mHealth for therapeutic adherence

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Abstract— **Smartphone, NFCs and web technologies are used in this work to help patients in carrying out their own therapies. The implemented system ensures the identification of the drugs through NFC and it allows remote assistance from healthcare staff and family members.**

I. Introduction

Therapeutic adherence is the measure by which a patient follows the doctor's directions and recommendations. According to the report "Adherence to long-term therapies: evidence for action" [1] issued in 2003 by the World Health Organization (WHO), only 50% of patients suffering from chronic diseases correctly follow the prescribed therapies in developed countries, a percentage that drops in the other countries.

Even the Italian Medicines Agency (AIFA), reveals worrying data: in 2013 only 55.1% of patients suffering from hypertension took continuous antihypertensive treatment [2]; almost 50% of patients treated with antidepressants stopped treatment in the first three months of therapy and over 70% in the first 6 months; in 2012 the percentage of patients adherent to antidiabetic treatments was 62.1%, while for asthma and chronic obstructive pulmonary was only 14.3% (data obtained from observational studies and from the administrative databases of the ASL). In addition to being a danger to patients, non-observance of care is a significant economic burden on the health system coffers. Many studies have been carried out in recent years to analyze the problem and propose solutions.

Often, the incorrect medication intake is not intentional. As highlighted in [3], the drugs themselves can mislead the patient: the same drug can occur in many similar packages but with different dosages and modes of administration, or completely different drugs can have almost identical name or packaging. All this shows that the problem relating to therapeutic adherence includes not only the missed drug intake, but, even more dangerously, the error in therapy, from the dosage and method of administration to the incorrect identification of the drug to take.

The main cause, remains distraction; especially in long-term therapies, repeating the same gestures several times a day reduces due attention, often leaving the patient with the doubt of having taken or not the drug and consequently with two possible choices, both potentially dangerous: skipping the dose or doubling it. The frequency of error increases significantly in visually impaired people, or elderly people: AIFA has established a special study group, the "Geriatrics Working Group" (GWG), whose investigation [4] reveals that 50% of over 65s take between 5 and 9 drugs a day and 11% more than 10 drugs, resulting in a drastic decline in adherence to treatment.

This work aims to remedy these problems operating in the context of the Ambient Assisted Living (AAL), with the attention paid especially towards the elderly and people with disabilities. To this aim, the technologies we used are Smartphone and Near Field Communication (NFC). High connectivity capacity, increasing performances and extremely wide diffusion make smartphones the basis of mHealth (mobile health), that is the use of mobile devices in medicine and in public health.

Many are the applications available for smartphones addressed to the therapeutic adherence, but few of them have features that go beyond the functions of electronic diary. They offer a good monitoring of drugs intakes schedule, sometimes offering also storing the measurements of vital parameters, such as heart rate, arterial pressure and glycemia; some offer also the possibility to easily share such information, for example to send it to the doctor. Advanced features, such as support for web services, access to drug databases, saving data to the cloud, integrated ordering services linked to pharmacies, can also be found. Finally, the use of automatic verification systems of the identity of drugs, is almost totally absent, entrusted at most to the presence of images with which the user can make a visual comparison. A brief list of commercial apps is the following:

- Whatpills [5], one of the few based on the NFC technology.
- MediSafe [6], which has the ability to synchronize data in real time with other devices, such as family members, in order to allow them to assist the user and be notified in case of intake omission, and it is also characterized by a great care in the realization of the interface in order to simplify understanding and use.
- myHealthbox [7] instead is a service accessible via the web and through mobile applications, which does not offer intake scheduling, but creates a huge international database of information on drugs and

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more generally on health products, allowing not only to have all drug data at hand, but also by providing real-time safety warnings, for example in the case of finding new side effects or withdrawing lots from the market unsafe.

- Med Helper [8], Pill Reminder [9], are free apps which are almost exclusively limited to the scheduling and notification of appointments, with good results from the point of view of clarity and simplicity of use;
- Pill Manager [10] allows to manage the ordering of medicines to registered pharmacies;
- Dosecast [11] offers a flexible scheduling of intakes, allows to access to a drug database.

Researches in the AAL area have proposed solutions to the problem of poor therapeutic adherence, or more generally, they have highlighted the potential of mobile health and NFC. Dohr et al. in [12] analyze how the combination of NFC technology together with active remote monitoring can bring benefits in the implementation of an effective system of AAL. In [13] Engel et al. explored how mobile devices and NFC can be used in the implementation of medical assistance systems, suggesting the decentralization of functions and information with the aim both of involving the patient more in his own care, also improving the self-sufficiency. Strong emphasis is placed on the need to create applications with a clear, immediate and simple to use interface and flow. The work in [14] by Morak et al. is based on a so-called smart blister, a typical blister for medicines to which an electronic circuitry has been added, capable of detecting, storing and then transmitting via NFC the instant in which a pill is extracted. The system presented in [15] by M. Vergara et al., also based on NFC technology, is addressed to enable patients getting prescriptions from home: tables with explanatory images are provided, approaching the phone to the NFC tag equipped image, activates the related function.

In [16], Tsuruoka et al. present a patient-pharmacist communication system enabling pharmacists to remotely monitor the prescription drug compliance of home-bound patients. The studies presented in [17]–[19] focus on the construction of systems based on centralized databases, with detailed information on medicinal products as well as on the clinical situation of patients, and on the implementation of applications for consulting them in order to avoid complications due to adverse drug reactions, due to allergies and intolerances or negative interactions between multiple therapies carried out simultaneously.

The projects carried out in [20]–[22], addressed to visually impaired people, are aimed to develop "talking" packs of drugs, using identification through NFC, to convey the appropriate information, such as name of the drug, expiry date, dosage and timing of administration, through audio messages generated by the device's voice synthesizer.

The aim of the present work, novel with respect to the state of the art, is to create a user assistance system that can respond to the previously evidenced problems, in particular: it reminds for drug intakes (or more generally for therapeutic adherence); it verifies the correctness of the drug intake; it is a centralized system of the patient's therapeutic condition and provides a complete clinical review of ongoing care. It allows external monitoring of the state of adherence to the therapies, so as to be able to intervene in case of need. Furthermore, the system must be as user-friendly, convenient and easy to use as possible, taking into due consideration the fact that it is aimed above all at elderly people. The idea of inserting an NFC in the drug box has been presented by the authors in [23]. The present work shows the development of the complete system with new features and with the development of the central database and the interaction between user and assistants.

Section 2 presents the assistance system with details on user client, assistant client and administration interface. Section 3 draws the conclusions.

II. System Archiecture

From the analysis of the state of the art, we defined the key guidelines that the system we propose must follow:

- Decentralization of assistance functions: providing the user with the means and systems to be able to carry out autonomously and self-sufficiently his life at home environment.
- mHealth: the maintenance of a contact with the assistance staff through mobile communication devices guarantees the patient autonomy and awareness of being followed, giving him greater security. Through the use of dedicated web services, the assistance staff can carry out active monitoring and also a direct intervention in the management of the patient's therapeutic regime.
- Centralization of information: the implementation of a web service allows the creation of a centralized information of the patient's clinical situation, available anytime and anywhere. This can avoid harmful situations due to its fragmentation, as episodes of adverse drug reactions due to intolerances or allergies or negative interactions between multiple therapies carried out simultaneously.
- Simplicity of use: the simplicity of use must be a fundamental point of its development, especially considering that it is mainly addressed to elderly people. This translates into the care of both the graphic interface, both of the flow of use of the application. However, this simplification must not be achieved by hiding the information from the user, but organizing it in such a way as to present it only when necessary.
- Relevance of NFC technology: the immediacy in the use of NFC technology is one of the main factors that can help to realize the simplicity of use desired in the previous point. As already pointed out, the ability to automate device operations based on the content read allows you to create new ways to interact with the application. The NFC technology, thus, should be a constituent part of the interaction interface.

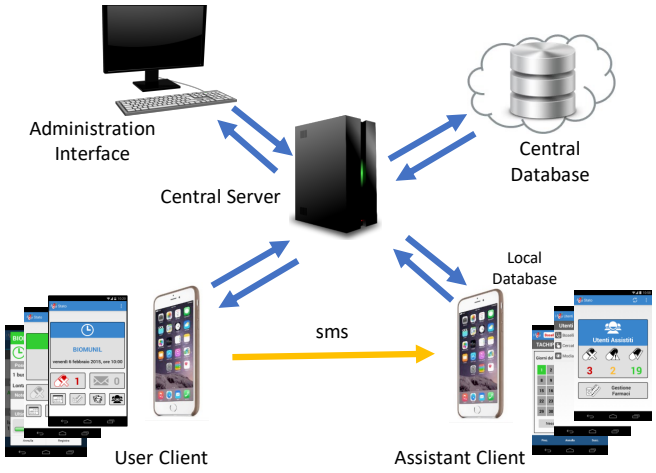

Figure 1. Architecture of the assistance system.

Keeping in mind these general guidelines, we created a system that can provide new functionality without changing the current doctor-pharmacist-patient relationships. No ad hoc device and no interference with the usual methods of supplying medicines must be introduced; the only change required is to insert NFC labels on the packages. Considering that the application is dedicated to people with a high number of prescriptions and long-term care, its use must be reduced to a few simple operations; a great contribution in this sense is given by the use of the NFC.

To reduce the complexity of the patient involvement, the only operation required to the patient is to record the successful intake of a drug. The phase of inserting data about prescriptions, that in the other apps often constitutes the last stumbling block in the simplification process, must therefore be entrusted to who assists the patient. Furthermore, the monitoring activity by the assistants will have to be as least invasive as possible.

The structure of the assistance system implemented is represented in Figure 1. The system consists of:

- an Android app, called "user client", intended for the person who needs assistance; it provides the reminder functions of drug intakes, the safe identification of drugs by reading the NFC tags affixed on the packages and finally the recording and communication to a central server of the events of successful or missed intake;
- a second Android application, called "assistant client", intended for assistance staff (doctors, family members, ...), through which it is possible to remotely manage the patient's medical prescriptions, interacting with the related user clients, and at the same time supervising the continuation of the therapy;
- a central server, the primary depository of information, with the aim of making it available and thus guaranteeing the assistance functions performed by the Android applications;
- an administration interface created on a web platform, through which the user accounts of the system can be managed.

Each assistant can follow multiple users through its application and to each user can be associated multiple assistants: a register keeps track of the actions performed by each of them in order to be able to go back to the author. In addition, assistants can take on different roles that are distinguished by the degree of operation: a role dedicated to medical personnel, and a role designed for the patient's family, which allows to follow the correct continuation of therapy without being able to modify it.

The system has been tested and verified by the developers. Furthermore, it has been applied in few real situations with some middle age users accustomed in the use of smartphone and some elderly people not used in app and smartphone.

III. Conclusions

The entire system has been developed for the implementation of following services: drug identification, recruitment reminders, information centralization and remote monitoring. The system does not require any disruption to the habits of the subjects involved and is immediately usable, although exclusively through NFC technology.

The target that the monitoring activity is the least invasive possible and transparent to the user has been realized through the automatic sharing of data and not being present any form of direct interaction between the assistant and user. Perhaps in this way the application is too aseptic and without a human contact, but it must be underlined that the system must be simply complement and support to the doctor-patient relationship.

The graphical interface and the flow of use have been developed following principles of clarity and simplicity, made up of elderly people, often not accustomed to the world of information and technology.

However, a first testing phase and the different hours of use during the development phase have already confirmed at least the potential of the features on which the system is based, highlighting the importance and effectiveness.

The creation of a central repository of information has made it possible to share among the various subjects, allowing to avoid that fragmentation of knowledge of the therapeutic situation of the patient, potentially harmful, and at the same time to monitor the effective compliance of the therapies.

The increasingly widespread use of mobile devices compatible with NFC technology and the simplicity and immediacy of its use were the reasons that led to focus on NFC as a fundamental mechanism in the use of the application.

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