Titolo: Quality of service, safety and protection of privacy in hospital: a method for impact assessment of RFId technology in healthcare

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Abstract

Background: Radio Frequency Identification (RFId) technology is rapidly integrating into hospital practices to track assets, identify patients and manage personnel; it is important to assess its impact on privacy, safety and quality of health services.

Objective: This paper describes the methodological approach adopted and the tools used by the authors to evaluate the quality and effectiveness of applications and systems using RFId technology in health care facilities to solve problems due to lack of traceability.

Methods: To analyse the actual and/or potential effects of this technology, the method adopted is taken from the multidisciplinary approach of Health Technology Assessment (HTA), with particular reference to the assessment of quality of services provided, of safety and of protection of personal and sensitive data. Tools developed during the research include survey, verbal questioning and interviews involving hospital staff members (Management, Technical, Clinical&Service Implementation), and audit in Italian healthcare facilities.

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Results: We identified the current applications and technical characteristics of RFId technology and we calculated priority levels to determine impact health indicators. Results were used for evaluate the diffusion, the applications and the characteristics of RFId technology and also for calculate its impact on healthcare processes.

Conclusions: Using the tools described in this paper, health managers can evaluate the impact of the RFId-based applications in their healthcare structure.

1. Background and significance

Inside healthcare structures circulate large volumes of information relating to patients, health professionals, assets and biological samples. The management is usually carried out by hospital staff, recording data on paper and, in some cases, later transferring data into the department server of the structure.

These procedures may create a lack of traceability that, from a clinical point of view, may cause problems:

- in the activities of the health facility (risk of mistaken identity of patients and operators).
- in the location and in the maintenance of biomedical equipment, (risk resulting from the use of inappropriate equipment or potentially dangerous medical devices).
- in managing of biological material that have to be analysed or administered to the patient (risk owing to the uncontrolled movement of potentially hazardous biological materials).

In hospitals RFId technology can solve these problems, improving the quality of health services provided and ensuring the safety and privacy.

A recent literature review describes its common applications and benefits in healthcare: RFId allows tagging, identifying, tracking and managing assets, personnel and patients (Yao et al. 2012).

Some studies have focused on the impact of RFId technology on the quality of health services provided, in particular were estimated tangible and intangible benefits arising from its introduction (Sbrenni et al. 2010).

In other papers, the use of RFId technology is related to the clinical risk reduction, to improve patient safety and reduce medical errors, e.g.: detection of retained surgical sponge (Armisi et al. 2012), traceability in blood collection and transfusion process (Sandler et al. 2007).

In these cases, RFId is used as an instrument of error prevention; so, in some applications, a device with this technology can be considered a medical device, or a part of it (EC 2007).

Fuhrer et al. 2006 state that the implementation of RFId systems in healthcare should evaluate the impact on security and privacy, because of the possibility they offer to send, in wireless mode, information and sensitive data relating to a patient. These data could be susceptible to interception, inappropriate collection, intentional misuse, unauthorized disclosure (Karygiannis et al. 2007).

However, any concerns over privacy issues should be alleviated because passive RFId tags can only be read when the reader is close (Richmond et al. 2009, Nagy et al. 2006).

2. Objective

The Istituto Superiore di Sanità (Italian National Institute of Health) has developed a research project, funded by the Italian ministry of health. Within the project, entitled "Safety and Health Technology", our research unit is responsible for the study of "use of RFId technology as a tool for safety".

The activity of the unit needs dedicated assessment methods and tools; this paper describes those developed by the authors and the results obtained from using them in some hospitals located on the Italian territory.

3. Materials and methods

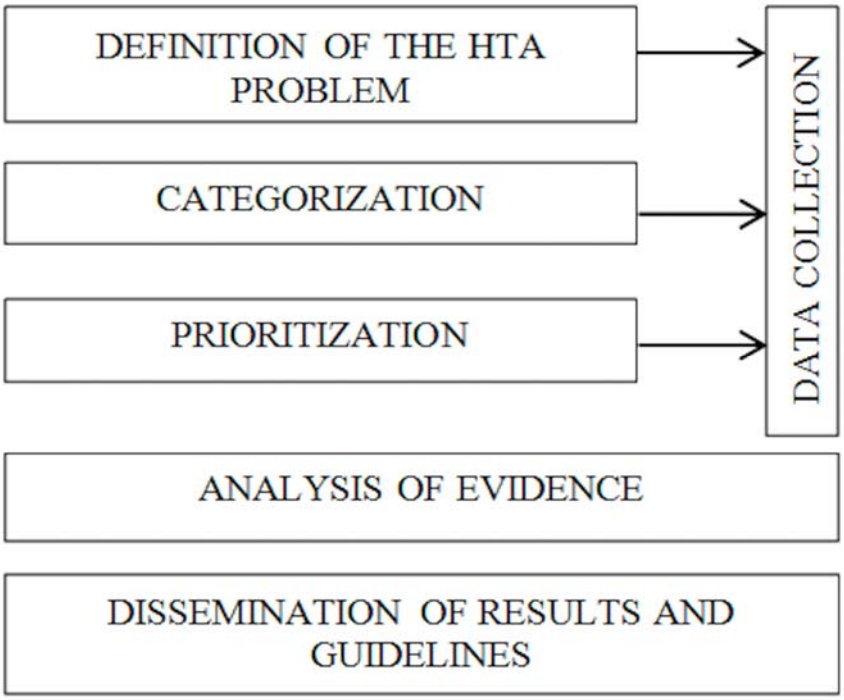
The study was carried out in different but complementary directions: analysis of the methodological approach, procedures and tools developed, adopted and validated by international health technologies assessment (HTA) research groups. The study was also based on previous experiences of the group in other healthcare fields (Macellari et al. 2010).

Among the international proposals for standardization of HTA procedures, the HTA Core Model developed by EUnetHTA, was selected (EUnetHTA 2012). This methodological approach to the problem was incorporated in our method, consisting of the following activities:

- Definition of the HTA problem
- Categorization
- Prioritization
- Data Collection
- Analysis of evidence
- Dissemination of results and guidelines

We didn't carry out these activities in a sequential order, three of these were performed parallel to the data collection task, as shown in Figure 1:

Figure 1 *Block diagram of activities*



The data collection activity was carried out through the use of different tools. In the choice of methodological tools, we identified, analysed and adapted to our scopes the instruments currently used in the various domains of HTA (Corio et al. 2011).

Since the use of RFId technology in healthcare facilities on the Italian territory is still in an experimentation phase, for the data collection we adopted the "direct inquiring" method, that is useful to find up-to-date information on the implementation status of a technology.

Tools that can be developed to support this methodology include:

a) survey

b) verbal questioning and direct interviews

c) audit on-site

We chose this set of tools because it allows:

- a good control of the overall process (a,b);
- high level of standardization of data collection process (a,c);
- to reduce the number of missing and standard answers (b);
- to adjust the schedule of the interview to the needs of the interviewee (b,c);
- to ask more complex questions, obtain clarification, confirmation or supplementation when needed and give additional explanations and examples if required (b);

- to reach high level people such as the top management (b,c);
- to provide information on ongoing research (a,b,c).

The following paragraphs shows the model we adopted and the set of tools to be used for collecting information.

3.1 Definition of the HTA problem

Beyond the scope, methods and level of detail, the definition of the assessment topics is one of the basic steps in any practice of HTA (Goodman 2004).

The HTA Core Model is based on nine domains to be investigated:

- Health problem and current use of technology
- Description and technical characteristics of technology
- Clinical effectiveness
- Safety
- Costs and economic evaluation
- Ethical aspects
- Organizational aspects
- Social aspects
- Legal analysis

All aspects were analysed, with the exception of costs and economic evaluation, because the economic impact following the adoption of RFId technology is clearly positive, since the cost of tags continuously decreases, reducing initial investment and running cost (Polycarpou et al. 2012).

The remaining domains were condensed into three main fields of evaluation, relating to the aspects of quality, safety and privacy.

The quality domain includes technical, organizational aspects, and clinical effectiveness in terms of patient's quality life.

Enhancing quality along the patient care supply chain is critical for all healthcare organizations, and technology can play an important role (Revere et al. 2010).

The safety domain incorporates technical and legal analysis, dealing with the clinical risk management and the analysis of possible direct and indirect harms due to the technology itself, to the environment or to the processes, towards patient, caregivers, visitors and

healthcare professionals. In privacy domain join social, ethical aspects and legal analysis about the protection and processing of personal and sensitive data.

The importance and benefits of conducting privacy impact assessments for RFId applications are described in a PIA Framework (EC 2011), referring to the EC Recommendation 2009/387.

We therefore developed a model based on three domains to be investigated.

3.2 Categorization

In order to define a thorough, functional model, we proceeded to the categorization phase, that is the definition of topics within the main three domains, so as to identify the elements whose management is relevant in the delivery of health services. We focused our attention on processes and resources, following the rules of an international standard (BS EN 2012).

We considered several types of processes: strategic, operational (clinical and non clinical), support.

With regards to resources:

- human resources: competence, education, training, skills and experience;
- infrastructure: buildings, workspace, process equipment (both hardware and software), communication and information system;
- working environment: safety and security requirements.

On the whole, we identified 22 topics.

In the topics about quality characteristics of health services we evaluated: documentation and process management; provision of care services; assets management; ability to use new technologies from the staff; procurement processes; protection of patient's property.

With reference to safety of people living in or passing through healthcare facilities (workers, patients, caregivers, visitors), eight topics were developed: clinical risk regarding structural-technological, organizational-managerial factors and environmental and working conditions (respect and maintenance of the legal requirements of health and safety of workplaces and work equipment). Great consideration is dedicated to new or emerging technologies, their use in the prevention of possible adverse events, their suitability to the conditions and needs of workplaces, and their compatibility with the already existing technologies and with the life support devices.

Figure 2 *Template of topics Matrix*

DOMAIN	TOPIC
QUALITY	q1.
	q2.
	q3.
	q4.
	q5.
	q6.
	q7.
SAFETY	s1.
	s2.
	s3.
	s4.
	s5.
	s6.
	s7.
	s8.
PRIVACY	p1.
	p2.
	p3.
	p4.
	p5.
	p6.
	p7.

Privacy topics concern the protection of personal and sensitive data, and the adoption of security measures of management system of output data from electronic devices; the focus is centred on the efficiency, effectiveness, reliability and accessibility of the system (electronic devices and procedures) of detection and management of sensitive data.
The structure of the matrix containing the 22 topics is shown in Figure 2.

3.3 The first tool: Survey

A questionnaire was developed and was sent to 287 sites of potential users of RFId technology (local health agencies, healthcare structures, hospitals).
A fax machine was dedicated to receive the questionnaires, a help desk was activated.
Questions allow us to collect information on:

- distribution of the use of RFId technology in hospitals, at regional and national levels;

- type of media of tags;
- operating frequency of tags;
- type of RFId reader;
- main use of RFId technology in healthcare;
- details on any faults related to medical devices or information systems, detected during the use of RFId technology;
- quality perception level.
- safety perception level after the introduction of RFId technology.

3.4 Model for the selection of sample

Information derived from the questionnaires were used to classify healthcare facilities that had responded into two groups: facilities that currently use devices with RFId technology, and those that have planned their future use.

In the selection process, within each group, facilities were classified on the basis of the applications developed or planned and of the type of technology chosen (media, reader and operating frequency of RFId tags used), focusing our attention on innovative solutions.

Particularly, for the first group, we considered the judgments on the impact of RFId technology on quality, safety and protection of privacy; the occurrence of faults while using devices with RFId technology that had caused, or might have caused, damage to the operator, patient, caregiver or visitor was considered to be a highly relevant event.

The sample selected consists of healthcare facilities located throughout the Italian territory, which differ in size and type of treatment (general or specialized in specific diseases).

These facilities were visited and involved in the prioritization phase.

3.5 Prioritization

The next phase of the study is the prioritization that consists in determining what importance the 22 topics have in the management of a health facility and in health service provision.

In general terms, prioritization is a process whereby an individual or group places a number of items in rank order based on their perceived or measured importance (APEXPH).

Prioritization is a very important task in HTA processes. Deciding which of the many healthcare aspects should be given priority is strategic for the organization: it allows the health structure to focus and direct resources to those issues that are deemed most critical.

In literature several different prioritization methods are described (NACCHO 2010).

In our study, prioritization was carried out through verbal questioning and individual direct interviews, involving both structures that already employ this technology, and those that have planned its future use.

3.6 The second tool: Verbal questioning and interviews

Interviews are a common assessment technique, which is used in several situations such as: Vocational Education and Training (VET; Government of Western Australia 2012), quality assurance, HTA. Responses can provide useful evidence of:

- quality and safety perception level ;
- understanding of procedures, legislation and safety requirements.

We identified three categories of people to be interviewed, corresponding to different professional and assessment fields: Management, Technical, Clinical and Service Implementation. The involvement of different professionals in the prioritization process ensures proper distribution of the answers, and so reliability and effectiveness of the evaluation outcomes.

The assessment was conducted in order to collect data from staff without the involvement of patients, manufacturers and suppliers. .

To make the interviews were taken the following simple rules:

- keep questions short and focused on a key concept;
- make sure the questions are well structured, not ambiguous and easily understandable;
- make sure the interviewee understands very well the questions;
- encourage a conversation with the interviewee.

Before interviewing the professionals, an introductory talk is conducted to describe the goals of our studies.

This preliminary phase is necessary to:

- clarify objectives along with the prioritization process;
- establish criteria on which to judge the importance of potential focus areas.

Beyond the commonly used prioritization criteria (NACCHO 2010), it is also important to consider the occurrence of sentinel events, near miss and adverse events for the evaluation of the clinical risk (Italian Ministry of Health 2013).

After that, the implementation of our method requires each interviewee views the topics for about ten minutes. This careful and individual examination is necessary for the interviewee to

set them in the performance of his own job and field of expertise, and to make a comparison between the topics to be assessed, which are interdependent and interrelated, so as to assign each one a relative (not absolute) priority level on a scale from one to ten, so as to provide a wide range of choice, discrimination of values and accuracy of responses.

Figure 3 *Template of priority levels Matrix*

	ASSESSMENT FIELDS			PRIORITY LEVEL	NORMALIZED PRIORITY LEVEL
DOMAIN	Management	Technical	Clinical & Service Implementation		
QUALITY					
SAFETY					
PRIVACY					

To determine the priority level related to each topic, we calculated the median of the values assigned by the professionals interviewed; since the interviewees belong to three distinct assessment fields, very different values are expected, so we chose the median which is preferred to the arithmetic mean that may be skewed by extreme outlying values.

The median was normalized with respect to the maximum priority level assigned during the interviews.

With the results obtained from data processing we developed a matrix of values (Figure 3), which represent the priority levels, deriving from the importance that health facilities give to each topic related to the three main domains.

The prioritization matrix will be used to weigh the items belonging to a check list to be submitted, during audit on-site, to personnel working in other healthcare facilities that currently use RFId technology, to assess its real impact.

3.7 Audit on-site

Audit on-site is an effective and reliable tool in collecting information in order to assess the impact of new technologies on quality, safety and protection of privacy in health services.

An operating procedure providing guidance on the conducting of audit to systems and modes of operation adopted by health services was prepared.

Audits are conducted according to an international standard (EN ISO 2011), by an audit team consisting of one or more qualified auditors with appropriate knowledge and skills, supported if needed by technical experts. The criteria used as a reference in the assessment process of health services are those specified in the standards concerning quality systems (BS EN 2012, EN ISO 2009, UNI 2003), in the legislation on personal data protection (Italian Government 2003, Italian Data Protection Authority 2005), on health and safety in workplaces (Italian Government 2008), and in the Medical Devices Directives.

During the audit, the audit team collects information, evidences and comments relating to:

- organization of the health services and the risk related to the use of RFId technology;
- the use of RFId technology for gathering reliable and useful data with the aim of converting such data into information necessary for decision making;
- the impact of RFId technology related to the regulatory standards concerning the protection of personal data;
- tangible benefits (for the patient or for the costs of the service), and intangible benefits (level of perceived quality of the end user, compliance to regulatory standards).

Methods of collecting information include interviews, observations and review of documents, including records.

Audit evidences and comments are recorded by the audit team on a dedicated check list.

3.8 The third tool: Check List

The use of our checklist is intended to assess the real level of quality, safety and privacy, perceived by the interviewee after the introduction of RFId technology in the facility where he works, or detected by the auditor on the basis of evidence.

The check list consists of almost 110 items that have been developed starting from a national and international regulatory framework (BS EN 2012, Italian Government 2003, Italian Data Protection Authority 2005, Italian Government 2008).

Each check list item is structured as the basic unit (assessment element) of the assessment table used in the HTA Core Model Application for Screening Technologies: it refers to an issue, a specific topic and domain, contains clarification, information sources and reference.

Each issue describes a typical healthcare service, whose provision may include the use of RFId technology, and so its possible application.

An issue about quality domain is: "Management of equipment and medical devices for analysis and measurement: prevention of their loss; information on their state of maintenance/usability; evaluation of the time for the preventive maintenance".

An issue concerning safety domain is: "Access management to restricted areas only to authorized personnel, through the use of RFId technology in the gates for the automatic control of access; control of people entering the health facility (patients, professionals, caregivers, visitors, suppliers); locating of patients within the hospital and the wards through the use of RFId wristbands; ease of access in the wards through hands-free gates with RFId readers".

Finally, in regards to privacy domain, an issue is: "Proper treatment and update of personal data; correct connection with the patient".

During the submission of the check list, the interviewee is asked to express his opinion, or to give evidences to the auditor, about the implications of use of RFId technology: an improvement or deterioration in quality, safety and privacy. The judgment must be given on the basis of a unipolar balanced rating scale, based on 5 concepts; each response option is associated to a number.

An example of score ranging is: much worse (-2), worse (-1), unchanged (0), improved (1), much improved (2), or "not applicable".

In the check list, each issue is associated with the priority level of the topic it is linked to; by multiplying it with the perceived level, an impact health indicator will be calculated for evaluating the impact of RFId technology on quality, safety and privacy.

4. Results

At the end of the data collection phase, the study continued with the analysis of evidence and data processing.

4.1 Questionnaire

In all, 287 questionnaires were sent out on the Italian territory; 159 filled questionnaires were received, recording a response rate of about 55%.

It was necessary to send only a reminder letter of the response to 48 recipients who responded in a short time with a rate of 69%.

A year after the first survey, a request for notification of any changes was sent; five facilities responded to communicate changes: three have started to use RFId technology, while another has stopped using it; one has launched three new experimentations and introduced a new type of RFId reader.

Based on the questionnaires we classified hospital applications (table 1) of RFId technology, that turn out to be consistent with the data issued in a review by Rand Corporation (table 2, Vilamovska et al. 2009).

Table 1 *RFId applications currently in use in Italian healthcare facilities*

HOSPITAL APPLICATION OF RFId TECHNOLOGY	**PERCENTAGE OF DIFFUSION**
Access control	23%
Managing of biomedical equipment and medical devices	2%
Control of the administration of drugs	12%
Identification and traceability of biological materials and samples	14%
Traceability of patient, blood, and devices for the minimization of blood transfusion risks	16%
Mother - newborn identification and link	2%
Identification and traceability of the medical staff in the unit and in the operating rooms	6%
Identification and traceability of the patient in the unit and in the operating room	15%
Not specified	2%
Other	8%

Table 2 *RFId in hospital: classification of applications (Vilamovska et al. 2009)*

	Healthcare Applications				
RFId Enabling Functions		Patient safety/quality of Healthcare services	Pharmaceutical applications	Management of medical devices, assets and biological materials	Patient and Operators support/management
	Tracking				
	Identification and Authentication				
	Automatic data collection and delivery				
	Sensing				

From the information collected it was possible to assess the rapid spread of RFId technology in healthcare applications.

The comparison with data collected for the period 2008-2009 (table 3, Sbrenni et al. 2011), shows a general increase of the applications of RFId technology in healthcare to improve traceability and recognition processes, but also an increase in the number of applications that were started in the past but not carried out at the moment; this phenomenon is probably due to an inappropriate choice of technology and relative ICT applications, or to poor patient/health professionals satisfaction.

Table 3 *Comparison between two studies on the Italian territory*

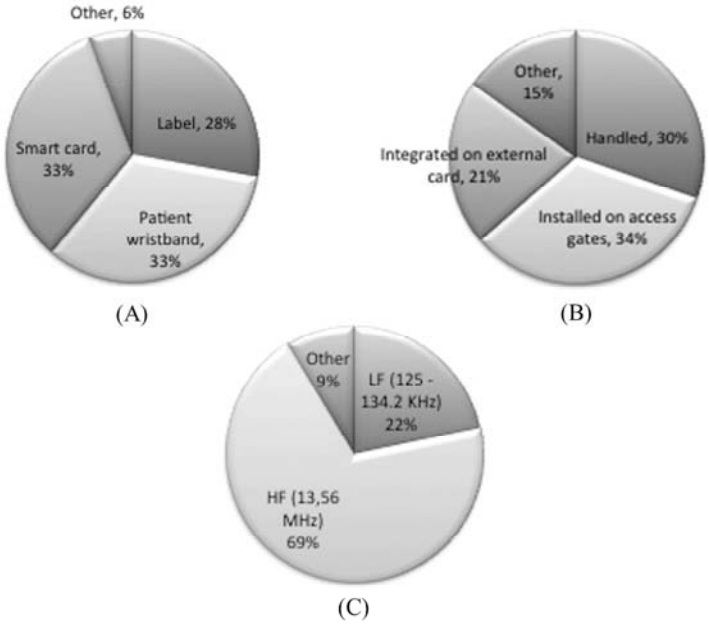
RFId TECHNOLOGY DIFFUSION	**This study**	**2008-2009**
Currently in use	15%	9%
Used in the past	4%	1%
Planned for future use	12%	18%
Not in use	69%	72%

Below (Figure 4), the data extracted from the questionnaire about the levels perceived: in most cases, the hospital staff has perceived a general improvement in the quality of services provided and in the level of safety.

Figure 4 *Level of quality (left) and safety (right) perceived after the introduction of RFId technology*

The most used type of media for RFId tags (Figure 5) are: patient wristbands, smart cards and labels. They are respectively related to the three main uses of the technology: identification of patients; access control of health professionals, equipped with personal badge; traceability of biomedical equipment, medical devices, blood, biological materials and samples. Connected with the three types of media, the most used types of RFId readers (Figure 5): handled, integrated on external card and installed on access gates.

Figure 5 *Types of media for tags (A), types of readers (B) and operating frequencies (C) currently in use*



Relating to operating frequencies (Figure 5), because of the lack of anti-collision protocols, LF tags (125 kHz-134.2 kHz) are less commonly used than HF (13.56 MHz): the latter are

the most used operating frequencies, due to the low cost of the RFId tags, to their high availability, and to the presence of free software libraries.

4.2 Interviews

The priority levels collected during the interviews are distributed unevenly along the scale; they place at its upper extreme: values between 7 and 10 were assigned in 90% of cases.

From the data collected through the interviews, quality and privacy domains turn out to be slightly prevalent on the aspects related to safety.

The normalized priority levels related to the topics are 0.8/0.9/1.0; these three values are associated (table 4) respectively to three different degrees of importance (optional, important, critical; EUnetHTA 2012), which is assigned a number (priority weight) to be used to calculate the impact health indicator.

Table 4 *Correspondence priority Matrix*

PRIORITY LEVEL (given by interviewees)	**IMPORTANCE**	**PRIORITY WEIGHT (to be used in the check list)**
0.8	Optional	1
0.9	Important	2
1.0	Critical	3

During the interviews the points of view of the different professionals emerged, stressing the aspects deemed to be critical in the execution of their own job.

Management considers as crucial the aspects related to privacy and to technology governance; regarding the latter one, during the phase of new technology assessment, it is important to evaluate the real needs of the structure, the staff skills, and, if necessary, provide additional and specific vocational education and training. For Technical, it is essential the integration with already existing systems, and the protection of aspects related to safety.

Clinical and Service Implementation professionals consider of great importance the 100% reliability of the devices they use.

4.3 Check list

The check list administering phase was performed during audit on-site in two healthcare facilities that are not involved in the research project.

The first health structure was a big hospital that is comprised of a wide range of services and functional units. These include diagnostic and treatment functions, such as clinical

laboratories, imaging, emergency rooms, and surgery; hospitality functions, such as food service and housekeeping; and the fundamental inpatient care or bed-related function. Their best application of RFId technology is the detection of retained surgical sponges inside a patient following surgery.

The second health facility was a rural hospital, less than 100 beds, and far more than 30 km from the nearest hospital. Their best application of RFId technology is the patient traceability in E.R. processes.

Results of audits are shown in table 5.

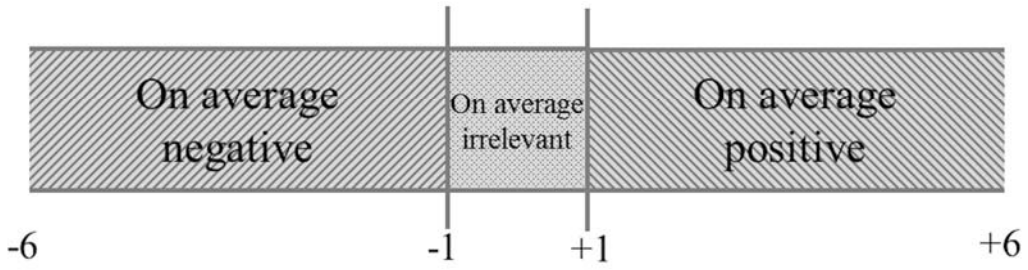
Table 5 *Impact of RFId technology on Quality, Safety and Privacy*

	IMPACT HEALTH INDICATORS		
	Quality	**Safety**	**Privacy**
BIG HOSPITAL	$\overline{Q} = \frac{1}{n_q}\sum_{i=1}^{n_q} q_i =$ **2.06**	$\overline{S} = \frac{1}{n_s}\sum_{j=1}^{n_s} s_j =$ **1.48**	$\overline{P} = \frac{1}{n_p}\sum_{k=1}^{n_p} p_k =$ **1.58**
RURAL HOSPITAL	$\overline{Q} = \frac{1}{n_q}\sum_{i=1}^{n_q} q_i =$ **2.27**	$\overline{S} = \frac{1}{n_s}\sum_{j=1}^{n_s} s_j =$ **1.65**	$\overline{P} = \frac{1}{n_p}\sum_{k=1}^{n_p} p_k =$ **2.57**

On a scale of values between -6 and +6 (Figure 6), the impact on quality, safety and privacy is found to be on average positive; the calculated mean values are out of bound of the neutral interval (values from -1 to +1) representing an average irrelevant impact.

In rural hospitals, the impact is higher, since in these kind of facilities the overall number of technological solutions adopted is lower, therefore, the implications resulting from the adoption of a new technology are immediately evident and easily seen, so they have a strong impact; on the contrary, in a big hospital the number of technology applications is higher, and their benefits are well-known, so the impact of a new technology is less.

Figure 6 *Impact assessment intervals*



5. Discussion and conclusion

This paper describes tools and methods for the impact assessment of RFId technology on quality, safety and protection of privacy in health services.

The methods and tools adopted are taken from the multidisciplinary view of HTA.

The assessment model developed is based on three domains to be investigated (Quality, Safety, Privacy) that were expanded into 22 topics; this model was completed with a set of tools to be used for collecting structured information and data related to general aspects in the healthcare management and to specific applications and uses of RFId technology.

All assessment methodological tools have been tested and validated on site; the methodology that allows the calculation of the impact health indicators can be used by healthcare facilities.

The three impact health indicators can be useful to decision makers, for the purpose of an effective and safe government of technologies, as recommendations and guidelines to orient the assessment process of RFId technology and identify the consequences of its adoption.

Acknowledgments

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