1. Procure research into:
 - The effects of RFID; in order to establish an evidence base and common understanding of risks, limitations, benefits and opportunities of the technology and specific issues concerning the application in healthcare settings.
 - The barriers, risks, and weaknesses of RFID, in order to solve them and improve the technology and its applications
 - Developing appropriate middleware
- 2. Develop and facilitate public private partnerships (PPPs) across Europe thematic networks or more specific and dedicated groupings to
 - issue common messages
 - develop common, open en healthcare sensitive standards
 - load the RFID logo with positive attributes 'RFID inside' and ensure uniformity of the message
 - champion the need for dedicated frequency band
 - establish a set of European quality norms for safety, privacy, reliability, and security
- 3. Review of data protection framework and assessing common minimum standards for privacy in the specific context of healthcare delivery
- 4. Increase the support of cross-border service delivery; through the CIP Large Scale Pilots and/or mechanisms like eTEN
- 5. Continue coordination and support to the establishment of a common EU eIDM principally through the large scale eIDM pilot STORK and the eHealth pilot B;
- 6. Also use these pilots to assess what the spectrum needs in healthcare are going to be, as well as the spectrum requirements; and determine the most appropriate frequency for health care and emergency services
- 7. Sensitise and effectively use competition policy to avoid technology lock ins
- 8. Assemble best practices and facilitate knowledge transfer in the EU

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Introduction

Radio Frequency Identification (RFID) technology is becoming increasingly common in a wide array of every day applications. It has an established track record in the logistics and retail sectors. It is also a component technology of the Internet of Things, which promises a world of disappearing ICT, seamless connectivity and ubiquitous computing power. Here things, machines, and people all exchange information continuously making our environments more intelligent and aware. This environment is friendly to technology for outbound and preventive healthcare delivery and monitoring. It provides support to the elderly and enables longer independent living.

This future may be around the corner. It may or not be desirable. All we know is that the underlying technologies are there and that rapid change is putting pressure on policy makers to act effectively and decisively in the face of uncertainty. This report - and the study of which it is part - sets out to review one of the essential technologies and its development and deployment in the healthcare sector: RFID.

The objective is to determine what could be effective policies for stimulating the ICT industry and its ability to develop useful services and products for the health care sector in Europe. But also to ensure healthcare delivery can optimally benefit from the potential of ICTs in particular RFID to improve quality and efficiency of care. And finally, to promote the application of these technologies in ways that suit overarching policy objectives, such as the pursuit of integrity, privacy, inclusiveness, equality, safety, etc.

To derive at the policy recommendations, the report first discusses the state of the market for RFID and healthcare; then presents findings from previous work on the current deployment of RFID in healthcare delivery and identifies the most promising RFID applications; finally it discusses a number of possible future scenarios to allow an assessment of the robustness of policy recommendations. This is required to ensure that policies will be able to perform under a range of possible uncertainties in the medium and long term. "RFID will not succeed if it is considered to be a replacement for current solutions. RFID will succeed where added value is clearly visible in comparison to existing solutions." (Heinrich Oehlmann, EHIBCC, 2008)

This chapter looks at the economic outlook of RFID deployment in the healthcare sector. Our analysis is roughly structured around supply and demand. We will review demand for RFID technology globally (Section 1.1.1) and in Europe (Section 1.1.2) and focus on market projections for RFID in healthcare (Section 1.1.3). To sharpen the image, we will distinguish between active and passive RFID solutions and incorporate the concept of hype-cycles to explain its update and evolution. We will then look at the supply side by region, country and market segment (Section 1.2). This chapter concludes with a brief summary of key findings relevant to European policy makers (Section 1.3).

1.1 **Demand for RFID**

1.1.1 Economic outlook - global RFID market

Recent commercial RFID development has been driven by large-scale demand mandates, most notably by the U.S. Department of Defense (DoD) and Wal-Mart in 2005. Early technology adopters operating on tight profit margins pushed hardware producers to lower costs, squeezing their profitability. This trend has started to fade and innovation rather than cost has become the driver of RFID adoption. Innovative solutions and new applications have started to stimulate interest and investment in RFID. In particular combinatory solutions linking environments and technologies (e.g. RFID+sensor, RFID+GPS) are increasingly receiving attention. Furthermore, we see a trend in investment decisions towards closed systems that show robust returns on investment. Closed systems are often specified within particular organisations for use by those organisations in a way that is effectively under their control. Agreements are internal or between the respective organisations and as such are effectively closed by the system specification and associated agreements. Competitive opportunities, technological developments and product diversity each contribute to the diversity of systems subsequently adopted on closed system basis.

Gartner (2007) estimates that total RFID revenue (software and hardware) will grow from approximately \$0.9 billion in 2007 to \$3.5 billion in 2012.⁴ IdTechEx (2008) extends projections to 2018 and expects strong growth to continue. According to their estimates, the value of RFID tags and the value of sales of systems and support for these tags will increase about ten times over the period 2008-2018. Growth will be driven by the tagging of high volume items – notably consumer goods, drugs and postal services – often at the request of retailers, military forces and (for legal reasons) postal authorities. RFID is not only expected to improve cost-effectiveness and increase sales, but also to deliver broader benefits to society, including better safety and customer services (IdTechEx 2008).

Gartner (2008) identifies the following key trends for the global RFID market:

- Healthier conditions because of greater RFID adoption
- Asset management applications gaining interest in all industries
- In-store inventory as opposed to closed-loop supply chain inventory management is driving many noncompliance retail projects. These projects do not need to be interoperable and thus do not need to form part of the critical mass for standards, governing interoperability.
- The market is beginning a second wave of adoption (beyond initial pilots) in which businesses rely on RFID to increase their business competiveness.

1.1.2 Economic outlook - RFID market in Europe

RFID markets have developed most rapidly in the North America. North America and in particular U.S. markets account for nearly two thirds of total RFID revenues (65% in 2007). Europe is the second largest market, generating less than a quarter of total RFID revenues (23%), followed by Asia/Pacific (6%), Japan (3%), Latin America (2%) and the Middle East and Africa (1%). Figure 1 illustrates the market size of RFID in 2007 and forecasts for 2012 by region (Gartner 2008).

In 2007, RFID revenues in Europe grew at an average of 29%, well below the expectations of many within the industry. As a result of a few high-tag volume RFID deployments and new market introductions, RFID uptake by retail and logistics industries is expected to modestly increase in the very short term. Capitalising on earlier investments, Europe is expected to follow up successful pilots with a significant upturn in RFID activity by 2012 as it explores and adopts new standards and takes advantage of the latest tag and reader technology, reaching a market size of \$0.9 billion in 2012 (Gartner 2008). The compound annual growth rate of RFID investments in Europe between 2007 and 2012 is estimated at 34%, higher than in the US (29%) but less than in than regions starting from a considerably lower initial RFID investment such as Latin America, Middle-East and Africa and Asia Pacific (38%).

⁴ Note: In sizing the software component of RFID, Gartner projections exclude royalties associated with RFID patents. Hardware projections exclude embedded software, but represent all hardware purchases.

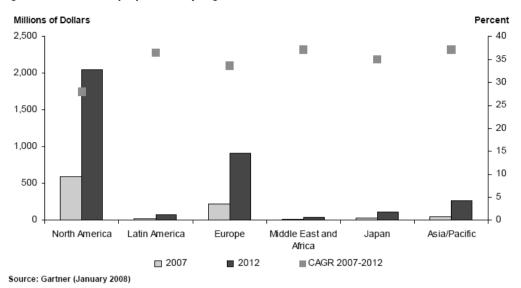


Figure 1: RFID market projections - by region

1.1.3 Economic outlook - RFID in healthcare market

Market estimates for RFID in healthcare have been overly optimistic, calling it a veritable "hotbed of activity" (RFID Journal, 2008). Kalorama Information, a medical market research firm, estimates the value of RFID in the U.S. healthcare industry to grow exponentially from \$297 million in 2007 to \$1 billion by 2010 and \$3.1 billion by 2012 (Kalorama Information 2008). IdTechEx predicts that the market for RFID tags and systems in healthcare will rise rapidly from \$120.9 million in 2008 to \$2.03 billion in 2018. Growth is expected to be mainly driven by item level tagging of drugs (outside the scope of this study) and active Real Time Locating Systems (RTLS) for staff, patients and assets to improve efficiency, safety and availability and to reduce losses.

Market estimates require a note of caution: one factor is hype another is the source of such figures, in particular industry sources trying to 'talk up' prospects to build investments and (their own) revenues. Also, the distinction between active and passive RFID provides essential shading.

Hype cycles

The introduction of new technologies is never linear. The concept of 'hype cycles' allows us to contextualise uptake and evolution of RFID in healthcare. According to Gartner's hype cycle literature, it takes between 3-5 years on average for a technology to pass through the stages of the hype cycle: invention and market introduction (technology triggers); unrealistic expectations of capability and performance (peak of inflated expectations); acute disappointment (trough of disillusionment); and finally a realistic understanding of capabilities and adoption by mainstream users (slope of enlightenment; plateau of productivity).

Gartner's hype cycle on healthcare provider technologies showed that when DoD and Wal-Mart issued mandates (in July 2005) RFID was at the peak of inflated expectations; by July 2006 it was half down "trough of disillusionment" and is estimated to require 5-10

years to mature and start to achieving its potential. This is not the only cycle involved; the hype cycle report for healthcare provider applications and systems (2008) lists RFID as an enabling technology for two applications: Patient Throughput and Logistics management (PTL) - placed at the peak of inflated expectations; and Wireless Healthcare Asset tracking - climbing the slope of enlightenment and one step away from the plateau of productivity.

Underlying the cultural evolution of the hype cycle lie barriers relevant to any new IT investment such as risk-aversion, operational complexity and lack of understanding and best-practice. These help explain why RFID does not seem to be more widely adopted. Gartner groups potential adopters of IT into three classes:

- Type A enterprises see technology as a competitive tool and CEOs running these enterprises are technological proponents who encourage technological take-up. Type A enterprises are considered aggressive adopters and comprise roughly 0.1% of all healthcare delivery organisations. In some cases type A enterprises, such as large academic centres may become development partners with their vendors.
- Type B enterprises are risk neutral organisations (mainstream followers) that wait for a technology to peak but then adopt it fast; they make up roughly 15% of all CDOs. Type B (mainstream) followers will wait until the next-generation applications and integration standards are more mature.
- Type C enterprises are risk-averse, smaller, organisationally-slow entities that comprise 85% of all CDOs. Type C enterprises are most interested in mature technologies that have successfully demonstrated value and effectiveness and hence reached a plateau of productivity.

A large majority (85%) of healthcare delivery organisations are considered to be of Type C, hence likely take a wait-and-see position towards new technologies such as RFID. Besides, healthcare delivery organisations are often IT heavy and run on already complex IT infrastructures that host up to 400 separate applications operating simultaneously, while an average type of business runs about six IT applications. A greater heterogeneity of stakeholder needs combine with overall system complexity and the difficulty of identifying and tracking the benefits of a specific technology to slow its adoption. Also, the dearth of best-practice⁵ for RFID in healthcare and confusion over what RFID technologies ought to be used inhibit its dissemination.

Active versus passive RFID

As highlighted in our introductory quote, RFID will only succeed where added value is clearly visible in comparison to existing solutions (Oehlmann, 2008). A recent US-based

⁵ In healthcare, the argument runs that replicability is often limited due to larger variability and distinctiveness of organisations, hence making 'good practice' (e.g. successful applications) 'best practice'. However, public healthcare systems are often very large (though containing many hospitals) and subject to overwhelming cost and centralised management pressures to make their routine functions (at a minimum) as homogenous as possible. It is likely that the pressures for homogeneity prevents individual hospitals from experimenting with RFID and makes centralised purchasing agents worry about the consequences of what would necessarily be a very large mistake (when rolled out across the entire system).

survey of over 100 healthcare professionals conducted by Spyglass Consulting (2008) highlighted that:

- Healthcare organisations had difficulties identifying a strong business case for passive RFID in the absence of industry-wide standards and government or regulatory mandates, especially when barcoding systems are less costly. As a result, only 23% of the organisations that invested in RFID chose the passive form;
- (2) Returns on investment (ROI) on active RFID are compelling, together with improved operational efficiency and quality of care (Spyglass Consulting, 2008).

IdTechEx expects the market for active RFID systems including tags to grow considerably, from \$40.05 million in 2008 to \$931.63 million in 2018 (IdTechEx, 2008). Over this period, active RFID systems are significantly catching up with passive systems, growing from one third of the RFID in healthcare market in 2008 to close to half of the market ten years later. In total, the number of active tags is expected to grow from 0.5 million (with a value of \$20.03 million) in 2008 to 140 million (with a value of \$139.75 million) in 2018, reflecting large potential efficiency gains.

Table 1: Market for healthcare and pharmaceuticals RFID systems including tags in \$ millions 2008-2018

| | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 |
|---------|--------|--------|--------|--------|--------|--------|---------|---------|---------|---------|---------|
| Passive | 80.81 | 91.31 | 155.33 | 273.84 | 484.50 | 614.37 | 739.34 | 833.97 | 932.46 | 1033.29 | 1097.92 |
| Active | 40.05 | 60.63 | 115.97 | 200.83 | 234.20 | 224.35 | 450.50 | 397.00 | 495.93 | 551.00 | 931.63 |
| Total | 120.86 | 151.94 | 271.30 | 474.68 | 718.69 | 838.72 | 1189.84 | 1230.97 | 1428.38 | 1584.29 | 2029.56 |

Source: IdTechEx (2008)

Without quantifying the market size for RFID in healthcare, our evidence agrees with key areas for RFID in healthcare identified in commercial market scoping studies. Promising application areas for RFID are expected to be:

- Active RFID applications combining environments and technologies (e.g. RFID+sensor, RFID+GPS)
- Applications for palliative care, home care and preventive care, including telehomecare applications.

1.2 Supply of RFID

RFID is still a young and relatively small market with good growth potential, open to innovation and to subsequent mergers and acquisitions.

Both chip producer and assembler markets are already highly concentrated. Initially, assemblers were primarily small SMEs. Recently, most have been bought out by bigger conglomerates as part of a diversification strategy, making RFID an add-on – one of many complementary and/or competing technologies in their product portfolio (next to barcodes, DataMatrix, etc).

The RFID solution providers market is dominated by North American companies. More than 60% of the 181 companies identified by IdTechEx are companies registered in the US, 23% are European and only 7% are Asian (Table 2).⁶ The RFID solution provider market also appears to be rather segmented and specialised. Out of the 181 companies, only 1 (Zebra/Wherenet, US) provides the full suite of products from chips/tags, readers and printers to networking, software and integration; only 8 provide everything but printer, of these 2 are European (Lyngsoe Systems, DK and Ubisense, UK).

| Table 2: RFID solution providers - by region & | & country |
|--|-----------|
|--|-----------|

| North-America: | | 114 |
|--|----------------------------|-------------|
| US | 111 | |
| Canada | 3 | |
| EU | | 42 |
| France | 8 | |
| Germany | 8 | |
| UK | 8 7 3 3 2 1 | |
| Finland | 7 | |
| Austria | 3 | |
| Sweden | 3 | |
| Italy | 2 | |
| Denmark | | |
| Netherlands | 1 | |
| Spain | 1 | |
| Asia: | | 13 |
| Japan | 7 | |
| India | 2 | |
| China | 1 | |
| South-Korea | 1 | |
| Taiwan | 4 | |
| Talwall | 1 | |
| Thailand | 1 | |
| | | 5 |
| Thailand Switzerland Israel | | 4 |
| Thailand Switzerland | | 5 4 3 |
| Thailand Switzerland Israel Australia & NZ: Autralia | 1 | 4 |
| Thailand Switzerland Israel Australia & NZ: | | 4 |

Note: The following companies have been registered as European companies: AIDA Centre (ES), ASK (FR), Atos Origin (FR), Bibliotheca (DE), Caen(IT), GapGemini (FR), Confidex (FI), Cypack (SE), DAG System (FR), Deister Electronics (DE), Ekahau (FI), Feig Electronics (DE), HID/Assa Abloy (SE), Identec Solutions (AT), Infineon (DE), IPI (UK), LogicaCMG (UK), Lyngsoe Systems (DK), Mannings (UK), Microlise (UK), Montalbano (IT), Nokia (FI), Nordic ID (FI), NXL Semiconductors (NL), PolyIC (DE), Proveo (DE), Psion Teklogix (UK), RF-iT Solutions (AT), SAP (DE), Siemens (DE), Sokymat/ Assa Abloy (SE), Spacecode (FR), ST Micro (FR), STiD (FR), Stockway (FI), Tagsys (FR), TwinLinx (FR), Ubisense (UK), UPM Raflatac (FI), Wisteq (FI),Xident/Trierenberg (AT).

Source: IdTechEx (2008)

If we look closer into these markets we see that European participation in all six segments more or less reflects global market distributions. The chips/tags, reader and integrator

⁶ Please note that figures presented have to be interpreted with caution. Because of data limitations, figures do not reflect importance of companies in terms of revenues, sales, etc. but merely list key players identified in literature, in particular industry journals and commercial websites. Most companies operating in these markets are private and financial statements are not publicly available; companies that are publicly listed share financial statements that are not detailed enough and do not specify 'healthcare' or 'RFID' in their accounting.

markets appear to be the most competitive. European companies seem to be particularly present in readers and integrator markets and to a lesser percentage in markets for chips and tags.

| Table 3: EU | presence in | RFID | solution | providers | markets |
|-------------|-------------|------|----------|-----------|---------|
|-------------|-------------|------|----------|-----------|---------|

| | Chips/Tags | Readers | Integration | Software | Networking | Printers |
|----------|------------|---------|-------------|----------|------------|----------|
| Global | 86 | 68 | 67 | 56 | 39 | 18 |
| Europe | 22 | 20 | 20 | 11 | 7 | 4 |
| % Europe | 25.58 | 29.41 | 29.85 | 19.64 | 17.95 | 22.22 |

Source: IdTechEx (2008)

In particular the very promising active Real Time Locating Systems (RTLS) market has been going through a process of consolidation in the U.S. For example, over the past 5 years about half of RadardFind's 126 direct competitors have disappeared from the market mainly through consolidation, buy-outs, acquisitions or market exist. The market for RTLS suppliers appears to be strongly U.S. dominated. Out of 22 key players serving this market, 17 solution are listed to be developed in the U.S., followed by UK (2), Australia (1), Switzerland (1), and South Africa (1), see Table 4 below (IdTechEx, 2008).

Table 4: List of RTLS suppliers (2008)

| - | Radianse USA | - | Siemens Roke Manor UK |
|---|--------------------------------|---|--------------------------------------|
| - | G2 Microsystems Australia | - | Trolley Scan South Africa |
| - | Versus Technology USA | - | Ubisense UK |
| - | Ascom Switzerland | - | BioRfid Solutions USA |
| - | AeroScout USA | - | Verichip Corporation USA |
| - | RF Technologies USA | - | Axcesss Internationla Inc USA |
| - | Sovereign Tracking Systems USA | - | ActiveWave USA |
| - | RF Code USA | - | HealthCare Pilot USA |
| - | Ekahau USA | - | WhereNet USA |
| - | Wherify USA | - | Visonic Technologies ELPAS EIRIS USA |
| - | Savi Technologies USA | - | Agility Healthcare Solutions USA |

Source: IdTechEx (2008)

In a nutshell, like most maturing technology markets, RFID seems to be undergoing a shakeout phase, giving a brief window of opportunity for European firms to secure a foothold.

1.3 Concluding remarks

The evidence presented in this chapter suggests that active RFID applications combining environments and technologies (e.g. RTLS, RFID+sensor, RFID+GPS) and closed-loop

proprietary solutions are most promising in shaping up near future demand and markets for RFID in healthcare. RFID is still a young and relatively small market with good growth potential. In terms of total RFID revenues, North America (65%) and Europe (23%) have been most significant markets in 2007, however strong take-up is expected in particular in Asia/Pacific and Japan, Latin America, the Middle East and Latin America. Recent mergers and acquisitions mirror interest in active RFID markets, giving a brief window of opportunity for European firms to secure a foothold.

We conclude with a note of caution. In healthcare as in many other settings, RFID *per-se* is not driving applications. As highlighted in our key-informant expert interviews, RFID is seen as only one of the technologies that provide functionalities to improve hospital logistics, planning and better care delivery. Thus demand is very strongly dependent on the healthcare setting in which it is to be deployed and one should not expect a technology push. Indeed, given the process of consolidation and the strong US lead, it is not immediately clear that fast and widespread adoption of a homogeneous RFID approach (especially passive systems) is *necessarily* desirable from either the economic or healthcare perspectives. The fragmented EU markets are likely to develop different deployment trajectories, favouring different applications and technologies, following from differences in rules, funding mechanisms, and healthcare strategies. This diversity is important and valuable.

Besides, public healthcare systems are expected to become important consumers of those promising RFID solutions over time. Public healthcare systems tend to coordinate their purchases, which tends in general (especially for new initiatives) to favour large contracts and large suppliers. At the same time, cost pressures are managed aggressively by public clients, who cannot recoup investments in superior technology in the form of market share gains over rival providers. This may increase dominance by a few providers, but this could increase suppliers' incentives to invest in innovation beforehand. Growth may be slower to get started (given the greater risk aversion of public sector purchasers) but is likely to accelerate more quickly (both in volume and geographic extent) once it does kick off. If RFID is provided through a strategic partnership, there may be further chances for collaborative innovation between suppliers and providers (and other stakeholders). Other minor elements include the possibility that public sector healthcare purchasing agents may not be so keen on RFID uses that cut headcount. One may expect that broader socioeconomic evaluation concepts will become more important and serve as prominent evaluation tools, and complement solid documentation of proven returns on investment (ROI) as an important factor influencing adoption of RFID solutions.

CHAPTER 2 A review of RFID deployment for better quality of Healthcare at lower cost

This chapter summarises the findings of earlier reports of this study. To complement a view on the market it is important to understand where RFID has a real and/or potential for impact on the quality and cost of healthcare. These factors together – the market supply and the actual demand – will frame the future of RFID development and deployment in healthcare in Europe, and thus are the two pillars on which policies should be based: policies to improve patient care and efficiency of health care delivery on one hand and on the other stimulating EU competitiveness and high tech development.

2.1 Actual deployment of RFID in health care in Europe

2.1.1 General findings emerging for case studies

Six European and 1 US case study provide useful insights in the actual status of RFID deployment in Healthcare. In the U.S. as well as the EU most successful applications so far seem to be in logistics and operational management; and less in patient care and quality of care improvement. Compared to logistics, patient care delivery applications face greater implementation problems; in particular because critical treatments and processes require near 100 percent reliability and because the complexity of hospital environments raises the likelihood and consequences of electromagnetic interference between technologies.

When comparing the U.S. and the EU there does seem to be a difference in emphasis. Whereas in the U.S. RFID is mostly deployed to reduce costs and increase efficiency, in the EU healthcare providers more often seek to improve the delivery of care. This may also be an explanation why on average care providers in the EU do not effectively measure and monitor cost and benefit data of the RFID application. It was found that particularly in the European cases there rarely existed a pre-investment baseline in order to quantify the added value and ROI of technology investments. Moreover cost and benefit categories were often poorly defined and understood.

RFID solutions in Europe also seem geared to address specific issues. Neither in the cases, nor in the literature was there much evidence of solutions where RFID applications where integrated in the overall ICT environment of the hospital, let alone in a wider a context of outbound eHealth solutions. This suggests that RFID pilots and applications are still viewed and developed in closed loop environments. Each application seems to be designed

for a specific purpose, without a view on capturing the overall benefit of the information that is generated, for monitoring and management purposes.

This fragmentation and single purpose nature is also reflected in the great variation of the implementation and running costs between cases and applications. There do not seem to be many off-the-shelf solutions, or exchanges of good practices. For now in Europe the dominant assumption on the demand side seems to be that one size does not fit all, and bespoke solutions are preferred.

Overall the case studies suggest that there is apparent potential for realising economic benefits in addition to improving the delivery of care when RFID applications are successfully adopted in a healthcare setting. This requires taking account of technical, organisational and financial issues. Moreover, the technology in itself is not widely embraced. From a care provider view the functionality and cost are the leading factors. If the same or satisfactory functionality can be achieved by another technology at lower cost, these will be chosen. Also there still is a legacy of barcode technology and equipment that continues to prevail in healthcare today.

2.1.2 Reasons for investing in RFID applications in Europe

From the case studies, literature review, Delphi survey and interviews it becomes apparent what drives healthcare providers to invest in RFID applications. These arguments can be broadly clustered by: 1) the demand for increased patient safety and quality of care; 2) organisational and financial considerations; 3) desire to lead and/or innovate.

As patient safety and care quality are among the primary concerns of healthcare institutions, the promise of improvements in quality, safety and service, as well as the associated cost savings resulting from RFID have been main drivers to pilot the technology. Typical applications for improving care are tagging of equipment to ensure timely maintenance; identification of patients to avoid wrong surgery; tagging of plasma and other life material to monitor due dates, temperature, and other essential qualities, but also supporting patients' compliance with medication routines.

RFID has a proven track record in retail and logistics. This explains why there are relatively many applications that support the management of operational processes and inventory in hospitals. Improving hospital management and increasing efficiency have been important reasons to implement RFID. This argument is compounded by the sheer complexity and number of hospital processes and the critical nature of inventory and process management. RFID holds the promise of making processes transparent and allowing objects, equipment, patients and staff to be traced which increases the control and reduces redundancy and error.

Another important element for introducing new technologies and processes in healthcare institutions is the leadership of senior management. The organisational changes that accompany the implementation of RFID and the required ICT skill level demand an active senior commitment. Such commitment also requires an understanding of the possibilities and limitations of the technology, and a vision on how the technology would affect and be integrated in the structure and processes of the organisation. These are all critical elements for acquiring staff support and involvement.

At a wider scale, RFID roll out can be supported by government policies or public/private initiatives aimed at fostering the use of RFID as part of a drive towards operational and strategic innovation. This may include positive publicity leading to a temporary "hype", around the technology and its benefits for healthcare. The effect of such government involvement depends on the capacity and the nature of the healthcare system to adopt new technologies - relevant factors being the nature of healthcare financing, independence of healthcare institutions, liability and regulatory considerations.

2.2 Most promising applications

The full range of current applications were assessed to determine their ability to reduce costs and to improve quality of care. The Delphi survey (assessing the views of experts from industry, academia, care providers and 'others') indicated that asset (especially inventory) management applications are rated highest for cost reduction. While patient tracking applications are seen as most likely to raise quality of care, staff tracking is judged to be less relevant on both cost and quality criteria. Views differ between respondent groups, with practitioners especially sceptical about the cost and quality benefits of staff tagging.

The most promising functionalities for European healthcare provision are the following:

- **Tracking assets:** RFID systems can allow healthcare delivery organisations to have a better operational overview of their medical assets, with positive results in terms of tools availability and general asset management.
- **Tracking patients:** Tracking patients allows for a better through-put and offers the potential for reducing errors. This application is particularly relevant to patients wit dementia requiring the tracing and monitoring of their whereabouts within healthcare institutions, and possibly also in the community.
- Identification of patients: RFID systems can improve the overall reliability of identification and authentication of a patient. The potential benefits of their uses are an increase in patient safety connected to the reduction of errors, such as in cases of drug prescriptions and administration.
- Automatic data collection and transfer: as in other operational domains, RFID applications can improve the automatic collection of data and their transfer to back-office mechanisms which manage the overall supply chain management of an healthcare delivery organisations;
- **Monitoring of patients through sensing:** RFID can help in the collection of health-related data to be match with relevant indicators.

The identification of these promising areas for RFID deployment suggest that significant potential benefit can be achieved from this and complementary technologies. The actual ability to achieve these benefits depends largely on organisational, financial and technical considerations.

2.3 Current factors restraining effective RFID application

The applications discussed above are being implemented or piloted. There have been strong arguments for deploying RFID as a solution to improve quality of care and a reduction of costs; in the back office of hospitals as well as in patient facing applications. However there are also a considerable number of factors that hold back further implementation and broad scale roll out of RFID in healthcare in Europe; either by presenting concrete obstacles, or by creating uncertainty about the nature of the technology, its risks, impacts on the organisation and costs, etc. This section briefly discusses the factors that were identified for European healthcare institutions.

2.3.1 Obstacles to RFID deployment in healthcare

The evidence collected through the case studies and interviews with experts have highlighted several operational obstacles to the deployment of RFID in healthcare delivery organisations. As technology advances, these obstacles can be overcome. However, at the present, they are to be noted as issues. These obstacles may be technical in nature, or relate to the management of data and security on information systems, as well as organisational and financial concerns.

The technological issues relate to safety concerns like electromagnetic interference between e.g. RFID readers and medical devices; as well as problems with legacy systems and lack of wireless ICT infrastructure in hospitals. In addition there are practical difficulties of physically integrating parts of RFID technology (e.g. tag size) with the object of interest (e.g. metal containers, tag size); and insufficient battery capacity causing limited portability of RFID technology.

As with all RFID applications, the technology's ability to capture, store and transmit data about people, has caused resistance to its use. Justified or not privacy remains a major issue to be dealt with, especially as the personal information which is generated and monitored in a health care environment is typically very sensitive. Moreover there are also safety concerns with electric data; any errors in the data, systems failures, and interruptions can have life threatening consequences.

As stated before, the introduction of new technologies often also implies a change in working methods, processes, structures and even skill sets and headcount. The organisational change required to make the application a success is often not considered properly. This leads to incompatibilities between the functionalities that the technology may offer and its use by hospital staff. Sometimes the interfaces do not display sufficient user-friendliness, or understanding of the context in which the technology is applied, but mostly the legacy processes and organisational culture are resistant to change causing pilots to fail.

A final barrier, though less pertinent that often assumed, is the cost of hardware, software, and the implementation and maintenance of the system. Where competing technologies such as barcodes or DataMatrix offer superior, similar, sufficient functionalities at a lower cost, these will obviously be preferred over RFID. However it remains striking that the negative impacts of the direct costs, are hardly substantiated through analysis of net present value of the investment, nor is there effective identification and monitoring of the returns (financial and other benefits).

2.3.2 Uncertainties affecting future RFID deployment in healthcare

Beyond the direct obstacles to RFID deployment in European healthcare settings, there are also uncertainties that impede its roll out; or at least affect the way RFID is implemented and the scale on which this may happen. Some of these factors can evolve into obstacles but they may also lead to faster implementation.

In some ways RFID technologies and applications have not reached maturity. Costs are still dropping and critical improvements are still made, to allow the level of resilience and reliability expected for applications in critical hospital functions; i.e. related to patient safety. Depending on the speed of development and emergence of other technologies RFID will either become a general purpose technology in care environments or remain a technology for specific services and applications.

Other apparent issues with the technology are difficulties in scaling up RFID applications and integrating them within the physical and the IT environment of the healthcare delivery organisation. This is further complicated by the use of applications that are based on proprietary standards. These factors can limit the ability to collect and aggregate information and to develop more sophisticated solutions, including for outbound care.

How privacy concerns will be addressed – within the technology and in the actual use of personal information generated by RFID – will be critical for the acceptance of the technology by staff and patients. The whole issue of data management remains critical. Preserving data integrity and reliability is essential for patient safety, as wrong, inconsistent data or disruptions in the flow of information can potentially have fatal consequences. On the other hand the data generated by RFID can help in patient registration, identification and authentication, thus avoiding mixing up patients and other errors related to the exchange of information. Moreover, an effective use of data can assist management in improving the flow of patients through the hospital, in planning staff allocation and controlling inventory and other logistics processes.

The organisational challenge probably poses most uncertainties for the broad roll out of RFID. First the full potential of costs and benefits need to be understood in the widest possible sense; including the consequences for the organisation, costs and savings from organisational change. Then users and providers of care must understand how these benefits actually affect them, and what risks they may endure to ensure conscious engagement and cooperation. To do this effectively RFID applications should be supportive of healthcare processes (not the other way around) and align with the organisational complexities and culture.

2.4 Summary of the current status of RFID deployment in healthcare in Europe

The overall picture of the potential of RFID in healthcare is nuanced: there seem to be many arguments in favour of a wide RFID roll-out (especially in hospital logistics and operational management), but considerable impediments remain. Moreover, there are important organisational factors that have to be taken into account for successful implementation of RFID. Based on the evidence collected during this study, it is possible to reach a set of conclusions about the potential use of RFID within healthcare delivery organisations in Europe:

Technical:

- 1. RFID is not unique in many of its functionalities. Other, more consolidated technologies such as barcodes and DataMatrix offer similar functionalities. In several contexts, RFID are seen as complementary to these technologies, increasingly in combination with WiFi infrastructures.
- 2. RFID applications need to be integrated in pre-existing technological environments, including medical equipment and ICT. Hence, the need for their "technological neutrality", in a sense that their supporting hardware and software should be in a position to be integrated with open standards as in the case of web services.
- 3. Interference of RFID and other wireless equipment with (critical) electronic equipment in the care delivery environment, especially operation and intensive care wards, remains the single biggest obstacle to RFID roll-out in healthcare, as there is a direct risk to patient safety.
- 4. Physical constraints like tag size, ability to attach tags, the hospital environment still impede or complicate the implementation of certain RFID applications.

Organisational

- 5. RFID is not only an IT instrument, but an important support tool for management and care delivery. It will only deliver its full expected results if it is embedded within the overall organisational and operational structure of the institutions. The introduction of RFID is likely to lead to operational and organisational changes.
- 6. Therefore, RFID application design, development and implementation require the strong commitment of senior management and the direct engagement of all relevant interests (data protection, workers' interests, ethics, etc.), especially during the design and testing phase.
- 7. Full endorsement by individual stakeholders within a healthcare delivery organisation may also require appropriate change management mechanisms to induce behavioral change and increase operational ability to exploit the new functionalities. The motivation needs to be constantly reinforced to avoid the risk of reverting back to the "old" way of doing things.
- 8. This points to the importance of awareness and ownership. The organisational and operational evolution may lead to a certain level of degree of resistance from interested parties, especially among those individuals who are concerned about the lack of regulatory and normative certainty associated with the use of RFID in the healthcare domain. Also there still exist justified or not negative perceptions about the overall potential health risks associated with the use of RFID. This is particularly important where a RFID system is rapidly implemented, risking low levels of awareness and buy-in among stakeholders. These issues need to be

addressed in full transparency and due attention should be given to communication and awareness raising activities.

Financial

9. Beside the organisational aspects of RFID deployment, there must also be appropriate attention and resources allocated to the actual technology. Investments vary substantially among the different technological providers. It is apparent that no off-the-shelf RFID systems exist that would be ready to be implemented by healthcare delivery organisations. The lack of these COTS solutions (commercial off-the-shelf) is also confirmed by the fact that there are significant differences on the individual costs and solutions of RFID implementation. This has been strongly demonstrated in this study where costs were limited in the case of the Caravaggio-Treviglio or prohibitive in the case of the use of RFID by the Geneva and Jena hospitals.

Political/policy

- 10. Negative perceptions among different categories of users still exist and need to be taken seriously. It requires a continuous, frank and open sharing of information about potential societal risks associated with the use of these tools, for example privacy breaches. The sharing of information, nevertheless, should involve all interested stakeholders and users of healthcare delivery organisations.
- 11. All of these factors are to be supported by appropriate national and international policies aimed at creating an innovation friendly environment. These are to support healthcare delivery organisations in looking beyond their current technological infrastructure towards solutions, such as (but not specifically) RFID, that can improve their operational framework provided that they reflect the interest and objectives of all involved stakeholders.
- 12. However, caution should be exercised when considering additional regulation, carefully balancing the policy objectives with the risk of impeding the roll-out of beneficial RFID applications.

The next chapter presents a view on possible future developments, to enable the development of robust policies to:

- 1. Support the beneficial deployment of RFID and other ICTs in the healthcare delivery chain
- 2. Support the high tech industry in Europe, in particular in developing RFID and other ICT applications for the healthcare sector

This chapter looks towards future application of RFID technology in healthcare. By definition, the future is uncertain. This is captured by developing and reviewing three scenarios representing possible extreme outcomes and the issues they raise. Each scenario is assessed independently on its strengths, weaknesses, threats and opportunities. We use the SWOT analysis to look back from 2020 to identify the policies that should have been taken in 2009 to enhance the strengths, exploit the opportunities, address the weaknesses and mitigate the threats. Policies that appear promising across all scenarios are likely to withstand the inherent uncertainties of the future. Their pursuit is thus likely to be less risky and hold a more robust chance of reaping benefits in the medium and long term.

3.1 Approach

To identify future policy issues and develop appropriate responses requires some form of foresight exercise. For this study the chosen approach was the scenario gaming workshop. Experts are challenged to engage with future scenarios, assessing their strengths and weaknesses. After that they are asked to look back from the future and identify policies and actors that could have dealt with the future challenges in an effective and timely fashion.

The scenarios are constructed around 3 dimensions that represent key uncertainties identified earlier in the study. The scenarios start from a common starting point, represented by the *status quo* assessment of RFID & Health markets and RFID deployment in Europe (see previous chapters). They differ in terms of the involvement of public and private bodies in healthcare delivery and the influence of healthcare providers and patients in shaping demand (esp. the trade-off between cost reduction and quality of service enhancement). A range of other issues were considered in fleshing out the scenarios, including the impact of the financial crisis on the availability of investment capital, the impact of general demographic developments and other relevant socio-economic developments on healthcare needs and the effectiveness of EU support strategies.

The scenarios do not represent predictions, but are intended to give insight into relevant future developments and the linkages among different aspects shaping the development of RFID utilization and impacts. The number of potentially relevant details is enormous; for clarity it is customary to summarise those by defining a few key dimensions define the total 'scenario space'. While considering these and other uncertainties; the following dimensions relating to health care and (RFID) technology deployments were chosen and applied:

- 1. <u>Nature of healthcare delivery</u>: This is the principal dimension whether healthcare delivery is concerned with, management of health incidents (and/or delivery of specific services) or "total health management" (and/or the promotion of healthy living or "wellness"). The former approach is more passive the focus is on the activities, organisational units and functions of healthcare providers, typically activated by health incidents and organised around their management. By contrast, "total health management" emphasises proactive intervention, greater patient or community involvement in healthcare decisions and a holistic, through-life approach which emphasises continuity of care. This dimension applies generally to healthcare delivery posture, and not solely to RFID.
- 2. <u>Level of RFID deployment</u>: This combines quantitative and qualitative aspects and ranges from narrow, small-scale adoption of specialised RFID solutions (generally focused on logistic processes) to large-scale, wide-spread adoption of RFID (tags and readers) for a wide range of purposes (i.e. RFID becomes "normal" and is regularly used in daily life). This dimension applies specifically to RFID, but is not limited to healthcare settings.
- 3. <u>Propensity to data sharing and use</u>: linking of medical data from different environments (.e.g. social care, lifestyle, diet) vs. keeping all data separate, to be released at request only.

These dimensions are connected with other aspects of the healthcare value chain, which arise both as drivers and consequences. These include the following:

- Whether RFID adoption is driven more by cost reduction or quality of service improvement.
- Which RFID uses and business models predominate uses include asset tracking, patient and medical staff location, tracking and matching of consumables (e.g. medications) and others rehearsed in the earlier sections; business models refers to the penetration of e.g. foreign producers, the market shares of hardware, software and integrated solution providers, and the 'length' of the value chain (e.g. whether RFID solutions are supplied to healthcare providers by manufacturers, dedicated system integrators or bundled with other procurements such as ICT, medical equipment, pharmaceuticals, etc.
- Whether development is driven more by technology (supply) or potential uses (demand)
- Whether the level and diversity of RFID deployment is sufficient to realise significant economies of scale and scope (resp.) and/or to favour modular or integrated solutions.

In addition to the critical uncertainties aligned with he scenario dimensions, there are other factors exogenous to RFD policy, which apply across scenarios. These include:

- Demographic changes the demand for different RFID solutions varies with e.g. the age distribution;
- Globalisation of healthcare supply and demand the prospects for European development depend on both Single Market integration (e.g. cross-border supply of RFID solutions or mobility of patients to healthcare systems offering more attractive combinations of cost and quality) and on international globalisation (the degree to which foreign competition influences the competitiveness of European RFID suppliers, the nature of RFID innovation⁷ and the extent to which global demand is accessible to European suppliers.
- The availability of investment capital this refers to the costs and risk tolerance of investors whose support is needed for innovation, market development and deployment investment. Of course, the *impact* of such investments varies among scenarios, but the overall investment posture is unlikely to be affected by RFID markets alone.

Based on these three dimensions we could in theory develop 8 different scenarios. However, for practical reasons we choose three, each differing from the other one in two places. In particular, a focus on "total health" seems logically connected either to high general uptake (lowering the entry barriers to an RFID-centric continuity-based healthcare delivery system) or to the expansion of integrated public healthcare systems (wherein the general collection and linkage of healthcare data is used to maintain continuity of care on the provider side, but where RFID uptake may be retarded by institutional barriers). These should be viewed as the 'landing place' of development trajectories, allowing positive feedbacks between the dimensions to develop gradually. These landing places can be characterised in terms of the overall healthcare regime (and the resulting extent and nature of RFID development and exploitation) as listed in the table below:

| Scenarios/ | SCENARIO 1 | SCENARIO 2 | SCENARIO 3 |
|---------------------|----------------------|----------------------|-----------------------|
| Dimensions | Private care society | Central care society | Incident care society |
| Total health focus | High | High | Low |
| General uptake RFID | High | Low | Low |
| Linking health data | Low | High | Low |

The next section describes these scenarios in more detail. For each there will be:

- 1. Brief summary of the scenario
- 2. Description of RFID and healthcare implementation and market prospects
- 3. SWOT analysis

Finally we discuss the crosscutting policy issues that emerged from expert analysis of all three scenarios, signalling some level of robustness towards future uncertainty.

⁷ esp. active vs. passive solutions and frequency specificity

3.2 The Private Care Society (PCS)

3.2.1 Summary

The private care society is very well equipped with RFID to monitor and manage health issues, albeit with different levels of (price-rationed) quality and limited interoperability. The availability of RFID is not limited to healthcare; everybody has a portable RFID reader bundled into mobile phones or other converged devices. Electronic healthcare data (including patient records) are widely used, in distributed form – in other words, patients retain (authenticated and synchronised) copes of their records and have (in principle at least) extensive access and control rights. Data are jointly 'owned' by the patient and the provider(s) responsible for collecting the records and making the entries – and by the patient's GP in systems organised around the 'medical home' concept. Although patients cannot change critical health data without co-authorization of the relevant medical professional(s), she or he can read the data and add "personal remarks". Medical professionals need to have permission from the patient to read⁸ the data, which are protected by a patient-owned pin. However, in case of emergency, access to the chip⁹ can be obtained using specific equipment and indemnity rules that require strict ex-post justification for its use¹⁰.

In this society, health is promoted at the individual level; the resulting key role of insurance companies reinforces a preference for preventive healthcare¹¹. For those recovering from health incidents and treatment, RFID enabled equipment can help to track progress and suggest specific action when required following a signal from (implanted) body sensors¹². This is a society with confidence in RFID and new technologies in general, with a strong European system of regulation effectively enforced at national level¹³. In many countries, access to high-tech healthcare is bundled with employment; those in regular work with strong employer health insurance plans enjoy

⁸ More complex rights apply to professionals' rights to enter, change or remove data, or to add their own comments to past data (e.g. when following up prior symptoms).

⁹ Each provider has its own provisions for backing up data, providing access if the device containing the records is lost, damaged or unavailable (e.g. in an accident that injures the patient) and maintaining configuration control across providers and over time. Data access transfer is mandated within preferred provider networks and among providers of publicly-funded healthcare schemes, but serious challenges arose in limiting access by insurers who underwrote those networks.

¹⁰ These access and ownership provisions were regulated in a manner consistent with existing data Protection rules, but raised a number of issues going well beyond the usual scope of these rules. These issues are discussed in the "threats" part of the SWOT analysis below.

¹¹ This applies generally to healthcare; in relation to RFID it includes active solutions that interact with gyms and exercise, food suppliers etc..

¹² Such embedded sensors are only available under limited circumstances and to a minority of citizens, in view of privacy, accuracy, etc. concerns and associated liability issues.

¹³ Note that Europe started from a range of very different regulatory systems and stances, but that convergence resulted from a confluence of various forces including the credit crunch, demographics, changes in income distribution, political polarisation, the trans-European power of big pharma and private medical establishment, major failures in publicly-provided healthcare, and the progress of the Single market in relation to healthcare and technology.

steady increase in available treatments. In a few countries, this is provided on a public utility basis – citizens have an entitlement to health premiums but choice over where to pace them. They key element is the connection between providers and insurers – insurance systems often limit patient choice (PPO arrangements, differences in coverage, use of pre-existing condition rules to limit patient mobility etc.). As a result, public 'safety net' arrangements are available to supplement private healthcare, with special provision for marginalized groups and collective or "public health" interventions aimed at benefiting the whole of society.

Healthcare provision is regulated – even in light-touch regimes there are controls on competition, privacy and quality of service. This regulatory relationship is used as the basis of a healthcare 'universal service obligation¹⁴' funded on the basis of 'pay or play' requirements for major healthcare providers and contribution levies on niche providers.

As in the US, private healthcare providers and most private insurers promote integrated service delivery and continuity of care provisions as ways of reducing their costs and competing on quality. This is especially strong where competition has moved from fee-for-service to 'whole-life' contracts, reinforced by the proliferation of expensive specialised treatments both on the consumer side and as a result of health care reform. A small but vocal minority is hostile to high technology solutions to what they see as ill-health created by a spiritual malaise.

3.2.2 **RFID & Health implementation and market prospects (ICS)**

General socio-economic outlook (PCS)

In 2010, Europe saw the start of recovery from the financial crisis, with most of the MS economies starting come up to full speed in 2011-2012. Still the depth and duration of the crisis varied by region, and so did rates of recovery. In Europe most Member States chose to address the crisis by supporting private investment through tax breaks and strategic use of public procurement, positioning governments as launching customers. Governments and the EC also initiated large scale projects in ICT infrastructure roll-out (like FTTH), and technology research (in both public and private sectors). The EC reallocated much of its structural funds for this purpose.

In general, responses to the recession have led to a wealthier Europe overall, but more quickly in some countries than others. For example, the Nordics, Germany, Netherlands, and Austria benefited more and quicker in terms of recovery than many Southern and Eastern European Member States. The redirection of structural funds could not bridge this difference at the same pace, However, many small 'near sourcing' firms in ICT and software sectors in Eastern and Central Europe fared very well, as Western firms sought to reduce costs of supply (including transport and quality validation) by overseas suppliers (particularly in Asia). This helped to boost local innovation and drive demand for skilled engineers in the EU. Although comparatively worse off in GDP terms, many 'new' Member states have realised higher growth rates.

¹⁴ the way builders are required to put up a certain number of units for poor people or eco-friendly homes in exchange for permits to build the homes on which they want to make profits.

The post-crisis period was characterized by a buzzing innovation environment with many SMEs launching new products and services. Old rigid companies had been allowed to fail which opened the way to new business models and services. Where national strategies were open to international investment and trade, recovery went faster. Many markets consolidated in the period 2010-2012, followed by steady government divestments. A second round of international consolidations followed between 2012-2015 - creating European giants, but also international companies (US, India and the Gulf States) taking significant market share in Europe.

Technology uptake and awareness (PCS)

In 2020 Europe embraces technology, following the growing up of the 'Net Generation', and also because of the technology push early in the decade and the wide deployment in the following years. People have become both inquisitive and aware of latest technologies and their applications available on the market. It is an information rich society, where technology penetrates all aspects of everyday living. The exposure also led to reliance and acceptance of its values and utility.

Nevertheless people remain wary of privacy and security risks, and therefore accept only those technologies that have strong built in privacy features. People are comfortable with using a range of ICT enabled technologies (such as intelligent interfaces in the home that control energy, lighting, fridge content, social networking, the location/activity of the kids), because they have the possibility of using local dedicated networks which they trust for these services and/or relying on heavy encryption technology to make sure their (digital) environment remains under their control.

This attitude also affects perceptions of RFID. Although RFID is generally well accepted by the public, some concerns over private information protection, security and data integrity do persist – particularly regarding leakage of health record information. The concerns tend to rise and drop over time, associated with incidents of misuse. In general, there have been only few incidents of leakage of information and malevolent use and errors, but when they occurred they have been highly publicized. Activists against identity and authentication technologies like RFID tend to become particularly vocal during those times. This has been followed by increased government and private sector collaboration in public engagement campaigns aimed at increasing public confidence – both in the country of the incident, and at EU level.

Technology and Pharmaceutical industry (PCS)

Government and business worked together in Public-Private Partnerships (PPPs) to develop common electronic Identity Management systems and other platforms to facilitate effective and efficient government, whilst reducing administrative costs and burdens. These PPPs had their roots in the nationalised banks, which sought to roll out efficient identity based services and were more amenable to developing joint platforms with the public sector.

In the early 2000s, many pharmaceutical companies were suffering from thinning pipelines as there R&D budgets shrunk. They looked for new ways to extend, manage and increase their product portfolios, and the efficiency and time-cycles of the drug-development process. Which lead to investment in ICT technologies, including identification technologies and electronic patient record databases, as one way of improving the speed and efficacy of clinical trials. The strong technology push witnessed in the aftermath of the early days of the recession also provided a number of opportunities in preventative medical care and outbound treatment (e.g. telemedicine) in the healthcare sector.

This influenced the pharmaceutical industry to develop strategies which focused on providing 'whole-range' product solutions for specific types of customers/patients, and more personalized medicine approach to the prevention and treatment of specific conditions. Traditionally, the pharmaceutical industry focused on the development of treatments, but by 2015 there was a growing realization of the potential to make a profit from a product portfolio in which preventative pharmaceuticals were developed as well. Pharmaceutical companies continued to differentiate themselves by specializing in specific disease areas, but were in a position to develop a more efficient drug development process, based on the latest research on disease pathophysiology and genetic risk factors. For example, a therapeutic agent could be marketed on the basis of a companion diagnostic test. Pharmaceutical companies acquired diagnostic companies with genetic tests of proven accuracy. In addition, the pharmaceutical industry adopted marketing and sales models whereby different therapeutics for a condition would be marketed to specific segments of patient populations (based on their genetic traits, age, gender, and behavioural information).

RFID competitive environment in healthcare - market dynamics (PCS)

In the mid to late 2000s, the European supplier market for RFID solutions was rather specialized and fragmented. Very few companies (indeed less than 10, 2 of which were European) provided complete, integrated RFID solutions. By 2018 that supplier market had to a large extent consolidated, following a number of M&As and conglomerate or consortium deals.

The potential of RFID applications for boosting the quality of care – beyond merely increasing efficiency – was recognized and many more pilots followed. The development was initially boosted by the healthcare service integrators and RFID suppliers, and increasingly supported and demanded by health care providers. In focusing on specialized applications. Europe successfully differentiated itself from the large and leading RFID producers of the early years (mostly US companies) to develop much more targeted high end applications; leaving the logistics domain largely to the dominant US firms¹⁵.

As quality of care and patient safety were the main focus in RFID development for healthcare and not merely cost reduction, much attention was given to user friendliness and effective integration of the technologies in care environments. The European producers and software designers' products became renowned for their resilience and reliability, and for the way privacy was designed into the products. With the gradual shift to total care systems and outbound treatments, the European RFID solutions could exploit

¹⁵ The health care market is the US was historically more competition driven than in the EU, and the focus of RFID applications have been on logistics and cost reductions. With higher-liability risks in the US than in Europe, technology companies in the US stayed away from near-patient applications. Big clients such as Walmart drove the RFID market in logistics.

these qualities of user friendliness, data protection and integration in the wider health care environment.

However, many smaller companies that thrived in the initial market of pilots and specialized applications had difficulties to develop the full product suits for integrated applications. Competitive health conglomerates had not always embraced open standards as they attempted to protect their specific ICT solutions with IPR. Thus after the initial boom of specialized RFID and eHealth businesses, a period of consolidation followed in the midst of the decade (2012-2018); leaving 5 major European "complete solution providers" of RFID for healthcare. Three of them are integrated companies which have acquired smaller specialized players over time, and two are conglomerates. There are also still a number of smaller enterprises working on further improvements the software, networking and integration aspects of the value chain, but many of them are not specifically focused on health applications.

Competition and lower-cost solutions imported from China and India are also less threatening to EU competitiveness than in the past, for a number of reasons. China and India have started focusing more on their own internal economies, and are now less reliant on exports than in the past. Their RFID solutions have focused on retail, and logistics rather than healthcare applications (which need customized solutions). In addition, in the 2010-2020 period, Europe has established a strong reputation for workforce quality, regulatory standard excellence, workforce management and is seen as a key, competitive, reliable and efficient player in the global RFID-related innovation community.

RFID in Healthcare (PCS)

Adoption of RFIDs in the healthcare sector came later than in retail, transportation and logistics, military and other uses. Healthcare providers, insurance companies, and governments wanted to first see how adoption unfolded in other sectors, how performance was affected, and for "economies of scale" to decrease costs. Cost and profit considerations were far from the only or major concern: privacy, security and safety issues had equal if not higher weight on healthcare adoption patterns. Between 2004 and 2016 research advances had addressed many of these issues, and as concerns over patient safety decreased, confidence in RFID solutions for healthcare had increased amongst adopters. In healthcare, some countries were champions in RFID adoption, and others followed, at a moderate rate. The RFID systems have been rolled out largely by private businesses, but these businesses had to develop and test their systems first, and began doing so in the most attractive markets

The strong technology push experienced over the past decade provided a number of opportunities for improving service quality and realizing cost-efficiency gains, specifically in preventive medicare and outbound treatment (telemedicine). Investing in RFID solutions was a strategy that became widely adopted in both public and private healthcare systems: first for efficiency and later for better patient safety and quality of care. However these initiatives were not coordinated and often perceived as strategic; thus depending largely on proprietary solutions. There had been efforts to establish a European common Electronic Patient Record (EPR) token and system, but it failed, which left the marginalised with a set of fragmented solutions, where some countries had a national state system, others only had private solutions. In some cases, the state provided subsidies to the

marginalised to allow accessing these services. In others there was no electronic EPR available; especially in countries where the civil liberties lobby had consequently undermined each attempt to establish an effective EPR system. For those who could afford private services there remained interoperability problems, customer lock in and high switching costs. Vertically integrated or linked up Health care silos are becoming a prominent feature of the system.

In 2020 RFID is widely deployed with many applications, thus most people¹⁶ have a RFID reader integrated in their mobile phones and RFID chips on a smart card or other token. Different private and public solutions are available; where in some countries the EPR is carried on the eID card, in others EPRs are provided by private companies using dedicated tokens. However most solutions share a common feature, which is that the patient is in control of his own data. A patient cannot change critical health data without co-authorisation by a medical professional, but he can read data and add personal remarks. Medical professionals have to have permission from a patient to read the data, which is protected by a patient-owned pin, or identification and authentication solutions based on biometrics. But in case of emergency, medical professionals can access the information through a trusted third party, which could be a commercial service provider or your GP, with strict ex-post justification requirements.

Patients generally have long-term relationships with a healthcare provider, and because providers are competing for patients there is a strong focus on ensuring privacy, security and data integrity, and preventing misuse. Data does not flow easily from one provider to the next, except in integrated or linked care delivery chains. Overall, public confidence is relatively high, and has steadily increased over time. It is lowest (but not low, approximately 60% as an EU average) amongst the elderly (65+), who also feel funny about having a chip in their body - but generally feel the increase in convenience makes-up for initial unease. Many public engagement campaigns are targeted at the elderly specifically. The younger generation is very accepting of the technology and finds it 'pretty cool'. They are familiar with it because of use in sectors such as retail, and even entertainment (some of the 20+ aged youth have chips for nightclubs they frequent). In Italy, it has become fashionable to get tattoos done at the sight of your tag implant. Whereas in Japan printable RFID chips are actually applied as RFID tattoos

There are some vocal medical professional groups in all countries who are against wearing tags, because they feel it increases surveillance above acceptable levels, and that it has also resulted in excessive labour intensification. Governments promote the tagging of medical professionals as essential for preventing misuse of the technology, and organisations and government both argue that it is necessary for realizing for efficiency gains in the healthcare system.

Some medical professionals also feel that the pressures on their time have increased substantially with the adoption of RFID technology, because they are now more easily

¹⁶ As patient choice is a central feature, some private care providers offer RFID free care for those who do not want RFIDs, but this is a small minority

accessible to patients, and have to spend more time checking and filtering information and personal remarks patients add to tags, for validity and reliability. This is particularly problematic in nations with a shortage of medical professionals. Some doctors just feel overwhelmed by the amount of new information they have to deal with. There are concerns that referrals to secondary care are in some contexts increasing unnecessarily, so that specialists (rather than GPs) can continue to deal with the patient and manage information and communications.

3.2.3 SWOT Analysis (PCS)

Strengths

- Automation has lead to more efficient healthcare systems: In the innovation and technology-intensive private care society, automation in the healthcare system has led to greater efficiency, leading to cost-savings and facilitating better quality (safer, more accurate, more reliable and more user-friendly) care. RFID adoption has enabled the faster more reliable identification tracking and and of patients and equipment/consumables alike, and logistics and inventory management is less laborious than in the past. RFID solutions are now favoured over barcode and DataMatrix solutions because of their added functionalities. The wide-scale adoption of RFIDs is also reducing their costs.
- Although the RFID solution provider landscape is consolidated (with 5 dominant players), competition for market share between these players is strong. Coupled with a more demanding market and a society where patient choice is strong and heavily exercised, the competitive landscape is still driving the main RFID solution providers to continue innovating and delivering ever more user-friendly, reliable, accurate and safe RFID applications for healthcare. There is continuous optimisation of solutions in the sector, and diversification in the range of services a solution provider can offer.
- Ambient assisted living (supported by RFIDs and ICT) is enabling remote healthcare services, which were not available in the past. These reduce the time-demands on medical professionals (i.e. number of patient visits to hospitals), and allow for more convenient lifestyles for both elderly patients and their families. There is less need for elderly-care homes. These advances in the healthcare system are releasing more time for people (elderly and their families alike) to spend on other activities be they work or pleasure related.
- The patient is control of his/her own personal data, and of how it can be used.

Weaknesses

• A 'consolidated' RFID industry presents barriers to entry for new innovative enterprises. The consolidation of the RFID industry into the 5 major integrated solution providers that dominate the EU landscape has created barriers to entry for new innovators – in particular SMEs. The same holds true for ICT suppliers. There are concerns that this will hinder innovation in the long-run. In addition, some ICT suppliers (which now hold large market shares) have compromised quality and safety of their services for costdifferentiation competition strategies, making it particularly difficult for smaller companies, which have tried to offer alternative technological solutions of higher quality, more user-friendly interfaces, and better privacy and security features to enter the market.

- Poor interoperability between different RFID solution providers leads to lock-ins or high switching costs, and gaps in geographical coverage for patients. Most RFID/ICT solution providers use incompatible proprietary technologies. A lack of interoperability between the different solutions (applicable both within and between countries) creates challenges for: (i) healthcare service providers who may want to change which RFID and ICT systems they use over time, (ii) for patients wishing to switch healthcare providers, and (iii) for the "traveller market" in our increasingly mobile society, due to gaps in geographical coverage for specific RFID solutions. Coupled with the lack of a common EU-level EPR, the costs of transferring patient information to a new healthcare provider (who uses a different ICT/RFID system) are high and the process administratively cumbersome, leading to barriers to switching and perpetuating 'lock-ins'.
- Poor interoperability has also impeded standardisation and the efforts to realise a ubiquitous information society. There is little standardisation at the EU level, largely due to how the supplier markets evolved and the resulting interoperability challenges. The RFID and ICT adoption trend followed the logic of the market, and there is not a unified (standards) framework to deal with that 17. There is a need for a set of common standards, that are credible and that people trust, and that allow for effective data sharing and management.
- Health gaps still follow income lines, and disparities persist. The 'have-nots' do not have even remotely similar levels of access to the services enabled by new ICT/RFID technologies.

Opportunities

- The demands of healthcare service providers and the choices/preferences of patients for additional functionalities favours RFID (in healthcare) over other competing technologies (e.g. barcodes, DataMatrix). This creates potential for increased demand for RFID solutions in the future, as well as for further cost-reductions over time (due to economies of scale).
- Ambient assisted living is a very big market opportunity for RIFD adoption. In an aging Europe, where more and more people are living alone, the size of the market for digital home technology and ambient assisted living is likely to increase considerably
- If, (and as) economies of scale are materialised and costs drop, there is potential for improving the provision of RFID-related healthcare services to marginalised people, and reducing the health and well-being gap between the rich and the poor (i.e. between different social classes)
- If the right guarantees for privacy, security and confidentiality are put in place to protect personal rights and interests, there is potential for significant improvements in the linkage and exchange of complementary data, to further improve service provision and standards of care. At present, this is a world where people have multiple partial identities which are not widely shared. If we move to a more linked-up world, the patient must still retain control over personal information, how it is used, and by whom.

¹⁷ Key for adoption of RFIDs is how RFID tags communicate with other IT technologies in hospitals, and IT solutions within hospitals are still relatively immature

Threats

- A set of key threats arose from the tension between access and ownership arrangements for RFID device-borne electronic patient records and Data Protection rules.
 - 1. The overall approach to privacy and integrity of EPR was governed by simple extension of existing data protection principles to electronic patient records (EPR). This was adopted on the expectation that it would be relatively easy to enforce if patients retained the definitive copy of the records. However, the implementation of this principle had some unforeseen consequences, which could be seen by comparing different (private sector) implementations. In systems where patient records reside on a single chip, provider knew that patients could take these data to rivals as well as complementary providers, and could use them in litigation. Therefore, providers took steps to retain some information, not record others, and/or use proprietary protocols (jargon) to maintain market power and limit liability, especially for systems where such data are used in automated medical decisions. Providers therefore tended to 'bullet-proof' the data recorded, which limited their scope and utility to other providers and hence the patient.
 - 2. Important 'ownership' issues also relate to data collected via IPR-protected tests, analyses and diagnoses based on the experience and broader evidence base of the practice involved, etc. In some countries, this conflicted with healthcare reforms aimed at enhancing continuity of care via a 'medical home' concept whereby a patient's interests are represented by a nominated practitioner (e.g. a GP). This proved to be particularly troublesome when patients were referred to a range of specialists, each of whom dealt with only a small subset of the patient's health needs. The access provisions allowing specialists to read the RFID records do not recommend specific information to their attention, and proved unable to inform patients' health care decisions. It was found that giving patients (physical, not analytical) ownership of health records especially when these were maintained in local copies (RFID chips held by patients) inevitably affected the agency relationship between patients and their provider(s).
 - 3. Emergency access created a further set of challenges, adding a set of 'patient interest' conditions for access in addition to the law enforcement and security conditions embedded in personal data protection rules. In particular, it was necessary to spell out to whom and on what grounds access could be granted and to make arrangements for policing possible retention and reuse. These were particularly important in a private care context, where some form of effective regulation must be maintained, but where the affected parties (patients) may not be in a position to know what has happened or where the emergency provider needing access may be different from the medical co-owner (the patient's 'usual doctor').
 - 4. The misuse of patient data: Since insurance companies own many careproviders, there is potential for them to access personal information and implement practices which would be against the interest of patients (e.g. excessively raising premiums for patients they feel are presenting excessive costs to the insurer; declining to cover costs, etc). Effectively enforced

legislation has a big role to play in preventing such incidents, as well as effective, user-friendly technologies and services for data protection

- The social implications, trade-offs and consequences of an automated healthcare world where there is less human interaction needs to be considered (particularly in the context of ambient assisted living/telehealth). Is the wide-spread adoption of ICTs leading to a more isolated and individualistic society? How will this influence social relationships? What are the risks of reduced human interaction in healthcare (as well as in other spheres of life)? Where and when is a non-virtual interaction necessary and why? How is the pervasiveness of technology in our lives affecting us 'mentally'?
- Although the demand for added functionalities is driving increased RFID adoption, the value added of RFIDs over other technologies is still not clear or verified. (NOTE: What will happen if other technologies take over? How will service providers who have now adopted RFID technologies adapt?
- Spectrum-related capacity constraints might exist and impede the scale of adoption of RFID in the EU. It is not clear whether there will be capacity available to support potentially higher-volume RFID usage in the EU. How the radio-spectrum and data traffic can best be managed needs to be considered.
- From a competition and innovation policy perspective, if the trends of consolidation of ICT/RFID suppliers (which characterise our scenario) materialise, there are threats that this impedes market entry and innovation by new players.

3.3 Central Care Society (CCS)

3.3.1 Summary (CCS)

The central care society attempts to bring together continuity, consistency and centralisation of care, though it is most successful in centralisation, measuring and bringing together as most medical data as feasible in order to inform and actively engage citizens about health risks and thereby to control incidents and the societal costs associated with illhealth. Centralisation of individual citizens' supports holistic and preventive care; access to complete records improves emergency treatment and pooling data across citizens improves society's ability to recognise and respond to collective and emerging threats, provide a better evidence base for health-related policy and address causes of and contributors to health problems¹⁸. The visible (and documented) public value created through preventive care and life style support (reduced healthcare costs, fitter people, higher economic productivity, etc) provides a positive feedback, if not always a virtuous circle; people are encouraged by policy and peer pressure to adopt healthy behaviours and follow physicians' RFID enabled sensors reporting to centralised databases allow analysis of advice. individual behaviour¹⁹ and health status outcomes. Due to centralisation, system costs are more than covered by savings to the healthcare system as a whole. As a result, RFID adoption in the healthcare system is stronger than in other sectors. Health incentives are

¹⁸ E.g. by correlating environmental, demographic and local economic data with health care problems and outcomes.

¹⁹ They can provide (limited) information on diet, exercise, etc. More information is provided by remote medical sensors, but some level of monitoring can be achieved even by location sensing (e.g. visits to gyms).

strengthened by conditionality, with entitlement or co-payment linked to levels of past compliance, at least in relation to chronic and especially behaviourally-linked conditions (e.g. obesity, smoking, alcohol consumption). The coercive aspect led to resistance and refusal to participate in RFID-enable health care and thus some exclusion from the main healthcare system and provided with a more basic service. This differential access has strengthened educational and regional divides. However, not all 'opting out' is based on citizen's unwillingness to follow medical advice or adopt healthy lifestyles, especially in countries where the information thus collected is used for other purposes, or even shared with non-government parties (e.g. in food marketing, alcohol retail etc)²⁰. Regulations to limit the degree of coercion and preserve data rights exist at the European level but Member States have tended to give these very different interpretations through national regulation.

3.3.2 **RFID&Health implementation and market prospects (CCS)**

General socio-economic outlook (CCS

The financial crisis starting in 2008, left important scars worldwide. The crisis and postcrisis years brought about important changes in world politics and policies. Most significantly, the size of the public sector burgeoned. The shift towards a more coercive (and more expensive) public sector was partly associated with a backlash against marketbased and/or light-touch neo-liberal policies embraced by many Western countries during the late 20th and early 21st century. On the positive side, the financial crisis did trigger a wholesale re-examination of the boundaries and respective roles of the state, the market and communities, and a modernisation of thinking about public goods and private provision that transformed education as well as health and produced more equitable and/or more efficient social models. But these advances came at a cost: many people lost their livelihoods, many positive innovations never saw the light of day, and society as a whole adopted some excessively managerial and risk-averse attitudes that greatly delayed economic progress.

The spread of persistent unemployment and labour market rigidities had multiple consequences and ramifications. Newly-poor families decided to have even fewer children, exacerbating already-falling levels of fertility, accelerating the ageing of society. This increased dependency ratios (the proportion of economically-inactive people), reduced tax revenues and disproportionately increased healthcare demand. At the same time, the political power of the rising elderly proportion of the population increased the priority of comprehensive health care – taken together with falling tax revenues, wellness-promotion and healthy ageing became the watchwords of healthcare policy. At the same time, perceptions of intergenerational inequity and the increasing disparity among Member States with different age and economic structures led to rising political tensions and a strong preference for national, if not generational self-sufficiency over equalising cross-subsidy.

²⁰ Such reuse of public sector information was already evident in the late 2000's, with authorities selling access to tax, property, driving and other information, and creating legal precedents for exchange of information between government and insurers. Genetic and behavioural information are especially sensitive.

Under these circumstances, and with growing evidence of widening gaps from official and unofficial statistics, governments increasingly had to assume responsibility for a range of social goods from education to healthcare. To sustain this level of expenditure, increasingly-coercive and paternalistic controls were imposed on both providers and beneficiaries. Also, in stark contrast to the market-led, individually-orientated objectives of the market-led systems gaining ground at the end of the 20th century, collective interests tended to dominate individual interests in the form of limitations on choice and more extensively rationed access to these public services.

The infrastructure for this centralised society was an evolved Internet with greater interconnection, greater access to computing power, storage and content, but radically lower levels of privacy. The Web now incorporates a universe of relationships among people, services, businesses and other entities and offers higher quality services and more efficient search engines. At the same time, much of the openness of the old Internet has been lost; compliant net-citizens have wide access, but monitoring is pervasive and service providers are expected to ensure that their subscribers like healthcare recipients, pursue "healthy online lifestyles".

But this control is strongest in relation to 'closed' environments. In response to the regulation of 'public' online life, a wide range of voluntary organisations and social networks have flourished to create independent, but interconnected networks of values and ideas. Some of these attempt to defend individual's (or at least members') privacy, confidentiality and security. Others work on behalf of vulnerable groups and other social causes, such as the recent successful campaign to eliminate (through a combination of policy advocacy and influence on social attitudes) instances of domestic violence. For these social movements, technology has been crucial for the formation of social networks. Overall, the struggle between libertarian and communitarian attitudes persists, but in this world, the latter has the upper hand and the boundaries of individual freedom and privacy are, for the moment at least, somewhat in abeyance.

Technology uptake and awareness (CCS)

The difficult economic circumstances have not significantly retarded the advance of technology, though of course we cannot know how things would have gone in the absence of the crisis. Despite high levels of economic uncertainty and a worldwide shortage of credit, the imagination of engineers and scientists has flourished both in relation to sharper cost and competitiveness challenges and as the elimination or congestion of proximate 'low hanging fruit' forced innovation to tackle more profound challenges. Furthermore, even risk-averse investors see technology companies in a more favourable light in view of the poor performance of traditional 'safe' sectors such as housing, commercial real estate, financial services and established blue chip manufacturers, even before taking into account the underwriting provided by national and EU economic recovery strategies. The transport industry has been transformed as a consequence of the policies implemented by Member States, renewed progress towards low-carbon economies and renewable energy and collective endorsement of energy independence as a national strategy. Other sectors such as the clothing industry have also been transformed with the production and sale of 'clever clothing'.

Smart fabrics have been widely adopted by people to reduce health incidents and associated medical costs. This is both a natural consequence of the emphasis on preventive care and a specific response to demographic and lifestyle changes; for example, women experiencing their first (often planned or artificially supported) pregnancy in their forties wear 'stylish', but smart pregnancy belts that help to monitor foetal heart rates and other indicators, while athletes (including sportive 'prosumers') wear smart fabrics developed to monitor muscular overload and help prevent injury²¹.

The fear of an uncontrollable decentralised Internet has been met by extensive coordination and an international Internet governance organisation has effective oversight and control over the world-wide-web²². The Internet is widely trusted as a reliable, if not very private medium for personal, social, business and political interactions.

RFID Industry outlook (CCS)

The great opportunities offered by RFID for personal identification - for health and other purposes – went largely unrealised after a series of highly-damaging instances in 2012 involving not merely data loss or theft, but data misuse and substantial and long-lasting loss to those involved. Opinion polls documented an enormous shift in attitudes; while 80% of the population between 18 and 30 years old supported RFID in 2010 (before the scams) only 35% did so in 2015. The collapse in attitudes led, of course, to persistent reduction in RFID use; in the first place, early adoption and voluntary use dried up, this reduced expected commercial prospects and starved potentially more-secure solutions of needed investment capital, and the low rate of participation meant that, even when the situation became much safer there were few data to document this.

Low adoption of RFID also reflected the inability of RFID providers to convince government clients and other possible 'launching customers,' argue for a more favourable regulatory climate (in areas ranging from low-power spectrum access to legal liability) and agree on the common standards needed to realise scale economies and thus recoup substantial initial investments. As a result, the market fragmented and price, performance and application performance remain disappointing in most applications.

In essence, the only healthy areas of RFID application (beyond traditional logistic applications) are healthcare (in monitoring individual behaviour) and the pharmaceutical sector. "Big Pharma" has taken a joint approach to changes affecting the industry, organising international conferences to set standards and include RFID as part of their core IT and product development strategies. Pharmacies can use RFID tags to improve dosage, drug and patient validation of drugs, supply chain logistics, and inventory management. Furthermore, with RFID pharmacies can help secure the integrity of the drug supply chain by providing an accurate drug 'pedigree', which is a secure record documenting the drug was manufactured and distributed under safe and secure conditions. In addition, 'talking label' applications reduce wasted drugs and guard against inadvertent overdose or adverse reactions from unforeseen drug combinations. All these features offered by RFID have

²¹ http://cordis.europa.eu/ictresults/index.cfm/section/news/tpl/article/id/90101

²² http://www.foreignaffairs.org/20051101facomment84602-p30/kenneth-neil-cukier/who-will-control-the-Internet.html

been key in helping the pharmaceutical industry adapt to a new market structure characterised by the disappearance of small pharmacies in favour of big chains and e-pharmacies.

Healthcare environment - market dynamics (CCS)

As noted above, the paternalistic role of government, especially in relation to healthcare (unlike education, whose per-capita costs and returns are relatively unaffected by population aging), pits rising prices and expectations against moderating tax and public finance revenues. To control costs, health and healthcare related policies have adopted a prevention approach and actively seek to compel citizen cooperation. Currently, individuals have to adhere to compulsory health guidelines, while at the same time bearing both health and financial penalties for failure to comply. Citizens are asked to present evidence of healthy behaviours when seeking healthcare, preferable through RFID generated records²³. Failure to produce such evidence can lead to loss of benefits or higher co-payments.

Workplace health promotion is also compulsory for businesses. By and large, companies have not objected to the European regulation of workplace health promotion. The advantages in terms of reduced absenteeism and enhanced productivity have been amply demonstrated, and to some extent the legal mandate levels the playing in terms of costs and labour market competition. Of course, this does not apply across the board; per-capita costs would be higher for SMEs and firms with high labour turnover, but most Member States allow the legal obligation to be met collectively either by groups of businesses working together or by contracting-out to health promotion providers. The same rules apply to foreign firms in respect of European premises and employees, and the emergence of strong voluntary organisations, social networks and initiatives at the international (e.g. ILO, WTO) level has put pressure on national and international companies to adopt sustainable and social corporate governance strategies. As with other labour conditions, workplace health promotion is seen as part of a company's ethical stance and is increasingly important to consumers worldwide.

A culture of preventive and consciousness health is 'en vogue'. Disregard of healthy behaviour is negatively perceived by society. People want to be seen to follow beneficial health practices such as (twice-) daily exercise, often in public or social settings. Furthermore, social activities do not involve excessive alcohol consumption, though a daily glass of red wine is acceptable on health grounds. The resulting shift in social attitudes

The values and principles of social protection have been embraced at the European level. Integrated care has been able to improve coordination, continuity, quality, and efficiency in the delivery of health and social services to vulnerable populations with chronic conditions and disabilities, particularly in meeting the needs of older people. Processes and partnerships have been put in place for continuous monitoring and caring. By coordinating health and social care, older people's needs are assessed, and appropriate actions are coordinated so that older people can live as independently as possible –

²³ Medical evidence (e.g. of non-smoking or daily exercise) may be more compelling, but is also more costly to obtain – and not provided by public health systems.

provided always that they take whatever steps are appropriate to maintain their health. For example, older people receive help such in adapting their premises/housing to their particular needs and in gaining on-demand (or even automatic or sensor-triggered) access to assistance with both medical and other needs. Old people's health is a shared task and responsibility between older people themselves (self care and care by family members), their primary (informal) social networks, volunteers and paid care workers. This network is supported and monitored by a range of technologies including RFID chips to provide access to patient information, locate people and things (from drugs and monitors to house keys and eyeglasses) and record/report data from implanted and ambient health monitors.

This example highlights the importance to this integrated care society of information and communications technologies (ICTs) as a means to promote cost-effective delivery of health and social care (e.g. tele-health, etc)²⁴. Contact and awareness are vital; the loss of privacy and (to some extent) individual discretion are the price collectively agreed. To provide effective 'wrap around care,' all medical data are brought together, linking medical and patient data from social care, health care and lifestyle domains. The healthcare industry, in particular, has adopted information infrastructures to make patient records and related data accessible to a variety of health professionals regardless of their location and of the systems they use. The implications in terms of patient choice, privacy and potential 'mission creep' (e.g. the medicalisation of old age) have been noted and hotly debated, but these debates have tended to ease as the population ages (increasing the relative weight attached to tangible service quality benefits) and system integration proceeds (increasing the individual cost and stigma of opting out and choking off the flow of counterfactual innovation and experience).

Furthermore, the cost drivers for this centralised health and social care approach also reflect the ageing population. As individuals age, the (current) costs of meeting their health needs increase while the (current or present-value) economic productivity decreases. As the population ages, therefore, the case for economy becomes more pressing. Increased supply and enhanced efficiency can only do so much, beyond a certain point demand reduction and rationing are also required. But in a society based on communitarian principles, this does not necessarily create a conflict of individual and collective interest, or a tendency to force healthcare costs and responsibilities onto the individual or their families. Both society and its citizens prefer healthy lives to less healthy ones; it is only in relation to treating illness that conflicts arise. Therefore, the promotion of healthy ageing is a matter of mutual benefit; this has supported the development of a political consensus around centralisation and a broad determination to avoid free-riding.

This does not mean that there are no conflicts; at a certain point, people do become ill and require expensive treatment. The scarcity of resources also forces society to set priorities that by definition help some citizens (or conditions) to the detriment of others. In addition, the general endorsement of the 'public good' of healthy living does not necessarily protect adequate levels of privacy, confidentiality or even individual dignity. Information and knowledge management of such vast data resources have become almost

²⁴ Note that it is now recognised that improved social care leads directly to reduced healthcare needs and (to a lesser extent) *vice versa*.

unmanageably complex, and many citizens are unhappy with the levels of security, privacy, discretion and dignity provided for themselves or their loved ones. The resulting differences of opinion have also, and quite naturally, led to different implementations in different member States and regions and limited interoperability and 'health mobility' as a result.

RFID in Healthcare (CCS)

The 'health data scams' in 2012 lead public opinion to strongly oppose any form of identification/ localisation of persons (except for very specific circumstances) by organisations and public authorities. This has lead to strong measures in privacy and data management, which affected adoption of RFID technology, which is currently not used to identify people, but has only evolved for logistical purposes.

Along with the inability to make the case for RFID in its widest sense, European governments tried, but failed in 2012 to agree on certain standards for RFID. Northern countries favouring high standards feared common lower standards would lower quality of EU-branded products and would not add any value added compared to emerging market products. However, Southern and Eastern European countries were arguing that higher standards for RFID would lead to a loss in EU's competitiveness. This 'battle' for setting common standards for RFID, led to a fragmentation of the market and to lost opportunities for the RFID market and for effectively supporting the integrated care system that has been evolving.

On the other hand, EPR information is required for 'wrap around care', so RFID devices are used to provide localised access to centralised records. This automation has had an unintended but welcome side-effect; much of the medical support required by the elderly is in fact a mixture of information-gathering, discussion and explanation of recommended or mandated treatments or regimens, and social contact. While these have traditionally been provided in medical(ised) contexts by trained health professionals, the combination of remote monitoring and accessible RFID information allows them to be provided by other citizens, including the healthy aged themselves. This frees up (or magnifies the impact of) trained medical staff, provides sensitive and context-sensitive advise and interaction and provides employment and social contact to all parties, provided only that suitable technological/informatics support is available. Similar initiative have been developed for other contexts, such as outpatient recuperation and in-home delivery of children.

3.3.3 SWOT Analysis (CCS)

Strengths

Information is used to encourage, nudge and oblige individuals to behave more healthily. Different information strategies promote healthy living and reduce the costs of the health system Communication is one of many strategies used to encourage healthy living. Asking individuals and professionals to comply with certain obligations in response to shared challenges is received positively by society. In addition, government can use these social forces to encourage compliance with guidelines or (personalised) behavioural adjustments without coercion, conscious choice on the part of individuals or the risks of inappropriate 'one-size-first-all' requirements.

- Governments are able to set (informed) priorities, direct resources to greatest needs/preventive measures and implement relatively fair or evidence-based rationing. The use of suitably configure RFID and other ICT technologies allows greater cost and quality of service control. Furthermore, the centralisation of control and information makes health care outcomes easier to predict and optimise.
- Information pooling *may* reduce errors, standardise delivery, and promote continuity of service. Provided configuration control issues can be resolved (e.g. when different providers have different information about the same patient), shared information can offer significant benefits to patients and health care professionals²⁵. A single multidisciplinary record with shared access offers patients a single pathway thereby ensuring continuity and efficiency of services.
- Improved quality of healthcare and monitoring. In the long-term various approaches to healthcare can change the structure of services and the impact on health:
 - 1. With preventive healthcare supported by better monitoring, better information and advanced technology, people can start actively participating in their own health.
 - 2. Preventive health accompanied by increasing self-management may change the way physicians provide their services; they could offer virtual services for standard consultation, saving travelling, waiting and missed/delayed appointment times in order to provide face-to-face service for critical diseases or specific health circumstances.
 - 3. Centrally directed strategies allow a combination of standardisation and personalised access. Technology provides great opportunities to enhance monitoring and prevention. By enabling patients to capture their own data on daily activities, body indicators and vital signs, physicians can provide better and possibly more targeted personalised care.
- Single purchasers can drive down costs. The government is virtually the only purchaser of health related services and technology. In this monopsonised market healthcare companies may compete vigorously (depending on procurement and commissioning practices) to sell their goods or services. The resulting monopsonistic distortion may be better than the 'double marginalisation' of a concentrated supply side confronting a concentrated demand side, but in any case allows public sector demand fully to express preferences for non-price aspects (e.g. security, reliability, quality of service, etc.) that might be lost externalities in a wholly competitive marketplace. In particular, procurement tenders can specify standardised technologies and/or commoditised RFID equipment; this standardisation can, in turn, establish the basis for a breakout into other sectors.
- Technology empowers patients by helping them to manage their health, supporting their decisions and actions, thus reducing the need to physically visit a doctor. With RFID and other healthcare technologies, people with e.g. hypertension or diabetes can manage their health more efficiently and effectively. Technology also gives people more access to their own health records and the opportunity to share healthcare data with other

 $^{^{25}}$ But see 'threats' discussion in section 3.2.3 for a discussion of the implications of sharing for the completeness and accuracy of records.

professionals for purposes of referral, management of possibly related conditions or second opinions.

- Continuous and comprehensive healthcare. Continuous health and social care in this Society means that the patient experience is seamless and personalised. Patients are provided with a single point of contact (the 'medical home') and a coordinated single pathway that allows them efficiently to move through complex healthcare institutions. This reduces medical errors, provides a more satisfactory service for the patient and reduces duplication while improving capacity utilisation.
- Trusted identification of patients. As the scale and complexity of healthcare systems increases, reliable patient identification becomes increasingly important. By using RFID to securely identify patients it becomes possible to minimise the occurrence of medical errors from mis-identification, mismatching of medicine or failure to take other treatments or conditions into account.
- Drug and medical equipment authentication. With RFID, providers of medication can help secure the integrity of the drug supply chain by providing accurate drug 'pedigrees'. This can provide traceability all the way from manufacture through administration (or disposal). As a result, RFID can serve as a trusted technology to reduce counterfeiting, improve the flow of clinical information about drug effectiveness and minimise the damage done by 'grey markets.' The inclusion of validating information in tamper-proof packaging also allows traceability for on-line drug supply, thus increasing the competitiveness and social utility of competing e-pharmacies. These changes will also improve expected returns to drug marketing, thereby motivating companies to invest more in R&D.

Weaknesses

- The state may become too powerful. A society where all health and social services are offered by the public sector may have some important drawbacks in diversity of supply, efficiency and effectiveness of care delivery. Patients might see their range of health and social services choices reduced, and may be excluded from choices on the future strategic direction of health and social care. Suppliers may also have to adapt to a 'single-purchaser' market. Instead of being responding to the needs and requirements of market composed of many different clients and stakeholders, suppliers in this society might be limited in the range of products and services they can offer. In addition, monopsony, like monopoly, may not provide optimal innovation incentives.
- Too few carrots, too many sticks. The Central Care society is too focused on obligations and too little focused on positive incentives. Medicalised 'policing' by social pressure and strong prohibitions gives rise to black markets, contrarian 'rebound effects' and other negative consequences.²⁶
- Administering access to data may become too complicated and raise ethical and practical problems. Self-management of healthcare and access to data empowers patients to somehow decide on their own health. But the patient and his providers and the state

²⁶ This world sometimes appears to be like the film 'Gattaca', in which society discriminates between people based on their genes, and physical and mental capacities. Only genetically 'perfect' creatures have the choice to carry out certain jobs like travelling to the stars.

may differ as to appropriate choices and care, and will use the system to express those differences²⁷. At the same time, patient records that can be accessed by different stakeholders and health and social care professionals, might be complex to manage and administer. Different ethical and practical questions arise such as who the right person is to access which (part) of the patient's record. In fact, on the patient's record, data might need to be compartmentalised to limit and target the access to data based on a defined set of variables. On the other hand, government ownership of patient's records is potentially dangerous as it could mean too much control by one single entity (the government).

- Lack of human contact with providers. Technology, especially technology that pre-empts specific communication, can interfere in social relations. By effectively automating some of the traditional health and social services, patients in this Society would suffer from miscommunication and lack of human contact. This may be particularly true for complex conditions, since the initial contacts (before diagnosis and referral) are likely to offer the greatest opportunity for both personal contact and discovery of 'unexpected' information on both sides.
- Over-dependency on technology, risk of security breaches or data errors and lack of authoritative and reliable back-up. Significant failures still exist within the medication system, which makes developments towards a technology-dependent society rather troubling, especially if no security back-up systems and plans are developed.
- Redefinition of 'normal' conditions; the use of automated screening, re-diagnosis and refinement creates a cascade of classifications, narrowing the scope of 'normal' health and triggering potentially unnecessary, worrying and even exclusionary interventions²⁸. In this society, more and more individuals are defined by their health risk and face an over-medicalised lifestyle with preventive health interventions becoming the norm rather than the exception. RFID might be used either to ameliorate or worsen this.
- Conflicts of interest as noted, treatments and 'healthy' behaviours are prescribed and coercively enforced in order to optimise the overall cost-effectiveness (or value for money) of public expenditures on the health care system. This may be very different from population health *per se* e.g. as represented by the judgements of healthcare providers in making medical decisions. The prescriptions and proscriptions might be very different with different budget levels, but such alternatives would not be considered or evaluated once implementation has begun. In addition, the tension among lifetime cost of illness (in Disability-adjusted and or Quality –adjusted Life Years) might not be resolved consistently throughout the system, over time, across different conditions or in relation to different groups. Finally, the individual's interests may depart from those of the system, especially for those with expensive or painfully terminal illnesses. The combination of a centralised system supported by RFID-reported information and strong societal and other incentives to follow a prescribed course of action may seriously harm certain patients.

²⁷ This is already visible in systems where payment and treatment entitlement are linked to diagnoses or "diagnosis related groups" (DRGs). To protect patients' health or their own commercial interests, physicians in such systems routinely alter diagnoses, with the result that costs and treatment intensities creep up over time.

²⁸ This can be seen, for instance, in the evolution of the Diagnostic and Statistical Manual of Mental Disorders.

Opportunities

- Identification of patients (with implants) can produce savings and benefits (accuracy, safety, data security, and time to answer). True identification through different types of technologies such as implanted RFID or iris scans can produce significant savings and benefits, especially in reducing medical errors. Although personal identification raises concerns about privacy, the issue is not directly about recording personalised and confidential data, but rather about the concerns of how information can be used and by whom.
- RFID can support a convergence of technologies to overcome legal/ethical and social barriers, in particular the allocation of rights to access specific data. The RFID market already offers some versions of secure access control cards, smart cards, and other technology with a lot of processing and built-in security solutions. However, the costs of security are still too high at this point in time.
- RFID offers 'control' to individuals if used well (could be used to balance access and control). RFID has often been identified as limiting people's control over data. However, access to data could be limited by creating decentralised storage systems instead of central systems and by offering the 'carrier' of RFID the option of controlling who and when can read RFID data.
- RFID can be used as alternative payment and reimbursement systems, similar to the role and functions played by mobile phones.
- The enhanced provision of continuous care enabled by RFID can promote the achievement of non-medical goals in relation to inclusion, personal welfare, labour productivity, patient empowerment, etc. For instance, a policy of encouraging walking, running or cycling reinforced by RFID location tags could promote sustainable transport goals as well; RFID-labelling of healthy foods could promote organic farming or reduce harmful additives, etc..
- The independence promoted by RFID-enabled central care may stimulate the development of health-related sectors serving the needs of e.g. the non-medicalised elderly or those encourage to take up healthy physical activities, (e.g. gyms, cycle manufacturers, etc.)

Threats

- Failure to provide balanced access to data could lead to loss of individual control. Universal access and central storage might be cheaper and simpler to manage, but raises significant privacy and security issues. On the other extreme, targeted access and decentralised systems raises issues of defining who the owner of the data is, and consequently who will provide access to whom. Administrating and managing access rights poses a difficult and challenging balance.
- Reaction to pressure to conform may lead to opting out and other forms of moral hazard. In particular, citizens may be encouraged to substitute prescribed activities for self-chosen activities and may derive sub-optimal health benefits as a result (e.g. exercising for a minimum period instead of commuting by bike for longer).
- Emergence of new previously hidden costs and illnesses created by improved prevention. As screening and preventive health interventions become increasingly normal, not only are false positives identified but underlying diseases are made more apparent requiring

still further health interventions²⁹. Many people will be needlessly worrying about illnesses which will remain asymptomatic.

- Costs and patient burdens will tend to creep up as physicians and others attempt to reconcile patient, medical and policy incentives. At the same time, the transfer of responsibility to patients may go too far (compared to efficient risk allocation), and discourage patients or crowd out effective patient empowerment.
- Mission creep the potential of the new technologies and systems invites policymakers to include an increasing range of behaviours. These may be recommended in advance of a sound and applicable evidence base, or may go beyond the realm of healthcare.
- Rise of the "health police" and a neurotic, health obsessed, unhappy population. The paternalistic and coercive Central Care Society, can engender a neurotic, health obsessed, unhappy and effectively passive population that only does what it is told to do (or violently refuses). Hence the initial aim of both improving health and reducing costs through prevention might produce exactly opposite effects. Furthermore, prevention is not always cost-effective³⁰, nor can it really be properly evaluated. The counterfactual to why people have been 'saved' from certain diseases is difficult to measure.

3.4 Incident Care Society (ICS)

3.4.1 Summary (ICS)

This world would have been hard to imagine a decade ago, except maybe in countries like the US; providing only the most basic medical care, with little emphasis on preventive care or on providing effective early treatment for potentially prolonged or progressive conditions. Small 'emergency care facilities' serve (only) the urgent medical needs of the poorest parts of a largely underinsured population. However, advances have been made in handling emergencies and urgent incidents. The impact of RFID is primarily as a means of rapid identification of people and their specific medical needs; this is provided via a (frequently implanted) "Medical Alert Chip" (MAC) standardised throughout Europe as an interface and to store information. Only key medical information (allergies, current prescriptions and existing conditions) is stored. Resources and innovation incentive focus narrowly on specific health treatments and short-duration interventions such as elective surgery, accidents and emergency, short term ill-health. Chronic conditions, long-term multifactoral health problems, mental health care, the problems of ageing and other long term conditions are under-funded and under-managed. Care is provided in a largely lowtech environment and reflects the limited information and short duration of patient-

²⁹ Of course, some of these new threats are real and represent opportunities rather than threats.

³⁰ The costs of prevention fall on everyone; the costs of treatment fall only on those affected, so rare conditions may be efficiently 'accepted.' In much the same way efficient management of some epidemic diseases involves allowing them to become endemic. Finally, certain forms of prevention mask information on the true (and changing) prevalence and severity of certain conditions, thus effectively preventing society from deciding whether prevention is or is not appropriate. A specific example is provided by the Swine Flu pandemic of 2009; in many countries, patients were urged *not* to come to surgeries for testing, but were given precautionary doses of non-specific anti-flu drugs like Tamiflu. This measure, which prevented contagion, effectively also prevented public health authorities from gathering accurate information on the evolution of the virus or its clinical impact.

provider treatment; relationships are perfunctory at best and quality of care correspondingly minimal – except for those able to buy both better and more attentive care. This reinforced the division between the 'occasionally unwell' and the 'long-term sick' with older, poorer and non-employed people tending to be in the latter category. European policy has attempted to limit this trend but with little success and indeed European regulations intended to benefit excluded groups have been blamed for hampering improvements.

3.4.2 **RFID&Health implementation and market prospects (ICS)**

General socio-economic outlook (ICS)

In the crisis of 2007-2017, some businesses (including many banks) were partially or wholly nationalised; others failed completely. Recovery was delayed (especially in Europe) and very gradual. Over the last decade, governments had neither the tax revenues nor the borrowing capacity to provide additional support for industry; even those with relatively sound finances were constrained by harmonised Eurozone recovery agreements. In contrast, BRICs and other OECD members – at some social cost - continued to stimulate their economies with extra R&D, infrastructure and education investments. This left Europe lagging the recovery in the rest of the global economy, which exacerbated both the shortage of public capital and demands on social services (including health).

Overall, Europe struggled to maintain minimal levels of support for health and education (as essential public services), but other areas of activity and anything more than minimal quality can only be afforded by those households that set this as a priority or are wealthier than average. There is considerable concern about the elderly, whose pensions are wholly inadequate to meet basic needs for food, shelter and more than emergency care, but this is tempered by the needs of the long-term unemployed. Whereas healthcare remains primarily a national responsibility, European standards have been agreed on medical alert information available on and via the MAC.

Technology uptake and awareness (ICS)

The ICT environment has been evolving gradually over the last decade. Due to the shortage of long-term capital and the thinning of European markets, levels of infrastructure and physical capital investment (and associated R&D expenditures) have remained low, and the economy is continuing the shift towards services based on low levels of required expenditure and entry barriers and the potential to exploit Europe's still-strong human capital stocks. Increasingly these services are dividing into 'low-tech' services where margins are thin and the required ICT investments are fairly basic and 'high-tech' services dominated by foreign providers able to amortise needed investment over the very large user base in their (recovered) home markets.

There has been little progress on uptake of technologies in healthcare with the exception of the simple, passive RFID chips used for the MAC. This is standardised throughout Europe, and effectively commoditised. Public procurement arrangements ensure that the demand is met by a range of European-based providers, but levels of innovation remain low and the breakout potential into other sectors is also limited. Every emergency care worker has a device for MAC chips that can retrieve the (locally stored) information and make limited entries to record treatments given and alert her or him about crucial information. The limited and standardised information fields made wide dissemination and effective portability possible. Private care providers use advanced technologies for specific applications, mostly developed and produced outside of Europe. These systems do not interact with the government supported MAC system, which makes them even more expensive than they otherwise would be.

Concerns about privacy remain but are trumped by more pressing needs, as is clear from the widespread use of (dumb) customer loyalty cards etc. Even these devices do not carry profile information; rather, they authenticate customers to databases maintained by the stores. Short term cost considerations are still the major concern: privacy, security and safety issues have therefore become a lower priority on the agenda of policymakers – and citizens.

Although over time it has become clear that some (non-MAC) RFID solutions are more efficient and capable than others, switching costs are high, in particular in terms of training and integration with legacy systems. Therefore, "old" institutions suffer from competition of new (and often foreign-based) private institutions that source RFID applications from the global market. They are able to earn higher revenues through enhanced performance of RFID-enabled services, and use this to pay the higher cost of advanced technologies. Prices are kept above those of incumbents using older technology, but not so high as to encourage those older firms either to incur switching costs or to exit the market (they serve as marginal operators to serve the less-profitable ends of the market (including public emergency care) and thus protect the new firms from adverse selection.

Industry outlook (ICS)

The global market has made it possible to have very high quality products and environments developed by market leaders that support continuous monitoring of specific health conditions and assisted living for richer clients around the world. European engineering firms do play a role in these global RFID consortia, but the lack of a 'home' market has weakened their bargaining position and the returns they obtain do not provide a basis for sustainable expansion.

Healthcare environment - market dynamics (ICS)

Due to the pressure of other welfare concerns, health care is not the top priority in Europe. Increasingly, it is seen as primarily an individual responsibility except for accidents and emergencies, for which governments assume responsibility for providing certain minimal provisions. Thus, health care has become analogous to crime prevention; the state deals with serious and unexpected incidents, but individuals are responsible for insuring against loss, managing their assets and promoting continuous 'civil order.'

What is striking is that even the "old" institutions have now become less affordable, mainly due to their failure to maintain investment during the recovery period; although the equipment was itself affordable, the required shifts in training and market orientation could not be financed. Conversely, without the increased incomes and tax revenues produced by rapid recovery, those few firms making unilateral investments in higherquality (and higher-cost) systems found themselves unable to win public healthcare system contracts.

Health care insurers and private entrepreneurs have responded to this development by introducing a higher tier of health care services based in networks of private facilities shared by multiple health care providers. The costs of the latest technology are shared, as are the revenues from complementary provision of a range of services. Profits are protected from 'new centre' competition by proprietary information systems, and from 'old institution' competition by the latter's thin margins and uneconomic customer base. However, these legacy institutions still provide the basic care, and are arguing that the new centres should have to pay into a 'Universal Minimum Healthcare Fund.'

RFID in Healthcare (ICS)

RFID application in health care has been dominated by the MAC. The MAC was developed as a European solution as an extension of the European Health Identity card (eEHIC), containing critical information in a standardised format and providing limited capability to certify entitlement to treatment. Plans to include local codes or provide secure access to enhanced patient records or to mediate payment arrangements never came to fruition.

The wider value of RFID has been recognised by private care providers, who buy the best technologies from one of the few globally leading providers of these technologies (unfortunately none of these consortium leaders is European, though European firms do play a minor role). There are some very high tech solutions available, developed for the more affluent, on a global level, by countries that were able to continue investments in innovation during the years that the financial crisis hit the world.

These proprietary systems are on offer as "additional care" in many countries across Europe, yet hardly affordable for most. In these environments, RFID has been implemented where useful in particular in combination with biometric sensors and aids for people that need to be assisted in their daily activities (like sight or hearing impaired, etc). Since the age of Internet, there is no strong connection anymore between geographic location and income generation. While the "market" for additional care (i.e. interested "affluent" people) is geographically more scattered, it has become much less of a problem as service provision and delivery of medic aids has become much more affordable through the Internet.

3.4.3 SWOT Analysis (ICS)

Strengths

- There is an increased expertise in the provision of certain healthcare services, also growing at global level, allowing (global) exchange of best practices in treatments;
- The ubiquity and consistency of incident-based care produces a highly equitable baseline of care; there are no regional or national disparities, and most people have highly comparable healthcare experiences.
- Basic Pan-European healthcare coverage is supported by a standardised information systems and a basic information infrastructure – quality is consistent, and the system automatically provides a large (if lean) database of clinical data;

- Better-targeted use of (limited) resources, as the economy is weak and all investments had to be explicitly justified;
- The system provides a good basic emergency coverage, which is useful and drives overall service improvement this can be seen in the process that led to agreement on standards of data exchange (see above) and more directly in the fact that improvements to basic care apply immediately to most of the European population (meaning that cost-effective innovations will not starve for lack of introductory markets) ;
- Technology allows general ubiquity of basic care, where people need it, and affordably at point of delivery. This base supports a higher tier of quite advanced and sustained care, There is thus a potential for the wide base to adopt improvements and even to move beyond incident to sustained care as and when the upper tier gathers enough experience to make them affordable.

Weaknesses

- Widening social divide in terms of healthcare provision. In the incident care society, additional care is only available to those with deep pockets. This does not just mean 'better' care or plusher surroundings as in the PCS scenario, but involves any access to effective care for those with long-term, complex, chronic or progressive conditions;
- Lack of a patient-centric view and little focus on improving quality of life and ambientassisted living. Demographic changes are likely to push democracy towards a better provision of healthcare, in particular for the elderly, but the system is not configured to provide this care, so the burden will increasingly fall on families, employers, etc..
- A limited and very linear idea of innovation: The Incident Care Society takes a very linear approach to the future and does not seem to consider disruptive technology changes. In particular, improvements in lifetime cost-effectiveness will always be rejected in favour of savings in incident cost. There is no regulation that forces healthcare providers to assess and improve processes or to take responsibility for the health (rather than the treatment) of the population they are intended to serve, but to whose needs they cannot respond.
- Innovations are likely to take place outside EU and thus to benefit non-EU citizens and businesses. In addition healthcare needs specific to the EU social and economic circumstances are unlikely to be met.
- Lack of overarching technological and operational standards: the complex global healthcare value chain may not produce agreement on technological and operational standards. This is not too damaging on a global scale; there is 'room' for several competing standards in a large enough market. But for European 'upper-tier' providers there is a stark choice between accepting the dominance of a single global solution (thus limiting innovation spillovers to the public system) or adopting different systems which will limit interoperability, competition and care integration within the much-smaller (private) European continuous healthcare market.
- Lack of appropriate overarching legislation no state will be able to lay a foundation for promoting the health of its citizens; private healthcare will have to be controlled by burdensome regulation rather than the need to compete with an effective public system on relatively equal terms.
- Lack of general cost transparency in the provision of healthcare services which leads to limited ability to exploit EU strength (in particular EU research) in this field and thus,

eventually, to a loss of that advantage in relation to non-healthcare as well as healthcare applications.

• Poor use of healthcare data (data sets and standards).

Opportunities

- Opportunities to learn from other experiences with additional care (which may well become wider and wider available against affordable prices, due to the distribution model (Internet) and with (ensuring) access to data (e.g. RFID enables incident/emergency care information system (MAC) to access to ERP online)
- The potential to reap high returns from investment in innovative healthcare medicine (e.g. electronic medicine) – this is strengthened by the low level of public provision in two ways; in a positive sense, innovations will first have to pass a tough cost-reduction test. In a less positive sense, innovations destined for foreign markets will be immune from the cost pressures, political delays, adverse IPR and contract arrangements and other aspects of public health system adoption that might otherwise be expected of European solution providers – in other words, they could expect to be treated as potential global high-tech champions rather than national assets capable of meeting illfunded public needs.
- To improve the overall quality of life irrespectively of people's income and social status. It is already possible to improve the life of people with deep pockets, and this shows that it can be done, when public and private sector collaborate to push down costs and improve the service.

Threats

- Security and privacy issues: MAC and the underlying information system are unlikely to provide adequate protection of the data on the chip. It will be important to continue to assure agreed levels of data protection. Minimization of data (as done with the MAC) is just one step in this.
- Concerns about the side effect of implants: An implanted MAC raises concerns about the side effect of implants, and these issues should be tackled with priority. In 2008, cases were known of implants that started "walking" through the body.
- Innovation is likely to take place outside EU. Increasing dependence on health care providers and developers in foreign countries, and mostly in the private sector i.e. with a focus on profit maximisation rather than public value.

3.5 Issues that are common in all three futures

Policies and vision

- *Need for a vision*: It is noted that RFID is only a small part of a tech investment. Discussions should focus on functionalities and carry a particular vision for healthcare in the future.
- *Learning from others*: Health care development should benefit from experiences elsewhere, and technology is inevitable as a means to enable affordable healthcare for all. For example in Japan, the Cabinet is currently financing a major foresight study to picture Japan in 2025 (including health). It will help in setting priorities; allocate budgets and roles, and necessary tech investments. In the health domain,

it particularly looks at person at personal care in home environments and its implications for healthcare and the pharma industry.

Technology issues

- Substitution vs Complementarity: RFID is only one ID technology out of many (barcodes, 2D barcodes, DataMatrix, etc). 2D barcodes or DataMatrix solutions are modern technologies and affordable printers have very recently been brought to the market. 2D barcodes and DataMatrix solutions allow to get a lot of data in a printed form. From an evolutionary perspective, 2D barcodes and DataMatrix solutions may be considered as a follow-up solution to barcodes and passive RFID. Many problems can be solved with barcodes or other ID technologies and do not necessarily require RFID.
- *Integration*: RFID applications in healthcare in use today are often task specific and not coherently embedded in existing infrastructures. To progress, it will require industry to provide a better understanding on how tags communicate with existing technologies and how to implement RFID in a barcode infrastructure.

Functionalities

- A *clearer distinction* needs to be made between RFID as a therapeutic device versus RFID as an identification device.
 - In therapeutic use, RFID is used in combination with sensor providing additional information (e.g. on vital signs).
 - As an identification device as in any other sector it can be used to identify a person (e.g. patient, staff) or assets (e.g. medical device).
- *Quality vs Cost*: When considering investing into RFID it should be to improve care and not only to reduce costs. The real challenge lies in evaluating quality improvements, in particular when no (or insufficient) data exists on the status quo, and hence no benchmark to compare to.

Possible risks:

- *System Failure*: Any cost-benefit analysis on any RFID system should consider the requirements for and costs of the back-up system and try to evaluate the risk of system failure. In the health care sector, system failure can be mortal.

This chapter sketched pictures of plausible futures to cover a wide range of uncertainties and generate ideas fro possible policy issues. The three futures have been critically assessed by experts and presented in the form of a SWOT analysis. After this scan of future issues the next and final chapter will draw conclusions on the policy relevance of the findings, and recommend actions where they are due.

4.1 Conclusion

It is clear that the number of RFID applications continues to grow, both in size and in areas. However, the outcome of the study does not allow the development of a roadmap for large scale roll out of RFID as such. Practitioners emphasised throughout the project (interviews, workshop) that they do not take a technology centric view. They look at solutions for their specific issues related to health care.

Focus is on functionalities and costs of the different technologies, in which there is no ex ante preference for RFID over other ICTs (including WiMax, DataMatrix, other near-field technologies). In addition, other identification and authentication technologies like barcodes continue to be applied and seen as useful way forward – except where there is a clear added value in electronic storage and transmission of tagged information. RFID is just one of the technologies that can provide solutions towards better healthcare, and should be seen from a healthcare need perspective rather than from a RFID potential perspective.

That does not mean that there is no need for attention to what RFID could do for healthcare. Currently, application of RFID to provide solutions is often not considered because health care professionals are not aware of the potential, or may base their decision not to use RFID technologies on assumptions that have not been validated.

At the same time RFID development can benefit from the (cautious) demand by the health sector, which is continuously pushing for cheaper, more reliable and in some perspectives more innovative solutions. Specifically in Europe, demand for health care services is very much for personalised services, for which RFID is an enabler with high potential.

These main conclusions lead to a series of practical recommendations that basically can be distinguished in:

- 1. How to best benefit from RFID in healthcare environments;
- 2. How the RFID industry in Europe can serve the demand for its products in the important Health care sector

4.2 Recommendations for improving delivery of care using RFID

RFID technology offers a number of functionalities that can significantly improve the quality, effectiveness and efficiency of the delivery of care. These have been explored at length in an earlier report from this study. However these benefits are not self-evident. Legal, organisational, technical, financial and ethical barriers to implementation remain. These relate not only to the technology, but also to the way it is integrated in the health care delivery process; how staff uses the applications, how perceptions are managed, etc.

The expert workshop and previous analysis of cases suggest a number of actions that may be considered to overcome some of the barriers and to create more safe and enabling environments for the effective application of RFID. In this final phase of the study the focus has been on identifying the policy options for the European Commission and DG INFSO in particular. However, they are presented here in a broader perspective to benefit a wider group of stakeholders in policymaking, and care delivery and the providers of technology.

Concluding from this study we make the following recommendations:

- 1. Awareness raising and informing the public debate; take away the myths and make healthcare practitioners and decision makers aware of the real opportunities and challenges arising from RFID;
- 2. Privacy and security; remain key priorities that require careful handling, and that could benefit from proper implementation from the start;
- 3. Spectrum access and management; in order to ensure spectrum availability and prevent interference;
- 4. Research priorities: listing of specific topics for further research to further enhance the potential application of RFID technologies in healthcare.

1. Awareness raising and informing the public debate

The lack of information is an issue that needs to be addressed, to remove the hype about RFID as well as undue negative perspectives. The purpose of this is ultimately to empower the patient and to allow policy makers, care providers and health insurers to take evidence based decisions (investments, policies, reorganisation) to the real benefit of the quality and the decrease of the cost of care.

<u>The topics</u> that need addressing are:

• Explaining the facts, including the benefits and risks of RFID deployment in general and in healthcare in particular; and options to overcome the risks.

Among the *risks* that need to be communicated:

- Interference
- Privacy
- Health effects

Benefits to communicate:

- Patient safety
- Patient empowerment, though more (real time) information
- Increased mobility of patients enabling outbound care

- Explaining the different kinds of RFID: active vs passive and open vs closed loop applications; and what these differences entail
- Managing the tension between collective benefits and individual freedom, and making the trade offs transparent

The instruments that may be considered to achieve these objectives are:

- *Training*: specific training and embedding teaching (in the regular curriculum of the education system) on the use of ICT, the management and ways for processing of information and the value of privacy
- *Develop PPPs* to issue common messages
- Inclusivity: when developing a new ICT system in a care delivery environment especially involving RFID and similar technologies providing functionalities like sensing, tracking, tracing and identification it is important to involve all stakeholder at the start of the process to achieve acceptance and (possibly) ownership
- *Branding* of RFID as a positive technology, by getting across what the positive attributes of RFID are and how this relates to the specific kinds of RFID.
- *RFID logo*: increasing the uniformity and clarity of the message expressed

2. Privacy

Privacy is a reoccurring theme and needs to be specified further to be relevant for policy development.

- *Centrally storing* patient data on remote servers (electronic patient records (EPR) database), allowing the effective monitoring who accessed the data, when and for what purpose; also ensuring that the data set of a patient is complete and contains all relevant information.
- Creating an effective, accurate and reliable *eIDM system*, which caters for multiple identities and/or the use of different aspects of patients' identities along the healthcare value chain; determining if this should be at the national, sectoral, EU or even global level and who should manage and maintain it.
- Patient centric healthcare provision will require the exchange and processing of personal patient data. To allow this to be done effectively in an environment where the patient is vulnerable and the stakes are high i.e. the propensity to give up privacy is very high too

 a delicate balance needs to be struck between the responsible use of data and the protection of the data subject.
- Patient safety aspects of *system failures* need to be acknowledged and dealt with through effective back up plans.

The instruments that may be considered to achieve these objectives are:

- *A Review of the legal framework* for data protection may be considered. Creating sector specific laws to allow more flexibility and more control by the data subject; with better ex post enforcement, restitution and recovery mechanisms.
- *Effective monitoring mechanisms* for data abuse and instruments empowering the patients to claim indemnities in case of data breached.

- Use nudge options and opt outs; allowing the patient a choice but suggesting one that is preferred over the other in line with some perceived and communicated private or collective benefit.
- *Develop protocols* which catalogue the medical data, which is accessible by who, under which circumstances, and back these up with appropriate legislation.
- Using where possible *technical solutions* to overcome current regulatory challenges, and enforcement/ implementation difficulties.

3. Spectrum access and management

Spectrum management is an issue that is particularly relevant for future uptake. It involves a number of different angles such as interference prevention schemes, and bandwidth management. Some generally applicable suggestions for policy actions are:

- The need to identify the most *appropriate frequency band* (ISM?); assess what is still possible and what bottlenecks are occurring. Analyse capacity going forward in anticipation of much larger volumes of data being transmitted
- Consider a *dedicated frequency* band for critical/emergency services
- Assess spectrum access requirements (free, licences, etc)

The instruments that may be considered to achieve these objectives are:

- Emphasising RFID in health applications within the *large scale eIDM pilot* STORK and the smaller *pilot B on eHealth*
- Use both to assess what the spectrum needs in healthcare are going to be.

4. Research Priorities

A number of issues remain to be clearly determined, which continue to cast doubt on the appropriateness of the deployment of RFID in the healthcare environment, and especially in life critical applications:

- Health risks of RFID radiation
- Reliability of RFID in critical healthcare delivery processes
- Interference issues
- Interoperability challenges in cross border applications
- Spectrum capacity requirements for supporting the future data transfer and processing needs in healthcare

4.3 **Recommendations towards RFID development and deployment**

Many of the recommendation in the previous section will also improve the market conditions for wide scale RFID deployment in healthcare; by improving perceptions, safety, reliability, user-friendliness, accessibility, and privacy. Thus it is expected that the demand for RFID will grow. Some measures could be considered for strengthening development in the European RFID and software industry.

1. Setting clear European quality requirements

These specific requirements will force the RFID and supplying services industry in Europe to innovate and improve its offering; as such positioning itself in the global market for RFID solutions as suppliers of premium applications in the healthcare domain.

The specific challenges arising from healthcare environments provide an interesting source of inspiration for further RFID development and deployment, mainly for two reasons:

- 1 The specific requirements from the healthcare domain lead to high standards on reliability for applied technologies. This could mean that the quality and robustness of RFID applications in healthcare might well lead to:
 - 1. increase in application in other sectors;
 - 2. premium healthcare applications as Universal Service Provider (USP) for European RFID firms.
- 2 Healthcare is a priority sector for EU countries that has high demand for services, and the budget limitation leads to an ongoing strive for doing things better, and cheaper. This means that the healthcare sector will not hesitate to invest in RFID applications, when and where it is clear that such advantages can be met.

2. Interoperability and open standards

There is a need to find a balance between innovation and making sure that practitioners and patients do not get "locked in" to specific technologies that are not interoperable with existing infrastructures. Support for interoperability is important for a number of reasons:

- Expected impulse to *innovation* if systems are open to all software providers particularly SMEs for developing and offering new data based services. It would also allow patients to engage more actively in self-diagnostics and in better monitoring of their own data using a much greater variation of tools possibly developed by themselves (user driven innovations)
- Possible solutions like uCode, in which the information regarding the objects is in online databases, and the systems allows standardisation and interoperability between different systems to take place at *middleware level*. With such a solution, barcodes, RFID and other automatic identification methods may easily complement each other;
- Lack of interoperability (and easy transfer of data) leads to *lock in* of patients by certain healthcare providers and insurers. In turn care providers could be locked in by technology suppliers that delivered closed systems.
- *Travellers and mobile citizens* want to move across borders and still be insured and have access to appropriate high quality care. This requires interoperability of the underlying systems, especially if electronic patient records (EPR) become a common feature in healthcare.

The instruments that may be considered to achieve these objectives are:

- The specifics of the healthcare environment need to be taken into account when setting standards
- Push the development and deployment of technical middleware

- Intelligent public procurement for pushing the use of open standards
- Public private partnerships (PPP)

3. Needs and wants analysis

Look at specific challenges arising in health care, and target areas where RFID may make a difference, i.e. identify problems where RFID might be a solution.

4. Learning from practice

Develop and present case studies on RFID application in healthcare, both for informing the healthcare sector itself and for inspiring other sectors by presenting clear and accessible business cases for RFID application.

4.4 Specific recommendation on the role of DG INFSO:

Based on the points raised above DG INFSO should:

- 1. Procure and/or support research into:
 - a. The effects of RFID; in order to establish an evidence base and common understanding of risks, limitations, benefits and opportunities of the technology and specific issues concerning the application in healthcare settings.
 - b. The barriers, risks, and weaknesses of RFID, in order to solve them and improve the technology and its applications
 - c. Developing appropriate middleware
- 2. Develop and facilitate PPPs across Europe thematic networks or more specific and dedicated groupings to
 - a. Issue common messages
 - b. Develop common, open en healthcare sensitive standards
 - c. Load the RFID logo with positive attributes 'RFID inside' and ensure uniformity of the message
 - d. Champion the need for dedicated frequency band
 - e. Establish a set of European quality norms for safety, privacy, reliability, and security
- 3. Review of data protection framework and assessing common minimum standards for privacy in the specific context of healthcare delivery
- 4. Increase the support of cross-border service delivery; through the CIP large scale pilots and/or mechanisms like eTEN
- 5. Continue coordination and support to the establishment of a common EU eIDM principally through the large scale eIDM pilot STORK and the eHealth pilot B;

- 6. Also use these pilots to assess what the spectrum needs in healthcare are going to be, as well as the spectrum requirements; and determine the most appropriate frequency for health care and emergency services
- 7. Sensitise and effectively use competition policy to avoid technology lock ins
- 8. Assemble good practices and facilitate knowledge transfer in the EU

REFERENCES

References

Baalbaki R. 2006. Mesure de al fiabilité du controle ultime avant l'administration des medicaments aux patients, Université de Geneve, Faculté des science Section des sciences pharmaceutiques.

Bacheldor B. 2007. At Wayne Memorial, RFID pays for itself. RFID Journal April 3, 2007, available at http://www.rfidjournal.com/article/articleprint/3199/-1/1/

Botterman M (2008). Interview protocol: Lara Srivastava, ITU, RAND Europe, internal document.

Bradshaw T. 2008. Resource tracking using RFID/RTLS: A hospital's experience. IDTechEX presentation.

Bundesministeriums für Gesundheit (BMG). 2007. Kooperation und Verantwortung, Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen

Capgemini, n.d., RFID in de Gezondheidszorg – experiment met RFID in de Zorg: eindrapportage van een drietal pilots in het AMC.

Countess of Chester Hospital Integrates Training and Service Records to Ensure Compliance. June 2008, Oracle Customer Case Study

De Vries H, van Oranje C, Schindler R and A Vilamovska (2009). The importance of RFID applications in healthcare to contain costs and improve quality: results from a Delphi study, RAND Europe, internal document.

Garets D (2007). Healthcare IT Trends and Glimmers, HIMSS Analytics.

Gartner (2007). Dataquest Insight: Healthcare Trends, Western Europe, 2005-2010.

Gartner (2007). Forecast: Healthcare IT Spending, Worldwide, 2006-2011.

Gartner (2007). Forecast: Healthcare Provider IT Spending, Worldwide, 2007-2012.

Gartner (2007). Vendor Survey Analysis: Healthcare Providers' Rapidly Changing Landscape Worldwide, 2007.

Gartner (2008). Care Delivery Organization Consulting, System Integration and Application Development: Market Drivers and Key Players.

Gartner (2008). Case Study: Architecting an Emergent Business Ecosystem at the UK National Health Service.

Gartner (2008). Dataquest Insight: How the Changing Global Economic Outlook will Affect IT Spending on Healthcare Worldwide Through 2010.

Gartner (2008). Hype Cycle for Healthcare Provider Applications and Systems, 2008.

Gartner (2008). Hype Cycle for Healthcare Provider Technologies and Standards, 2008.

Gartner (2008). Hype Cycle for Telemedicine, 2008.

Gartner (2008). IT Key Metrics Data 2008: Key Industry Measures: Current Year: Health Care Analysis.

Gartner (2008). Market Trends: Radio Frequency Identification, Worldwide, 2007-2012.

Gartner (2008a). Dataquest Insight: Healthcare Provider Industry Primer, 2008.

Harrop P, Das R and G Holland (2008). RFID in Healthcare and Pharamceuticals 2008-2018, IDTechEx, Cambridge UK.

Kalorama Information (2008). RFID Opportunities in Healthcare in the U.S., Kalorama.

Malkary, G (2006). Active RFID popular pick. ROI for the passive form is weak, but overall prospects look better, says study. Healthc Inform. 23(2): 108.

Mun K and A. Kantrowitz (2008). Active RFID for Patient Care.

RFID Journal (2008). RFID in Healthcare, RFID Journal.

Schindler R (2008). Interview protocol: Dr. Rof Dahm, n-tier, RAND Europe, internal document.

Schindler R (2008). Interview protocol: Heinrich Oehlmann, EHIBCC, RAND Europe, internal document.

Spyglass Consulting (2008).Healthcare without Bounds: Trends in RFID 2008, July 2008.

Vilamovska A (2008). Interview protocol: Dave Garets, HIMSS Analytics, RAND Europe, internal document.

Vilamovska A (2008). Interview protocol: Dr. Vincent Carrasco, Radar Find, RAND Europe, internal document

APPENDICES

| Implementation Costs |
|---|
| Hardware costs |
| Software costs |
| Middleware costs |
| Installation costs |
| Training costs |
| Process re-design costs |
| Labor costs (including business case development costs, system integration costs) |
| Maintenance Costs |
| Software costs |
| Hardware costs |
| Data back-up costs |
| Labor costs (system maintenance and expansion) |
| Efficiency Gains |
| reduction in capital expense outlays for purchasing assets and inventory |
| reduction in capital and operative expense outlays for renting and managing equipment |
| labor savings from automatic data capture and transfer |
| labor savings from improved process status visibility |
| cost capture improvement via automatic data capture |
| reduced care-provider turnaround rate due to improved work satisfaction |
| increased patient through-put |
| decreased patient subversion |
| Quality Gains |
| elimination of wrong patient/wrong medication errors |
| elimination of wrong patient/wrong procedure errors |
| improved care coordination leading to more timely & available care |
| improved coordination of auxiliary services (eg transportation) |
| improved patient satisfaction |
| improved infection control capacity |
| improved asset preventive and corrective maintenance |
| Other Gains |
| improved regulatory compliance |
| reduced insurance premiums |
| improved process and event audit capacity |
| improved management & forecasting capacity |

Various stages of the project involved external experts. We acknowledge their very valuable contribution.

As part of the evidence collection, RAND Europe staff has interviewed the following experts:

- Thomas A. Bradshaw, VP of Operations, Wayne Memorial Hospital (WMH)
- Roberto Birago, CEO, SICED System Integrator (Treviglio)
- Guenther Braun, HCS Consultants
- Jason Britton, CSci, Principal Clinical Scientist, St. James' Hospital, Leeds, UK; (formerly Clinical Scientist, Royal Alexandra Hospital, Renfrewshire, UK)
- Vincent Carrasco, Chef Medical Officer, RadarFind
- Bill Crounse, Senior Director, Worldwide Health, Microsoft
- John T. Collins, Director, Engineering and Compliance, American Society for Healthcare Engineering, USA
- Rolf Dahm, n-Tier construct GmbH
- Massimo Damiani, CEO Softwork, RFID Solution provider (Treviglio)
- Jonah Frolich, MPH, Senior program officer, Better Chronic Disease Care program, California HealthCare Foundation
- Ross Folland, Head of Product Development, Safe Patient Systems, Lincoln House, Brimingham Heartlands Hospital, Birmingham
- Mr. Dave Garets, President and CEO of HIMSS Analytics and Executive Vice President of HIMSS, USA
- Tobias Goetz, SAP Sales (Jena)
- Michael Hartmann, Head of pharmacy Universitaets Klinikum Jena
- Stephen Miles, Chair, MIT Enterprise Forum RFID SIG, Research Affiliate, MIT Auto-ID Labs, USA
- Dr. Björn Kabisch, Head of research and development; project manager Universitaets Klinikum Jena
- Peer Laslo, SAP, Key account manager Audto-ID (Jena)

- Christian Lovis, Director of Clinical Information Unit, Service of Medical Informatics
- Heinrich Oehlmann, European Health Industry Business Communications Council
- Deven McGraw, Director, Health Privacy Project, Center for Democracy & Technology
- David Morgan FRCS, Founding director, Safe Surgery Systems Limited, Lincoln House, Brimingham Heartlands Hospital, Birmingham
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- Kevin Rustill, Head of Testing & Quality, Safe Patient Systems, Lincoln House, Brimingham Heartlands Hospital, Birmingham
- Gerard Scriba, Professor of Pharmaceutical Chemistry, Department of Pharmaceutical Chemistry, Universitaets Klinikum Jena
- Lara Srivastava, ITU, New Initiatives Programme Manager with the Strategy and Policy Unit (SPU)
- Stéphane Spahni, project manager at SIM
- **Patrick Solier,** Administrator DEX, Deputy manager, responsible for accounting and financial management, technical projects and informatics for department of logistics (retired Geneva)
- Martine Velkeniers, Mobility Solutions Marketing Manager, Marketing/CMO, Cisco Systems Inc.
- Dr. Albert Villarin, Chief Information Officer, Director of Medical Informatics, Lead Clinical Director – Electronic Medical Record Implementation, Department of Emergency Medicine, and Chairman of Hospital Information Mgmt & Quality Assurance Group, Albert Einstein Medical Center, PA, USA

The following experts participated in the scenario gaming workshop, partially overlapping with the previous list.

- Jason Britton: CSci, Principal Clinical Scientist, St. James' Hospital, Leeds, UK; (formerly Clinical Scientist, Royal Alexandra Hospital, Renfrewshire, UK Catalina Ciolan European Association of Healthcare IT Managers
- Christian Chabannon: Institut Paoli-Calmettes Biotheque / Tumorotheque / Centre de Ressources Biologiques en Oncologie Centre de Therapie Cellulaire et Genique. Departement de Biologie
- Oliver Christ: SAP
- Rolf Dahm: n-Tier construct GmbH
- Jeorg Focke: Asklepios Klinik Bamberg

- Florent Frederix: DG INFSO, D4 (RFID Unit)
- Andreas Gereke: ITH icoserve technology for healthcare
- Ase Kari Haugeto: Norwegian Board of Technology
- Ryo IMURA: Hitachi Ltd, Tokyo University
- Bjorn Kabisch: Head of research and development; project manager Universitaets Klinikum Jena
- Oliver Koch: Fraunhofer Institute for Software and Systems Engineering
- Sandra Lindon: GlaxoSmithKline
- Stephen MacMahon: Irish Patients Association (representative to the International patient groups consortium)
- Lee McGill: EC DG SANCO C5
- Saad Mezzour: ETSI EP EHEALTH Chairman / Medtronic
- David Morgan: Safe Surgery Systems, Birmingham Heartlands Hospital
- Heinrich Oehlmann: European Health Industry Business Communications Council
- Hana Pechakova: DG JLS, C 5 Data Protection Unit
- Chris Ranger: National Patient Safety Agency
- **Maurizio Salvi:** Europen Group on Ethics in science and new technologie (EGE), Burea of the European Policy Advisers (BEPA)
- Peter Segeroth: Siemens AG, Siemens IT-Solutions & Services: Auto ID/RFID solutions
- Lara Srivastava: ITU
- Mira Trebar: University of Ljubljana, Faculty of Computer and Information Science
- Jiri Vorlicek: Masaryk Memorial Cancer Institute
- Kevin Warwick: University of Reading KTP Centre

Appendix C: Workshop Terms of Reference

Introduction

It has been suggested that the application of RFID technology in healthcare has great potential to improve patient safety, reduce medical errors, and overall contribute to the quality of care delivered to patients. In addition, the costs and efficiency of healthcare delivery may also benefit from RFID technology. It is expected that availability of the technology, both inside and outside healthcare, will grow quickly over the coming years (for example, one forecast predicts that the number of tags delivered in 2016 will be over 450 times the number delivered in 2006). A key question for policy makers is what actions should be taken, and what further research is necessary, to ensure the new technology will reach its full potential. It is possible that without taking timely and appropriate action, cost savings, improvements in patient safety and reductions in medical errors might not be realised.

At the same time, the application of RFID raises issues of privacy and security. For example, a patient might be concerned about her privacy if hospital staff can track her whereabouts through RFID. Furthermore, when RFID is used as a means of identification, illegal copying of tags could pose a security threat. A key question for policy is what kind of policy intervention is needed and what level of regulation is required to ensure the privacy and security of patients and providers.

In order to respond to these questions the project team has carried out literature review and a Delphi survey, as well as a number of specific case studies. While this provides a solid under-pinning with respect to the current situation regarding the application of RFID in healthcare, the next phase is to identify policy and research options for the European Commission (EC) to ensure large-scale, effective, and secure implementation of RFID in healthcare and the pharmaceutical market.

These options will be assessed for their future robustness in a scenario based workshop.

<u>Objective of the workshop</u>: Based on the work done so far, the workshop will focus on validating the emerging results, and explore with the participants what best can be done next at the EU level in terms of policy action and research.

Approach

By definition, policy and research options will have an effect in the future. We are able to determine where we stand today in terms of how healthcare is delivered, what is possible today with RFID in terms of technology solutions and costs, and what the level of

implementation of RFID in healthcare and its impact so far is. However, it is important today to consider the key uncertainties with regards to future developments in healthcare, and the possible role of RFID in healthcare, when considering policy options and research needs.

For that purpose, we have developed scenarios, with as their dimensions the key relevant uncertainties that we cannot influence directly, against which we will play out the different options for policy action that could be decided. In that way we will be able to recommend the most robust policy options.

During the workshop we will play with these scenarios ("scenario game") by employing hindsight for each of them (i.e. "looking back from the future"). Then we compare the hindsights amongst these different projected futures to identify what sort of planning is needed regardless of which of these futures arises, and what sort of planning is dependent upon which type of future we see.

There are three major components to a scenario game: the scenario(s), the players, and the tasking. We will build the scenarios on the work done during the first phase of the study, using the RAND-developed XLRM method.

The **players** (total 20 to 30) will be chosen in close coordination with the European Commission. They are selected on their specific interests and insights in this multidisciplinary field, ranging from technical expertise in ICT to health care knowledge and experience.

Tasking for the scenario session is to analyse the strengths, weaknesses, opportunities and threats (SWOT analysis) of the scenario participants will be asked to be living in. Then, taking the SWOT analysis into consideration, to think, in hindsight, about how they would have done things differently in the time period around and shortly after 2008 in order to seize the opportunities better and mitigate the weaknesses and threats, while maintaining the strengths.

In the afternoon, we will work with breakout groups representing different stakeholder groups ("government", "medical profession", "ICT supplier", "patient"). In each group we will consider what is needed, and can be done about the effective use of RFID in relation to the following issues, from the perspective of the group:

- empowerment of patients
- removing barriers to the use of RFID
- supporting drivers for RFID type technologies
- developing effective regulation and enforcement to incentivise care delivery in the interest of the patient
- supporting other incentives

The scenarios

The scenarios build upon the findings from the literature review, the online Delphi exercise and the assessment of RFID case studies. We have foreseen the following steps in developing the scenarios for the scenario exercise during the expert workshop.

Applying XLRM framework

We will build the scenarios by systematically interrogating the issues using the XLRM framework. This examines the eXogenous factors affecting ways in which the future is uncertain and also that are not under the control of the various actors (European Commission and other stakeholders that would expect to work with the Commission towards a common goal). The Policy Levers are the options that, in the relatively nearterm, are open for action by the various actors. These might include new regulations, agreements over standards, the creation of collaborations or new networks and so forth. Relationships are the ways the factors relate to one another including trust, economic relationships, network evolution, power asymmetries and so forth. Measures are the ways of assessing what is desirable and undesirable from the point of view of the actors and these might include privacy, efficiency and trustworthiness. For this we will draw upon the findings of earlier work.

Building the scenarios

The scenarios are designed around the certainties and uncertainties arising from the XLRM framework. A scenario is a logical and consistent picture of the future that is not only credible yet also challenging in important respects to the stakeholders. Important and relatively certain developments are included in all scenarios, important and uncertain are used to differentiate the scenarios. Unimportant certainties are used to support a concrete picture and unimportant uncertainties are used to give colour to the scenarios.

To check the plausibility of each scenario we will identify a timeline showing how the scenario could unfold over the coming fifteen years. Each scenario needs to be internally consistent.

Key uncertainties

The following key critical uncertainties were found during the earlier phases of the project:

- cost of RFID;
- acceptance of national or supranational RFID standards on private information protection, security and data integrity (especially with respect to open-loop applications);
- promulgation of sub-national, supranational or national mandates/regulations on RFID implementation in healthcare (e.g. in connection to patient safety, such as e-handshake for positive identification at point of care) as opposed to similar mandates for technologies viewed as alternatives to RFID (e.g. bar coding and Bluetooth);
- public opinion on RFID and acceptance of use of RFID by medical professionals and patients.

In addition, we feel that general uptake and acceptance of RFID in society at large will also affect its uptake in healthcare environments. This means that the first two points raised above should be truly seen in a wider perspective, but it also affects the third and fourth point as outlined below:

- The cost of RFID is not only about specific RFID applications in hospitals, but also about general costs of both RFID and RFID readers. With widespread availability of RFID readers a lot more becomes possible than without. With lower costs for different types of RFID chips, including passive and active chips, but also very small chips and bio-degradable chips, because of use at large scale, use within healthcare environments becomes much more attractive;
- When these standards have been established at international level and when they function in society at large, they will no longer hold back RFID deployment in healthcare. However, we would still need to take into account the specific measures needed for this sector;
- Accepting RFID as a robust technology that government supports and embraces will allow optimal use. Whereas today (2008) other technologies such as bar codes and zigby (in particular in hospital environments) play a role in areas where RFID might do even better, if RFID were functioning well, active support of those alternative technologies might postpone further introduction of RFID at places where it would function better than these technologies.
- The public attitudes towards RFID in general obviously affects the public opinion on RFID use in healthcare. In particular wider use of (and getting used to) RFID leads to easier implementation, and will also take away fear for failure of systems. Systems failure will be less frequent, will be more manageable, and we will know what to do when it happens in all walks of life, including in health care environments.

Furthermore there are some megatrends that might affect use of RFID in healthcare environments:

- Financial crisis may lead to lack of investments in technology innovations, including further development of better, smaller and cheaper RFID tags and readers;
- Internet may scatter in many different networks because of too many and unmanageable security risks arising in the open internet. In this situation, being connected would lead to high personal risk, and/or because of increased policy intervention by national governments insisting on having a grip on Internet usage;
- Healthcare becomes more embedded in society as a whole, supporting independent living as much as possible and involving health care professionals as well as other care takers, both professional and voluntary citizens (family, friends, neighbours);
- Next to competition in healthcare delivery, there is also a lot of cooperation, and consolidation (horizontal and vertical).

Scenario dimensions

While considering all these possible megatrends, and other uncertainties in the process, we have selected the following megatrends for creation of the scenarios:

- 4. Focus of health care delivery on "total health management" vs. focus on health incident management. With "total health management" we mean continuous caring about the health and –in extreme- lifestyle of people through continuous monitoring and action whenever needed, not only to resolve health issues but also to prevent them. A focus on health incidents reflects much more a hands off approach with no action until a health incident takes place;
- 5. Wide adoption of RFID (tags and readers) for a wide range of purposes (i.e. RFID becomes "normal" and is regularly used in daily life) vs. a narrow focus of RFID on logistical processes only;
- 6. Linking of medical data from different environments (.e.g. social care, lifestyle, diet) vs. keeping all data separate, to be released at request only.

Based on these three dimensions we could develop in theory 8 different scenarios. However, for practical reasons we choose three, each differing from the other one in two places. The scenarios selected are listed in the table below:

| Scenarios/ | SCENARIO 1 | SCENARIO 2 | SCENARIO 3 Incident |
|---------------------|----------------------|----------------------|---------------------|
| dimensions | Private care society | Central care society | care society |
| Total health focus | High | High | Low |
| General uptake RFID | High | Low | Low |
| Linking health data | Low | High | Low |

The private care society is very well equipped with RFID to monitor and manage health issues, in a local context. Everybody has his or her RFID reader at hand, coupled with the mobile phone. RFID data are with the patient, who is in control. Whereas she of he cannot change critical health data without co-authorization of a medical professional, she or he can read the data and add "personal remarks". Medical professionals need to have permission from the patient to read the data, which are protected by a patient-owned pin. However, in case of emergency access to the chip can be obtained using specific equipment that will require justification for its use, after the fact. In this society, health is seen as something that needs to be protected by actively signaling health risks (prevention) and for those recovering from health incidents RFID empowered equipment can help keeping track of progress and suggesting specific action when sensors connected to RFID tags signal action is needed. This is a society with confidence in RFID and new technologies in general, with a strong European system of regulation effectively enforced at the national level. For those in regular work, with employer contributions to health insurance, it is a world of steady health improvement and growing security. However, few incentives exist to ensure that these benefits are spread to marginalized groups and more collective public health interventions aimed at benefiting the whole of society are often difficult to deliver. Few incentives exist to integrate health care with related services (social care, diet and exercise support, healthy workplaces and so forth) although the technology to do so is

available. A small but vocal minority is hostile to high technology solutions to what they see as ill-health created by a spiritual malaise.

The central care society is truly measuring and bringing together all medical data of its citizens, in order to be able to prevent health incidents by actively informing citizens about health risks. Also, in case of accidents as well as in cases where continuous health care assistance is needed, linking all data has proven to be effective and useful: even if patients don't feel they need help they are obliged to take the recommended measures. And if they don't, RFID enabled sensors will report this to the medic responsible for the health of that specific citizen. It is expensive to do it in this way, as RFID is not widely spread, but this is paid back by the overall health of citizens that obey to the strict regime required. The incentive to implement RFID is the perceived cost savings it can make available to central authorities and this has driven the particular way it has been used. The coercive aspect to this has led to some resistance and refusal to participate in RFID-enable health care has led to people being excluded from the main healthcare system and provided with a more basic service. Such people tend not to adopt a more 'natural' or 'holistic' approach to healthcare; instead they suffer poor levels of health status and health care. Particular anger has been expressed by those who object to data being collected in one sector (health) being made available to elsewhere (e.g. in food marketing, alcohol retail etc). Regulations exist at the European level but Member States have tended to give these very different interpretations through national regulation.

The **incident care society** is one where RFID is integrated in the incident handling activity, though expensive it helps keep the medical professionals alert and informed. It is all done on an incident basis, while only key medical information like allergies and heavy medicine use are available. In this world, resources, and therefore the incentive to innovate, focuses narrowly on specific health incidents such as elective surgery, accidents and emergency, short term ill-health. This leaves chronic conditions, long-term multifactoral health problems, mental health care and other long term interventions under-funded and provided in a largely low-tech environment. This has reinforced a division between the 'occasionally unwell' and the 'long-term sick' with older, poorer and non-employed people tending to be in the latter category. The European level has attempted to limit this trend but with little success and indeed European regulations intended to benefit excluded groups have been blamed for hampering improvements.

In each of these worlds there may be something participants to the workshop like, and what they don't like. First this is to be explored, followed by a second round in which we consider options that could help make a positive difference. Those options that are most effective in all cases are those that will be presented as 'robust'. Those that are merely useful in some occasions will be kept as just that: when society would move in a specific direction, these measures may become useful. We will determine what it takes to know that this is the case.

The participants

People from industry, government (healthcare, enabling technology, responsible), and civil society as well as a limited number of selected researchers.

Preliminary agenda

In order to be able to have two cycles of parallel sessions, we will ask people to plan to be there for a full day, starting promptly at 0900 with the programme, ending at 1700 with concluding remarks and after that drinks.

| 0830 | registration | | | |
|------|--|--|--|--|
| 0900 | welcome, what are we going to do, introduction of participants | | | |
| 0930 | presentation of results so far | | | |
| | Q&A | | | |
| 1000 | coffee and start of parallel sessions | | | |
| | Parallel sessions per scenario (participants divided in 3 groups) | | | |
| | Introduction of scenario | | | |
| | SWOT | | | |
| 1200 | Buffet lunch | | | |
| 1245 | Plenary: feedback per session on SWOT | | | |
| | Discussion on commonalities and differences | | | |
| | Tasking for afternoon parallel session explained | | | |
| 1400 | Parallel sessions per actor (participants divided in 4 groups: "government", "medical profession", "ICT supplier", "patient") | | | |
| | Discussion on what the specific challenges are, and what needs to be done | | | |
| 1530 | tea | | | |
| 1545 | Plenary: findings per actor | | | |
| | Discussion, cross validation | | | |
| 1700 | Conclusions, closure | | | |

1730 drinks, snacks

Please don't plan to leave the meeting before 1730. If you would like to come, and may have to leave before 1730 please contact us beforehand.

Location and date

The conference will be preference be held in Beaulieu 33 room 0/54, Brussels, using the main room and two breakout rooms (BU33 0/58 and BU31 0/84). The conference will take place on 26 March 2009.

Travel Reimbursement

The air fare shall be reimbursed on production of the ticket, which shall be for economy class air fare.

Reimbursement is made in €, at the rate of the first day of the month of the meeting.

The daily allowance is currently $149.63 \in$ per meeting day. It is a standard amount covering all expenses at the place where the meeting is held, including the costs of accommodation, meals and local travel but <u>taxi fares are not reimbursed</u>.