# SHARING HEALTH DATA IN BELGIUM: A HOME CARE CASE STUDY USING THE VITALINK PLATFORM

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## Abstract

In 2013, the Flemish Government launched the Vitalink platform. This initiative focuses on the sharing of health and welfare data to support primary healthcare.

In this paper, the objectives and mission of the Vitalink initiative are discussed. Security and privacy measures are reviewed and the technical implementation of the Vitalink platform is presented. Through a case study, the possibility of interaction with cloud solutions for healthcare are also investigated upon; this was initially not the focus of Vitalink.

The Vitalink initiative provides support for secure data sharing in primary healthcare, which in the long term will improve the efficiency of care and will decrease costs. Based on the results of the case study, Vitalink allowed cloud solutions or applications not providing endto-end security to use their system. The most important lesson learned during this research was the need for firm regulations and stipulations for cloud solutions to interact with the Vitalink platform. However, these are currently still vague.

## **Keywords**

Health data, healthcare, cloud, privacy/security, Belgium, Vitalink

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#### 1 INTRODUCTION

Medical informatics originated in the 1970s in France and was adopted in the USA in the 1980s [1]. In recent years, eHealth has risen to the foreground on the international agenda [2]. Within the healthcare domain, three different levels can be distinguished, namely the macro, meso and micro level [3][4]. The macro level focuses on the national level, where organizational decisions are made and finances are being regulated. The meso level can be seen as the local level. This level is determined based on a specific territory, for example a city, which is defined by borders. The third level, also called the micro level, involves the individual patient, with his/her specific needs.

In Belgium and Flanders, measures are being taken to shift towards more IT-driven healthcare solutions. Examples of new IT-based initiatives are the eHealth platform [5], the introduction of effective, efficient and secure electronic services and information exchange in secondary healthcare, i.e., specialized care, care after referral and care offered in hospitals, and the Hub/MetaHub system, which enables data exchange by interconnecting caregivers, care consumers and care actors [6]. These new initiatives will enable improved healthcare delivery and will contribute to a sustainable and affordable healthcare model.

Recent initiatives often focus on the meso and macro level. The risk exists that these new initiatives will not focus on supporting care organizations, which are responsible for offering daily care to patients i.e. the micro level of care. In Belgium, different (smaller) care actors and care organizations exist, which all have their own focus on different aspects of care delivery and support. For example, one specific organization is responsible for meal delivery at home, e.g., offering meals to older people, while the other institutions will focus on the daily care of the patient, e.g., getting a patient out of bed in the morning. As patients rely on different/several organizations to organize their care, it is important that they exchange important information and are aware of important medical information, available in for example the Electronic Health Record (EHR) of the patient. However, currently there is little to no information exchange between these organizations [7][8]. For example, the deficits in communication and information transfer between primary and secondary care can have implications for patient safety and the continuity of care, such as discharge medication and

follow up plans [9]. Moreover, even between different employees within the same organization, there is often limited knowledge transfer or handover. One of the reasons is the lack of budget to develop IT services, enabling efficient communication [10]. Often care organizations do not have direct access to the EHR of their patients. Care given to a patient, by multiple care providers should always be coordinated to avoid unnecessary or duplicate testing, interacting medication and conflicting care plans [11].

Next to care provided by professional organizations, so called formal caregivers, informal caregivers offer help to patients as well. Informal caregivers can be identified as family members, neighbors and acquaintances of the patient. Knowledge transfer or information exchange would not only be beneficial for the patients and their (in)formal caregivers, as they would all be informed better, but it can equally happen that care organizations miss out on a wealth of potential valuable information. Being informed on relevant medical information could mean a huge improvement in efficiency of care delivery and would also improve the patient's well-being, for example, the patient has to take pills in the morning or together with food. As such, even a cost reduction could be achieved [12]. By optimizing knowledge transfer and exchange between all parties, the patient is being put at the center and in control of his/her health care [13].

To optimize the data exchange and storage in Flanders, the Flemish Government launched Vitalink, a digital platform, which can be used to safely share health, care and welfare information. Within this paper, Vitalink and its use will be explored and analyzed, together with a case study on how this platform can be integrated within cloud solutions. This integration is investigated because of the current trend of deploying software solutions in the cloud [14] and because of the benefits cloud solution can offer small organizations [15]. The remainder of the paper is organized as follows. Section 2 elaborates on the Vitalink initiative and discusses the objectives and vision of Vitalink, data exchange with the secondary care, the security measures taken to make Vitalink successful and the technical realization of the platform. Section 3 discusses the use of Vitalink in cloud solutions and focuses on a case study, namely the OCareCloudS project and the Medication Reminder. The implementation of the OCCS Medication Reminder Service is briefly discussed in Section 4. Some concerns and lessons learned are discussed in Section 5. Finally, the main conclusions of this research are highlighted in Section 6.

# 2 VITALINK [16]

At the end of 2010, a conference on primary healthcare was organized by the Flemish minister of Welfare and Public Health. At this conference, a strategic vision for the future of primary care was agreed upon. It became clear that there was a need for a secure platform to share health data between professional caregivers, such as physicians, nurses and care organizations. In the following years, the idea of Vitalink was made more concrete and the platform launched pilot projects.

Section 2.1 discusses the objectives and vision of Vitalink. Section 2.2 elaborates how data storage is handled in Belgium in secondary care. The security and privacy measures taken to secure the Vitalink platform are described in Section 2.3. Finally, Section 2.4 focuses on how software developers can interact with the Vitalink platform.

## 2.1 OBJECTIVES AND VISION OF VITALINK

The Flemish Agency for Care and Health [17] is an Internally Autonomous Agency within the Flemish authorities. It falls under the Welfare, Public Health, and Family policy area. The agency was established on April 1 2006. In the Flemish care and welfare policy, the use of IT plays a very important role [18]. Flanders is convinced that using IT is necessary to tackle the challenges arising in the healthcare sector, with sharing of data as one of most important goals. As there are many different players in the healthcare sector with very different expertise and target groups, the use of multi-disciplinary data sharing is needed and has following benefits:

- Better and more efficient collaboration between different professional caregivers
- More efficient care
- Administrative simplification
- An increased involvement of the patient/client

For professional caregivers, it is important that the government facilitates the sharing of data. For the patients/clients, it is important that this data sharing has direct benefits and that the government guards against misuse and ensures the privacy of the end user. This is because of the concerns of end users when sharing or storing their data elsewhere. If there

is a direct result or benefit from sharing data, end users will give their consent more quickly; more so when they are confident that the government will protect their data. To tackle this, Vitalink was created. Vitalink is a digital platform, which enables primary care actors to share health and welfare data in a secure manner. This will clear the way for more (cost) efficient care. Through the use of applications, created and offered by Health Insurance or other organizations, the patient/client is able to consult his/her data and follow-up its own care through Vitalink. Currently, end users are already able to consult their medication scheme and get an overview of their vaccinations. Vitalink information can be consulted by primary care actors, who have the necessary permissions. Using integration adaptors, the data can be used in other software packages, offered by care organizations. In fact, Vitalink can be seen as a database, which stores health and welfare data and the system will only grant access to actors who have the correct permissions and have a trust relationship with the end users/client. These end users are able to approve and establish these trust relationships and also remove them, for example when the medical rehabilitation of the client has ended.

As indicated, Vitalink is an initiative of the Flemish Government. By facilitating this infrastructure for data sharing, all information can be through one central point. Moreover, small care organizations, not capable to invest in such infrastructure, are able to access and share information through Vitalink. Eventually, by using Vitalink, redundant infrastructure and procedures will disappear, which will lead to an improvement of the work quality and efficiency of the caregivers. The Flemish Government has an important role in guaranteeing the privacy and security aspects of the platform.

#### 2.2 SHARING DATA WITH SECONDARY CARE

Secondary care also uses data sources with information on patients. These data sources are called the Hub/Metahub System [19] and are available 24/7. Within this system, all information of patients from all participating hospital settings can be accessed. The hospitals are interconnected through hubs and metahubs. This way, it does not matter at which location the data is actually hosted. Hubs can be seen as regional exchange systems, whereas metahubs are local ones. In Belgium, there are 5 hubs, namely in Antwerp, Brussels, Louvain, Ghent and Wallonia. With these two systems, Vitalink and the Hub/Metahub System, data exchange can be enabled between primary and secondary care. It has been shown that improved data sharing between secondary and primary care will improve the outcome of the patient [20][21][22]. The Hub/Metahub System is only accessible through the hospitals, the patients and care organizations do not have access to this system.

#### 2.3 SECURITY AND PRIVACY

The main goal of Vitalink is to support the exchange of data between different professional caregivers. Therefore, security and privacy are of the utmost importance [23]. Four mechanisms are used to make sure that data is kept secure:

- 1. Strict access control:
  - First, a distinction is made between the different roles one can use when he/she logs in to the Vitalink system. When a user logs in as a patient, he/she gets access to his/her own personal data. When he/she logs in as a professional caregiver, using an eHealth certificate, an authentication process starts, in which the Secure Token Service (STS) [24][25][26] of the eHealth Platform is used to verify whether this person actually has access to Vitalink in its role as professional caregiver. Authentic data sources from the National Service for Medical and Disablement Insurance System and the Federal Public Service of Health and Food Chain Safety are used to check the identity. These data sources hold an official record of all the professional caregivers in Belgium. eHealth certificates are similar to a digital passport and are issued to actors operating within the healthcare system. This can be a single person or an organization. eHealth certificates are used to make use of the services of the eHealth platform and thus also to gain access to

Vitalink. More technical details on these certificates can be found in [27]. Trusted certification service providers are used to issue these certificates. This instances are supervised/accredited by Belgium to comply with the relevant provisions of Directive 1999/93/EC of the European Parliament and the Council of 13 December 1999 on a Community framework for electronic signatures [28]. The eHealth platform uses the ETSI TS 119 612 specification to provide its own list of trusted certificates. This list is available at [29].

- Second, patients have to give permission before Vitalink will disclose any information. Approval needs to be given using the eHealth Platform and when consent is given, this applies to the sharing of all health information. This consent can be withdrawn at any moment.
- Third, there needs to be a therapeutic or care relationship between the patient and the caregiver. When care is provided through a care organization, a relationship can be established between the patient and this organization. This way, there is no need to give permission to the individual caregivers working for the organization. It is also possible to define exclusions between the patient and an individual caregiver or a care organization.
- Fourth, as different caregivers have different roles, they only need access to specific information. The Vitalink system filters the information based on the role of the caregiver. Moreover, not all caregivers can manipulate the data in the same way. Authorization rules are set in place to control this. For example, a physician is able to change the medication scheme of the patient, while the pharmacist is able to suggest a change and a nurse will only be able to read this information.
- Finally, Vitalink has built in an exception to the above procedure, namely the "break the glass" procedure, where physicians can request data of a patient in case of emergency. This request has to be motivated.
- 2. Data exchanges between an end user and the Vitalink platform always use a secure connection.
- 3. Double encryption: Data sent between the Vitalink platform and the software application, requesting the data, is always encrypted. Vitalink uses encryption when

sending and storing data. This is often called end-to-end encryption. Vitalink uses a unique, especially for Vitalink developed, double encryption algorithm to encrypt data. This way, data is made unreadable for the technical administrators of the platform as well as for the government. Only the client and caregiver can decrypt the information.

 Every action and request to the Vitalink platform is registered. This information can be analyzed to detect illegal use. The "break the glass" procedures are logged separately.

#### **2.4 INTERACTING WITH VITALINK**

The Vitalink platform only offers the infrastructure and tools for data sharing and will not create end user solutions for professional caregivers. One of the main reasons is the fact that different care organizations use different software solutions. Creating and maintaining all these different plug-ins, would overshoot the mark of Vitalink. Software developers can interact with Vitalink using the Vitalink Connector. These solutions can be stand-alone or can be integrated in existing software solutions for care. How the technical solution of Vitalink works, is shown in Figure 1 and is detailed in the following paragraphs.

As shown at the bottom of Figure 1, the Vitalink Platform component encloses the central storage facility, which stores the encrypted data. The necessary logic is implemented to make sure that storing and requesting data adheres to the strict process of authentication and authorization. Highly secured Web Services are used.

Two decryptors are used, which decipher the data in the Vitalink platform. When the request is successfully validated through the authentication and authorization process, each decryptor will decipher one specific part of the key of the end user. These decryptors are offered using a Web Service. Both decryptors are hosted on different locations and are controlled by different entities.

As can be seen on the figure, services of the eHealth Platform are used. These services are mainly responsible for the security of the Vitalink Platform. End users can identify themselves using the Secure Token Service (STS) of the eHealth Platform. A Security Assertion Markup Language (SAML) token [31] is created through the eHealth Platform, which can be used to communicate with the Vitalink Platform. The end user is responsible for the creation of this token, but the Vitalink Connector supports this operation. An eID card or eHealth Platform certificate can be used to request the token.

As discussed in the previous section, informed consent is required to exchange patient data with professional caregivers. Moreover, a therapeutical or care relation needs to exist before a professional caregiver can request information. Also, exclusions can be defined. Data sources of the eHealth Platform store this information. These data sources are queried by Vitalink when specific information is requested. The Vitalink Client Application consists of two parts. On the one hand, there is the end user software application or the software application of an organizaton. On the other hand, the Vitalink Connector can be identified. The Vitalink Connector is a software library offered to software developers. This connector enables the interaction between an external software solution, the end user or organization software application, and the Vitalink Platform. The Vitalink Connector offers different services, namely session management and access to Vitalink services.

The external software application, making use of Vitalink, is responsible for:

- the creation of a valid eHealth Platform session,
- the identification of the patient, using the Identification Number of the Social Security (INSS),
- the registration of informed consent,
- the registration of the therapeutic or care relationships,
- the interaction with the different Vitalink services, using the Application Programming Interfaces (API) offered by these services, and
- the visualization of the data through a Graphical User Interface (GUI).

The INSS is the number is assigned to each person born or living in Belgium. It is also sometimes referred to as the national number of a person. This is the number that is used whenever a patient logs into the Vitalink platform with his/her eID. The use of this number is restricted by the Law on the Protection of the Privacy and can only be used for specific goals. Authorization for using this number is obtained from the Sectorial Committee of the National Registry. This number is chosen, because hospitals and EHR records often use different means to identify a patient. Using the INSS guarantees that the patient can be identified correctly.

During the development of the Vitalink initiative, new emerging solutions, such as cloud computing, were not taken into account. The primary goal of Vitalink is the sharing of data between care actors, where the decryption of the data happens at the local device of this actor and thus not in the cloud or on a remote server. When the developer agreements were created, which allowed software developers to develop end solutions, using Vitalink, the

Flemish Government did not take into account the potential interest of the research community in investigating tools like Vitalink.

## **3** CLOUD SOLUTIONS & VITALINK

As the Vitalink solution seemed an interesting track to investigate during research projects, a meeting was set up with the Flemish Government to discuss the possibilities. In the following subsections, the research project OCareCloudS is presented, together with the integration of the medication reminders based on Vitalink data. This section is concluded with some points of interest regarding the use of Vitalink in cloud solutions.

## 3.1 THE OCARECLOUDS PROJECT

The research project, "Organizing Care through trusted Cloudy-like Services" [32], also called OCareCloudS, wanted to research the design of a cloudy-like software system. The system offers information and knowledge-based services, which focus on crossing the borders between the different personal spheres of the client or patient, namely the daily care needs, social needs and the need for daily assistance. As already mentioned in Section 1, patients receiving care at home often come in contact with different care organizations and different care professionals. Moreover, their relatives, family and neighbors are involved in their care. Nowadays, this collaboration is far from efficient. Supporting the data and information flows on the micro level of primary care was on of the main goals of this research project.

As previously mentioned, the OCareCloudS platform supports the patient/ client, using innovative IT services to offer better support in the organization of his or her daily care. Such a system should also allow the care recipient to live longer at home in a more qualitative way and to have better and more frequent contact with friends, family, carers and (in)formal caregivers. The focus of the OCareCloudS platform is to be interoperable with and complementary to both existing and emerging eHealth and eCare solutions, both on the level of the government and of the software solutions of the care organizations. Trust and reliability in the care network, together with the user-centric control in this network by the client/patient are important. Trust relationships are thus very important within this platform. The results of this 2 year research project were translated in a Proof of Concept (PoC), where the different partners of the project (research groups, industry and care

organizations) contributed to.

During this project, the Vitalink initiative launched some pilot projects, used to evaluate and refine the initiative. As the OCareCloudS project wants to overcome borders and the communication gap between the different care organizations, interaction with Vitalink was one of the interesting tracks. As the OCareCloudS platform focuses on offering services using the cloud, which was not the focus of the Vitalink initiative, several meetings between the consortium and the Flemish Government took place to discuss this PoC. As the government recognized the added value, approval was given to include Vitalink in the PoC.

#### **3.2 IMPORTANCE OF MEDICATION COMPLIANCE**

Patients needing care at home, often have chronic diseases or chronic conditions. These conditions are usually treated using medication. Studies [33][34][35] have shown that medication compliance is very important, especially in the case of chronic diseases. Not complying with prescribed medication may lead to the decreased effect of the medication and can increase the likelihood of a poor outcome [36]. Compliance or adherence can be defined as patients not taking their medication as is prescribed by a professional caregiver and according to the instructions on the label [37]. Examples are improper timing, inappropriate dosage and not being persistent. This can be due to disease, patient specific issues or financial constraints [38]. Theofilou [39] states that compliance to prescribed medication, which depends on an interaction of different factors, e.g., personal influences and economic factors. Over 50% of people are non-compliant in their medication use [40]. Studies indicate that the use of medication reminders can improve compliance [41].

The Vitalink initiative launched a pilot project to evaluate the need and use of the platform. Sharing medication data between physicians, pharmacists, nurses and carers was the focus of the pilot, called the Medication Reminder. It launched in 4 different regions in Flanders [42].

#### 3.3 THE OCARECLOUDS PROOF OF CONCEPT AND THE VITALINK MEDICATION REMINDER

The global overview of the OCareCloudS platform is visualized in Figure 2. Data from the patient/client is gathered within the home setting. This means that sensors are installed to gather information, which can be used to derive useful knowledge. Also, smart devices are used within the home, such as smart phones, tablets and TVs. These devices can be used to interact with the patient. All data originating from the home are sent to the Controllers using the Terminal. The Terminal is thus responsible for acquiring all data. The (in)formal caregivers and other personnel of care organizations are equipped with devices, such as cell phones, smartphones or tablets. These actors can also access the OCareCloudS solution using desktop computers.

The Controllers are used to send data from and to the cloud and are also equipped with the

necessary software to handle requests from the cloud. For example, when a notification has to be sent to the patient, the most suitable device can be chosen by the Controllers and the information can be sent to that device accordingly.

The OCarePlatform is situated in the cloud and is responsible for the processing of the data. The OCarePlatform is data-driven, which means that actions and notifications are sent from the OCarePlatform based on the data it is processing. The Semantic Communication Bus (SCB) [43] is responsible for sending the information to services, which have indicated to have an interest in that particular type of data. On top of the SCB, services are deployed, which implement different functionality. The services process the data and send actions or notifications to the Controllers to act upon. Examples of services are: a Notification Service, responsible for sending notifications to the Controllers and the Physical Activity Service, able to analyze the activity of a patient and trigger alarms when the patient is not moving around.

The most relevant service of the OCarePlatform for this paper is the Medication Reminder Service. This service directly interacts with the Vitalink Platform, requesting the necessary medication information of a specific patient. Based on this information, reminders can be sent to the patient, taking interesting context information into account. For example, the preference of the user about the device where the reminder should be sent can be taken into account, or when the system knows that the patient is not at home, then the reminder should not be shown on the TV. Users of the OCarePlatform, making use of the Medication Reminder Service, should identify themselves using their eID. This way, this information can be used when requesting medication information to the Vitalink Platform. Based on the information from Vitalink, patients receive timely medication reminders on their devices. If necessary, these reminders can also be sent to specific caregivers in order to follow up the compliance.

Data Sources are used by the Controllers and the OCarePlatform to log the data and information. This is the data captured by the sensors and devices in the home of the patient and the information and knowledge as a result of the reasoning process within the OCarePlatform. Medical data, such as medication status of a patient which originates from Vitalink, is checked for its correctness and being up to date by accessing Vitalink.

More technical details on the internal operation of the semantic OCarePlatform can be

found in [44].

#### **3.4 VIEWPOINT OF VITALINK REGARDING CLOUD SOLUTIONS**

Based on the request of the OCareCloudS consortium, the Vitalink initiative reflected upon the use of Vitalink in the context of cloud solutions. As cloud solutions can have several advantages [45], such as lower costs for smaller organizations, the access to the required hardware resources and the scalability and back-up possibilities, they decided to open up the Vitalink Platform to cloud solutions.

However, developing cloud solutions using Vitalink does not change anything to the regulations, whom have been set in place for the end-to-end software applications. The care actor (or organization) keeps being responsible for data exchange using Vitalink, even if this actor employs an external partner to create a software solution. The actor should make clear arrangements in order to respect the terms of use of the Vitalink Platform. Software and web solutions, where data is processed not at client side, but for example in the cloud or at an external server, can encipher and decipher Vitalink data at a distance, provided that some measures are taken into account. These measures were defined thanks to the request of the researchers of the OCareCloudS project and will be applied to all future cloud solutions, willing to interact with the Vitalink platform:

- 1. The Privacy Legislation should be observed: A Belgian Act, defined on December 8, 1992 [46], also referred to as the Privacy Act states that "the parties commit themselves to comply with the obligations arising from this Act on the protection of privacy with regard to the processing of personal data, as well as the willingness to observe medical confidentiality regarding the data of the patient". This Privacy Legislation, together with the Royal Decree of 13 February 2001, which implements the Privacy Act on the protection of privacy in relation to the processing of personal data, fulfils the European Directive 95/46/EC that focusses on the protection of individuals with regard to the processing of personal data and the free movement of such data.
- 2. There should be an agreement with the end user. In this agreement, there must be an explanation of how the Privacy Legislation is complied with. Also, an indication should be given on the responsibilities and the engagements made between the end

user and the actor. The Flemish Government offers a checklist with respect to the needs of the user and a table with feasible agreement stipulations. An evaluation by Smals Research will be done to check the security aspects on four different criteria: (i) governance, (ii) identification management and access control, (iii) IT security and (iv) operational security. Also, an evaluation will be executed on the conformity of the cloud service against the Security Policy concerning Cloud Computing Services.

3. Information from Vitalink may never be passed to others, unless the Privacy Legislation approves this.

## **4** DISCUSSION ON THE OCCS IMPLEMENTATION

The OCareCloudS project created a successful PoC, in which two ways to communicate information on the medication scheme to the end user and his/her (in)formal caregivers were designed. The medication scheme is requested from the Vitalink and processed by the Medication Reminder Service of the OCarePlatform, where the necessary medication information is extracted. Within Vitalink, the KMEHR standard [47][48] is used. An example of a medication scheme can be seen in Listing 1.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Only designed for illustration purpose. No valuable medical content -->
<kmehrmessage
                   xmlns="http://www.ehealth.fgov.be/standards/kmehr/schema/v1"
                   xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
                   xsi:schemaLocation="http://www.ehealth.fgov.be/standards/kmehr/schema/v1
                   file:///C://ehealthxsd-hubservices-1.0.1/ehealth-kmehr/XSD/kmehr_elements-1_3.xsd">
         <header>
                   <standard>
                             <cd S="CD-STANDARD" SV="1.4">20120401</cd>
                    </standard>
                   <id S="ID-KMEHR" SV="1.0">11530231003.201112210907000000</id>
                    <date>2016-02-10</date
                   <time>14:35:47</time>
                    <sender>
                              <hcparty>
                                       <id S="ID-HCPARTY" SV="1.0">11530231003</id>
                                       <id SV="1.0" S="INSS">49112002395</id>
                                        <cd S="CD-HCPARTY" SV="1.3">persphysician</cd>
                                       <firstname>GP</firstname>
                                       <familyname>ForDemonstrationPurpose</familyname>
                             </hcparty>
                    </sender>
                    <recipient>
                              <hcparty>
                                       <cd S="CD-HCPARTY" SV="1.3">application</cd>
                                        <name>OCCS VITALINK Integration Demonstrator</name>
                             </hcparty>
                    </recipient>
          </header>
          <folder>
                    <id S="ID-KMEHR" SV="1.0">1</id>
```

#### Listing 1: Example of a Vitalink medication scheme

```
<patient>
         <id S="ID-PATIENT" SV="1.0">85999999999</id>
         <firstname>Jef</firstname>
         <familyname>Jansen</familyname>
         <sex>
                  <cd S="CD-SEX" SV="1.0">male</cd>
         </sex>
</patient>
<transaction>
         <id S="ID-KMEHR" SV="1.0">1</id>
         <cd S="CD-TRANSACTION" SV="1.4">medicationschemeelement</cd>
         <date>2015-12-04</date>
         <time>14:35:47</time>
         <author>
                  <hcparty>
                            <id S="ID-HCPARTY" SV="1.0">11530231003</id>
                            <id SV="1.0" S="INSS">49112002395</id>
                            <cd S="CD-HCPARTY" SV="1.3">persphysician</cd>
                            <firstname>GP</firstname>
                            <familyname>ForDemonstrationPurpose</familyname>
                   </hcparty>
         </author>
         <iscomplete>true</iscomplete>
         <isvalidated>true</isvalidated>
         <item>
                  <id SV="1.0" S="ID-KMEHR">2</id>
                  <cd SV="1.4" S="CD-ITEM">healthcareelement</cd>
                  <content>
                            <cd SV="1.0" S="CD-ITEM-MS">adaptationflag</cd>
                            <cd SV="1.0" S="CD-MS-ADAPTATION">medication</cd>
                            <cd SV="1.0" S="CD-MS-ADAPTATION">posology</cd>
                   </content>
         </item>
         <item>
                  <id SV="1.0" S="ID-KMEHR">3</id>
                  <cd SV="1.4" S="CD-ITEM">healthcareelement</cd>
                  <content>
                            <cd SV="1.0" S="CD-ITEM-MS">medicationtype</cd>
                            <cd SV="1.0" S="CD-MS-MEDICATIONTYPE">onprescription</cd>
                  </content>
         </item>
         <!--
         **********
         * RELEVANT INFORMATION FOR POSOLOGY IS CONTAINED BELOW *
         ******
                   -->
         <item>
                  <id SV="1.0" S="ID-KMEHR">4</id>
                  <cd SV="1.4" S="CD-ITEM">medication</cd>
                  <content>
                            <medicinalproduct>
                                     <intendedcd SV="2015-05" S="CD-DRUG-CNK">1799121</intendedcd>
                                     <intendedname>Dafalgan tab Forte 50x 1g</intendedname>
                            </medicinalproduct>
                  </content>
                   <beginmoment>
                            <date>2015-05-25</date>
                   </beginmoment>
                  <temporality>
                            <cd S="CD-TEMPORALITY" SV="1.0">oneshot</cd>
                  </temporality>
                  <frequency>
                            <periodicity>
                                     <cd S="CD-PERIODICITY" SV="1.0">D</cd>
                            </periodicity>
                  </frequency>
                   <posology>
                            <text L="nl">3 x 1 a day after meal</text>
                  </posology>
                  <instructionforpatient L="nl">
```

```
Take with a glass of water
                                    </instructionforpatient>
                           </item>
                           <item>
                                    <id SV="1.0" S="ID-KMEHR">5</id>
                                    <cd SV="1.3" S="CD-ITEM">healthcareelement</cd>
                                    <content>
                                             <cd SV="1.0" S="CD-ITEM-MS">begincondition</cd>
                                    </content>
                                    <content>
                                             <text L="nl">Flu</text>
                                    </content>
                           </item>
                          <!--
                           *****
                                 ******
                           * RELEVANT INFORMATION FOR POSOLOGY IS CONTAINED ABOVE *
                           ****
                          -->
                  </transaction>
        </folder>
</kmehrmessage>
```

The current medication scheme can be requested through the start screen. As can be seen in Figure 3a, a start screen was developed for the OCCS system. This screen can be shown on a smartphone, tablet or smart TV. Various widgets are offered to the user. The one relevant for this research is the Medication Scheme widget and is depicted as the sixth icon on the start screen. This widget gives the end user or (in)formal caregiver the possibility to check the medication scheme, as shown in Figure 3b.

Alternatively, reminders are sent to the end users. Figure 3c shows an example of a medication reminder. These screenshots match the medication scheme shown in Listing 1. Moreover, medication reminders can also be sent to the (in)formal caregivers by the OCCS system, based on the urgency of the reminder. For example, when the first reminder is ignored by the end user, a second reminder can be sent to the end uses and a caregiver.

Thus, two scenarios are possible using the Medication Reminder functionality of the OCareCloudS system. First, a pull scenario is designed, able to request the medication scheme. Second, a push scenario has been devised, enabling the OCareCloudS system to send medication reminders to the resident and his/her caregivers.

During the implementation of the medication reminder functionality, some issues were identified. Updates of medication in the medication scheme, or new medication added to the scheme, is not automatically pushed from Vitalink to the OCCS system. This is a design decision made by the Vitalink team. Therefore, a connection between the Vitalink platform

and the OCCS system is established every time the Medication Widget is called. Moreover, specific fields in the medication scheme should be checked to see whether the scheme was updated. The fact that the correctness of the medication scheme should be checked on regular time intervals, makes the implementation more complicated and overloads the OCCS system. Normally, the session between the Vitalink platform and the OCCS system will expire after a fixed time, meaning that the end user needs to identify him/herself to the system again to establish a new connection with Vitalink.

If the end user receives home care from a recognized care organization and the OCCS system is installed in the home of the end user, it is possible to make use of the general certificate of the care organization. This certificate makes it possible to establish a connection with Vitalink without the need to log in every time by the formal caregiver or the end user. However, if no care organization provides care, then the end users or formal caregivers are required to log in to the Vitalink system if the session expires. This makes making use of the Vitalink Medication Scheme a cumbersome task. The duration of a session depends on the role of the user, for example a general practitioner will be able to establish a session of 4 hours, while pharmacists can create session which last 12 hours.

Within the OCCS system, a general certificate for testing purposes could be used, making the authentication process easier. Each time a Medication Reminder was sent or the Medication Scheme was requested, it was compared with the up to date version in the Vitalink platform, making sure that the end users receives the most up to date information and no wrong medication advise is given.

## **5** LESSONS LEARNED

During the use of the Vitalink platform, several lessons were learned and concerns were identified:

 Formal caregivers employed by a care organization, can use an authentication certificate on the level of the organization. This means that they do not need to authenticate themselves to the Vitalink platform, the software application of the care organization will use the general certificate. This may be of some concern towards the privacy of the patients of the care organizations, as it will be more difficult to limit access of the different caregivers to the data of the patients.

- Currently, only formal caregivers have access to the Vitalink platform. These formal caregivers have to be registered in the authentic data sources from the National Service for Medical and Disablement Insurance System and the Federal Public Service of Health and Food Chain Safety. This leaves informal caregivers in the cold, while the patient at home counts on their support. The Flemish Government should look into the possibilities to register these informal caregivers and enabling them to also have access to some information in the Vitalink platform, providing they are approved by the patient.
- With the new emerging trends like the Internet of Things and cloud computing, questions may rise on privacy for the end user. As discussed in Section 3.3, the Vitalink platform does have some guidelines towards cloud solutions, but how will they enforce them and how will this be checked against new updates? Will the Vitalink platform give technical support to how these guidelines can be followed?
- The Privacy Legislation [49] ensures that personal data is handled with care and is protected. However, the point of view of the Privacy Legislation on cloud computing [50] still remains vague and they are currently still working on it. Two documents are being created regarding "the risks and challenges of the unfolding of cloud strategies at the level of public services, including the Federal Police and Defense" and a recommendation on cloud computing for the industry. As the Privacy Legislation still is defining stipulations, it is difficult for software developers to follow them.
- There is a need for a technical evaluation of the Vitalink platform and the Medication Scheme as some improvements could be made or taken into consideration.
  - Could it be possible to place triggers on the medication schemes in the Vitalink platform? This way, a notification could be sent to the software system to notify that an update has been made. Or would this burden the Vitalink platform and its performance too much?
  - How can we overcome the issues with the session expiration? Is there a solution that can be used by end users and formal caregivers, enabling them to not always create a new session. Moreover, the general certificate of the care organization makes it possible for all employees to access the data of the

end user if consent is given to this care organization, also this may burden the privacy of the end user.

 The above mentioned issues go hand in hand, if triggers could be used to notify the software solution of a medication update, then the software system would not be required to check the scheme every time a reminder is sent.

## 6 CONCLUSIONS

The Vitalink initiative from the Flemish Government facilitates data sharing among actors in primary care. Data sharing with different actors responsible for the care of a patient will improve efficiency and decrease cost. In this paper, the internal operations of the platform are discussed with special focus on the security aspects. A case study within the OCareCloudS project was executed to evaluate the use of the Vitalink in cloud solutions. To this end, interaction with the Vitalink pilot project, namely the Medication Reminder, was set up. Based on this interaction, the Vitalink initiative opened up the Vitalink Connector for applications not providing end-to-end encryption. The most important lesson learned during this research was the need for firm regulations and stipulations for cloud solutions to interact with the Vitalink platform. However, these are currently still vague.

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## **CONFLICT OF INTEREST**

The authors declare that they have no conflict of interest.

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## FIGURES



FIGURE 1: GLOBAL OVERVIEW OF THE VITALINK SOLUTION [30]



FIGURE 2: GLOBAL OVERVIEW OF THE OCARECLOUDS PROOF OF CONCEPT



(a) Start screen of the OCCS system

(b) Medication scheme



(c) Medication reminder

FIGURE 3 – EXAMPLES OF THE IMPLEMENTATION OF THE OCCS MEDICATION REMINDER