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On the Combination of Patient-Generated Data with Data from a Secure Clinical Network Environment – A Practical Example

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***Abstract*—**With increasingly more mobile health applications appearing due to the popularity of smartphones, the possibility arises that these data can be used to improve the medical diagnostic process, as well as the overall quality of healthcare, while at the same time lowering costs. However, as of yet there have been no reports of a successful combination of patient-generated data from smartphones with data from clinical routine. In this paper we describe how these two types of data can be combined in a secure way without modification to hospital information systems, and how they can together be used in a medical expert system for automatic nutritional classification and triage.

***Keywords*—**Data integration, disease-related malnutrition, expert systems, mobile health.

I. Introduction

THE rise of the smartphone has affected many aspects of our daily life, such as work, entertainment, interaction with others, and even our health; as of 2014, more than 99,000 applications related to health and fitness are available in online stores [1].

Whilst these mobile health (mHealth) applications support us in our desire to eat better [2], be fitter, prevent or unlearn unhealthy lifestyles [3], [4], or even manage illnesses [5], [6], they rarely interact with hospital information systems, and thus the information that is gathered in using these applications is not available to medical experts. Naturally, care should be taken when allowing external information sources to be adopted into the clinical diagnosis and monitoring process, but nevertheless with thorough verification, medical apps could prove to be useful in expediting medical workflows, as well as further shifting the emphasis of healthcare to home-monitoring instead of ambulance treatment, thereby potentially saving time as well as resources, for both patient and healthcare institutes.

In this paper, we will describe a method of data combination that we applied when using patient-generated data together with data from clinical routine, in order to provide automated nutritional classification and triage in cancer outpatients. Using the patient-generated scored global assessment (PG-SGA) method [7] for the classification of nutritional status and nutritional triage in oncological patients, we constructed an mHealth application that presents a questionnaire to oncological outpatients, gathering information on a weekly basis concerning their eating habits, activity and functioning, and weight. These data are then transferred to a secure server, where they are combined with patient data from clinical routine, and used by an expert system to automatically determine nutritional classification and triage. These results are then forwarded directly to the hospital information system where they can be observed by oncologists as well as nutritional experts.

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II. Methods

A. Cancer Cachexia

Nutritional deterioration in cancer patients proceeds in three subsequent stages: pre-cachexia, cachexia, and refractory cachexia [8], [9].

In the first stage, the pre-cachectic state, patients suffer from small weight loss, a chronic or recurrent inflammatory response, and from disease-related anorexia [8]. In this case, anorexia is defined as the reduction or loss of appetite, which is a common occurrence with chronic illnesses, including cancer [10], [11].

Depending on factors such as cancer type and stage, the presence of systemic inflammation, low food intake and lack of response to cancer treatment, the pre-cachectic state can progress into cancer cachexia, a multifactorial wasting syndrome identified by the ongoing loss of lean muscle mass due to a negative protein and energy balance [8]. The effects in this stage can no longer be fully reversed, as patients become less responsive to conventional nutritional and pharmacological therapies [12], [13].

Due to advanced cancer or rapidly progressive cancer, cachexia can progress into a clinically refractory stage. In this stage, management of weight loss is no longer possible, and often therapeutic interventions will focus solely on controlling cachexia symptoms [8].

Nutritional deterioration and moderate involuntary weight loss in cancer patients are quite common [14], and are significantly related to worse clinical outcomes, poor tolerance of anti-cancer treatment and reduced quality of life [8], [15], [16]. Finally, malnutrition is also associated with increased mortality [8], and linked to increased hospital visits and stays,

Open Science Index, Health and Medical Engineering Vol:9, No:3, 2015 publications.waset.org/10000692/pdf

and increased cost of treatment [17], [18].

Due to the irreversible effects of cachexia, nutritional deterioration should be identified as soon as possible, i.e. in or even before the pre-cachectic state; treatment options in the cachexia and refractory cachexia stages are severely limited [8], [9], [19], [20]. Several tools exist for the detection of nutritional deterioration and anorexia, such as qualitative assessments like the Functional Assessment of Anorexia/ Cachexia Therapy (FAACT) and the North Central Cancer Treatment Group (NCCTG) Anorexia/Cachexia questionnaire. A more comprehensive method using both patient-generated and clinical data is the PG-SGA.

B. The Patient-Generated Scored Global Assessment

The scored PG-SGA is a nutritional assessment method that was specifically designed for cancer patients [7]. Unlike its predecessors, the method uses a numerical scale and thus supports a continuous quantitative measure instead of a categorical one. The assessment comprises two parts, one part to be filled out by the patient, and the remainder to be filled out by the attending physician.

The patient part comprises four sets of questions related to a patient's physical attributes, food intake, presence of symptoms, and activities and function. Each set contains either open questions, such as a patient's weight, or scored multiple-choice questions that describes various states of activity and nutritional intake; the patient needs to select one or more options that correspond best with his or her situation in the past week (or month, in case of activity). Scores are then determined for each set, and are accumulated to a single score.

The remainder of the survey comprises four worksheets be filled out by the physician. These worksheets require patient history and objective (medical) criteria to categorize a patient's physical health in the categories weight loss, disease description, metabolic demands, and results of physical examinations. These data are then used to determine which predefined category applies to a patient, which is then translated into a score.

After all scores have been calculated, a patient's nutritional state can be determined using the global assessment categories, and nutritional triage can be performed. There are three global assessment categories: Stage A, which means the patient is well-nourished, Stage B, meaning that the patient is moderately malnourished, or that malnutrition is suspected, and Stage C, indication that the patient is severely malnourished. Furthermore, based on the score, one of four nutritional triage recommendations can be proposed: no intervention (PG-SGA score 0-1), patient and family education (PG-SGA score 2-3), intervention by a dietician together with a nurse or physician (PG-SGA score 4-8), or a critical need for improved symptom management and nutrient intervention (PG-SGA score > 8).

C. Hospital Information System Infrastructure

At the Vienna General Hospital, the secure network environment (SNE) can be divided into the clinical routine data domain, and the research domain, and both are shielded from the public domain by firewalls and access protocols.

Within the clinical routine domain, a new hospital information system has been in operation since 2 years called i.s.h.med. The i.s.h.med provides a graphical user interface called a parametric medical document (PMD), which provides a framework for customized medical documentation that can attend to special medical needs. Communication to and from the i.s.h. med proceeds through web services and can be accessed by systems in both the clinical and the research domain.

Within the research domain, an expert system platform is operational that supports expert system creation and data processing using Arden Syntax [21], [22]. Within Arden Syntax, units of medical knowledge are encoded using medical logic modules (MLMs) [23]. Each MLM contains a computer-readable translation of medical knowledge for a single medical decision or diagnosis. Input data for the processing of an MLM are received as parameters via web services, or acquired via a database connection module.

D. Evaluation

In this paper we will present a method for the secure acquisition and transport of patient-generated data from an mHealth application to an SNE, and the subsequent integration of this data with clinical data from the medical routine SNE, without modifying data in the clinical domain itself. We will discuss security measures that have been taken in each of the system components, i.e. mHealth application, expert system and i.s.h.med component, and discuss benefits and drawbacks of design and implementation choices.

E. Implementation Specifics

The MONTE mHealth application supports devices using android version 2.2 (API 8) or higher, but was optimized for high-resolution mobile phones using android version 3.0. The application was implemented in Java version 1.6 using Eclipse Juno and the Android SDK Tools, revision 22.0.1. Patient data were saved locally using an SQLite database, and on the server side using MySQL via PHP scripts running on an Apache webserver.

III. Results

Below the descriptions and design-and implementation choices for individual components are presented. An overview of the entire system architecture and data flow is shown in Fig. 1.

A. The MONTE mHealth Application

The MONTE mHealth application was meant to enable patients to provide feedback about their eating habits and nutritional wellbeing on a weekly basis, without the need to make use of healthcare facilities. Patients are presented with mini surveys that correspond with the patient part of the PG-SGA on a weekly basis, thereby minimizing the time and effort needed to complete the survey.

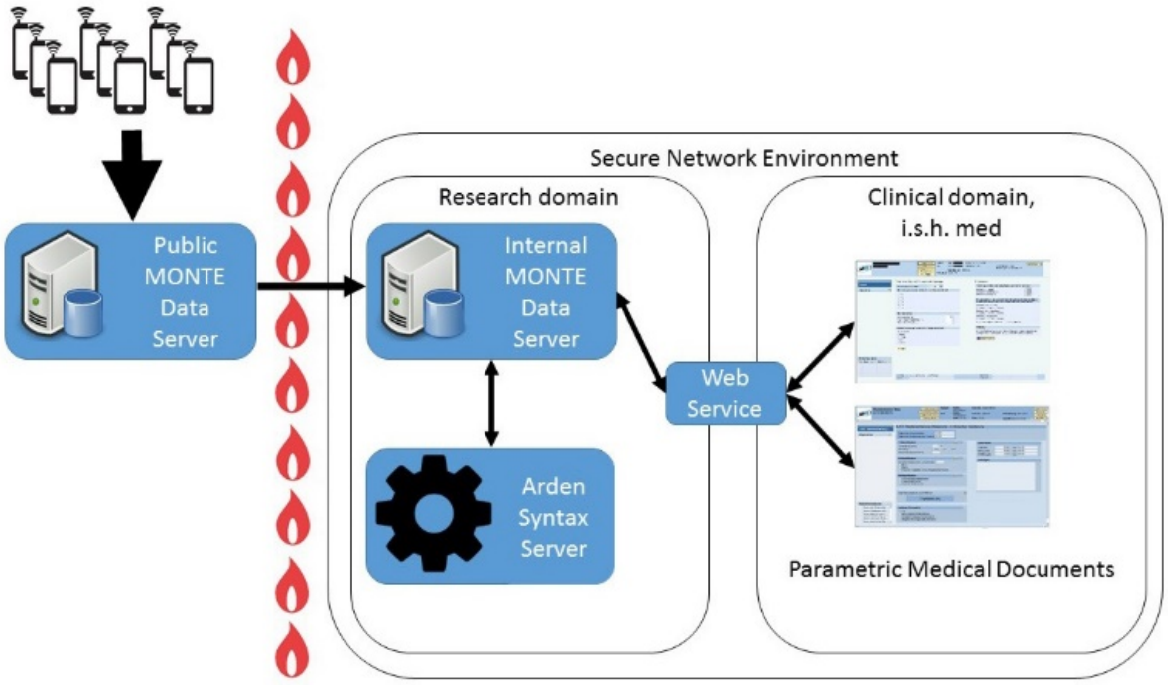


Fig. 1 The MONTE system architecture and data flow

The use of the application is very straightforward. Upon starting the application, the user is presented with the opening screen, which lists the categories that were scheduled for that particular day. After starting the survey, the user is asked if he or she noticed any difficulties related to eating, activity or mood; if so, a sub-question appears where the user can select all the problems or difficulties experienced over the last week, and to what degree (Fig. 2). After the mini-survey has been completed, the answers are stored locally, and uploaded to the server if an internet connection is available; if not, the answer will be uploaded as soon as one becomes available.

There were several security measures implemented to ensure safe access, data storage and data transport. First, the application is not widely available for download, but instead is uploaded by a clinician to the patient's smartphone if he or she chooses to participate in the program. Upon this time, the patient is also registered on the MONTE server with a username and password, which are by the client together for server-side verification. Second, upon first use of the application, the user needs to register a pin code that serves as an identity verification method in the application itself; whenever the application is accessed after being paused or returns from sleeping mode, the patient needs to enter a 4-digit pin code in order to continue with the surveys. Finally, to ensure safe communication with the server, all data are stored and communicated using an AES-256 encryption.



Fig. 2 The MONTE mHealth application

B. Data Integration and Combination

To be able to use the data stored on the MONTE server, which is in the public data domain, a second data server was configured within the research domain, and a synchronization protocol was setup on this data server to copy data from the public MONTE server once a day, at a random time at night. By using this data pull strategy, the firewall did not have to be reconfigured or compromised, but the drawback was that it could only be done once a day to minimize any risk of unauthorized breaches. However, as there was no need for

Open Science Index, Health and Medical Engineering Vol:9, No:3, 2015 publications.waset.org/10000692/pdf

real-time data updates or processing, this drawback was acceptable for the system.

On the aforementioned data server in the research domain, the data needed from the clinical domain was also copied to using a web service data transfer protocol. These data correspond with the data required in the physician part of the PG-SGA, such as patient disease diagnoses, metabolic demands, and results of physical examinations.

C. The MONTE Expert System

The expert system was implemented using MLMs that emulate the medical decision process as it is done manually with the PG-SGA forms. MLMs were created for the import of data, the calculation of scores for individual patient and physician data modules, and for the determination of the global assessment category applicable to the patient, as well as the assessment of nutritional intervention needs.

Data used for calculation and classification were provided either as parameters or imported using an SQL statement within the MLM; these SQL statements were then forwarded to the database using a JDBC connection; individual data items were passed as parameters, while data sequences were retrieved using SQL statements.

After calculation of an MLM result, said result was both forwarded to the calling MLM as well as to the data server, both for debugging purposes as well as result verification by and explanation and elaboration of the results for the requesting physician.

D. Clinical Routine Graphical User Interface

Several PMDs were programmed as an i.s.h.med graphical interface to the MONTE expert system. As can be seen in Fig. 3, these PMDs show patient administrative data, and the input values for each of the PG-SGA data categories (both patient-generated and clinical values), and allow modification of clinical data in order to interact with the expert system to fine-tune the results. After committing the changes, recalculation of results is done on-the-fly.

Apart from intermediate scores for each PG-SGA category, the PMDs also show data trends for PG-SGA categories, as well as the global assessment classification and the nutritional triage, which indicates to what extends intervention by a nutritional expert is needed. Using a button, the physician also has the option to view the raw data that underlie the categorical score.

IV. Discussion

In this paper we discussed a practical implementation of a method for the combination of patient-generated data and data from clinical examinations, in order to construct an expert system for the (semi-) automated classification of malnutrition in cancer outpatients, and to determine nutritional triage. We presented the overall system architecture, and described individual components, as well as design decisions and implementation specifics.

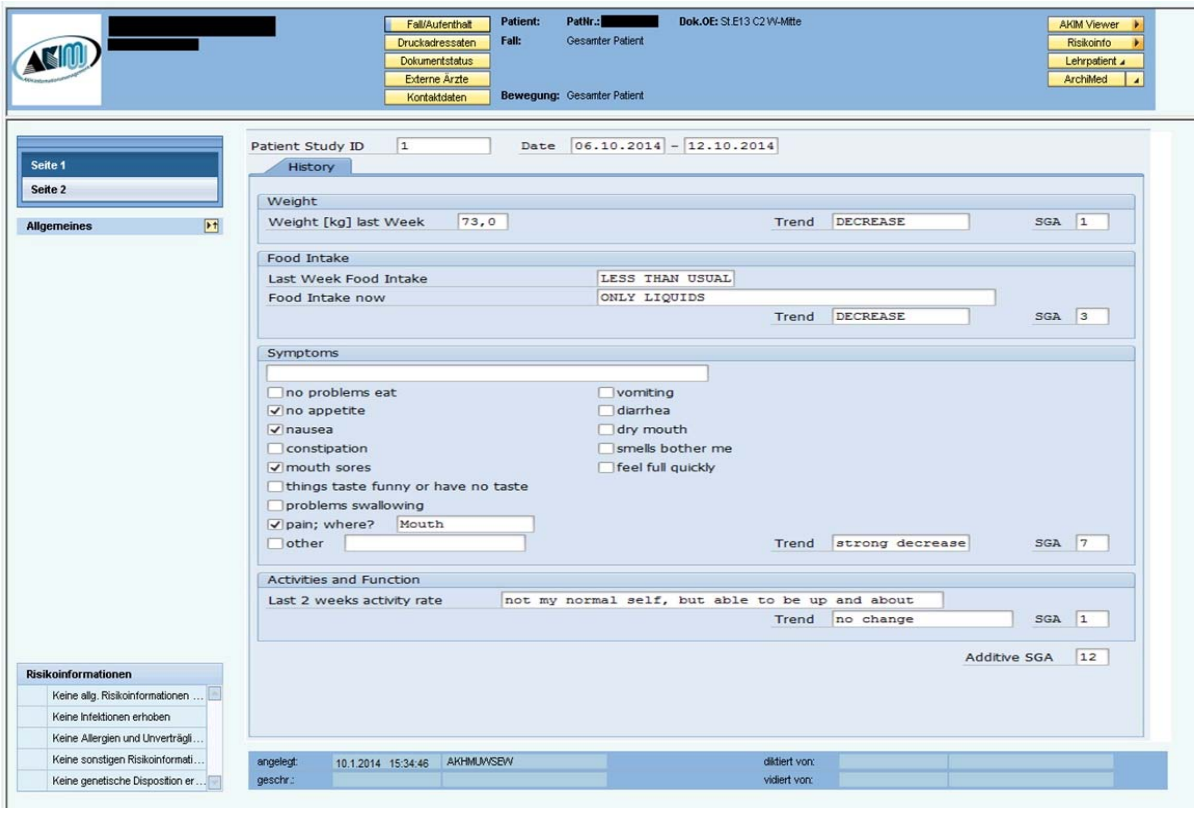


Fig. 3 The MONTE parametric medical document, fully integrated in the hospital information system of the Vienna General Hospital

Open Science Index, Health and Medical Engineering Vol:9, No:3, 2015 publications.waset.org/10000692/pdf

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Smartphones have become increasingly popular and widespread over the last few years; in Europe, smartphone penetration exceeds 50% in the top 5 EU countries [24]. Moreover, smartphone ownership among healthcare practitioners is likely to be even higher, at about 81% [25]. Smartphones also become increasingly more powerful, with better cameras, motion sensors, and increased processing power. This creates opportunities for the creation of novel mHealth applications for both medical practitioners and patients, in the hope to further improve healthcare while saving precious healthcare resources.

The system described in this paper is a first attempt to automate the PG-SGA survey. To achieve this automation, a combination of clinical data and patient-generated data was necessary. The integration of data from public domain with clinical data raises several political and technical issues, which need to be addressed first before the system can be employed on a larger scale. First, there is the matter of ownership of the data. As the system is still in its clinical trial period, patients that participate in the project are asked to sign a disclaimer, making the hospital owner of the data. However, if the system is to be employed on a bigger scale, this method becomes unfeasible and instead general regulation and disclaimers must be put in place.

Second, there is the matter of data separation. Although the system uses data from heterogenic domains, no clinical data is allowed to be stored outside the SNE, and only data generated in the clinical domain is allowed to be stored in the clinical domain. For this reason, we opted to use the research domain as an intermediary domain for data combination, as data from both domains are allowed to be stored and processed there.

Third point, and related to the second point, is data quality. Although the application has been developed with redundancies to check for consistency, such as asking questions more than once, and has mechanisms to resolve exceptions, data quality can never be guaranteed 100%, which can negatively influence the outcomes of the expert system. While this is to be expected during clinical evaluation, measures must be taken to minimize these occurrences, and risk-evaluation must be performed to clinically verify the system and transfer it to other hospitals.

For the migration of patient-generated data we chose a pull strategy once a day. Other options were a push strategy, which required the configuration of an HTTP tunnel to package data in an HTTP format and then tunnel it through the firewall, or the configuration of a virtual private network (VPN). However, the latter methods were deemed too unsecure by system administration, as both would allow for outside code to be executed in the SNE, which could lead to unauthorized access of data or systems.

Although there have been a multitude of mHealth applications published recently [26], to the authors' best knowledge, there are currently no other mHealth applications that monitor the nutritional status and combine those data with data from a clinical setting. However, there are also several limitations to the design of this system. First, the mHealth application is very basic still, and does not contain a direct feedback loop to the patient yet, which lessens the engagement of patients in the project. In order to make sure that people continue to use the application for a longer period of time, result feedback should be incorporated, as well as coaching and information elements, and not only address the clinical needs of the patient, but also provide emotional management and role management [27]. Second, the data migration as it is yet is effective, but not very elegant, and might not suffice for applications that do need real-time updates. Furthermore, it is an ad hoc solution that satisfies the needs of the project, but might not be scalable or transferrable into different domains.

For future work, we plan to address aforementioned limitations, and extend the project to also support other standards. The mHealth application is to be extended from a data reporting tool to an actual intervention application that contains information on malnutrition and its relation to cancer types and treatments, and tries to engage the patient actively in improving his or her nutritional status. Furthermore, there are plans for the implementation of a framework that takes a more standardized approach to data communication and integration between public data domains and the hospital SNE, thereby using Health Level 7 standards of interoperability and documentation.

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