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

Final report (D5)

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RAND EUROPE

The research described in this report was prepared for the European Commission Directorate General for Information Society and Media.

Executive Summary

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 report[1], 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

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[1]Creating 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 systems[2] 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 study[3]) 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

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[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 infrastructurees.

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