

ICT TO IMPROVE SAFETY, TRACEABILITY AND RELIABILITY OF CLINICAL PROCESSES WITH QUALITY ASSURANCE ISSUES

The Case of Stem Cells

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Abstract: Traceability and quality assurance of bedside processes are often still manual, without the appropriate support of information systems. Automatic Identification and Data Capture (AIDC) solutions integrated with Mobile&Wireless devices are key solutions to meet the needs of secure identification of persons and items and of traceability of processes in healthcare organizations. These technologies can fit a variety of processes, like enterprise-wide person/item identification, blood transfusions, surgical samples identification, therapy management. The challenge is to extend the use of these solutions also to other processes like biobanking, where stem cellular products require strict procedures of collection and manipulation, even in critical environmental conditions. Fondazione IRCCS Istituto Nazionale dei Tumori in Milan (Italy) has a wide experience in RFID projects and is starting to lead a project aimed to design, develop and implement a set of organizational models, acknowledged procedures and ICT tools in order to improve actual support to collection and transplantation of Human Stem Cells. In this paper we present a literature overview of cases of implementation of AIDC technology solution and of how its character of ubiquity and versatility could fit well with process requirements, discussing the Istituto's business case.

1 INTRODUCTION

The volume and the complexity of clinical and administrative information make Information and communication Technologies (ICTs) essential for both running and innovating healthcare organizations.

In this paper we want to focus on the use of ICTs to face lack of process monitoring information in healthcare, above all as regards identification, safety, quality assurance.

2 CRITICALITIES IN CLINICAL PROCESS MANAGEMENT

The process of patient care may be a complex and

composite sequence of visit, examination, treatment and so on. To attend the patient in a path of care means to deal with both staff workflow activities and direct contact with patients. Common literature states that most of the threats to patient safety are process-related, rather than clinical. Referring to a literature review conducted specifically in oncology by Schwappach and Wernli in 2010, for example, medication errors seem to be distributed among: 41% in nurse administration (predominantly omitted medications and wrong doses), 38% in medication dispensing (predominantly nursing dispensing errors such as incorrect dose or wrong medications), and 21% in order writing or transcription (predominantly pharmacy errors). In general, processes are characterized by inefficiency related to organizational and procedural issues: there are difficulties in timely accessing patient information; a

high number of actors involved in the process (e.g. chemotherapy) makes it difficult to ensure traceability of activities and completeness of information; procedures are different in each ward and also documents may differ between departments; there is limited knowledge and expertise sharing between professionals involved in the same process and taking care of the same patients. This reflects the actual situation in many organizations, where especially bedside activities are still manually managed, without the appropriate support of information systems. This is crucial in terms of patient safety. In this context the challenges to be faced to ensure quality and safety to the clinical process are:

- To ensure reliable patient identification throughout all processes during his/her stay in the healthcare organization;
- To enable process traceability, allowing clinical staff to record activities performed both in “back office” and involving directly the patient, increasing the amount and the quality of stored data;
- To support clinical staff in performing activities depending on the quality and the amount of available data about the patient. The fewer available data, the less decision making support for staff;
- To improve governance and cost control, reducing inefficiencies in information sharing and communication between practitioners involved in same workflow.

3 AIDC TECHNOLOGIES AND CLINICAL PROCESS

In the scenario described above ICTs become essential for support and governance, deeply affecting the management of information flows, allowing to extend and strengthen the capability to register, consult, search, elaborate and transfer data of very different kinds and uses. A key issue in this effort is to reduce errors and enhance efficiency by supporting process traceability and safe identification of patients and items.

Automatic Identification and Data Capture (AIDC) identifies tools for the identification and/or direct collection of data into a computer system, programmable logic controller (PLC), or other microprocessor-controlled device without using a keyboard. Many technologies that can be involved in AIDC solution are: Bar Code and Card Technologies, Radio Frequency Identification (RFID), Real Time Locating Systems, etc. The most

important application areas of AIDC technology in the healthcare sector are: identification and/or geolocation of people or objects, operations support, process tracking and logistics. This because solutions based on AIDC technologies (like RFID) can be used to ensure fast and unambiguous identification of items and patients within the organization, as well as they enable local storage and update of data during activities. The same technology can be used also for asset location and management of maintenance activities. Another high potential field includes applications implementing combined identification of people and items, thus enabling a patient-to-object cross-match.

Another relevant group of IT solutions available and valuable for healthcare process management are Mobile&Wireless technologies (e.g. PDAs, MCAs, ...), which enable mobile access to clinical applications also at patient bedside, continuous monitoring patients' conditions, ubiquitous registration and access to clinical data when needed.

When integrated, these two innovative technology families can provide staff with solutions both to support care processes and to monitor them. A survey issued in 2010 by the ICT in Health Care Observatory of the School of Management of the Politecnico di Milano shows that Italian CIOs are rating Mobile&Wireless and AIDC technologies as important to increase Electronic Patient Record (EPR) functionalities, increasing their effectiveness and thus care safety. Indeed Mobile&Wireless solutions, integrated both to AIDC technology solutions and to the Hospital Information System (HIS), enable to close the patient safety loop bringing EPR access to clinicians directly at bedside.

In literature we can find many organizations having started AIDC technologies implementation projects, in order to assure internal identification and tracking procedures, but until now the health-care industry has not invested systematically in information technology and many processes still rely on paper record-keeping and individual memory. Summing up, literature classification models for AIDC technology solutions distinguish between: Patient and/or staff identification and tracking, Asset management and tracking, Clinical process traceability (blood, specimen and drug management), Management of surgical instruments, Inventory management and drug counterfeiting, Patient documentation management and automatic biological parameters capture.

As regards asset management, Emory Healthcare, Georgia's largest health-care system, has deployed an RFID-based asset-tracking system to

improve management and utilization of infusion pumps and other high-value equipment. Here, RFID readers installed at doorways record when pumps enter or leave utility rooms. Location sensors are also installed at the entrance and exit points of the inventory areas, providing an inventory of tagged pumps available for use.

Other operations support systems, coming from manufacturing practice, are e.g. sample tagging for automatic processing in the laboratory, item tagging for blood bank or pharma cabinets control both in the replenishment and in the picking phase, systems for automated issue of medicine doses. For example the Masaryk Memorial Cancer Institute in the Czech Republic is using RFID to track vials of expensive chemotherapy medications, in an effort to better manage the potentially dangerous process of mixing the medication with infusion solution. Working in chemo-hoods, technicians take an RFID-tagged bag and fill it with the proper amount of drug. Patient's name and other basic information are electronically written on the label. The pharmacist wears a ring-shaped tag on one finger and after mixing the medication with the solution, he matches the tags on the bag, on the drug vial, and on his ring and, using a reader installed inside the chemo-hood. The bag is then removed from the chemo-hood, and another check is done when passing the output hatch. The information collected via RFID allows the hospital to track when, what, by whom, and how the specific medication was prepared.

Similar systems can also be used for process optimization, by monitoring real-time patient flows (and thus possible bottlenecks) in First Aid Wards or in Radiology Departments. Success examples are the St. Vincent's Hospital in Birmingham (UK) or Fondazione Macchi di Varese (Italy).

But most important implementations of AIDC technologies are for bedside support to clinical staff. This can be done by applying bracelets to patients at admission, and identifying all items related to a patient (e.g. patient records face sheets, vials, receipts, blood bags, drugs) by means of labels. AIDC solutions can be used for example to control drug administration, in the operating theatre and in the transfusion area for patient-to-treatment verification. An interesting case of study is Boston Beth Israel Deaconess Neonatal Intensive Care Unit (NICU), where babies are identified with RFID wristbands. Mothers' milk is tagged upon storage in refrigerators and when a nurse has to feed a baby, she first scans the milk, then the baby. A software application ensures that the right infant receives the right milk and automatically creates an audit trail.

Additionally, RFID scanners are fixed at door frames to detect babies carried in and out the NICU. Another example of this kind of applications is at the Wisconsin Blood Centre, where tags on donation bags are written with information on time, blood type, identification number, and expiration date. The center processes the blood, and when a bag of processed blood leaves a blood center en route to a hospital, its tag is read in order to register that bag's departure, and the time and date of that activity. When a hospital receives the blood bag, it utilizes a separate section of the chip's memory to register data on the recipient patient. When blood is administered to the patient, the bag tag will be read again, thus confirming that the patient is receiving the proper unit. Thus, the systems supports on one side shipment traceability from the Blood Centre to patients in other hospitals, on the other side it supports transfusion safety directly at bedside.

These few examples show how AIDC may help healthcare workers by enabling to automatically identify assets and patients, to track inventories, to control accesses, to enhance equipment utilization, to optimize staff time and to improve patient safety. In addition, traceability data can be used to improve business processes, from optimization of process bottlenecks to planning of equipment maintenance. The potential value of such technologies to healthcare processes can vary within a wide range of solutions and is applicable to a variety of processes, including pharmacotherapy, chemotherapy, blood transfusions, radiotherapy, medications, surgical activities and so on.

4 HAEMATOPOYETIC STEM CELLS TRANSPLANTATION PROCESS NEEDS

Human Stem Cells (HSCs) transplantation is a life saving therapy 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 (SIMT) collects stem cells in order to satisfy transfusion and transplantation clinical needs. There are two kinds of transplantation procedures: allogenic (between family members or genetically distinct individuals) and autologous (patient self-donation).

Human cellular products (HSCs and Therapeutic Cells-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. In particular, blood transfusion and HSC management have common needs of validated standard procedures, effective organization models and state-of-art ICT tools in compliance with international standards FACT-JACIE (Joint Accreditation Committee of ISCT-EBMT - International Standards for Cellular Therapy Product Collection, Processing, and Administration). Clinical studies state how clinical outcome of cell therapy is on average better in centres implementing FACT-JACIE standards.

HSCs and TCs management typically involves three actors: (i) the Transfusion Service manages donors selection and cell collection or receiving from external biobanks; (ii) the Stem Cell Lab processes, fractionates, and cryopreserves collected units and delivers the bags for transplantation to (iii) the Clinical Units. The most relevant steps are donor acceptance (new or known person), blood sampling, units labelling and processing before cryopreservation. Very important issues of this part of the process are donor identification and items labelling, particularly critical phases both for legislative and operational aspects (some possible adverse events can be generated here).

Italian healthcare providers implement a variety of organizational models (e.g. outsourced activities, duties of each unit,..), supporting tools, working procedures. Moreover, despite FACT-JACIE qualification of centres is strongly recommended by the Italian Ministry of Health, there is still a need for greater efficiency in the management of the transplantation process, as there are no standard and validated information systems for detailed monitoring and control of the process, neither in the wards, nor in the Stem Cell Lab.

Some examples follow. The Transfusion Service does not have full awareness of laboratory processing activities and actual stocks (e.g. units collected by the Transfusion Service get fractionated by the Lab, but no trace is on the Transfusion Service management system). In the lab, staff can calculate their stock mainly by manual checks of donors history sheets, where all information on donated bags is registered: such a procedure does not support an efficient management of such data.

Also bedside activities show some critical issues, many similar to those in the transfusion process: unambiguous patient identification, bags and vials labelling, 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.

Another common aspect regards self-donation for autologous transplantation: this particular procedure requires to be managed in order to collect, identify and trace for long periods of time huge stocks of cells collected and reserved for the donor patient. This is a very critical secondary flow which has to be supported carefully because of potential risks for patients in not correct identification (e.g. mismatch between fractionated units due to different identifiers used by the Lab and the Transfusion Service) or mistakes between patients.

A preliminary inquiry on actual critical points in process configuration can be summarized in some key topics:

- Absence of fast, safe and unambiguous identification system for patients, sample tubes and stem cell bags;

- Complexity of clinical datasets on units and patients;

- Process fragmentation between different units with different duties, low communication and poor information record;

- Paperwork and manual activities scarcely supported by existing IT systems, which are often just lists on files.

This is even more significant if we consider that product quality is given for granted by the mutual assumption made by staff, that each process step was performed by colleagues according to established procedures. These considerations highlight the need of a coherent and integrated approach to innovation through the analysis, design and introduction of organizational models and state-of-the-art ICT solutions to link actors and enable a safer management of bags and clinical information on transplantation. This is particularly challenging as it regards process revision and technology-related issues, because of the frailty of stem cells, of the particular environmental conditions (e.g. deep freeze long term storage), of the number of different departments involved in the chain of activities. Nevertheless, we believe that, despite many additional challenges, the main features of ubiquity and versatility of AIDC and M&W technology fit stem cells process management needs, and can improve quality, safety and efficiency.

5 AIDC TECHNOLOGIES AT ISTITUTO NAZIONALE DEI TUMORI DI MILANO

Founded in 1925, Fondazione IRCCS Istituto Nazionale dei Tumori in Milan (Italy) is recognized as a top Scientific Research and Treatment Institution in Oncology. In 2010, over 210 research projects were under way and nearly 426 scientific papers were published (IF 2274.38). Istituto cared for about 13,700 inpatients (482 accounted by the Regional Government), 9,600 day-hospital admissions, 1.1 million outpatient treatments, 11,500 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 implemented, aiming at digitalizing processes and incrementing traceability. The Istituto collaborates with partner Fondazione Politecnico di Milano, a research institution connected to the Technical University in Milan with expertise both on clinical process management and on technological aspects. Also in this case, Fondazione supports the implementation of project according to methodological frameworks like the Business Process Reengineering, to address the introduction of innovative ICT solutions with integrated action on three key levers: processes, organizations and skills, technology. At the same time, internal workgroups involving known experts analyse a variety of issues related to clinical risk management.

Aiming at completing the ICT support to clinical processes, the Istituto has been adopting innovative solutions integrated to the HIS in order to avoid errors and enhance patient safety and quality of care. The use of mobile devices is gradually spreading within 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 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. Nowadays, the Istituto's RFID 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 crossmatching (blood bags, sample tubes, surgical sampling..).

This is done through several different WiFi devices like handheld readers attached to standard desktop PCs or smart PDAs with a thematic workflow management application installed (e.g. the transfusion safety app, the bedside radiology app, and so on). The Istituto is also carrying on a project about pharmacotherapy digitalization and chemotherapy management, where also RFID technology will be used to track drugs manufactured in a centralized lab, sent to wards, and then administered to patients (as regards chemotherapy, the Istituto is leading a Strategic Program funded by Italian Ministry of Health involving over 20 Italian healthcare organizations to define a complete competence framework and an integrated solution for patient safety, process quality and overall efficiency improvement).

6 THE CASE: EXTENDING THE ISTITUTO'S RFID PLATFORM TO STEM CELL MANAGEMENT

Recognizing this expertise, the Regional Government of Lombardy and the Italian Ministry of Health have funded a research project lead by dr. Vittorio Montefusco, a physician working at the Istituto's Haematology and Bone Marrow Transplantation Unit (whose chief executive is the renowned oncologist dr. Paolo Corradini).

The 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 haematopoietic stem cells (HTCs) and therapeutic cells (TCs), in full compliance to the internationally recognized FACT-JACIE standards. This will allow clinicians to guarantee and trace high quality standards in procedures and data handling, also providing more accurate traceability data on stem cell collection and implantation (e.g. process lead times, haemovigilance).

A.O. Ospedale "Ca'Granda" Niguarda in Milan (which is the largest public hospital in Milan), Fondazione IRCCS Istituto Neurologico "Carlo Besta" (a research and care institute for neurological pathologies), and Fondazione Politecnico di Milano are involved in the project, each one bringing specific support needs. In fact, the Istituto and Niguarda run important storage and transplantation facilities, and Besta and Istituto are more focused on research activities even if respectively on oncology and neurology.

The idea is to extend the Istituto's RFID traceability platform in the field of HSC and TC process management, supporting the whole process: from 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). The designed solution will provide the Transfusion Service and the Stem Cell Lab specific tools for up-to-date traceability information on processes and using them to really control the overall process. The designed solution will raise the overall safety and effectiveness thanks to:

Unique identification of patient and bags through RFID tags;

Consolidated and shared information among all involved units throughout the process;

User-friendly mobile application supporting bedside activities (from donation to transplantation), tracing significant steps (time, operation, user), recording adverse reactions;

Sharing of adverse reaction digital information between doctor and other units involved;

Integrating all traceability and stock information to Transfusion Service and Stem Cell Lab information systems, in order to unify information on patients, cell units and stocks.

A model of the new process configuration, as well as a draft architectural model for the ICT solution will be provided soon.

The clinical relevance of the project refers to the purpose to directly measure the impact of the proposed solutions (methods, organization, tools) on collection, processing and transplantation procedures. This will regard: product quality, patient safety, process quality assurance, traceability of transplantation flows for clinicians and technical staff (e.g. vigilance on hematopoietic stem cells and therapeutic cells, traceability information, adverse reaction, etc.). The impact on cell quality will also be assessed analyzing vitality and other indicators, to understand how the new procedures and e.g. radio frequency radiation could affect their features.

In fact, the primary result will be an increase in patient safety and in secure management of the processes, thanks to secure and unique RFID identification of all items and people involved. Besides, this will be the first project able to realize a complete RFID traceability and tracking system of HSC and TC transplantation, transferable in order to give coverage to an area now scarcely garrisoned. This will also be measured concretely assessing As Is vs To Be process risk levels using methodologies

like the Health-Care Failure Mode And Effect Analysis (HFMEA).

The Istituto's experience in safe transfusion management with the RFID platform proves that the pervasive use of AICD technologies will force to a process review increasing its compliance to international standards and fostering a higher level of general accuracy in activities. Moreover, an increase in adverse events notification will surely be obtained by supporting bedside activities with mobile solutions fully integrated with the Hospital Information System. This would raise statistical relevance of adverse events notified to the Transfusion Service and improve process monitoring capabilities.

Finally, the project approach aims at achieving a general value model and a corresponding ICT solution which is easily exportable to other healthcare organizations. This will be guaranteed by the use of recognized methodological frameworks, recommended international guidelines (FACT-JACIE procedures should be implemented by all centres dealing with stem cells), international technology standards (e.g. ISBT 128, HL7-Health Level Seven, standard Web Services, etc.). But above all this will be guaranteed also by tight collaboration with physicians in designing and developing the solution and will be validated by other Italian hospitals collaborating with Istituto.

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