HEALTH-IDENTITY: Mobile services for consumers of medicines

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Abstract. New technologies for drug identification, traceability and mobile platforms make it possible to personalise the services provided to consumers of medicine. This paper presents the Health-Identity platform, a mobile application which gives consumers the assurance that the drug they have in their hands is a genuine product and can be consumed without risk according to their stored patient profile (allergies, health state, current medication, etc.).

Keywords. Medicine identification technologies, traceability, mobile platforms

Introduction

According to the WHO, 10% of all medicines sold are counterfeit [2]. Fortunately, this proportion does not correspond to what we see in Switzerland. This is not the case in other European countries such as the United Kingdom. Furthermore, many people self-medicate or take medicines which were prescribed some time ago. This may lead to drug interaction problems which specialists such as pharmacists cannot spot. Patients might therefore find it very useful to have a tool which certifies that the drug they have in their hands is genuine and that it does not present any risk according to their specified patient profile (allergies, medication taken/prescribed etc.). This is made possible by new technologies, exploiting drug identification, and by new personalised services made available on a mobile platform.

This article presents the Health-Identity platform [1], the vehicle for a business-to-consumer service offered to consumers of medicine, giving them information about the origin (known or unknown) of the drug and the dosage and compatibility with their patient profile. The *Pharmacie du Midi* at Sion (Switzerland) provided some realistic scenarios which can occur regularly in cases of self-medication. e-mediat[1] made available its Galdat database. This is the sole data source used in Health-Identity, because, in addition to

[1] http://www.e-mediat.ch/

containing the name and description of all drugs sold in Switzerland, Galdat also contains all the information about a drug's ingredients, interactions and other useful features. In addition, it is the database used by the majority of pharmacists in Switzerland.

1. The challenges of self-medication

Nowadays, patients are increasingly independent in their decisions regarding medication. Many factors explain this development, in particular the increase in the degree to which consumers are informed. A series of tools that enable patients to manage their health has appeared on the internet. Google Health[2] enables them to administer their "health account" through interaction with their computerised patient records which are kept by doctors, pharmacists and hospitals. At present, this project is largely aimed at healthcare providers in North America. Family History[3] complements this approach by adding the health profile of a patient's family.

As patients are independent, they may decide for themselves to purchase and take medication. It is therefore important that they have a tool which certifies that what they buy for themselves is genuine. This is why efforts to combat counterfeiting have increased considerably in the last few years. The WHO launched the IMPACT project (International Medical Products Anti-Counterfeiting Taskforce[4]) which draws together the players affected by this problem, including health authorities, manufacturers, wholesalers and pharmacists. These partners agreed that combating counterfeiting involves, firstly, the use of security packaging, and secondly, the traceability of each unit and its verification at the point of dispense. Initiatives have also emerged at regional level, for example in California[5] and in the European Union[6], and within the European pharmaceutical industry (EFPIA[7]). These initiatives all deal with the unit traceability of retail packs of drugs.

The technical aspect of combating counterfeiting is based on item serialisation, the items being selected by drug manufacturers because of their risk profile (risk to health, risk of being counterfeited etc.). The choice made in Europe is to secure the distribution chain within the wholesale trade (between manufacturers and wholesalers and between wholesalers and major clients) through intensive use of batch traceability. At dispensing level, a drug's authenticity is verified by checking its unique serial number, which is based on a Global Trade Item Number (GTIN) and a pseudo-random number.

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[2] http://www.google.com/health

[3] https://familyhistory.hhs.gov/

[4] http://www.who.int/impact/en/

[5] http://www.pharmacy.ca.gov/laws_regs/e_pedigree_laws_summary.pdf (22.5.2009)

[6] http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_12_2008/citizens_summary_counterfeiting.pdf

[7] http://www.efpia.org/Content/Default.asp?PageID=566

In 2008, a pilot study was carried out in Switzerland[8] to gain a practical understanding of what was involved in capturing the data on each individual pack, at each stage in the distribution chain. This pilot study concerned a limited number of legally-controlled narcotic drugs. It was thus possible to compare the data entered by optical reading.

One of the main aims of the Health-Identity project presented in this article is to prepare a tool for patients who wish to verify the authenticity of their medication, bought from a retail pharmacy, and offer them additional services related to their profile. To access this verification data, patients need a simple information vector. It is now the case that there are more than four billion mobile phones in use worldwide. The new generation phones (such as the iPhone), known as smartphones, have developed enormously: a camera, digital assistant, and the ability to get information via the internet have become standard. These devices allow access to the required information via interfaces and connections which are constantly being improved. They therefore constitute the ideal vector for verifying the authenticity of a drug and offering additional services to consumers. Health-Identity wants to offer just such a tool, making use of the technological possibilities of smartphones.

2. Identification technologies

To obtain certain items of information, it is necessary to have a serialised code, in other words, a unique identifier for each pack of a drug. This means that the same identifier will not occur a second time anywhere in the world. At present, only a GTIN code is applied to drug packs in a one-dimensional bar-code format, EAN-13 [3], as seen on all stock items (for example, 7680085370118 is the code for a 20-tablet pack of aspirin). At European level, there are projects under way in which drug manufacturers will use DataMatrix codes [4, 7] that can hold much more information, namely the GTIN, batch number, expiry date and serial number. This technology is promoted so that packs can be verified at the point of dispense. As matters stand with known projects, the use of RFID is unlikely; only in Spain is there a debate in which identification of drugs via RFID is mentioned from time to time.

In the projects mentioned above, security is thus increased through the generation, by the manufacturer, of a standard unique identifier for each pack. The authenticity of this standard unique identifier is then verified at the pharmacy but there is no check for inconsistencies in the distribution chain. Medication bought via the internet poses a particular problem which should be placed in context: firstly, these purchases are not recommended, and secondly, these drugs may be supplied in packs of a type not permitted in Switzerland. Consequently, if these packs had a GTIN, that number may not be referenced in Galdat, which contains only those products authorised for sale in Switzerland.

The information vectors chosen for this work were mainly DataMatrix (including serialisation) and EAN-13 (without serialisation) because these were the most widely-used codes at the time that the Health-Identity project was designed. One advantage of two-dimensional bar-codes is that their structure makes them easy to decode. At present, only

[8] http://www.gs1health.net/smartlog

around forty mobile phones are capable of decoding one-dimensional identifiers such as the EAN-13 code, because doing so requires a good lens and an operating system which enables either the autofocus or the macro mode to be controlled. In comparison, about 200 mobile phones should be compatible with DataMatrix decoding. It is also important to note that an identifier such as DataMatrix, which supports the "ECC200" [4] error correction method, has a data redundancy level of about 60%, which means that any decoding error can be prevented.

3. General description of Health-Identity

When consumers go to a pharmacy, they have no information about what they buy except for the information on the pack, the patient information leaflet and the pharmacist's advice. Health-Identity provides them with the maximum amount of useful information depending, in particular, on their health profile which is registered on a server via a web or mobile application (**Figure 1**).

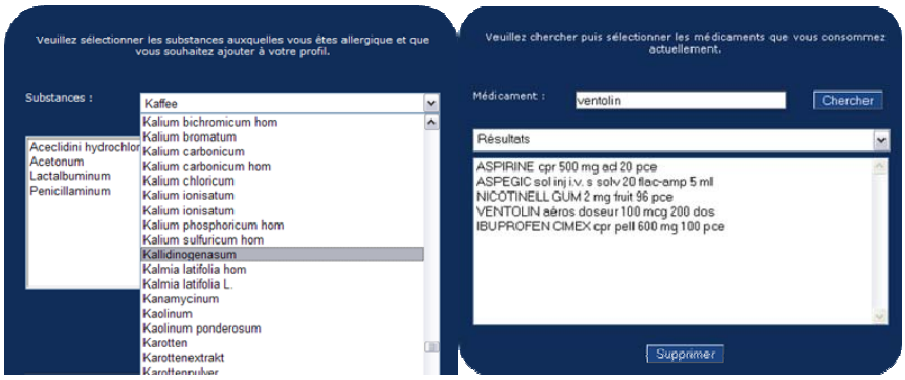

Figure 1. A. Patient profile: Allergy management **– B.** Management of current medication

When a patient wants to find out information about a drug, they use the Health-Identity mobile application to recognise the identifier (DataMatrix or EAN-13) on the pack, using the camera in the mobile phone (**Figure 2**). An internet browser opens on the phone and goes to a mobile web page which recognises i) the user, according to a unique identifier stored in the mobile application and ii) the drug, according to the code on the pack. The page is thus completely personalised.

Figure 2. Mobile application: A. Decoding a drug with DataMatrix and EAN-13 – B. Accessing the mobile application

Following an analysis of the specifications of e-mediat's Galdat database, the decision was taken to offer the following functions in the mobile application:

a. Data available from an EAN-13 identifier (standard bar-code):
   - product description with photo, recommended retail price, reimbursement payable by basic health insurance;
   - list of similar but less expensive products (generic drugs);
   - instructions in the user's own language;
   - contra-indications according to the user's profile (allergies, state of health, interactions with drugs taken during the same period).

b. Additional information available only by using a serialised identifier (DataMatrix):
   - expiry date of product;
   - batch recall;
   - "low-level" authentication to combat counterfeiting;
   - traceability of the drug using the EPCIS[9] standard [6].

Let's consider the following drug interaction scenario. A user's profile indicates that he is currently taking the following medication: Ventolin (antiasthmatic, Beta 2 +). He has been prescribed another drug, Atenolol-Mepha or Inderal (beta-blockers used during stress with tachycardia i.e. excessively rapid heartbeat). However, the beta-blocker prescribed reduces or negates the effect of the Ventolin and if the patient has an asthma attack, he risks having breathing difficulties despite taking Ventolin. The pharmacist would advise him to take stronger doses of Ventolin. The Health-Identity application can:

- Display a warning message indicating that it is advisable to consult his doctor or pharmacist before taking the drug entered, because it is problematic given his state of health;

[9] The goal of EPCIS is to enable disparate applications to leverage Electronic Product Code (EPC) data via EPC-related data sharing, both within and across enterprises.

- Alert the user where two drugs are incompatible, for example, by indicating a degree of danger;
- Warn the user in the event of a batch recall;
- Remind the user of the expiry date if that date has passed or is imminent;
- Give a warning that a uniquely-identified drug may be a counterfeit, if it has been scanned by several different users. This involves a low-level authentication [8], which although not infallible, is not limiting and is inexpensive to implement, unlike high-level authentication such as digital watermarks.

The project also takes account of people who do not have mobile phones, offering internet access with recognition of the identifier by webcam or by manual input.

4. Discussion of the choices made

Several solutions would have been possible for enabling an interaction between a patient and the product in their hand. The easy solution has been to use the EAN-13 system, which is printed on almost all drug packaging, and recognised within the Galdat database. The information taken from bar-codes (GTIN) is obviously very limited, and does not enable the anti-counterfeiting aspect to be dealt with. However, it is a worthwhile stage as regards feasibility and assessing the interest among industrial users, pharmacists and patients.

The choice of DataMatrix is based on trends which are becoming apparent in Europe within the field of drug labelling. Firstly, the French regulations issued by the AFSSAPS (the French health product safety agency) specify that the information vector will be obligatory on medication by 1st January 2011[10]. Secondly, DataMatrix has been chosen by the European pharmaceutical industry to contain a pseudo-random GS1[11] identifier, intended to verify the authenticity of the pack at the point of sale.

We did not choose RFID, even though it does have some significant advantages. Extensive use of radio frequency identification for medication at individual pack level would make it possible to document the supply chain at each of its stages; one of the most advantageous features of RFID is the ability to read a very large number of tags in a short time, without the items being within a line of sight. Within the health field, there are several projects based on the use of RFID that are at a test stage, but far fewer such systems in operational use. RFID can be found in applications for tracing equipment or beds, for example. These applications are described as “closed”, because unauthorised third parties do not have access to the identifiers. By contrast, within the field of unit traceability of drugs, RFID must be “open”, meaning that the number of partners authorised to read the tag and manage information about the item is in itself unlimited, as is the case with bar-codes. However, access to information, using the identifier stored in a tag, is restricted and

[10] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000275479

[11] GS1 is a leading global organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors.

must be reserved for recognised and authorised partners. Significant efforts have been made during the last ten years to standardise RFID tags, and GS1 has been a driving force in this field with EPCglobal. However, after an initial high level of interest, the players in the market did not want to pursue their initiatives beyond pilot schemes. As a result, Health-Identity cannot be based on this information vector because it is not used on the products with which we are concerned.

In addition, we chose to direct enquiries about a pack of medication to a single address. Therefore, only products referenced in Galdat can be the subject of an enquiry. If we had wanted to have another source of information, we could have used an ONS [5], a tool similar to the DNS (Domain Name Service) used in the internet. Although it is available, it would not have been necessary in the case of Health-Identity, since the GTINs for drugs in Switzerland always refer to the same data source, Refdata.

5. Conclusion

We have created a mobile platform which makes it possible to offer business-to-consumer services to consumers of medicines. There is significant potential for new mobile applications for management of medical information for specific profiles. Health-Identity is a tool which illustrates the complementarity between various services offered on the internet and mobile communications. Commercial exploitation of Health-Identity doubtless involves interfacing it with other platforms which patients will use to manage their computerised health records. Furthermore, Health-Identity is an application that can enable pharmacists to interact with patients in a new way. This is why particular care must be taken concerning data confidentiality and the accuracy of the dosage instructions.

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