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Telematics Integrated System to Perform Drugs Prescription and Administration Reducing Adverse Drug Events

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***Abstract* — In this paper we present PHARMA 2.0 a telematics integrated system aimed at reducing Adverse Drug Events (ADEs) in the phases of drug prescription, transcription, distribution and administration. The proposed system is grounded on three sub-systems: a CPOE (Computerized Prescription Order Entry), an RFID-based drug container and dispenser and a middleware system. The visualization and management of prescription and administration data are handled through a web application designed to comply with international usability regulation.**

I. Introduction

In this paper we focus on clinical risk management related to Adverse Drug Events (ADEs) in hospitals, a problem highlighted by many statistics collected by national and international studies. ADEs cause many human losses (150,000-330,000/year in USA) as well as significant costs (40 billion dollars/year) [1] [2]; errors percentage on ADEs are summarized in Fig. 1. Moreover, the British Department of Health reports that in National Health Service hospitals alone ADEs in which harm is caused in patients occur in around 10% of admissions – or at a rate in excess of 850,000/year – and cost the service an estimate 2 billion pounds/year [3]. A more recent study states that nearly 100,000 individuals per year in the US die of preventable medical errors [4].

There is a wide interest about this topic by the side of institutions. For example, the British Department of Health recommends the wider use of electronic prescribing to reduce the risk of medication errors [5], and the Italian Health Ministry in 2003 constituted a Technical Risk Reduction Committee that produced several recommendations [6].

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The increasing process automation, allowing a risk reduction, is sometimes achieved using intelligent medical cabinets and carts, software and electronic medical records. A systematic review [7] led in 2008 indicates that electronic prescribing seems to be a useful intervention for reducing the risk of medication errors and ADEs. In addition there is an especially good evidence for a positive effect of electronic prescribing offering advanced decision support functionality in hospitals settings.

Considering this scenario, it is the authors' opinion that ADEs reduction could be improved adopting computerized solutions supporting the whole medical process, from the drug prescription to the drug administration phases.

The proposed system, named PHARMA 2.0, allows risks reduction related to ADEs. This is mainly achieved through two components:

- a digital Integrated Therapeutic Chart (Italian acronym: STU, Scheda Terapeutica Unica) which extends and implements the specifications published by the Risk Management Group of Tuscany Region [8];
- an intelligent drug dispenser, called Drug-Tin [9], based on RFID technology.

The former is aimed at reducing the prescription and transcription risks while the latter is designed to reduce risks related to medication distribution and administration errors. PHARMA 2.0 has been implemented by exploiting collaboration and data sharing capabilities provided by the middleware system *InterDataNet* (IDN) [13]. Thanks to IDN data produced by the two components are reusable and granular so that they can be easily cross-checked to detect incongruities and dangerous interactions in order to prevent potentially harmful events. IDN tracks relevant data, thus

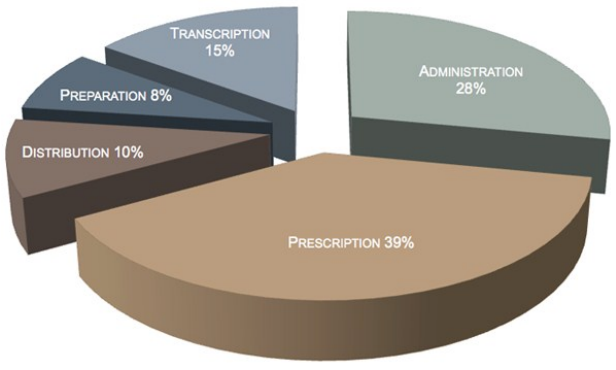

Figure 1. ADEs percentage from [1] [2].

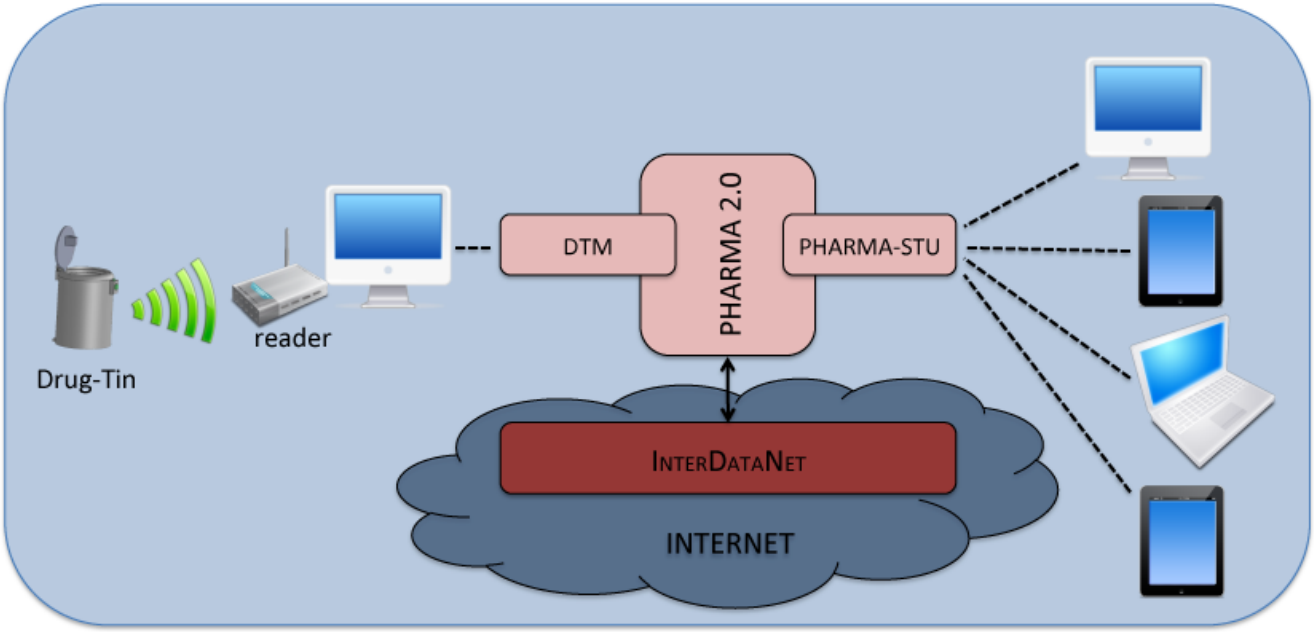

Figure 2. PHARMA 2.0 system architecture.

allowing further data analysis for ADEs investigations.

II. System Design

PHARMA 2.0 system is composed of hardware and software elements as shown in Fig. 2. Interaction among internal components and with external systems is compliant with the REST (Representational State Transfer) architectural style; the system leverages on HTTP protocol and resources are identified by HTTP URIs (see later in this section). The graphical user interface (GUI) is illustrated in Fig. 3.

PHARMA 2.0 uses the purposely designed Drug-Tin device, an RFID-based drugs dispenser relying on passive RFID technology to guarantee the correct association between patient and drugs and to mechanically prevent wrong medication administrations. The device is extensively described in [9].

In the following section we will describe the software modules of the proposed PHARMA 2.0 system.

A. *Drug-Tin Manager*

The Drug-Tin Manager (DTM) is part of PHARMA 2.0 and enables the drugs secure distribution in hospital wards using electronic Drug-Tin devices (see above).

The GUI for the user interaction with the passive RFID tags coupled with the device is shown in Fig. 4. These tags are contactless and are compliant to the ISO/IEC 15693 protocol. The disposable memory is 108 bytes and spreads over 28 blocks of 4 bytes each. The internal memory is organized to store information at specific positions to be properly displayed on the Drug-Tin. For the information storage, the application accesses a database populated via Web Service, which is part of Drug-Tin Manager application as well. In addition, in order to enter data into the device, the system manages counter values set into the Drug-Tin memory; such values are used to verify if the device has been opened and if the contained drugs have been picked by the patient they were assigned to, checking at the same time if other people have tried to access the system as well. For the development of the read/write tags ISO 15693 module a commercially available *HID Omnikey CardMan 5321* device, and the JAVA library *smartcardio* for communicating with the *ISO/IEC 7816-4 APDUs* protocol has been used.

B. *PHARMA-STU*

PHARMA-STU module is grounded on the Integrated Therapeutic Chart (ITC) designed by the Risk Management Group of Tuscany Region [8]. In its origin, the ITC was created, on paper format, with the main aim of reducing adverse events that may occur during the process of prescribing, administering and monitoring drugs. PHARMA-STU is an upgrade of PHARMA ITC described in [10], to handle administration errors and monitor patient treatments. PHARMA-STU implements many Computerised Prescription Order Entry (CPOE) features. Indeed, it supports medication ordering process features providing checks of drug-drug interactions, drug-allergy contraindications and checks of prescriptions concerning the patients' therapies working in synergy with the DTM.

PHARMA-STU (Fig. 5), is designed for healthcare personnel and acts as a tool to ensure the patients' security by promoting multidisciplinary collaboration. Using PHARMA-STU it is possible to identify responsibilities in the prescription and administration therapy stages by applying different technologies, such as digital signature and accountability protocols [11] [12], to handle granular information. PHARMA-STU works also on distributed information pieces to avoid dangerous information duplication. Health care staff will then be able to correctly

identify the prescriber and the prescribed therapy with the correct administration procedure. Besides the clinical risk management, PHARMA-STU innovative contribution is enriched by the ability to correlate data from Drug-Tin Manager with data related to the therapies for a complete check of the whole prescription/administration process. This feature requires a data interoperability support performed by the IDN framework (see below).

C. *InterDataNet*

InterDataNet (IDN) infrastructure [13] enables distributed users to collaborate on information elements belonging to a global area of distributed data. Users can interact with data adopting the metaphor of "document" (IDN-Document). Each represented resource (namely IDN-Node) is identified by an HTTP URI and its representation is expressed in XML format (hereafter IDN/XML format). An IDN/XML representation must be a well formed XML entity compliant with a specific XML-Schema. An IDN-Document is a graph $G = (V, E)$ where V is the set of vertices and E is the set of edges. The elements of V and E are the IDN-Nodes and the relations between IDN-Nodes, respectively. IDN supports different types of relations between IDN-Nodes such as containment, reference, and so on. Let D be an IDN-Document modeled as a graph. Hence the topology of D expresses the information model (IDN-IM) used to represent the document itself. In compliance with the REST architectural style, the resource interaction is URI-oriented.

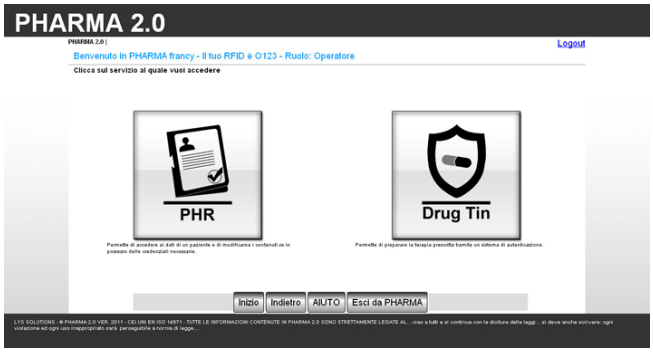

Figure 3. PHARMA 2.0 main page.

Figure 4. Drug-Tin Manager.

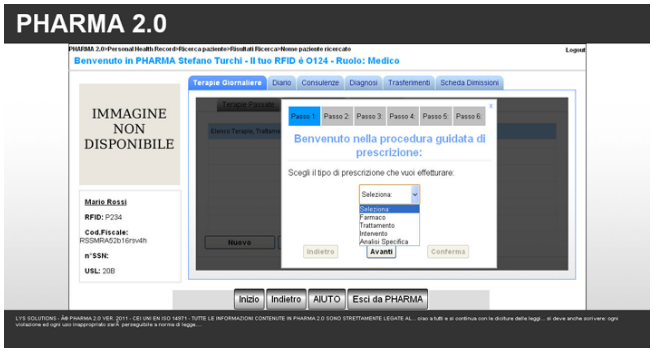

Figure 5. PHARMA-STU.

III. Drugs Prescription and Administration Process

According to what described in [9], the process begins with the patient admission phase. At the arrival in the ward, a

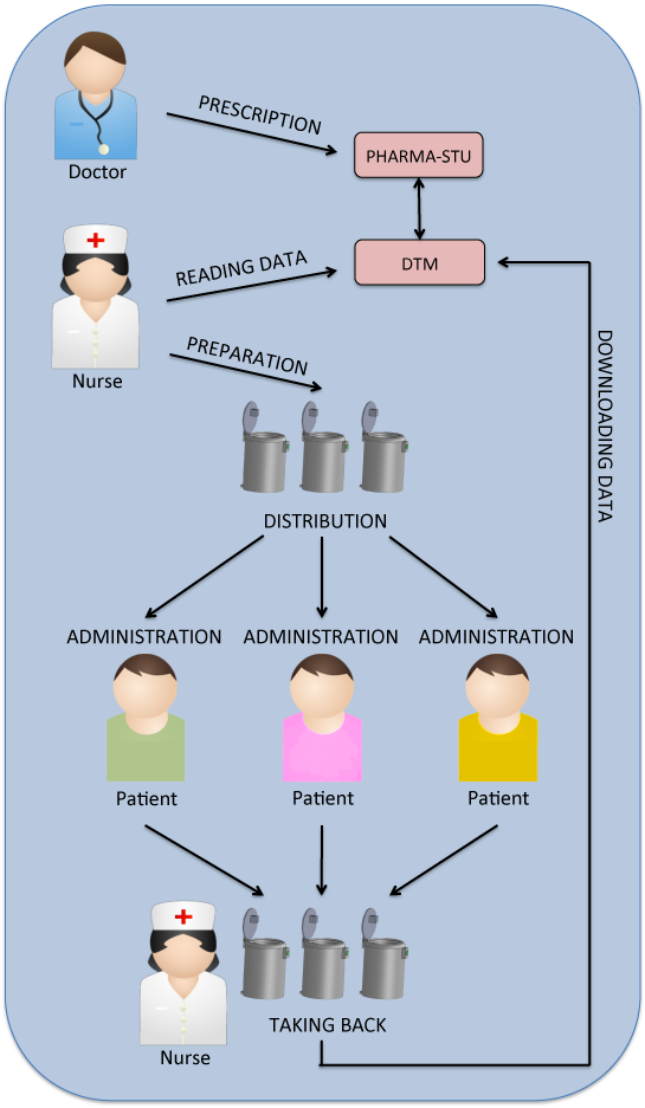

Figure 6. Prescription/Administration cycle.

disposable ISO 15693 compliant passive RFID wristband is associated to the patient. In this step, the system software will record on it (using a specific memory block) a unique identifier automatically generated.

Then (Fig. 6), authorized doctor will be able to prescribe the necessary medication to the patient using PHARMA-STU. The doctor can enter the appropriate treatments in the patient personal medical record via the GUI as shown in Fig. 5. It will then be possible for the doctor to carry out the prescribed procedure, confirming the operation by applying a digital signature.

The system will automatically create the appropriate messages, by means of an internal notification service provided by the IDN middleware. The dispensers' list to be prepared by Drug-Tin Manager (as shown in [9]) will be available for nurses and authorized health care staff, through a GUI compliant with the revised regulations concerning medical devices. In summary, health care staff will act to program the Drug-Tins and then prepare them with previously prescribed drugs.

Now the Drug-Tin containers/dispensers are ready to be distributed to patients and only the right recipient is able to open it and take his medications. Each event is recorded by the device [9]. To enforce the patient protection, the system traces every event related to a Drug-Tin device. This procedure allows the system to cross-check the prescription data with the actual workflow to detect dangerous interactions (unauthorized opening attempts or proper patient openings, to mention few).

IV. DISCUSSION

The proposed system is aimed to reduce ADEs due to errors in medication administration. This is obtained by also affecting the steps of prescription, transcription and preparation.

Although we still do not have clinical results coming from field tests, we can state that the synergy between the presented modules could significantly reduce the overall ADEs in a hospital ward at least as seen in similar solutions [5]. The Patient Data Management System PHARMA-STU can combine the errors-reduction provided by the paper version of the Integrated Therapeutic Chart with the use of a codified medication process (drugs, diseases, patient identifiers, etc.). The digital signature of every single modification in the chart provides a stronger assurance of knowledge of the process together with a full legal force. The Drug-Tin system can entail a major improvement to the safeness of the administration step, by preventing wrong administrations as well as by monitoring the preparation phase. By logging the number of granted/denied openings, the device could feed a Hospital Risk Management System [14], providing the risk manager with some valuable data to assess the quality of the medication service. If integrated in a CEP (Complex Event Processing) system [15] the proposed device could significantly increase the patient's safety as well as the knowledge of the process by the hospital executives.

Eventually, the IDN infrastructure gives us the capability to address every single grain of information, enabling a collaboration oriented paradigm of involved personnel. The IDN infrastructure supports and enforces coherence avoiding useless and dangerous data redundancy by design. Further investigation must be performed in a clinical ward, in order to assess the impact of the system on risk reduction and to evaluate the usability of the single components.

The impact on the existing workflow needs also to be deeply studied, since it can vary greatly depending on the initial endowment of ICT tools and devices.

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