

An integrated Diet Monitoring Solution for nutrigenomic research

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Abstract. The emergence of evidence pointing at diet as key risk factor for chronic diseases and at gene-diet interactions as key elements in the interplay between an individual genetic background and his/her lifestyle, pave the way for studies in nutrigenomics. Such studies need an integrated solution to collect, monitor and analyse a large set of data. In the frame of ATHENA, a European Commission FP7 project, we developed an integrated platform, called Dietary Monitoring Solution enabling the collection of phenotypic, genetic and lifestyle information, linked to a mHealth application tool. The data collection solution allows maintaining anonymized information and supports a number of features making it particularly suited for multicentre studies. The mHealth application was designed to translate the knowledge generated from research into a personalised prevention programme and to support the patient adherence to the programme.

Keywords. Nutrigenomics, Chronic Diseases, Prevention, Risk Reduction Behavior.

Introduction

There is an emerging attention to nutritional studies as it is more and more accepted that diet has a key role in influencing the risk for chronic diseases. The GBD 2010 study estimated that the main causes of global burden of disease are dietary risk factors.¹ At the same time, several studies indicate that the traditional approach used in nutritional studies, focused on caloric and macronutrients intake, fails in capturing essential features of dietary risk factors, such as dietary patterns and micronutrients intake. Moreover, recent evidence underline that the genetic background can alter the

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host's physiological response to diet.² For example there is strong evidence suggesting that changes observed in plasma lipid levels in response to dietary fat intake are, to a large extent, genetically controlled.^{3,4}

A systematic collection and analysis of nutritional data and their correlation to phenotypes and lifestyle is needed to assess dietary risk factors and designing appropriate interventions. However, existing tools are not appropriate to collect such a variety of data in a systematic way in the context of epidemiological and clinical studies. In this paper we present a tool aimed to systematically collect nutrigenomics and lifestyle data from patients and citizens in the context of a large epidemiological study.

1. Methods

In ATHENA, a European Commission FP7 project (Grant Agreement 245121) exploring the role of dietary anthocyanins in protecting against chronic disease, we developed an integrated platform, called Dietary Monitoring Solution (DMS), to collect phenotypic, genetic and lifestyle information linked to a mHealth application tool providing personalized dietary indications.

Our DMS was designed in close collaboration with clinicians, geneticists and nutritionists. In particular, clinicians provided specifications for Case Report Form's (CRF) sections related to cardiovascular diseases' risk factors while nutritionists defined methodologies and sources of nutritional information. Genetic information, represented by Single Nucleotide Polymorphisms (SNPs) was organized in PED and MAP files, which constitute standard formats for the most widely used genomic analysis software. The DMS is composed by: a) a web-based platform, based on a framework dedicated to CRF management⁵; b) a software, calculating the macro and micronutrients intake from each food/meal; c) a mHealth application monitoring and guiding the subject in his/her ecological context.

The web-based platform is used by the clinicians to create the CRFs containing patient's data. The same tool is used by the nutritionist to collect the patient's dietary habits, through 24 -hours-recall interviews and food frequency questionnaires. The system allows the management of patient's medications and therapies, and tracks the case history, physical, laboratory examination and dietary recalls. Genotypic data are managed by the healthcare professional and can be uploaded from PED and MAP files, which are generated from raw intensity data. Individual genetic data, particularly those for which there are evidences of interaction with the diet (e.g. micronutrients intake and preferences), are used as input for a Decision Support System (DSS), which provides suggestions on risk reduction behaviors. The suggestions provided by the DSS are meant to be validated by healthcare professionals to design an optimal personalized lifestyle plan. The mHealth application is dedicated to the subject and is used to track his/her diet and lifestyle. The monitoring information generated by the mHealth app is then transferred to the web-based platform and becomes part of the patient's CRF.

2. Results

Figure 1 shows the web-based platform for data collection and storage, based on an existing system.⁵ The system is flexibly designed to allow the configuration of CRF

templates, which define data collection fields and their eventual constraints, according to the focus of the study. In this case, the CRF template includes fields to assess risk factors for cardiovascular and metabolic diseases: the patient's medical history, medical examinations, exams, genetic data, diet and lifestyle.⁵ Dietary information, collected through 24-hours-recall interviews, includes a description of foods consumed during each meal and their macro and micro nutrients composition, computed by a software combining input data from dietary interviews and food nutrients composition, from validated food databases, further enriched with published and experimental data on anthocyanins contents. As previously reported⁵, the same CRF template is shared between different clinical research centres participating to the study and used for data collection, ensuring anonymous data processing. Also, the platform manages the direct exchange of daily diet data with the mHealth app used by the patient at home. Once logged into the web-based platform, the clinicians involved in the project can add a new patient into the registry, fill-in the CRF of a patient, and view the daily diet results coming from the mHealth application. The patients' registry is a local file managed only by the clinician. The web-based platform stores only patients' unique identifiers (MPI) and does not contain patients' personal identification information.

This platform was used to collect information from more than 500 volunteers participating to ATHENA project, in three recruitment sites. It also stores volunteers' genetic data, as generated by genotyping the DNAs with a commercially available chip containing ~280K highly informative genome-wide tag SNPs. The user with role "Data Manager" can extract anonymous data from the platform and analyse data, homogeneously collected through the web-based platform, from all the centres taking part into the project.

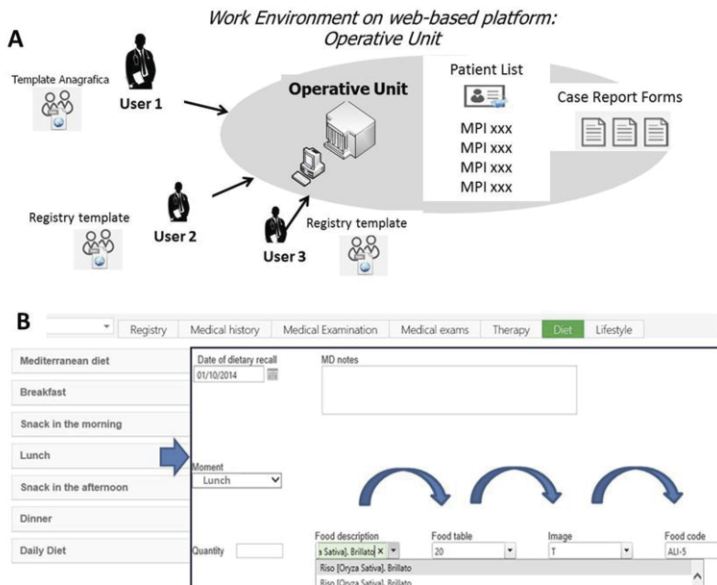


Figure 1. A- the cooperative work environment on the web-based platform in a single operative unit. B- the CRF allows easy data entry by the selection of a food name automatically mapping the selected food to its code in the food database.

The mHealth app is developed for the iOS environment. It is designed to monitor patient's dietary and lifestyle data. The user can fill in his/her meal (Figure 2A) taking

advantage of a visual atlas of foods, searchable and sortable by name and amount of grams per portions. Once selected, the food is coded using the same dictionary as in the web-based platform. The app also allows the user to examine his/her food diary and to view, export and share graphs about some main nutritional values with a settable timescale (Figure 2B). Each user can customize personal habits and profile information thus making the compilation process easier and faster. The mHealth app prototype is undergoing an extensive testing by different categories of end-users. In addition, the app includes a DSS built on a set of rules combining existing dietary guidelines with research-based evidences on genomics risk factors and their interactions with dietary habits. The DSS provides suggestions to the user according to real-time inserted data. The communication with web-based platform is secured by encryption and includes dataflow optimizations to ensure data accuracy.

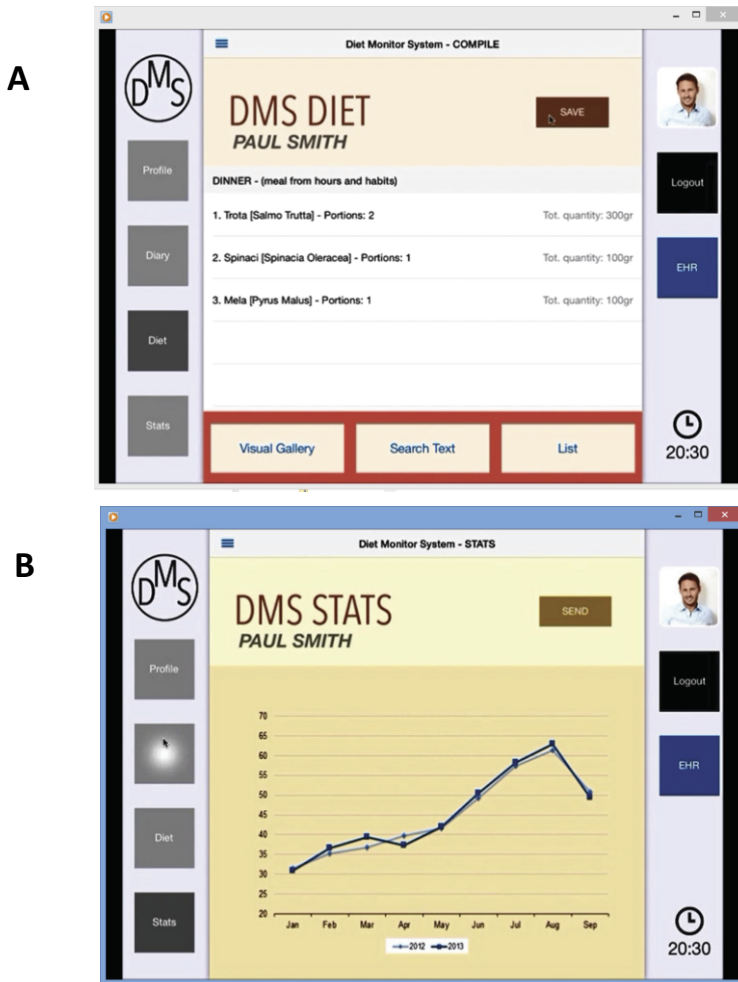


Figure 2. A- Snapshot of the application view for meal recording. B- Graphical representation of the data recorded by the application.

3. Discussion

Different solutions for the management of CRFs are currently available and can be adapted to dietary studies, while a number of apps on the market provide food characteristics in terms of calories and macronutrients and support the user in losing weight. However, to our knowledge, there is no comprehensive solution to collect all the information needed to define the risk of a chronic disease, considering the subject's genetic background and lifestyle, and to monitor such risk in an ecological context.

Compared to existing solutions for data collection, the DMS novelties include the possibility for the professional to refine data collection tools, to “supervise” the suggestions proposed by the DSS and to interact with the patients, responding in this way to the concerns raised by healthcare professionals toward the DSS approach. The mHealth app provides patient empowerment since it helps taking into consideration relevant aspects of daily diet as micronutrients intake and genetic risk factors which are neglected in existing apps and which represent a key element to foster personalised prevention. This approach allows to translate the knowledge generated from nutrigenomic studies, which indicate that genetic polymorphisms influence an individual response to diet, pointing at gene–diet interactions as key elements to gain insights into the inter-individual variability observed on the risk of chronic diseases and on the response to lifestyle interventions.

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