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# DigiSpenser – A GSM-Based Drug Management and Compliance Monitoring System

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*Abstract*—**Approximately one-third of all independently living elderly people are not compliant with their drug therapy. This lack of medication management results either in undermedication or overmedication, causing unnecessary and often serious health risks. This problem will worsen in the future with the change of demographics and cost constraints in the health sector. Therefore there is a need for (cost-) effective reliable approaches to compliance monitoring.**

**To date numerous care schemes, retrospective assessment procedures and compliance supports tools have been introduced, but none of them has fully solved the problem of medication non-compliance yet. This paper will address some of the factors that need to be considered when designing such systems and will showcase DigiSpenser, a recently developed compliance monitoring and drug management system.**

## I. Introduction

MEDICATION-related problems experienced by elderly, independently living individuals occur at all stages of medication management. Surveys indicate that the most problematic stage is that of administering drugs [1]-[2]. Many elderly people take four or more prescription drugs daily, which must be taken on time to guarantee the desired therapeutic effect. Non-compliance with a drug therapy happens in the majority of cases accidentally; the patient simply forgets to take the prescription drug or cannot remember whether he/she took it or not. This results in either undermedication or overmedication, which can have serious side effects on the health of the individual, leading to significant health impairments, organ damage and even premature death [3]. The economic cost of non-compliance is enormous [10].

Another side-effect of non-compliance is the improper disposal of unused drugs. It has been shown that there is already significant ground water pollution in many populated areas due to dumped medicines, since water treatment plants are not able to purify the sewage [4]-[5].

Traditional methods of monitoring the patient's adherence to a drug therapy have been very limited and consisted mainly of the introduction of simple drug dispensers and the involvement of an assessor (e.g. a home care or community care service provider), who checks on a regular basis whether a patient has taken all the prescription drugs.

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Such labor-intensive services are inefficient (because they are retrospective only) and will become more difficult to provide with the increasing aging of the population on the one hand and with ever increasing cost constraints in the health sector on the other. As a result various compliance monitoring tools (CMT) have been introduced in recent years. Their range extends from simple timers to intelligent pill bottles with GSM interface [6], [7] to traceable magnetic or electronic pills [8]. None of them seems to be a global, widely deployed commercial success.

This paper is structured as follow: In section II some of the characteristics and difficulties of compliance monitoring are being addressed, which in the authors' opinion hinder the wide and successful deployment of CMTs to date. Section III will introduce DigiSpenser, a recently developed CMT prototype that addresses most of these issues. A brief assessment and conclusion in section IV will conclude this paper.

## II. Design Aspects of a CMT

Drug distribution, drug handling and compliance monitoring are very cultural- and stakeholder-specific tasks. These tasks need to be sufficiently addressed by a CMT and include the following:

### A. *Blister-Pack or Bottle?*

There are 2 predominant methods for medication packaging, bottle and blister pack. While bottles are still widely used in North America, they are completely superseded by blister packs in Europe. Blister packs have the advantage of providing product protection against moisture and gas (resulting in a longer shelf life), while being tamper-resistant. Many Irish and UK based pharmacies use disposable blister packs with 7 by 4 compartments to repackage prescription drugs for their elderly customers in order to simplify the intake procedure. Since user acceptance is linked to recognition value, a CMT must be based on the predominant packaging method.

### B. *Identify the Stakeholders*

CMTs' end-users are the Elderly or chronically sick, but other stakeholders are involved in medication management as well. For example, in Ireland there are strong and long-term connections between the pharmacist, the GP, health care services and the broader community on the one side

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and the patient on the other. A CMT design must identify, embrace and incorporate all stakeholder groups in order to fulfill expectations.

### *C. User Requirements and Integration Issues*

Our experience has shown that rapid prototyping techniques are extremely helpful to model and evaluate system components dynamically in collaboration with stakeholders. Issues that were addressed and successfully resolved included the following:

- While many pharmacists have an interest in supporting CMTs (at the very least because of the potential repeat business), their handling with such a system (which typically includes its setup and the handling of medication) must comply with their own workflow and work practices. A complicated medication reminder that requires multiple cumbersome programming steps or requires a (non-existent) broadband Internet connection will not work for them.
- Patients require systems that are lifestyle-compatible (e.g. that are mobile, while protecting the privacy of the patient) and easy to use.
- Community-based support staff needs to be kept in the loop in an appropriate way, e.g. notified about medication errors by their customers.

### *D. Real-Time Monitoring and Reporting*

A compliance monitoring tool should be able to report a medication error (to other stakeholders) without delay. A retrospective assessment of compliance monitoring data as done by various systems [9] has no educational effect for the patient as it relates to medication errors that might have occurred days ago. Serious medication errors (e.g. overdosing) must also be dealt with straight away, for example by community-based support mechanisms (like neighbors, extended family members and public nurses).
Real-Time monitoring and mobility implies a widely accessible broadcast network. Since Wi-Fi-based setups work only in the vicinity of an access point, data communication via GSM-based communication is the only alternative to date.

### *E. Accountability*

Medication errors as well as handling errors must be properly reported and documented. This is needed to protect all stakeholders from legal repercussions and to prevent the repetition of such errors.

## III. DIGISPENSER

DigiSpenser is a distributed drug management and compliance monitoring system based on a 3-tier architecture (see Figure 1). Data communication between neighboring tiers is done via GSM. Data transport is based on SMS, which is archaic, but has various advantages:

1. It is widely available and has almost full geographical coverage (in contrast to other GSM data services).
2. Telecom providers use a store and forward mechanism for SMS, which reduces the complexity of all tiers.
3. SMS originators can be identified by their SIM (e.g. mobile number).
4. The system components are not open to (Internet) attacks.
5. SMS can be used to distribute plaintext messages to stakeholders as well as for system event notifications.

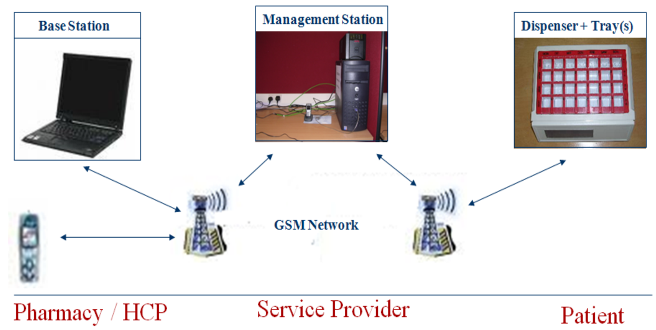


Figure 1: DigiSpenser: System Architecture

DigiSpenser supports four types of stakeholders:

- The elderly or chronically sick person as the end-user. He/she uses a computer-controlled and remotely programmable dispenser that reminds him/her of the next drug intake and that monitors and reports irregularities and non-compliance.
- The pharmacist as the medication manager. He uses a base-station that allows him to remotely program dispensers.
- Healthcare providers that provide patient support. They are notified about medication errors by their customers via two different messaging services for office and mobile staff.
- Service providers who run the entire CMT infrastructure. They use a management station to manage the entire system and to log all activities/events.

SMS-based data protocols are used for the exchange and update of data and events between all stakeholders. In its current implementation the system uses a simple data encryption scheme based on a Vigenère cipher to increase security.

### *A. The Medication Tray*

The reusable tray is based on a conventional drug container with 7 by 4 individual compartments, containing patient medication for typically one week. Similar devices are also used for medication re-packaging as mentioned in section II. A. Each tray has a label with a unique identifier and contains an electronic tag (based on a serial EEPROM with a USB connector), which is read by the dispenser. Trays are tamper proof, as each compartment is covered by a transparent foil.

### *B. The Programmable Dispenser*

This portable, battery operated device (see Figure 2) is used by the end-user. It consists of a simple user interface (e.g. one key, a graphics display, a buzzer and a set of recessed lights) and a slot to insert a single medication tray. A build-in GSM interface allows remote programming and event notification to the management station. The dispenser notifies the patient about a pending medication intake and provides further intake-related information. Recessed red/green lights illuminate the compartment to be opened; its opening is recognised by the dispenser. The dispenser also provides user guidance (via the display and recessed red lights) if one ore more intakes have been missed.

Since the patient can slot in new containers into the dispenser, it can be used for a number of weeks without being reprogrammed. As every tray is electronically tagged and labeled for identification and verification purposes, the patient can use multiple containers in a specific order determined by the pharmacist.

The hardware itself is based on an 8-bit Atmel microcontroller and uses MicroC/OS-II, a microkernel-based real-time operating system. The rechargeable battery pack lasts for approximately 6 days.


Figure 2: Medication Tray, Dispenser and Display

### *C. The Base Station*

A pharmacist (or other medical professional) programs a dispenser remotely using the base station, which can be any computer with a USB interface (to connect to a GSM module) and a Java VM (to execute the base station application). This platform independence was deemed to be an important requirement for pharmacists. The application itself allows the user to (see also Figure 3):

- Choose a patient.
- Select one or more trays for this patient.
- For each tray (which lasts typically for a week) specify:
    - when, e.g. what week the tray is supposed to be used.
    - the intake pattern and intake-related information for all compartments.
    - non-compliance time constraints (e.g. when is an intake deemed late),
    - advice to a patient for such a situation (e.g. skip intake altogether).
    - (multiple) non compliance alarms, which are the result of one or more missed intakes at certain times over a period of time.
- Print labels with medication and intake related information that can be attached to the tray (this is a legal requirement).
- Finally program the patient's dispenser device remotely.

Because intake patterns do usually not change over time, entire tray settings can be reused for new trays, therefore reducing the programming effort to a couple of mouse clicks.

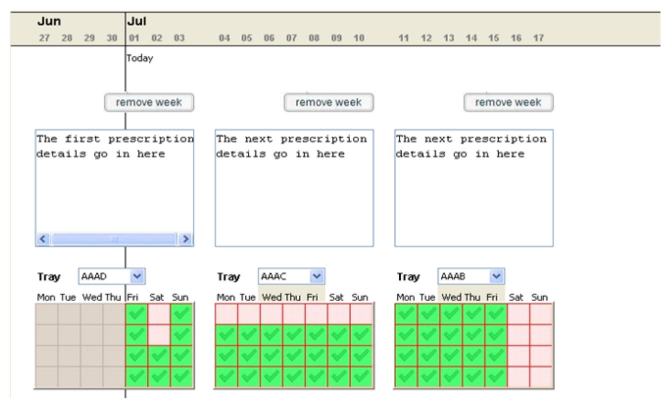


Figure 3: Base Station User Interface

### *D. The Management Station*

The management station is a central gateway between base stations and dispensers. Both accept messages only from the management station. It performs the following tasks:

1. It maintains and manages all associations between
    - the other stakeholders (e.g. what pharmacist / health-care provider is responsible for what patient).
    - patients and devices.
    - devices/base stations and their GSM connection details.
2. It verifies all incoming data and authenticates it before dispatching it to the destination(s).
3. It logs all network traffic in a database, therefore providing a paper trail of all events and activities.

*E. Deployment and Workflow*

Figure 4 shows the different steps in setting up the system. The outlined scenario is based on a patient who receives a (repeat) prescription from his GP. The dispenser is in the patient's home:

(1) The patient receives a prescription and presents it to the pharmacist.

(2) The pharmacist processes the prescription, fills and seals one or more trays as required. Finally the trays are handed over to the patient.

(3) The pharmacist programs remotely the patient's device specifying intake patterns, alarms etc. The information is passed on to the management station, where it is verified, logged and forwarded to the patient's device at home.

(4) The patient arrives home, where the now programmed dispenser requests the user to insert the first tray (as specified before). Once the tray id is verified the dispenser starts operating. Patients will also be notified when a new tray has to be inserted or if the wrong tray has been inserted.

(5) Late or forgotten intakes will be recognised by the dispenser and eventually cause the dispatch of an alarm event, which is received by the management station. It in turn will notify one or more support staff as configured by the service provider (6). Support staff is either notified via plaintext SMS sent to their mobile phones or through a messaging service that is part of the base station application, catering therefore for mobile and office-based staff.

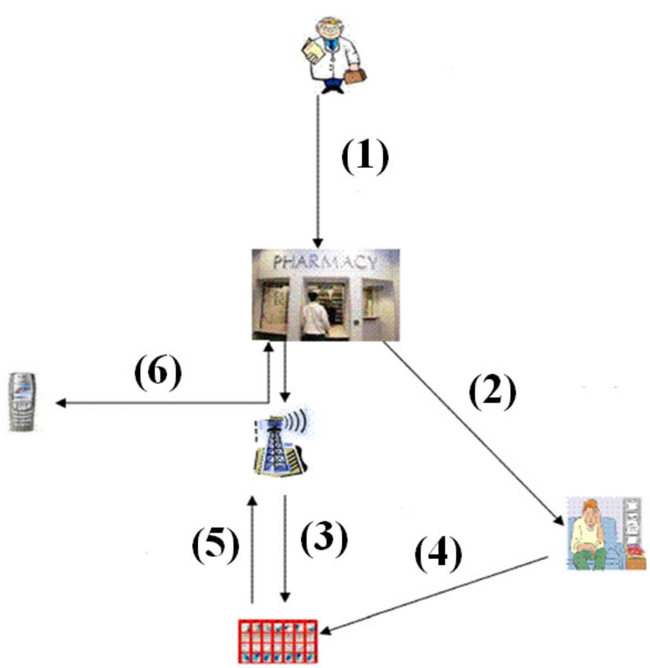


Figure 4: System Setup and Workflow

Dispensers can be reprogrammed via the base station at any time to accommodate changes in the drug therapy of a patient.

## IV. RESULTS & CONCLUSION

During a 3 months field test DigiSpenser was evaluated by a group of 15 individuals (e.g. pharmacists, patients and support staff). While the development team received very positive feedback regarding the overall stability, functionality, ease of use and ease of workflow integration, the main criticism related to the dispenser itself, e.g.:

1. The trays are difficult to seal and difficult to clean.
2. The dispenser is too heavy and bulky.
3. Users with reduced fine motor skills found it difficult to access the medication in the tray.
4. The dispenser's user interface could be simplified, while the screen is too small.
5. Despite its benefits some users questioned whether they could affort DigiSpenser.

The last issue also reflects the current status of this project. While all reported design issues can be easily sorted out, there are still open questions in relation to the commercialisation of DigiSpenser, e.g. who could act as a service provider (e.g. health care providers, health insurance companies, etc.), what business model could be applied and overall, who is going to pay how much to subscribe for such a service.

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