Towards a Clinical Risk Reduction: A Hospital Information System Based on Software and Hardware Integration

Raffaele Chianese
Department of Healthcare Solutions
KIRANET I.C.T Research Center
Aversa, Italy
e-mail: Raffaele.chianese@kiranet.it

Francesco Gargiulo
Healthcare Services
Napoli, Italy
e-mail: francescogargiulo@inwind.it

***Abstract*— This article presents FID-MED, an integrated platform composed of a web based clinical application, named FIDCARE, and a medical cart called FIDRUN and describes the possibilities that FID-MED offers, both for quality assurance and risk management, and for cost reduction. FID-MED is an industry research product and the design effort aims to reduce the risk in healthcare services by means of a deep integration between hardware and software and leads to a Hospital Information Systems (HIS) including a specifically designed medical cart. The introduction of key concepts, as abstract drug, and the overall and complete control of clinical processes provides valid tools for the control and rationalization of costs. FID-MED aims to overcome barriers that prevent the adoption of a HIS using enabling technologies – Radio-Frequency IDentification (RFID) and Internet of Things (IoT) – adherence to the main international standards – Health Level 7 (HL7), Digital Imaging and COmmunications in Medicine (DICOM®), etc. – and the ease of integration with third-party software.**

Keywords-Hospital Information System (HIS), FID-MED, FIDCARE, FIDRUN, healthcare risk management, healthcare cost control, medical cart.

I. INTRODUCTION

In the Health sector, risk management and cost control are very important. Risk management means the adoption of a set of actions and measures aiming to improve the quality of health services and to ensure the safety of the patient. The control of cost is related to the best management and scheduling of the available resource, such as expensive materials, products and drugs. For these reasons, the possibility to keep under control the involved processes, i.e., medical prescriptions, administrations of drugs, stock management and supply, etc., can lead to a reduction of the possibility of error and economic losses and to savings in time.

Errors in drug therapy represent an important percentage of medical errors and outline not only a clinical problem, with regard to the quality of care, but also an economic problem, with regard to the major cost derived [1] – [3]. The priority needs to ensure greater safety for the patient and the need to facilitate health workers in the performance of specific activities can find effective answers in the computerization and automation of the process of drugs management.

It is widely acknowledged that the patient's safety and centrality in the care process are of interest to anyone dealing with health care and that the best approach to reducing errors in therapy is multidisciplinary. This approach deals with the HIS that involve a number of roles and functions - doctors, nurses, pharmacists and the patient himself – and a set of related processes.

The error cannot be completely cancelled but it can still be strongly reduced with the use of technological tools, such as HIS [1] [4]. The rest of this paper is organized as follows. Section II describes the related works. Section III introduces our proposal named FID-MED. Section IV describes the clinical risk reduction in FID-MED. Section V addresses the cost control in the proposed HIS. Section VI describes a brief comparison with competing system. The conclusions close the article.

II. RELATED WORKS

International studies [1] [4] show how the introduction of HISs contributes to general errors reduction even if they also warn against errors related to the use of system.

Developers of health care software have attributed improvements in patient care to these information systems. Like any health care intervention, such claims require confirmation in clinical trials.

The authors of [4] reviewed controlled trials assessing the effects of HISs by searching the MEDLINE, EMBASE, Cochrane Library, Inspec, and ISI databases and consulting reference lists through September 2004. Very briefly, the results are that the HISs improved practitioner performance in 62 (64%) of the 97 studies assessing this outcome, including 4 (40%) of 10 diagnostic systems, 16 (76%) of 21 reminder systems, 23 (62%) of 37 disease management systems, and 19 (66%) of 29 drug-dosing or prescribing systems. Fifty-two trials assessed 1 or more patient outcomes, of which 7 trials (13%) reported improvements. Improved practitioner performance was associated with HISs that automatically prompted users compared with requiring users to activate the system (success in 73% of trials vs 47%) and studies in which the authors also developed the HIS software compared with studies in which the authors were not the developers (74% success vs 28% respectively).

While several studies [1] - [3] deal primarily with injuries associated with errors in health care, the cost of inefficiencies related to errors that do not result in injury are

 ISBN: 978-1-61208-675-0

also great. The effort associated with "missed dose" medication errors is just an example: when a medication dose is not available for a nurse to administer and a delay of at least two hours occurs or the dose is not given at all [6]. Nurses spend a lot of time tracking down such medications. Such costs are harder to assess than the costs of injuries and they may be even greater.

It is easy and common to blame operators for accidents but investigation often indicates that an operator "erred" because the system was poorly designed. In fact, machines can also produce errors or can mislead operators, e.g., if two medications that are spelled similarly are displayed next to each other, substitution errors can occur. Humans and machines are rather different and the combination of both has greater potential reliability than either alone. How best to make this synthesis is a very real problem. Humans are erratic, and err in surprising and unexpected ways; they are also resourceful and inventive and they can recover from errors in creative ways. In comparison, machines are stupid, more predictable but they cannot deal with a variable that was never anticipated, so that there was never any basis for equations to predict it or computers and software to control it.

As cited in [1], the system analysis [7] of a large series of serious medication errors (those that either might have or did cause harm) identified 16 major types of system failures associated with these errors. Of these system failures, all of the top eight could have been addressed by better medical information, e.g., laboratory systems do not communicate directly with pharmacy systems; prescribing, dispensing, and administering systems are not integrated, etc. Again, alerts are not delivered to caregivers in a timely way, while an increasing number of HISs contains data worthy of generating the alert message and many computerized physician order entry systems lack even basic screening capabilities to alert practitioners to unsafe orders relating to overly high doses, allergies, and drug–drug interactions.

An interesting side effect in HISs adoption is the awareness of the magnitude of problem human errors. In fact, [8] reports that while 92 % of hospital CEOs reported that they were knowledgeable about the frequency of medication errors in their facility, only 8 % said they had more than 20 per month, when in fact all probably had more than this.

Finally, several barriers have prevented implementation of these systems. Among these, the tendency of health care organizations to invest in administrative rather than clinical systems, the issue of "silo accounting" and the complexity of an effective systems integration due to the lack of standards and the difficulties with regard to the disclosure of data with third-party systems.

III. OUR PROPOSAL: FID-MED

The proposed HIS, named FID-MED, place itself in the sector of Health digitization and in particular of the computerized management of drugs, a growing sector seeking effective solutions. FID-MED is compliant with the main international medical standards, such as HL7 and DICOM, and can be easily integrated with third-party stocks management systems. It is oriented to the Electronic Health Record (EHR) and Electronic Medical Record (EMR) and it is compliant with Italian Personal Health Record (Fascicolo Sanitario Elettronico [9]).

FID-MED is mainly composed of a clinical Java web based application, named FIDCARE based on Oracle database, Figure 1, and an expressly designed medical cart, called FIDRUN, Figure 2. FIDCARE and FIDRUN work in synergy together and they are closely integrated. FIDRUN is equipped with PC on board with Monitor Touch 10.1" that allows accessing FIDCARE by Wi-Fi connection. FIDRUN has two series of drawers, one on the front (A side) and the other on the back (B side). Each series of drawers is divided into 8 configurable modules. Each module can be configured to with 6 small drawers or alternatively with 2 large drawer. FIDRUN represents a very valuable tool in the drug preparation and administration phases and has an operating autonomy that covers the working shifts.

A simplified deployment diagram of FID-MED is represented in Figure 3.

IV. CLINICAL RISK REDUCTION

FID-MED aims to reduce primarily the clinical risk through a tight control over the supported clinical processes (in accordance with the Italian applicable law) and consequently it works toward an efficient resources management and cost control. Mainly, FID-MED mitigates the clinical risk by means of:

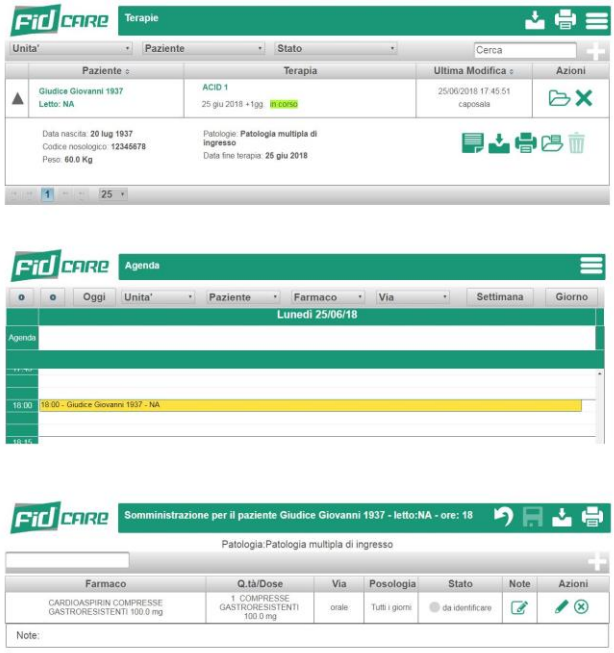

Figure 1. FIDCARE: Therapy prescription and administration pages.

- The tight control of the association of drugs to patient during the prescription, dispensing, and administration phases;
- The correct identification of the patients and the correct identification of the drugs in their therapies before drugs administration;
- The recognition and unique identification of the nurse who administers the therapy and the patient.

Once a physician prescribes a medicine to a patient through the computerized order entry, even if that medicine will be prepared (if needed) and administered by other operators (pharmacist or nurse) none of them can change drug, dose or the sequence without the physician permission. Through the correct identification of the patient and the drugs of his/her therapies, it is more difficult to be mistaken and the identification of the nurse who administers the therapy enforces the traceability of drugs from the physical order entry to the administration. After taking medications, the physician may perform a follow-up of your drug intake by displaying the patient's card.

The identification of patients, operators (physician, nurse, pharmacist, etc.) and drugs plays a central role in clinical risk mitigation with FID-MED. Essentially, in FID-MED the identification may occur in two different ways, other than the trivial selection in a list.

A. *Reading barcodes.*

The patient receives a bracelet with his/her own new unique barcode created by FIDCARE in the admission phase and the nurse uses a portable barcode scanner to identify the patient. The nurse may also type the barcode, if he/she does not has a barcode scanner or if it is temporarily unavailable or not working. In addition, operators have a barcode uniquely assigned to themselves, typically included in their badges, and they can use it for login in FIDCARE or FIDRUN, other than using user and password.

Figure 2. FIDRUN with fours modules. The first two at the top have each six small drawers and two modules at bottom have each two large drawers.

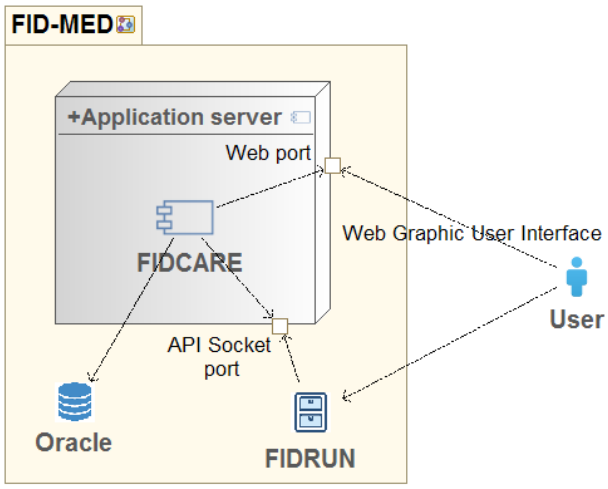

Figure 3. The deploy diagram of FID-MED.

All medicines have a barcode on the carton and it is quite easy to verify that, given a drug barcode, the corresponding drug belongs to a therapy (on that day, at that time) of a previously identified patient. A separate discussion is required for drugs that must be prepared before their administration, such as drips. In these cases, the package has not the barcode, and then FIDCARE creates a new unique barcode and print it on a sticker. The sticker includes details about the drugs, such as the chemical composition, the patient name and code, the preparation and expiration date and time, etc. From now on, FIDCARE will use this code to identify the drug, as in the previous case. Finally, barcodes can also be used to identify medical devices, such as stents. Here again, FIDCARE creates and prints a sticker.

B. *Reading RFID tags*

As in the barcode case, FIDCARE prints a new unique wearable passive tag during the admission and assigns it to the patient. Again, the nurse identifies the patient using a portable reader, and if necessary, the code may be manually typed. Substantially, RFID tags can be used in place of barcodes also for operators and medical devices identification.

These identification methods are reliable and fast, the main difference among them is that the reading of the RFID does not require the patient's vicinity to the nurse, unlike the barcode reading. It is worth mentioning that barcode and RFID technologies are not mutually exclusive. In fact, even if a drip may be tagged with RFID, it is not efficient to tag all drug's cartons due to the volume. A number of readers can read both barcode and RFID and FIDRUN is compliant with both of them. FIDRUN is equipped with this kind of reader connected via Bluetooth.

FIDRUN has two modes of operation: *patient mode* and *drug mode*.

 ISBN: 978-1-61208-675-0

In patient mode, before the administration of therapies, the web application requires an empty drawer for the patient and the cart automatically assigns and opens it. The nurse loads this *therapy drawer* with the drugs of the therapies of the patient and closes it. Then, when the patient is identified, the FIDRUN automatically opens the corresponding therapy drawer to allow the administration of the drugs. This operating mode contributes to the reduction of the risk of administration of a drug not present in the therapy of the patient. By default, the FIDRUN allows the opening of a single therapy drawer to further reduce the risk of administration of a wrong drug.

In drug mode, the FIDRUN automatically assigns a drawer, called the *drug drawer*, to each drug. The nurse pre-loads the cart by reading the barcode of a drug. If FIDRUN already assigned a drawer to the drug then it opens that drawer, otherwise FIDRUN assigns a new empty drawer. During the administration phase, the cart automatically opens the drug drawer if the corresponding medication is to be administered in a therapy. This case happens after the patient recognition and after the selection of a drug in its therapies in the web application. This mode of operation also reduces the risk of administration of the wrong drug.

Although these two modes of operation are described separately, FIDRUN can operate in mixed mode. In fact, it is possible to configure the medical cart to allocate a number of drawers to the patient mode and the remaining drawers to the drug mode. Finally, it is possible to use the drawers in a different way from the ones described above. This last operating mode, named *storage mode*, does not provide any form of drawer control by the cart and allows for greater freedom in their use.

V. COST CONTROL

As mentioned above, the control of cost is a matter of considerable importance in a HIS. FID-MED aims to controls the cost in multiple ways, among them:

- Introduction the concept of abstract drug;
- Optimization of chemotherapeutic medicinal products usage;
- Effective stocks management and usage product control.

A. Abstract Drug

Surprisingly, the introduction of the concept of *abstract drug* may affect significantly the cost related to drugs. An abstract drug has the following distinguishing features (pursuant to Italian legislation, DL n.95/2012):

a) *Active ingredient*: the active constituent of the drug. FIDCARE includes more than 1.100 active ingredients;
b) *Dosage form* (and its unit of measure) *and concentration* (and its unit of measure): e.g., *8% 100ML; 5 ml 400 UI/ml*.
c) *Pharmaceutical form*: the physical characteristics of the combination of active substance and excipients (non-active ingredients) forming a medicinal product (*tablet, liquid, capsule, gel, cream, sprays*, etc.). FIDCARE includes more than 150 pharmaceutical forms.

From a conceptual point of view, an abstract drug includes all information required for a physician order entry, i.e., a physician may insert a therapy using only abstract drugs. Of course, FIDCARE allows for commercial drugs selection if required. FIDCARE includes a list of about 2.500 abstract drugs and 3.200 commercial drugs. The association between abstract drugs and commercial drugs is one-to-many, that is, an abstract drug contains links to more than one commercial drug (having its active ingredient, dosage and pharmaceutical form) and a commercial drug is related to one abstract drug. Two commercial drugs are considered *equivalent* if they links the same abstract drugs. Under this assumption, before the administration, each abstract drug in a therapy can be substituted with one of the commercial drugs linked to it and FIDCARE allows a set of configurable rules with increasing degree of automation to do this. Given an abstract drug, the system can:

1) Require the explicit manual selection of the commercial drugs;
2) Choose the commercial drug having some (configurable) properties, for instance: bigger stocks, stocks as close as possible or any other rule. In this case, FIDCARE requires physician's confirmation to continue;
3) Same as previous one without confirmation.

The introduction of abstract drugs leads to a better drugs management because it allows a *separation of functions*. The physician can select an abstract drug without worrying about the policy on drugs stocks. Please, note that it is also possible to replace a commercial drug with an equivalent one. For instance, during the administration a nurse discovers that a drug package is empty. To complete the therapy, an equivalent commercial drug is needed and FIDCARE allows for the substitution after physician confirmation.

Finally, FIDCARE can automatically extract abstract drugs from a commercial drugs list. It analyses each commercial drug and extracts the abstract drug (if it does not exist) and creates the link between them. There are a lot of commercial drugs databases that FIDCARE can connect with, e.g., *Farmadati Italia s.r.l.* (Farmadati.it).

B. Chemotherapeutic Medicinal Management

The chemotherapeutic medicinals are among the most expensive medicinal products and their effective management can affect costs in a considerable way. From a point of view a little more formal, such medicinal can be seen as non-renewable resources that should be allocated to patients. Very often, such products may be used within a relatively short time-frame once the foil sachet is opened. The inefficiencies derive therefore from the non-use of products before their expiration. The optimization problem consists in the optimal planning of the therapy of the patients in order to minimize the non-use of the resources. The solution is a scheduling of therapy that also takes into

 ISBN: 978-1-61208-675-0

account some constraints. Several constraints are: time constraints on therapies; patients preferences (days, times, etc.), the number of chairs available for patients, staff shifts, etc. This optimization problem falls into a family of problems very well studied in the scientific literature and FIDCARE implements a genetic algorithm specifically developed.

C. *Stocks management and usage product control*

Stocks management and therapies management are processes strictly correlated. As mentioned above, the abstract drug represents a separation element among them and the tight control over therapies scheduling provided by FIDCARE allows for a reduction of the stocks of the departments and of the warehouse. Furthermore, FIDCARE provides an Enterprise Data Warehouse module for reporting and data analysis. FIDCARE exposes a set of pre-set reports but users who are familiar with data Warehouse tools can easily create their own reports. Reports allow analysing the consumption of drugs by department, by period, by pathology, Figure 4. Based on these data, FIDCARE provides also a number of features for automatic reordering of stocks. The cost of therapies is inclusive of a number of cost items: drugs, equipment, staff, structure, etc. The report on the use of medications and medical devices also includes non-use due to: expiration date, breakage and damage, rejection by the patient, loss, etc. Finally, FIDCARE is designed to integrate with third-party stock management systems.

It is important to note that FIDCARE provides *actual* data on the consumption of drugs and devices. Otherwise, these data must be *estimated* using specific methodologies, such as Activity Based costing (ABC) or must be collected manually from paper documents. In the first case, it is inaccurate data while in the second case a substantial effort is required.

VI. COMPARISON WITH COMPETING SYSTEMS

This section describes a brief comparison with competing system having similar features. From an in-depth market analysis, the main competitors of FID-MED, on the Italian territory, are the computerized medical carts of the companies SPID S.p.A., IPSA s.r.l. and Max Medical Group s.r.l., three companies located in the North of Italy.

The cart of SPID S.p.A. allows the computerized management of the process of administering the drugs in the department. The system is the result of the combination of a computerized drugs trolley and a software for the prescription/administration of pharmacological therapies, integrated with an identification system.

The identification system, based on barcode or RFID technology, allows to identify the individual operator, the patient and the drug to be administered. Unlike FIDRUN, the cart of SPID unlocks the single drawer on operator's command. FIDRUN unlocks drawers automatically as the clinical processes require even if a drawer can be also unlocked on operator's request, if needed.

The *Smart Cart* of IPSA s.r.l, associated with a software for the management of therapies, allows the optimized management of all the phases of the pharmacotherapy process directly in patient bed and guarantees the traceability of the drugs and the activities of prescription and administration.

Smart Cart guides nurses in the distribution of therapies and allows automatic identification of operators, patients and medications by portable wireless barcode/RFID readers, finger-print readings, smart-cards. It is equipped with PC with Monitor Touch 10.1", medical keyboard, Wi-Fi, Bluetooth, long-life battery and a system of an access mechanism controlled to the contents of the drawers. Unlike FIDRUN, the Smart Cart does not allow multiple operating modes (patient, drugs and storage modes).

The automated cart of Max Medical Group s.r.l, named *Click*, uses a software for the management of prescription/administration. Click is equipped with an automatic mechanism of opening drawers and a control system that allows the nursing staff to have access to the only drawer containing the drug to be administered, while the other drawers remain locked. It is possible to configure the drawers according to the principle of assignment bed-drawer or alternatively active ingredient-drawer. FID-MED provides a more flexible assignment patient-drawer and a strong patient recognition mechanism.

FID-MED has some other interesting distinguishing features, among them: Voice User Interface, Gesture Interface, Adaptive User Interface, IoT Architecture and API.

A. *Voice User Interface*

Users interact with FIDCARE and FIDRUN through a voice in order to perform some tasks, e.g., initiate a new therapy, confirm an administration an automated, etc. Furthermore, FIDRUN gives acoustic feedbacks for a number of functionalities (e.g., correct execution, alerts, errors, etc.).

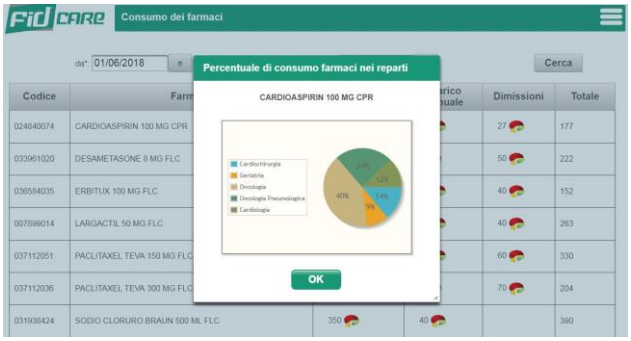

Figure 4. In the background, drugs consuption by period and by usage (therapies, manually unloaded, dismissal therapies). In the foreground, Cardioaspirin 100 mg consuption chart by departments.

B. *Gesture Interface*

Gesture recognition is achieved by FID-MED through small wearable three axis accelerometers for users. These sensors allow detection of a set of user gesture, such as move left/right and move top/down. The functionalities associated to that gesture (e.g., close, go to detail) can be customized.

C. *Adaptive User Interface*

FIDCARE adapts user interface in a light way. In particular, if the user must select a value from a list, it presents the preferred and most common previous choices of the user. For instance, this happens with drugs list, therapeutic protocols list, pathologies list.

D. *IoT Architecture and API*

FIDRUN implements a three levels IoT paradigm and, as previously described, it is deeply integrated into FID-MED but it is designed to be used in conjunction with third-party software as well. For this purpose, a set of Application Programming Interfaces (API) accessible via JSON messages on sockets or through Web Services is available. Through these APIs all capabilities of FIDRUN can be used in a programmatic way with any programming language (as FIDCARE do).

VII. CONCLUSION

This article presented FID-MED platform, a HIS composed by a Java web based application, named FIDCARE, and an especially designed integrated medical cart, called FIDRUN.

FID-MED is co-funded by Ministry of Economic Development START-Up 46/82 FIT DM 7/07/2009 (FID-MED 1.0) and Horizon 2020 – PON 2014/2020 and Campania Region Programma Operativo Regionale (POR) Fondo Europeo di Sviluppo Regionale (FESR) 2007/2013 (FID-MED 2.0). The article illustrates how the FID-MED platform may support the mitigation of the risk in healthcare activities leveraging on a tight integration between hardware and software technologies. Other than the complete control over all clinical processes (prescription, administering, stocks management, etc.), comparisons with competing system shows that FID-MED has some very interesting distinguishing features, such as voice and gesture user interface and easy integration with third party systems by design. FID-MED platform passed successfully several experimental usage trials to the hospital "Policlinico di Napoli". In this trial, FID-MED was integrated with the pre-existing acceptance module in the hospital from which it receives all information about hospitalized admissions. At present, the hospital in Pozzuoli uses FIDRUN in its urology department.

REFERENCES

[1] L. T. Kohn, J. M. Corrigan, and M. S. Donaldson "To Err Is Human: Building a Safer Health System." Washington, DC: National Academy Press, 1999.

[2] C. J. McDonald, M. Weiner, and S. L. Hui "Deaths due to medical errors are exaggerated in Institute of Medicine report". JAMA. 2000;284: pp. 93–95.

[3] L. L. Leape, et al. "The nature of adverse events in hospitalized patients: results from the Harvard Medical Practice Study II". N Engl J Med. 1991;324(6): pp. 377–384.

[4] A. X. Garg, et al. "Effects of computerized clinical decision support systems on practitioner performance and patient outcomes a systematic review". JAMA.2005;293(10): pp. 1223–1238. doi:10.1001/ jama. 293.10.1223, March 2005.

[5] J. H. Gurwitz, et al. "Incidence and preventability of adverse drug events in nursing homes." Am J Med. 2000;109(2): pp. 87–94.

[6] D. W. Bates, D. L. Boyle, M. B. Vander Vliet, J. Schneider, and L. L. Leape "Relationship between medication errors and adverse drug events." J Gen Intern Med. 1995;10(4): pp. 199–205.

[7] L. L. Leape, et al. "Systems analysis of adverse drug events." ADE Prevention Study Group. JAMA. 1995;274(1): pp. 35–43.

[8] Bruskin-Goldring Research. (1999, February). B-D.id and CAP Today Co-Sponsor Survey Among Hospital Executives to Determine Awareness of Medication Administration and Specimen Collection Errors, from http://www.bd.com/contentmanager/b_article.asp?Item_ID=21202&ContentType_ID=1&BusinessCode=20001&d=&s=press&dTitle=Press&dc=Worldwide&dcTitle=Worldwide. Rerieved: August, 2018

[9] nsis.salute.gov.it. Access date: August, 2018

 ISBN: 978-1-61208-675-0