Abstract

The volume and the complexity of clinical and administrative information make Information and Communication Technologies (ICTs) essential to run and innovate healthcare. Mobile&Wireless solutions, integrated to Automatic Identification and Data Capture technology and to Hospital Information Systems, can provide staff with software applications in order to manage critical activities on the go, associate data to objects and increase the volume and timeliness of available data on processes. This paper presents a project aimed to design, develop and implement a set of organizational models, acknowledged procedures and ICT tools to improve actual support, safety, reliability and traceability of a specific therapy management process – the one related to haematopoietic stem cell (HSC) and therapeutic cell (TC) donation, processing and transplantation. The project value is to design a solution based on mobile and identification technology in close collaboration with physicians and actors involved in the process to ensure usability and effectiveness in process and risk management.

Keyword: Hospital Information Systems, Mobile Health, Medication Therapy Management, Bedside Technology, Stem cells, RFId

Introduction

Hospital Information Systems (HIS) are fundamental tools in the delivery of effective and efficient care [1]. An HIS comprises several different applications that support healthcare organizations’, clinicians’, patients’ and policy makers’ needs for collection and management of data related to both clinical as well as administrative processes. This data can be processed by a number of systems with many different purposes (e.g. diagnostics, epidemiology, research,...), needs to be integrated across departments in order to effectively support processes [2], and must be subject to strict rules in terms of confidentiality and security safeguard [3]. Systematic reviews [1] show that, in most cases, ICT-based solutions tend to be adopted by healthcare providers - under the pressure of technologically-pushing forces (machinery) [4] - with a limited assessment of the organizational consequences of ICT adoption and with limited focus on supporting and making core care processes more reliable and cost-effective [5]. This concerns also additional issues on risks management related to how information system could influence clinical practice and human errors [6].

In recent years, however, organizations - faced with an unprecedented era of competition and cost-cutting - are changing this behavior [7] and exploring ICTs-enabled perspectives to improve the quality of clinical processes and patient and staff safety while simultaneously reducing costs [8][9].

This paper aims to show how deep the impact of systems based on innovative technologies focusing on process reengineering and organizational change could be, identifying an important synergy between traditional Information Systems and Mobile&Wireless technologies to deliver effective process support to clinical staff. On the other hand, it will show how several barriers could undermine the value of such systems. Evidences explained in the paper are found in literature and provided by the ICT in Healthcare Observatory (IHCO)1 of the School of Management of the Politecnico di Milano Technical University in Milan (Italy) and will be proven by the explanation of topic dealt in a research project ongoing on stem cell process management innovation through ICT.

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1 ICT in Healthcare Observatory (IHCO) is a broad and continuous research initiative promoted since 2007 by the Politecnico di Milano School of Management which focuses specifically on the analysis of ICT-driven innovation in the Italian healthcare industry. The research is a combination of a quantitative panel of electronic surveys, several qualitative case studies, and a series of focus groups.
Hospital Information Systems: main functional areas and evolution needs

How ICTs solutions can improve the healthcare ecosystem

The main areas of an HIS are three [10]: (i) administration and management, (ii) front-office and (iii) clinical area. The clinical area is the centre of the system, as it has to support all core care processes and appears to be the most challenging area in terms of management, because it involves critical patient data. Clinical systems are mainly departmental systems, typically independently implemented by each department or ward, or Electronic Medical Records (EMRs). Literature analysis [11] allows the identification of five functional areas that characterize EMRs: Admission-Discharge-Transfer management, Outpatient management, Diagnostics, Therapy management, Clinical Dossier. Among these, the latter – embracing the management of all medical and nursing sheets, including initial assessment, vital signs automated monitoring, anesthesiology documents, OR reports, etc. - and therapy management - supporting prescription and administration of drugs, transfusions, nutrition, etc. - are the less widespread areas and the ones of greatest expected growth in the future. They are also the most challenging to implement, above all with respect to change management and organizational issues. Case studies conducted by the ICHO1 in the last years showed that the main limit to current EMR projects is the lack of integration and the absence of an enterprise-wide approach to the solutions. However, many efforts have been made to drive EMR evolution towards maturity, enabling comprehensive support to healthcare processes [11]. Case studies reveal that effective digitalization of these core clinical processes is closely connected to the implementation of Mobile&Wireless (M&W) solutions to support operations and information management, integrated with Automatic Identification and Data Capture (AIDC) tools (e.g. Barcode, RFID, NFC...).

Such kinds of services are part of the Mobile Health solution category. Mobile Health comprises all devices (smartphone, tablet, ...) and applications enabling physicians and nurses to access the HIS services in mobility (e.g. to look up to the EMR on a tablet, to download clinical reports on a smartphone, ...). Mobile Health is considered as an opportunity to overcome time-space barriers and to improve care processes through higher availability of information for physicians and nurses. The World Health Organization refers to Mobile Health as “the use of mobile and wireless technologies to support the achievement of health objectives” [12]. According to the WHO, Mobile Health “has the potential to transform the face of health service delivery across the globe”.

Mobile Health to improve therapy management process

Through M&W and AIDC technologies – integrated in mobile solutions – it is possible to support heterogeneous processes such the therapy prescription and administration one. Therapy management refers to all the aspects of the therapeutic process, both in terms of staff workflow activities and in terms of direct contact with the patient. This includes a number of different kind of processes such as pharmacotherapy, chemotherapy, radiotherapy, blood transfusions and medications. Literature states that - above all in this field - most of the threats to patient safety are process-related, rather than clinical [13]. Paperwork, manual transcription and the lack of automated identification systems are the main criticalities affecting clinical processes. These are especially risky because they include a number of critical stages, involving different staff members in different departments and involve complex information management activities. Therapy management belongs to these error-prone processes [14]: misinformation and errors in data transfer are the greatest cause of incidents in treatment administration and they often remain under-reported, owing to a lack of awareness about closing the information loop whole clinical process, by identifying people and items throughout the process. IHCO research shows that past investments in Mobile Health in Italy have been limited: out of 86 Chief Information Officer (CIO), in 2011, almost half has not invested in these kind of applications and only 13% has invested more than 50,000 € on them. In 2012, the percentage of organizations that will spend more than 50,000 will grow up to 21%.

As mentioned above, M&W technologies can play a relevant role in improving both efficiency and effectiveness of healthcare for inpatients as well as outpatients (e.g. ambulance transportation and ambulatory visits). M&W solutions, integrated both to AIDC technology solutions and to the HIS, allow to close the safety loop directly to the patient, bringing operating support and identification/traceability features to patient bedside. This kind of application is, more than others, suitable to improve therapy management process, from patient identification to prescription and pharmacotherapy administration at bedside. The main challenges for therapy management involve the introduction of an enterprise-wide patient identification system, which could enable process traceability, governance and cost control, and the availability of application on mobile support to improve clinical operations. This is much more crucial than cost-effectiveness or resource optimization, because it has a direct impact on clinical safety and risk of processes. IHCO analyses show that M&W solutions already have been adopted in one third of the surveyed organizations. Considering Mobile devices, the most common ones are Notebooks/Netbooks (83%) and Tablets (62%), followed by PDAs with just 20%. Above all, more widespread application include barcodes printed on drugs’ boxes and patients’ wristband read by special PDAs at bedside. Moreover, some facilities are starting experimental implementations of RFID (Radio Frequency Identification) and NFC (Near Field Communication) technologies, as an “evolution” of barcode.
and improving practice. According to a WHO public report [15] regarding incidents in Radiotherapy management, more than 4,500 near misses were reported in the literature and on public databases from Australia, USA, Canada, UK, and other European countries. Of all injurious incidents, 54% were related to the ‘planning’ stage, 8% were related to ‘transfer of information’ and 10% to the ‘treatment delivery’ stage. Near misses had been intercepted through the whole process, 16% of which in the ‘assessment & decision’ step and 6% in ‘simulation & imaging’. Referring to a whole process, 16% of which in the ‘assessment & delivery’ stage. Near misses had been intercepted through the whole process, 16% of which in the ‘assessment & decision’ step and 6% in ‘simulation & imaging’. Referring to a literature review conducted specifically in oncology departments by Schwappach and Wernli in 2010, medication errors are distributed as follows: 41% in nurse administration (omitted medications and wrong doses), 21% in order writing or transcription (pharmacy errors) and 38% in medication dispensing (incorrect dose, wrong drug,..)[16].

A comprehensive approach to information management, process traceability and control - especially for activities performed on patients - is the way to enhance safety, efficiency, and governance in clinical practices. As for ICT support, nowadays in most cases specialized proprietary solutions cover more demanding activities (e.g. prescription of therapy) but they are usually not communicating with other systems because they don’t target the full process coverage (e.g. across departments or to bedside with M&W and AIDC technologies). Moreover, several activities in a single process are still paper-based (e.g. when patient has to sign procedure consensus), so the HIS is often prone to hybrid configurations. This gap between IT tools and clinical needs leads to an undetermined effectiveness of such tools on process performance and sometimes to higher risks for the patient. Moreover, the lack of reference standards and guidelines for the implementation of such technologies in healthcare, as well as the low maturity of ICT tools are two other issues that need to be dealt with. Moreover, the main challenges to be faced in the definition, design and development of IT solution in healthcare environment involve organization management. The solution to these issues is the improvement of staff skills, usability and compliance to needs through co-design of the solution among IT technicians and clinicians. In particular, it is necessary to design solutions with embedded mobile technologies that can support staff and enhance security throughout the whole process. These solutions must be integrated with the HIS, so that information can be shared among all systems. For example, digital and integrated pharmacotherapy management tools are identified as solutions able to gain strategic benefits (i) if designed to support end-to-end clinicians and nursing activities also at bedside, (ii) if integrated with AIDC technologies to support safe identification and bedside traceability, (iii) if properly integrated with the HIS, (iv) if implemented together with a review of processes.

In the next section we will describe a project based on M&W and AIDC technologies, aimed to improve actual support, safety, reliability and traceability of activities related to hematopoietic stem cell (HSC) and therapeutic cell (TC) process.

Mobile&Wireless and AIDC technologies in Therapy Management: a case study

A case of therapy management process to be improved

A therapeutic area that is still unsupported is stem cells management: HSCs and TCs transplantation are life-saving therapies in the treatment of several congenital or acquired hematologic disorders (e.g. a timely implantation is key for patient recovery after chemotherapy treatments). Despite FACT-JACIE qualification of centers is strongly recommended by the Italian Ministry of Health, there is still a need for greater efficiency in the management of the transplantation process. There is no standard and validated information system for detailed monitoring and control of the process, neither in the wards, nor in the Stem Cell Lab. Examples of critical points in the process are represented in Figure 1.

Figure 1. The autologous stem cells transplantation process

The Transfusion Service does not have full awareness of laboratory processing activities (e.g. units collected by the Transfusion Service get fractioned by a different Lab, but this phase is not managed in the Transfusion Service management system) and actual stocks. The same happens for patient records in the Lab, where donor history sheets recording all information on donated bags are still on paper or on a different system from the above mentioned ones. Also bedside activities show some critical issues, many similar to those in the transfusion process: unambiguous patient identification, bags and vials labeling, in the ward safe cross-matching, adverse reaction notification, process monitoring and traceability. The Transfusion Service often relies on notes about performed implantations to update patients’ transfusion record on the Blood Bank Management software or register. Due to absence of a pervasive IT support and to fragmentation between different units (different duties, low communication and difficult record tracking), there is a lot of paperwork and manual activities non-homogeneously recorded on personal files (docs or spread-
sheets). Raising the process complexity, autologous transplantation requires the cells to be cryo-preserved in liquid nitrogen tanks (at -196° C) for several months before administration; this stage is risky for both Lab technicians and for the stem cells (if thawed they start to die, so the faster the process is, the better). Because the treatment is based on "non-repeatable" products and because of the type of diseases treated, the Stem Cells process is recognized as having numerous critical points and risk management and prevention is required. A risk analysis performed on this process [17] show that the management of the bag – fractioning, cryo-preservation and stocking – is one of the more critical phase of the process. As far as concerns the management of the bags, an error in labeling can lead to the wrong bag being infused or a fall by the person carrying the units to the cryopreservation area can lead to loss of the product, as well as a mistake in bag identification in picking before the administration.

**The Research Project and the HSC Process Innovation**

Recognizing the great need (and opportunity) for innovative IT tools supporting the Stem Cells process, Italian Ministry of Health funded a research project named “Safety, traceability and reliability of collection, processing and transplantation of hematopoietic stem cells (HSCs) and therapeutic cells (TCs): integrated procedures and tools to support operations, clinical care and banking”. Fondazione IRCCS Istituto Nazionale dei Tumori in Milan (Italy), recognized as a top Scientific Research and Treatment Institution in Oncology, is highly experienced in such topics and, due to the already significant knowledge acquired on ICT support to clinical processes, proposed itself to manage and coordinate the project [18]. A.O. Ospedale “Ca’Granda” Niguarda in Milan (which is the largest public hospital in Milan) [19], IRCCS Istituto Clinico Humanitas (a private hospital and research center), and Fondazione Politecnico di Milano are also involved in the project. Each partner is bringing peculiar needs and competences: each hospital runs important storage and transplantation facilities with a different research focus on cells. Fondazione Politecnico, an academic institution connected to the technical university in Milan, contributes with expertise on methodological framework (e.g. process reengineering, risk assessment) ensuring a coherent approach in process innovation.

The project goal is to design, develop and implement a set of organizational models, acknowledged procedures and ICT tools in order to improve actual support, safety, reliability and traceability in HTCs and TCs, in accordance with the internationally recognized FACT-JACIE standards. This will allow clinicians to guarantee and pursue high quality in procedures and data handling, providing also accurate data traceability on stem cell collection and implantation (e.g. process lead times, haemovigilance). Istituto Tumori has been adopting innovative M&W solutions (embedded with RFId tags and antennas) integrated to the HIS in order to avoid errors and enhance patient safety and quality of care. The Istituto’s M&W strategy aims to build an ICT infrastructure (hardware and software integrated to the involved HIS modules) which guarantees secure identification of patients, staff, treatments, and critical items in crucial checkpoints within the clinical pathway. As of today, the Istituto’s traceability platform supports traceability and safety needs within a growing number of clinical activities, from general patient identification (access to the operating room, access to radiotherapy rooms...) to patient-to-treatment cross matching (blood bags, sample tubes, surgical sampling...). This is done through several different Wi-Fi devices like handheld readers attached to standard desktop PCs or smart PDAs (soon replaced by NFC embedded smartphone) with a thematic workflow management application installed (e.g. the transfusion safety app, the bedside radiology app, and so on). The new project is an opportunity to extend the Istituto’s traceability platform in the field of HSC and TC process management, supporting the whole process: cell donation, fractioning, lab processing, long-term cryopreservation, delivery of the bag and transplantation to receiver patient in clinical units (or extraction for research purposes). On the other hand, the solution will be designed and developed according to interoperability standards in order to be transferred to the other hospitals involved in the project. The target solution will exploit the AIDC technology features by the integration with the different HIS modules (Central Patient Registry, Transfusion Service System, Drug Management System, ..) aiming to provide all the process actors (Transfusion Service, Stem Cell Lab, Ward) with tools for process real-time tracking and monitoring. New and existing ICT tools need to be integrated and enriched with new data and features:

- The Transfusion Service System will be at first extended to support Stem Cell Lab processing activities, then new data and functions will be added to keep the record unified and updated throughout the process.
- The Stem Cell Lab will be provided of a system to manage stocks and assure quality of its procedures, up to the ward where the stem cells unit is thawed for administration.
- Technicians’ operations at deep freeze tanks in the stocking room will be supported by a mobile application and RFId identification of rack’s position, e.g. when positioning a unit in the right place, timely recording all actions.
- At bedside, a mobile application will support clinical staff while administering the unit to the patient; it will also keep record of administrations and adverse reaction, sharing the data with the HIS.
- The traceability platform will integrate the whole process, connecting the different systems and recording the identification data throughout the different steps (stem cells bag will be labeled with RFId label and it will be read from device available in the Transfusion Service Centre, in the Lab and in the ward).

According to the scenario, the entire process will be supported with customized tools that enable more effective and precise information sharing (e.g. about patients’ stem cells collection and transplantation history), and enforce process tracking and monitoring capability (e.g. tracking all the
steps, time monitoring, staff authentication). The project is challenging because extreme low temperature inhibits RFID tags and specific envelopes and layouts are needed in order to support technicians in storing each aluminum cassette containing the HSC bag in the N2 tank’s rack and subsequently recognizing and drawing out the correct one (assigned to the patient). This is relevant in order to reduce risk in an error-prone phase of the process with direct impact on patient safety. Besides, the project will contribute to public knowledge with electromagnetic compatibility tests between High Frequency RFID fields (13.56 MHz) and HSCs; though, considering the real operative scenario (low power RFID emission and short exposure time) these tests are more likely to be just precautionary.

The project will benefit from the involvement of different healthcare organizations (public and private, general hospital and specialized institute) and from the engagement of process actors (e.g. physicians, nurses, technicians) in solution design, test and evaluation. Therefore, the solution will involve cross-organization development and will result more acceptable for clinical staff.

**Expected impact of Process Innovation**

In the first phase of process analysis and tool design the value of the solution has been measured in term of how it can increase quality of care by reducing medical errors, improving clinical decision and helping to eliminate redundant information recording (increase effectiveness). The areas where the solution could be able to improve the stem cells process management are:

- **RFID Patient Tracking.** During every stage of the process patient and bag identification is ensured by RFID tag applied to patient wristband and bag label. RFID tags can also storage information related to the unit to control its usage (e.g. the time within the therapy has to be done).

- **Mobile Applications for Bedside Administration Management.** The application available on Smartphone (NFC integrated) will help clinicians in the ward to manage activities on-the-go. Bedside access to the application enables patient and bag cross-match before administration and can prevent dangerous errors before they happen.

- **Mobile Applications for Workflow Management** (Figure 2). The application available on PDA (RFID integrated) will help technicians in the laboratory to manage activities on-the-go. A workflow for laboratory staff will automate inventory management from the receiving of collected bags to their storage in liquid N2 at -196°C to reduce inefficiencies (finding free locations in the tank) and improving bag retrieval and dispensing accuracy (improving location and identification of bags).

- **Medical Records.** The mobile application in the ward will be integrated with the central repository of the Transfusion Centre. The one for stock management will be integrated to the Stock Management System. These integration will allow to share data on the overall process, on therapies performed on the patient and on state of bags in the tanks. These will merge with data collected by the other workflows supported by the traceability platform to complete the overview on patient treatments (e.g. surgery, transfusions, chemotherapy,..) and on bag lifecycle. Technicians, transfusionists and authorized clinicians will securely access patient and bag information when needed. Also real time recording will enhance the quality of the information.

- **Medication Error Tracking.** Patients and bags secure identification, real-time data recording and cross-match control will allow to analyze data on how and why medical mistakes occur. This will helps to proactively address mistakes before they occur again, such as changing flawed processes or improving staff training.

- **Electronic Management of Communications.** Clinicians will use a web-based application to send requests to the Transfusion centre (e.g. evaluation of donor suitability) or to the Stem Cells Lab (e.g. bag request for transplantation) improving timeliness, traceability and quality of the communication, avoiding paperwork and phone management of the communication.

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**Figure 2.** Storing and picking management through RFID mobile application at N2 tank area
Conclusion

Modern healthcare asks for effective, responsive, patient and process-oriented, cost-effective solutions to support clinical staff in their daily activities. An important issue for the future of the HIS is the growing need for real-time availability of legally compliant and paperless healthcare information. From this point of view, a first goal regards the complete integration of healthcare systems at all levels. This integration pushes for both the configurations of the current HIS and the operative procedures of clinical process. Mobile Health solutions – based on M&W with AIDC technology embedded - integrated to the HIS have to be powerful and strategic in order to support clinical process on the go and to record information related to bedside events and procedures.

Among the other functional areas in the field of therapy management, dedicated ICT tools and mobile devices could address approaching common challenges. The main goals of ICT supporting therapy management are secure patient identification, workflow support to activities, safety of treatments administration, process traceability and costs control. These are related also to Risk Management issues.

Research and projects promoted by Istituto Nazionale dei Tumori di Milano and Fondazione Politecnico di Milano explore these issues focusing on M&W and RFId technologies as a powerful tool to support process traceability and safety of bedside operations. A new project focuses on improving Stem Cell management with aiming to develop a M&W integrated solution to support the whole process: from cell donation to bags, to lab processing and fractioning, to long-term cryopreservation, to delivery to wards, to transplantation to recipient patients (or their use for research purposes). In the proposed scenario portable devices, like WiFi PDAs or smartphone with NFC/RFId antennas embedded, will support operations both in wards and in the processing lab. RFId-labeled bags will be tested to track with a single read/write item all process phases (also in deep freeze at -196°C). The value of the project is represented by the attention paid in process reengineering and change management issues, as well in the correct choice of the proper technology to build the HIS infrastructural backbone and to develop mobile applications to fit in different hospital environments. On one hand the co-design of the application with the involvement of clinicians since the earlier stages of requirement definition is crucial to ensure solution usability and acceptance by physicians and nurse. This also to face risk management issues related to low usability and effectiveness of the proposed solution. On the other hand, developing a flexible and scalable solution based on interoperability and technological standard allows not only to make the solution available for implementation in other hospitals (as Ospedale Niguarda and Humanitas in the field of the research project), but also to spread innovative solution to support different process (as, for example, pharmacotherapy and radiotherapy management, blood transfusion and so on), guaranteeing secure identification of patient, staff, treatments, and critical items at crucial checkpoints within the clinical pathway.

References


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