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CLOSING THE SAFETY LOOP IN THERAPY MANAGEMENT THROUGH ICT: MOBILE&WIRELESS SCENARIOS FOR BEDSIDE SUPPORT

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ABSTRACT

Therapy management is a critical clinical process that involves a variety of procedures (drugs, transfusions, medications,..), different professionals, a number of protocols, and medical instruments. It is an “error prone” process and mistakes may lead to harsh consequences. In this scenario ICTs become essential for support and governance. Nowadays bedside activities are still often managed manually and literature shows that processes are managed differently and supported by paper or local IT tools. Challenges are: secure patient and item identification, comprehensive information delivery to clinicians, traceability and control of costs.
Fondazione IRCCS Istituto Nazionale dei Tumori di Milano (Italy) and partner Fondazione Politecnico di Milano follow an unified approach addressing in an integrated framework processes, organization and ICT tools. This paper will describe the case of a number of projects done to bring safety features to bedside using Mobile&Wireless (M&W) technologies, and RFId above all. Starting with transfusion traceability, further projects concern safety of pharmacotherapy, radiotherapy and stem cells therapy treatments. Mobile&Wireless solution scenarios, impacts and benefits will be discussed in depth: RFId emerges as a key element to close the bedside safety loop, filling the gap left by traditional hospital information systems and M&W applications.

KEYWORDS

Healthcare Information System, Mobile&Wireless, RFId, Bedside Traceability, Transfusions, Chemotherapy Management, Stem cells management, Risk Management

1. INTRODUCTION: VALUE OF CLINICAL INFORMATION SYSTEMS

Healthcare providers constantly work on improving patient safety and efficiency. On one hand, this means keeping aware of and document all medical procedures performed on patients (e.g. entries on the patient record) or steps in treatment production (e.g. dilution of chemotherapy) and administration. On the other hand, healthcare staff may be usefully supported in tracking patients, personnel, drugs and equipment inventory, and other resources. Moreover, reliable information flows on processes are the basis for identifying critical issues as well as risks, and to start a business process reengineering effort. The volume and the complexity of clinical and administrative information make Information and Communication Technologies (ICTs) essential for both running and innovating healthcare. ICTs are often confused with general machinery, while tools like EPRs (Electronic Patient Records) and HISs (Health Information Systems) should be considered as strategic resources to review processes and information streams.

Since 2007 the "ICT in Health Care Observatory" (IHCO) led by the Politecnico di Milano School of Management, highlights the high heterogeneity in strategic ICT management in Italian healthcare organizations. In order to clearly understand the real level of diffusion of ICT tools among Italian healthcare providers, IHCO surveys analyzed the main areas whose processes are supported by ICT. Surveys and case studies outlined a still fragmented situation [1]. Literature analysis [2] allows the identification of five functional areas that characterize EPR: the "ADT Area" manages patient admissions, discharges and transfers within the hospital, as well as vital statistics and administrative documentation (e.g. informed consent); the "Diagnostic Area" allows exam requests and report delivery from/to wards; the "Clinical Dossier" embraces the management of all medical and nursing sheets, including initial assessment, vital signs automated monitoring, anesthesiology documents, OR reports, etc.; the "Therapy management" supports prescription and administration of drugs, transfusions, nutrition, etc.; the "Out-patient management" refers to admission and medical reporting in case of out-patients, and feeds the patient's EPR with information like preliminary report or follow-up examinations. Concerning these, the most widespread functions are: inpatient acceptance, discharge and transfers (79%), diagnostics management (with electronic clinical exams requests and reports available in 63% of cases) and outpatient management (51%). Clinical dossier and therapy management are instead less widespread (less than one third of cases) and are the areas of greatest expected growth in the future, but also the most challenging to implement, above all for organizational reasons.

2. BEDSIDE THERAPY MANAGEMENT

Therapy management refers to all 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 processes, as for example pharmacotherapy, chemotherapy, radiotherapy, blood transfusions, medications and so on. Common literature states that most of the threats to patient safety are process-related, rather than clinical [3]. In fact, paperwork, manual transcription and the lack of automated identification systems are the main criticalities affecting clinical processes, especially those related to therapy, which are especially risky. An

overview of evidences and studies related to transfusion, stem cells radiotherapy and pharmacotherapy therapy processes is presented below.

Transfusion of blood components is a complex process made of a number of critical stages involving staff in different departments. The workflow starts with the decision to transfuse, prescription and patient sampling, pre-transfusion testing, collection of the component from the blood refrigerator, and finally administration to the patient, the stage in which errors mainly occur. Moreover, transfusion errors remain often under-reported, owing to a lack of awareness about transfusion-related adverse events among hospital staff and inadequate feedback system in most of the transfusion centers. Supporting workflow traceability means to track staff, patients and blood units involved in the process but also time and conditions. Blood component transfusions to unintended receivers occurs approximately in 1 out of 10,000 units, and two-thirds of these errors are associated with incorrect identification that occurs at the patient's bedside [4]. Moreover SHOT UK, reviewing a large number of cases of transfusion adverse events from 1996 to 2011, highlights that both in 2011 and in the cumulative data about half of all the reports are of adverse events caused by process errors and that about the 50% (of the cumulative data) of this are related to episodes where a patient was transfused with a blood component that was intended for another patient or which was of inappropriate specification and did not meet the particular requirements of the patient [5]. Similar to blood transfusion, Human Stem Cells (HSC) and Therapy Cells (TC) 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). The Transfusion Service collects stem cells in order to satisfy transfusion and transplant clinical needs. There are two kinds of transplantation procedures: allogeneic (between family members or genetically distinct individuals) and autologous (patient self-donation). Human cellular products (HSCs and TCs) are transplantable products which require strict procedures of collection, preservation and administration in order to guarantee patient safety and exhaustive documentation in each phase of the process [6]. Referring to the 2012 SHOT UK report 7% (9 cases of 135) of the laboratory-related errors are about "Wrong component selected for Human Stem Cell Transplant Patient" and 2 of this 9 reported are related to procedural errors. Moreover 17 of a total of 1080 near miss reports were related to patients who were undergoing a haemopoietic cell transplant (HSCT). In particular, blood transfusion and HSC management have common needs of traceability requirements, validity checks, conservation, strict connection to the recipient, product quality issues; moreover procedures and system applied to HSC management must be compliance with international standards FACT-JACIE (Joint Accreditation Committee of ISCT-EBMT - International Standards for Cellular Therapy Product Collection, Processing, and Administration) [7].

Radiotherapy is a multi-stage complex process that needs single treatments to be targeted to each patient's condition. Giving staff complete clinical information and customized treatment procedures for the patient, represents an important support to daily activities, enhancing care and process quality. Misinformation or errors in data transfer are the greatest cause of incidents in modern radiotherapy services. Based on WHO public report regarding incidents from 1976 to 2007, in the last 15 years 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 among the whole process, 16% of which in the assessment & decision step and 6% in simulation&imaging [8].

Pharmacotherapy management is a critical process in terms of patient safety, traceability, and accountability. Medical prescription must take into account a large number of drugs, potential interactions among them, examination results, sudden changes in patient's clinical conditions. Similarly, preparation and administration have their critical issues, e.g. drug and patient identification, traceability, therapy sheets and so on. These are even more relevant in fields like e.g. chemotherapy. Referring to a literature review conducted specifically in oncology by Schwappach and Wernli in 2010 [9], medication errors are typically distributed as follows: 41% about omitted medications and wrong doses in nursing administration, 21% in order writing or transcription (pharmacy errors) and 38% during the drugs preparation (incorrect dose, wrong medications, ..).

At the same time, pharmacotherapy is an expensive process in terms of cost of materials and drugs, as well as in terms of time spent by staff to prepare therapies. There are many steps where actions could be taken to increase efficiency in order to reduce exposition to risks and free up nurses' time for a better care.

In general, therapy processes are often characterized by inefficiency related to some of the organization or workflow issues mentioned above, above all as regards bedside activities. Moreover, the high number of actors involved in the process (e.g. chemotherapy) makes it difficult to ensure traceability of activities and completeness of information. Procedures may be different in each ward and also documents and schemas may differ between departments and have often not been cross-validated. Knowledge and expertise sharing between the professionals involved in the same process is often limited. Starting from these issues, it is clear the need for a comprehensive approach to information management, process traceability and control especially for activities performed on patients. The main goal is to enhance safety, efficiency, and governance.

2.1 ICT Targets Clinical Issues and Process Challenges In Therapy Management

Together with digitalizing patients' records sheets, one of the most important improvement challenges for therapy management is the introduction of an enterprise-wide patient identification system enabling process traceability and support to clinical operations. This is more crucial than cost-effectiveness or resource optimization, because it has impacts on clinical safety of processes and requires relevant interventions on bedside processes. We will focus on this scenario, where ICTs can play a strategic role.

Automatic Identification and Data Capture (AIDC) technologies support unique patient identification, e.g. with barcode or RFId patients wristbands [10]. Mobile&Wireless solutions, integrated both to AIDC technology solutions and to the Hospital Information Systems, enable to close the safety loop to patient bringing EPR direct bedside access to physicians and nurses. This two innovative technology families can provide staff with software applications to manage critical bedside activities, associate data to objects and increase the volume and timeliness of available data on processes. Moreover, recording structured data enables to re-use valuable clinical information in decision making and research activities, not only for clinical purposes, but also for supervising processes and localize inefficiencies.

The "ICT in Health Care Observatory" (IHCO) led in 2012 by the Politecnico di Milano School of Management [11] identified four main fields of interest for Mobile&Wireless applications in healthcare processes:

- Mobile Hospital applications, to improve internal processes and improve patient safety;
- Mobile Service applications, to enhance availability of clinical data and services for the citizens;
- Mobile Care applications, to provide health assistance to people, anywhere and anytime;
- Mobile Medicine applications, to support physicians as far as collaboration and training are concerned.

Therapy management ICT solutions are classified in the "Mobile Hospital applications" cluster. Currently, the adoption of this kind of applications is still in an early phase. The most pervasive applications are therapy prescription and administration at bedside (34%), followed by the access to clinical data by hospital staff (33%). The research noticed an even lower adoption of mobile devices the management of the clinical diary (31%) and for the collection of patient's parameters/vital signs (30%) [11]. Developed solutions mainly support drug administration at bedside by medical staff, using a PDA to read the barcodes attached on patient's wristband and on the drug container. An increasing implementation of RFId and NFC (Near Field Communication) solutions will soon replace (starting from today) the traditional barcode solutions.

Previous surveys of the Politecnico di Milano School of Management IHCO show that Italian Chief Information Officers (CIOs) recognize that the implementation of EPRs integrated with Mobile&Wireless and AIDC technology solutions, allows to reach a number of relevant benefits: safety and clinical risk management (62% of respondents); process inefficiencies reduction (57%); quality process and service improvement (56%); timing and transparency of internal information (54%); decision making support (51%) [1]. These results are related to: implementation of EPRs improving effectiveness and enabling bedside patient care, integration of the EPR with Mobile&Wireless solutions improving data flows and process traceability, and improving patient safety by identification of persons and items and by patient-to-object cross-matching. However, the research result shows that, reaching all these benefits is delayed by several organizational barriers, like low budget allocated to ICT projects and the need for organizational changes to manage implementation complexity [11].

The main goal of ICTs in therapy management is now to manage activities, provide timely information and register clinical activities close to the patient, also in different locations and settings (e.g bedside in wards, in examination rooms, etc.), improving patient safety and its perception of being well cared.

2.2 State of Art of ICT Support to Clinical Processes

Healthcare organizations, instead of considering ICTs as strategic resources, usually simply adopt them for cost control or for boosting efficiency through automation [12]. Instead of this, the value proposition of ICTs in healthcare includes lots of options in terms of process support. Healthcare organizations typically approach Electronic Patient Records by a local perspective only, also because of difficulties associated with achieving a full EPR [13]. So, it is easy to find hybrid (electronic and paper) EPR implementations. Evidence in literature

shows that in hybrid environments there is significant decrease in timeliness and in the amount of accessible information: moreover, staff declares getting confused and frustrated in seeking information [14].

Therapy management itself is often prone to hybrid configurations also because of the lack of consolidated solutions supporting the final stages of the workflow (those involving the patient) and because of internal organizational challenges. Prescription is mainly managed by Computerized Physician Order Entry (CPOE) systems, used in groups of departments, not adopted organization-wide, and in some cases two or more applications run in the same organization. Similarly, therapy management systems do not support all process steps, but only prescription or administration, or address the very basic requirements of both. Specialized proprietary solutions cover more demanding activities (e.g. chemotherapy management) but they are usually not communicating with other systems. Administration is usually not supported online and beside. Similarly, transfusion centers in hospitals use dedicated systems to perform exams and to store and issue blood bags, often not integrated. These issues even worsen the problem of lack of homogeneity and integration among systems. As concerns radiotherapy, there are different systems both on the side of diagnostic and therapeutic activities and on the side of scheduling and data management. In general, most of the solutions are related to the first class of needs, while there are local dedicated systems related to the latter.

As regards change management and users acceptance, different kinds of specific critical workflows in therapy management have some common issues and challenges to be faced: hindrances are mainly related to migration of therapy procedures from paper to digital, need of smart bedside support to nursing, and legal constraints to digital data management according to national laws.

Summing up, there are very few non-invasive systems capable to effectively support risk management and process control, at the same time. Requirements are about updating patient record in real-time, sharing patient information among professionals and accessing them at bedside. Smart mobile devices and traceability tools are required in order to address bedside processes and risk management issues, approaching common challenges of the different therapy workflows. In particular, the aims of the introduction of ICTs in therapy process are about: secure patient identification, workflow support, patient safety, process traceability and control of costs. Identification systems generally increase the safety in processes in which patients are involved, above all in critical conditions (e.g. unconsciousness, emergency, etc.). Mobile&Wireless technologies have to be evaluated as an opportunity to design solutions to manage processes, also at bedside.

3. THERAPY MANAGEMENT: A CASE STUDY

Fondazione IRCCS Istituto Nazionale dei Tumori of Milan is one of the largest Comprehensive Cancer Centers in Italy. It is an IRCCS, that is an institute for cancer treatment and research. In 2011, 192 research projects were under way and nearly 450 scientific papers were published (IF 2353.98). Istituto cared for about 18,000 inpatients (482 accounted by the Regional Government), 4,000 day-hospital admissions, 1.1 million outpatient treatments, 10,500 surgical operations. It also inspired the Lombardy Oncology Pathology Network (ROL). Given high needs of process reengineering and more efficient

information management, in recent years organizational and technological changes have been adopted aiming at digitalizing processes and incrementing traceability. To address the introduction of ICTs, the Istituto has implemented methodological frameworks like the Business Process Reengineering [15], which supports the introduction of innovative ICT solutions in order to boost efficiency, traceability and quality of processes considering an integrated action on three key levers: processes, organizations and skills, technology. At the same time, internal workgroups and external experts like Fondazione Politecnico di Milano (a research institution connected to the Technical University in Milan), study and analyze the variety of issues related to clinical risk management using different assessment methodologies (e.g. Failure Mode, Effects, and Criticality Analysis) [16]. The main evidence of such activities in the field of therapy management are presented below.

3.1 ICT Adoption within the Istituto

The Istituto's ICT Unit has consolidated expertise in: (i) exploiting ICTs to rapidly switch from experimentation to clinical practice, and (ii) developing ICT solutions able to increase processes quality in day-to-day critical areas. Starting in 2000 from an heterogeneous and stand-alone portfolio based on a Legacy System, today the Istituto's Hospital Information System covers front-end and administrative processes with a pervasive IP-oriented infrastructure, widespread workstations, and best of breed information systems integrated with standard mechanisms (HL7, Web Services, …). The Istituto has also addressed the five EPR functional areas described before, starting from the replacement of the old HIS with modern systems, compliant to international interoperability standards. At last the Istituto's outpatient solution is fed by the Central Booking System and supports physicians during the visits and also for production and digital signing of medical reports. Moreover, core diagnostic departments are supported by state-of-the-art solutions (LIS, RIS-PACS, Anatomical Pathology, …); only smaller labs (e.g. genetics) are supported by local applications, not integrated within the HIS. The Istituto is supporting the Lombardy Region in the test of a new clinical repository of digitally signed medical reports, structured data, patient events (e.g. transfusions, surgery) and other relevant documents, from clinical placement to exam requests. Although part of the clinical patient record is still on paper the clinical repository feed patients' Regional Electronic Health Records (EHR, in Italian FSE). As far as regards therapy management the Istituto is implementing a therapy management systems and developing a solution based on Mobile&Wireless technologies.

Critical aspects related to Istituto's organization, procedures and ICT support were: (i) paperwork in prescription, drug preparation, and administration phases; (ii) absence of a CPOE system; (iii) several therapy protocol templates based on different chemotherapy schemas (customized by specialization wards). In general there is a lack of bedside ICT support, which should cover clinical reporting and therapy management activities.

Spreading the ICT support to clinical processes, the Istituto has been adopting innovative solutions integrated to the five EPR areas (see Section 1) in order to avoid errors and enhance patient safety and care quality. The use of mobile devices is gradually increasing within wards thanks to the evolution of an enterprise RFId platform for traceability and identification. In fact, Istituto has been considered a forerunner among European healthcare organizations in its application of RFId technologies.

3.2 Strategic Path to Safety and Traceability of Clinical Processes

According to its mission, the ICT Unit in collaboration with Fondazione Politecnico di Milano carried out several innovation projects with an approach aimed to better support most risky clinical processes, including bedside activities. In fact, bedside steps of many processes have been highlighted as a potential source of error by staff feedbacks and by a series of preliminary FMECA risk assessments during process analyses [12]. The Istituto's Mobile&Wireless strategy aims at building 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. According to this, the Istituto's ICT Unit evaluated different technologies in terms of benefits, capabilities and limits: the main evidence was that RFId technology (in particular High Frequency - HF 13,56 MHz), embedded in Mobile&Wireless solutions, can be a strong mean to reconcile a high degree of safety with a technology that is non-invasive neither for patients nor for staff. Thus, the Istituto started in 2005 a pilot project on blood traceability in a small ward to explore the potential of this technology in the clinical field and also to identify possible critical aspects.

On one hand, this experience proved potential benefits of RFId for safety and process control when extended to all transfusions and on the other hand this suggests the organization to approach RFId technology with a systemic scope: the result has been an enterprise platform, made up of a set of workflow applications and devices, integrated with the HIS in order to support cross-organization or vertical processes. The Istituto's RFId platform is designed as a flexible and integrable set of API (Application Program Interface), mobile RFId devices (handheld or plain read/write antennae, printers, and so on), tags (process items, patient's badge or wristband, staff badge). The idea is to have two types of components: (i) infrastructure services and (ii) specialized components. The first area is about all type of application services that are common to the whole organization: patient RFId identification connected to the central patient registry, RFId-traced event storage in the platform's database, staff authentication with their own badge, and so on. Starting from this basis, other different RFId platform's component are developed in order to satisfy specific needs within clinical processes, as highlighted in Figure 1: patient matching with blood bags, sampling tubes, and chemotherapy bags through several different devices (handheld readers, PDAs, …), surgical samples identification and tracking with a smart medical trolley.

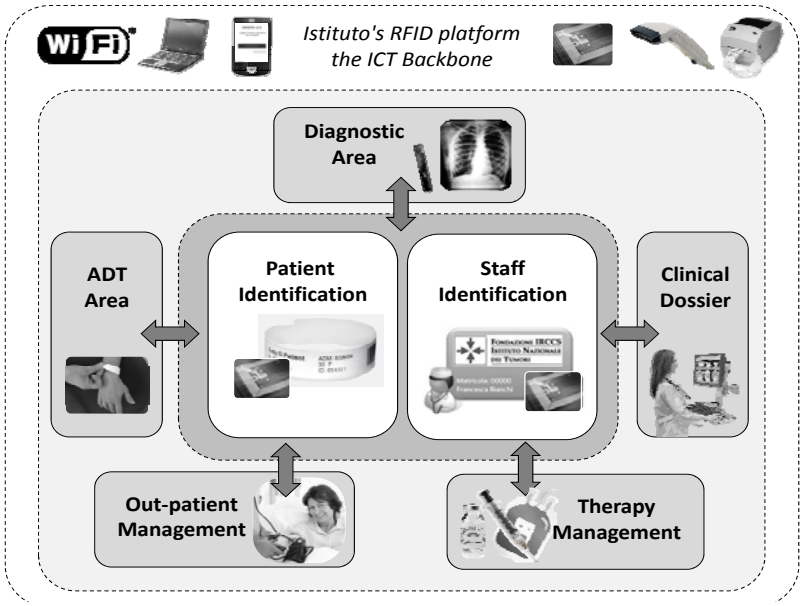

Figure 1. HIS's functional areas and Mobile&Wireless applications at the Istituto for patient safety

3.3 Projects Implemented in Istituto

3.3.1 Enterprise-wide Staff and Patient Identification

The most challenging task was developing and implementing the RFId infrastructure across the whole Istituto. In 2006-7, working with Fondazione Politecnico and the Istituto's ICT staff, Hewlett-Packard engineers identified the most suitable materials (wristbands, tags, labels, ..), aiming at achieving technological flexibility towards the needs of the various processes that could have been supported within the following years. Staff at the Istituto had to be provided by RFId identification badges and Wi-Fi handheld terminals (PDA), Wi-Fi access points had to be placed in each ward, RFId labeling devices had to be installed in working areas (e.g. control rooms, nurses' offices). Patient identification came next: RFId wristbands became unique patient identification devices, to which all following applications had to refer to. Now, when patients are admitted into wards, their names are checked against the central patient registry by using PDAs. During first half of 2012, the system usage rate monitor showed that 5,704 in-patients, 77% of total, were correctly identified. Nurses then give the patient a tamper-proof wristband and initialize its tag bedside (no batch procedure is allowed to avoid swaps). In parallel, the renovation of the enterprise access control infrastructure was done: staff badges were replaced with RFId ones. This means, the use of a sole card for staff identification to access control systems (e.g. access to restricted areas, access monitoring for staff accounting) and RFId applications (e.g. nurse authentication during transfusion administration). Once wards started implementing this procedure, the main step to enable the spread of RFId devices across clinical processes was completed: strong internal communication on the transfusion pilot and staff started becoming familiar with the new tools, then supported by new applications being developed, physicians and nurses could start using

PDAs fitted with RFId antennae or RFId readers installed on desktop PCs to identify patients, check them during procedures (e.g. to load the patient's surgery file as soon as he enters the operating room), cross-match patients to items (like blood bags). These systems now collect traceability data regarding ward activities and provide them to the appropriate subsystem of the HIS (e.g. data on tissue samples collected during surgery are sent to the biobank management system before they arrive at the labs).

The RFId evolution roadmap at the Istituto targeted a series of actions that gradually increase the impact of the system on the organization. Following sections describe the four most important projects regarding Mobile&Wireless support to therapy processes given by the Istituto's RFId platform.

3.3.2 Safety and Traceability of Blood Transfusions

The Istituto had a need for greater efficiency in the management of the transfusion process, as it had no information system for the detailed monitoring and control of the process, neither in the wards, nor in the Transfusion Service. As mentioned above this is the first field of application of the RFId platform but since 2009 bedside transfusion operations are managed within all Istituto's wards. The solution designed by and implemented into the Istituto consists of a mobile application for PDAs which is completely integrated with the HIS (ADT system, Transfusion Service system, ..) and with the RFId platform too. This means RFId tags are stuck on patient sample tubes at transfusion request and on blood bags. Staff admits patients, verifies patient-to-blood match, tracks transfusion administrations and eventual adverse reaction. During first half of 2012 the Transfusion Service had tracking data about 2,652 blood units (78% of total), with a yearly 100% increase in adverse reaction notifications, compared to when the system was not active. Estimates using an extended HFMEA Model for risk assessment on data handling, state that process safety may increase by nearly 64% in the transfusion-execution phase, or by 38% in blood sampling. Coherent results were obtained applying a FMEA-FMECA Model focusing on safety, service continuity, and blood quality. New funding from the Regional Government of Lombardy now aim at extending the solution to the entire cycle of transfusion and to deploy it to other hospitals of the Transfusion Medicine North-Milan District, which the Regional Government is pushing to adopt the same model. In fact, the Istituto, in collaboration with Fondazione Politecnico, Niguarda Hospital (Azienda Ospedaliera "Ospedale Niguarda Ca' Granda", the largest public hospital in Milan) and Varese Hospital (another public hospital in Lombardy), is now applying extensions which support critical areas like First Aid Unit, Intensive Care Unit, domicile transfusions, stem cells management.

Recently, the Istituto has achieved a major system upgrade to modern Android Mobile OS devices. The aim was to extend the targeted technological environment from RFId to NFC (Near Field Communication), an upcoming technology embedded in several upper-class smartphones and to improve device effectiveness and usability. Aiming at a stronger flexibility, the new mobile application has been implemented with a front end in HTML5, a choice which should allow in the future low porting effort to other devices or mobile OS platforms.

3.3.3 Human Stem Cells Apheresis and Administration Process

Starting from results on blood transfusion, the Istituto leads a new project aimed to design, develop and implement a set of organizational models, acknowledged procedures and ICT tools to improve operation support to Human Stem Cells collection and transplantation.

In 2011, Istituto performed 236 leukaphereses (221 of which autologous and 15 allogeneic) and 176 HSC transplants: 151 of which autologous (125 myeloablative and 26 non- myeloablative) and 25 allogeneic (15 from Stem Cell Bank, 8 from familiar HLA-identical and 2 HLA-aploidentical). Today Istituto's stock of cryopreserved stem cell bags counts 1,875 units (140 of which are lymphocite bags for allogeneic transplants). Aiming at a flexible and scalable solution, the Istituto involved in the project the Niguarda Hospital (which is the first public hospital in Milan) and the Istituto Clinico Humanitas (which is an important private care provider and research institution in the same region). Fondazione Politecnico di Milano also joined the project to liaise issues and process redesign in the different hospitals involved.

The idea is to extend the Istituto's RFId traceability platform in the field of HSC and TC process management, and to develop a portable solution to support the whole process: cell donation into a bag, lab processing into other cryo-bags, long-term cryopreservation, delivery to wards and transplantation to recipient patient (or their use for research purposes).

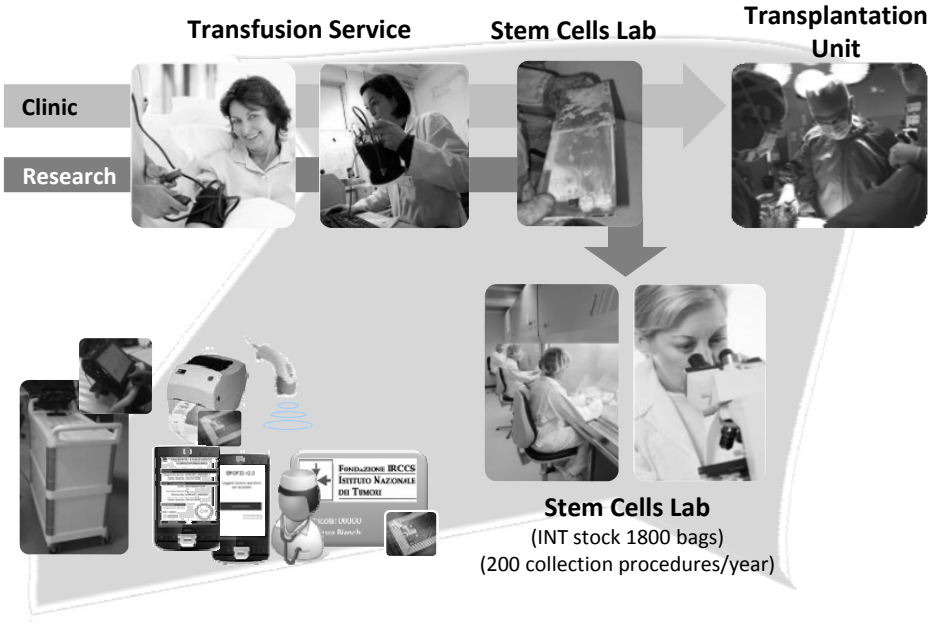

Figure 2. INT's new project: Stem Cells Process Management

The designed solution will provide the Transfusion Service and the Stem Cell Lab specific tools for access up-to-dated traceability data and using them to really control the end-to-end process. Cryopreservation of HSC bags and other related samples requires to assess different feasible solutions. In the proposed scenario (i) portable devices, like WiFi PDAs, will support

operations in wards and in the processing lab and (ii) RFId-labeled bags will be tested to track with a single read/write item all process phases. The main challenge is about whether RFId technologies will be cost-effective in order to support identification activities at temperatures up to -196°C, when bags are stored in liquid nitrogen tanks). Moreover, further tests will are currently investigating if RFId electromagnetic fields interact (and maybe damage) the delicate stem cells in the bags. In this project, as well as in the biobanking project we quoted, we realized that RFId and M&W are not at all an "on-the-shelf" technologies and in many situations their implementation is not supported by a mature environment due to lack of specific laws and guidelines for the healthcare sector; this required experimenting solutions and developing technology skills on our own together with partners.

3.3.4 Radiotherapy Process Management

Radiation therapy is a high performing and extremely personalized curative and adjuvant treatment in Oncology. Because of the use of ionizing radiation this kind of treatment could be seriously harming in case of non-correct patient identification. Istituto has developed in partnership with a technology partner an innovative Radiotherapy information system completely integrated with the HIS and the Regional Government extranet. Moreover, the Istituto's RFId platform has been integrated in the process, enabling safe patient identification in preliminary radiation checks, ensuring that the patient entering a radiation room is the same configured on the LINAC radiation machine. Both in- and out-patients are admitted with an RFId identifier (wristbands of in-patients and badges for out-patients) which is read with handheld and desk scanners; this guarantees to treat the correct patient. Such integration has demonstrated that the extension of the RFId support from a process to another can be quite easy, once the infrastructure has been deployed and staff has become used to it, appreciating its value in terms of patient safety and staff protection.

3.3.5 Chemotherapy Process Reengineering: Centralization, Automation and Process Management

Due to a great need of safety in chemotherapy, the Istituto's Management defined a project aiming to drastically increase safety, quality and efficiency of therapy and chemotherapy management. In Autumn 2009, the project started in synergy with results and knowledge (in terms of risk analysis, process diagnose evidences, workflow recomendations, …) coming from "Towards a complete competence framework and an integrated solution for patient safety in chemotherapy", a research project led by the Istituto funded by the Italian Ministry of Health and involving over 20 Italian healthcare organizations. As Is analyses drew out that the Istituto's chemotherapy process was characterized by paper work in the most steps. Dilutions (56.000+ dilutions/year of cytotoxic drugs) were made in distributed chemo-hoods by ward nurses (13 points), and in addition there were several different therapy protocol templates even in the same ward. Moreover, FMECA analyses showed that the most frequent failure modes in chemotherapy were: patient identification, difficult interpretation of handwriting, missing patient data, drugs dosage, wrong data on prescriptions. Therefore, the reorganization scenario was based on an enterprise-wide CPOE integrated to the HIS and a centralized Pharmacy laboratory - able to check electronic prescriptions, automatically prepare chemo bags and distribute them to all wards with pneumatic transport. This radical and pervasive change required organization, procedures, and documentation standardization in order to achieve efficiency and quality. Moreover, a completely paperless therapy process (less risky than an

hybrid scenario) implied also pervasive ICT support to bedside care activities, especially in administration phase. Mobile&Wireless solutions (e.g. bedside RFId cross-matching) enable mobile monitoring of prescription and administration status reducing paperwork and enabling traceability and adverse-drug-event reports. This crucial part has been designed starting from the Chemotherapy Strategic Program's results in terms of BPR methodology for process reengineering and clinical risk assessment for risk management and patient safety. Starting from here, strict ICT requirements, like automatic appropriateness controls during prescription, patient RFId identification, drug labeling by robots or pharmacist in the lab, chemo bag shipment tracking, cross-match between patient and therapy before administration, and so on, were defined in order to guarantee a high level of safety and quality of care.

The reorganization project has started in July 2012 the implementation phase and is expected to complete the new Pharmacy lab (with automation and electronic prescription enterprise-wide) by March 2013 and then to achieve a complete paperless process through all Istituto's wards by April 2014.

3.3.6 Further Applications of the Istituto's Mobile&Wireless Strategy

Developing and extending the RFId platform has enabled the Istituto to cover other potential risky steps within the clinical pathway. A further example are analog radiographies taken at bedside, where patient could be unconscious and an identification error could be dangerous for the clinical decision-making process. A pilot has demonstrated that RFId tags can solve the problem if any image taken from the patient is tagged and correctly identified; further developments are required in order to integrate the mobile RFId solution to the Radiology information system, thus increasing efficiency and overall safety.

Another interesting field is patient identification before surgical operations. The Istituto's OR Information System was integrated to the RFId platform and since fall 2010 enables physicians and nurses to correctly identify patients and also to check that the proper documentation is loaded on the screens in the operating theatre. This integration has also been the first step to extend the RFId platform coverage to surgical sampling process in order to support traceability to the Tissue Bank: the process starts from the OR and passes through the Anatomical Pathology labs, tracking temperature and process lead times with RFId. This project is particularly interesting because it crosses clinical and research departments. Main results regard sampling and delivery traceability, transparency and higher effectiveness in collecting samples into the Tissue Bank; these aspects will affect positively future research projects using the collected materials.

In 2012, the Istituto has started a new collaboration project with two companies from the Region of Lombardy and the Region of Sardinia, in Italy. The project's scope is to design new procedures and a coherent ICT framework to tracking medical tools in the Operating Room. This applies to (i) surgical tools throughout the sterilization process up to the OR when they are used on the patient; (ii) prostheses implanted into the patient; (iii) other medical devices used on the patient. The ICT framework should assure higher safety to the patient and timely process data. Among the others, this project contributes to the Istituto's aim to further exploit its RFId platform pervasiveness.

4. CONCLUSIONS

Nowadays most of possible hazards to patient safety are process-related, rather than clinical. Among all criticalities, the most relevant are difficulties in access to information and the lack of automated identification systems. ICTs can play a strategic role addressing these needs for timely handling of large amounts of data and complex clinical information. The goal is to integrate ICTs in clinical processes focusing on the enabling role of Information Technology on process governance instead on the diagnostic aspects of technology (machinery). In particular for bedside activities the fragmentation of systems and the lack of support to clinical staff adds risk issues related to incomplete information, safe identification, hybrid information management (paper and digital at the same time). Dedicated ICT tools and mobile devices are required in order to address bedside and risk management issues, approaching common challenges of the different therapy workflows. The main goals of ICT supporting therapy management are secure patient identification, workflow support to activities, patient safety, process traceability and costs control.

Fondazione IRCCS Istituto Nazionale dei Tumori in Milan (Italy) has been adopting innovative solutions integrated to the Hospital Information System in order to avoid errors and enhance patient safety and quality of care. The use of mobile devices is gradually spreading within all wards thanks to the development and evolution of the Istituto's enterprise RFId platform for traceability and safe identification in clinical processes. The Istituto's approach has proved peculiar and winning: the main goal was to build an unique ICT infrastructure, made of hardware and software integrated to the HIS, guaranteeing secure identification of patient, staff, treatments, and critical items at crucial checkpoints within the clinical pathway. An example of this strategy is how the Istituto has reengineered the chemotherapy process, in a project which is going to change the whole pharmacotherapy procedures from prescription, to preparation, and administration. Aiming at a paperless therapy process (less risky than an hybrid scenario), the new layout includes pervasive support to care processes also at bedside. Mobile&Wireless devices (e.g. PDAs, MCAs,..) enable mobile check of prescription and administration, reducing paperwork and enabling real-time adverse-drug-event reporting.

Concluding, Mobile&Wireless technologies integrated to the HIS are powerful and strategic in order to close the loop in therapy management at bedside and to feed the Electronic Patient Record with precise information on bedside events and activities. But to succeed, organizations must pay a lot of attention in process reengineering and change management issues, as well in the correct choice of the proper technology to build the company infrastructural backbone and to develop mobile applications to fit in different hospital environments.

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