Supporting health research projects at the HES-SO

MedRed: A healthcare data acquisition service for research purposes

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Abstract

Research in the healthcare domain requires the collection of important and exhaustive datasets in order to validate a scientific hypothesis, or to assess the effectiveness of a treatment, technology, medicine, or procedure. The data acquisition phase for this type of work requires an often under-estimated amount of time and effort, while needing to maintain high quality standards for the entire process. Many of the tasks associated with data acquisition are often carried out manually, resulting in error-prone procedures, hand-transcription, inaccuracy, and time delays to produce a usable dataset. This paper presents MedRed (medical research data acquisition platform), an interface and a service designed to facilitate the data acquisition process for researchers in the healthcare domain, and using REDCap software for data capture. This service is available first of all to all scientists at the HES-SO (University of Applied Sciences and Arts Western Switzerland) schools in Switzerland, and is partially supported by the Swiss universities’ CUS-P2 programme.

Key words: clinical data acquisition, data capture, data life-cycle management

Introduction

In the medical domain, research protocols often require the participation of patients and volunteers in scientific studies. These are conducted in order to assess, evaluate and validate a certain hypothesis. Although these studies have important differences and are heterogeneous, depending on the topic, and the nature of the investigation, they usually follow similar data acquisition patterns. A large amount of data is obtained in these studies through data acquisition instruments, such as surveys, forms and questionnaires, both in quantitative and qualitative forms. Examples of these include demographics, symptoms, perceptual information, cognitive data, feedback, emotions, descriptions of experience, etc.

The implementation and usage of these instruments is challenging, considering the many different types of inputs depending on the type of study and the need to adapt instruments to the target population. This includes use of language, usability, and interaction. Moreover, overarching issues, such as data privacy protection, safe storage, and data quality assessment need to be handled, which are often not the expertise of clinical researchers. Furthermore, these instruments need to be implemented supporting different devices, including smartphones, tablets, laptops, etc., further increasing researchers’ workload.

Although in certain Swiss medical research centres these issues are addressed by a dedicated infrastructure (e.g., clinical trial units), there is a need and an opportunity for providing support for clinical data acquisition for researchers in research and education institutes. The University of Applied Sciences and Arts Western Switzerland (HES-SO) is an institution dedicated to applied research in different areas, including healthcare. Being the second largest higher education centre in Switzerland (in terms of student population), and having several affiliated schools and institutes working on different health research topics, it lends itself as a potential important player in clinical data acquisition at a national level.

This paper presents and describes MedRed@HES-SO (or simply, MedRed†), a medical research data acquisition platform, available for all researchers of the HES-SO affiliated institutes and schools, with a vision of national outreach. MedRed is based on the use of the REDCap (research electronic data capture) system, a widely used piece of software for data acquisition in the medical domain, with proven support in web and mobile environments. The MedRed project and its scope is discussed in length in the remainder of the paper, starting with its goals and approach in Section 2, implementation in Section 3, its relationship with previous work in 4, and sustainability and outreach aspects in Section 5.

MedRed: Platform approach

In the MedRed project, the general objective is to establish a research data acquisition and storage platform based on
The aim is to support current and future health research projects at the HES-SO (in the cantons of Geneva, Vaud, Valais, Fribourg, Neuchâtel and Jura of Switzerland). As a pilot project, in this first stage, MedRed will focus on the deployment of the platform in selected pilot projects led by the Haute École de Santé at HES-SO Valais. The project goals can be summarized as follows:

- To set up, install and deploy a data management solution for surveys and questionnaires for research medical data, coordinated by the HES-SO data centre, and based on the REDCap platform.
- To design, adapt and implement data acquisition instruments (e.g., surveys and questionnaires) for selected pilot projects led by the Haute École de Santé at HES-SO Valais.
- To provide validation and evaluation of the effectiveness and usability of the platform in the selected pilot projects.
- To implement ad-hoc training modules for HES-SO researchers.
- To analyse and formulate the needs of a middle and long-term strategy for a research lifecycle data service facility (methodological support for data science, support of writing of protocols for ethical committees, software for data acquisition, support in statistical evaluation).

The project is designed to cover the management of research data mainly from health science studies in an end-to-end fashion. Starting from the design of input questionnaires and surveys, we will then progress to the data acquisition process, the storage and persistence of data, and its later availability for analysis. This holistic data management approach includes general issues such as data security and privacy, authentication, validation and data integration. In order to attain the expected goals of the project, we propose adopting an ICT platform designed specifically for this purpose, namely REDCap (research electronic data capture).

REDCap is a web-based electronic data capture (EDC) solution for designing clinical research databases and questionnaires. It was built by a dedicated team at Vanderbilt University, and has been widely used as a platform for numerous projects in hundreds of institutions, including hospitals, universities, medical research centres, national research programmes, etc. The successful adoption of REDCap in such a large and diverse set of clinical projects provides substantial evidence that it can be used to coordinate the complete data management process efficiently. The adoption of such a platform entails several challenges that we address in this project. We can summarize them as follows:

**Paperless research data input**

Currently, most of the clinical data acquisition activities at the HES-SO Institute of Health are performed using paper-based questionnaires and forms. This form of data acquisition is prone to mistakes, including missing data, mistakes made while filling the forms, interdependence of questions, which are not respected, among others. These issues lead to reduced accuracy and quality of data. Moreover, when it is time to export the data and process it, this must be done manually, which leads to further potential mistakes.

**Computer-supported acquisition design**

Many clinical data acquisition protocols exist in standardized forms, and could be adapted to an electronic format. In these cases, it is necessary to preserve the characteristics of the original questionnaires so that their purpose is not altered. For new protocols and new studies, it would be expected that the electronic approach would facilitate the task of designing the data-input instruments.

**Mobile-device electronic acquisition**

In many cases the use of mobile phones and tablets will be instrumental to facilitating the data acquisition. However, this will change current workflows. While the mobile applications are designed to make this easier, it is important to avoid disrupting work and procedures during the clinical data acquisition.

**Distributed data acquisition**

The use of electronic data capture will allow automatic collection and storage of data, in a distributed fashion, from a series of smartphones and tablets. While this is advantageous and permits simultaneous data capture, it is also important to verify that the platform is capable of maintaining performance and accessibility and usability levels even if the system is under considerable load.

**Support for instrument designers and administrators**

Using the proposed new set of tools, we will change radically the way in which instrument designers work. It is important to guarantee that they are able to generate the forms and questionnaires that they need, avoiding mismatches and design mistakes that can have negative consequences during the acquisition process. Also, it is vital to train administrators in authorization management to determine who has access to functionalities such as importing/exporting data, access to identifiers, access to instruments, etc.

**Training for acquisition assistants**

Similarly, it is important to provide the necessary training for the people who will be in charge of the data acquisition. These people do not always have the technical expertise to master electronic data-capture tools. Therefore, it is important to provide them with learning material and easy-to-follow instructions to avoid mistakes and other issues.

**Deployment of an inter-institutional service**

The use of these tools is intended within all institutes affiliated within HES-SO. This will be challenging from an administrative and managerial point of view, as data belonging to different parties will be involved, although under the same institutional umbrella. Coordination and support at different levels should be considered. While in this project we limit the scope to studies carried out by the Institute of Health, it is important to take into account these aspects from the beginning.
Data security and privacy management
The data that is collected in this type of service can be very sensitive and should be subject to strict security and privacy regulations. These must be enforced not only during the use of the application, through the setting of the appropriate authorization rules, but also for the storage of the data, which would also require secure backups and, potentially, replication.

Implementation
The MedRed project is structured in such a way that it addresses the challenges raised in the previous section, and is composed of the following four main pillars: (1) infrastructure and technical support, (2) methodological support, (3) evaluation and validation, and (4) data lifecycle management. The general coordination of the MedRed service is managed by HES-SO Valais-Wallis in Sierre, providing support for all technical, methodological, validation and data-lifecycle management aspects. In addition, the technical infrastructure i.e., the deployment of REDCap, is managed by HES-SO central IT services in Fribourg (see Figure 2). Both HES-SO users of the platform as well as external partners can access the MedRed infrastructure through the same interface, secured with a SWITCH AAI authentication system. MedRed REDCap is available at the following URL: http://redcap-hes.so.ch.

Infrastructure and technical support
The first pillar of MedRed is to provide the technical infrastructure and support for the data acquisition platform. This translates first into the acquisition of the REDCap license, its installation and deployment, and its maintenance. The HES-SO Valais-Wallis Institute of Information Systems (IIG) leads this effort, with the support of the central HES-SO IT services in Fribourg, where the services are hosted, including backup and monitoring operations. This configuration enables the MedRed REDCap installation to be available from the start for all researchers associated with any of the schools affiliated to HES-SO.

REDCap has been running since autumn 2016, and its authentication system has been integrated with the SWITCH AAI mechanism provided for all shared HES-SO infrastructure. Nevertheless, the deployment of the platform is only the first step, and since the start of the project, MedRed has built a support service for technical issues, so that researchers who use the platform can find suitable solutions, work-arounds, and recommendations as needed. This also includes support for using the platform with mobile devices, and the REDCap app, which facilitates work in the field for administrators and end-users.

Methodological support
One of the key innovations of MedRed is the inclusion of dedicated methodological support and assistance, so that researchers who use the platform can create, manage and conduct their studies following best practices and guidelines for data acquisition. In a first step, this includes the design and adaptation of training material for data acquisition. This is mainly directed to health professionals who will use the MedRed infrastructure for conducting their studies. A first training phase has already been performed for the first pilot projects that started along with MedRed, but will continue through the lifetime of the project. The training ensures that the study administrators are first able to design their own instruments, use the REDCap designer (see Figure 3) to formulate the questionnaires, associate them with variables, make use of longitudinal, randomization, privacy preservation features, etc., so that the quality of the instruments is optimal. The second step is to provide tailored training for users of the instruments, meaning those who will actually perform the data acquisition in the field from patients and volunteers. The HES-SO Valais Institute of Health leads the conduction of the methodological support, which also includes aspects related to the posterior use of the data e.g., considering statistical data analysis, adherence to norms, and reuse of existing or similar instruments, etc.

In order to guarantee that at least an initial number of real studies are implemented using the platform, a few projects have been selected for piloting, including:
- Swiss CHEF trial: comparison of home-based exercise programmes for fall prevention and quality of life in older adults (randomized controlled trial).
- Validation of a decision tool for the prediction of non-return to work after occupational rehabilitation (cohort study).
- Non-invasive ventilation in Swiss hospitals (survey)
Self-reported tool for the prediction of falls in community dwelling older adults (cohort study with monthly assessment during 12 months).

Additional studies have also been added, and others are under discussion for inclusion in the pilot phase.

Evaluation and validation
In health-related studies, it is crucial to maintain high quality standards throughout all steps of the data acquisition process. For this reason, it was important to include a dedicated task for the evaluation and validation of on-going studies and their instruments, as well as evaluation of the datasets collected.

For the pilot phase of MedRed, the main goal is to assess the effectiveness of the use of the platform for the chosen pilot projects, and to assess the quality levels of the data obtained. This includes assessment of the usability of the tools, and identification of pitfalls and potential issues that would need to be addressed in future studies. Concerning the acquired data evaluation, this includes finding inconsistencies, missing data, violation to input rules, quality of answers, etc.

Research data lifecycle management
Data acquisition is only one part of the larger lifecycle of a scientific process. For this reason, MedRed incorporates tasks related to defining a strategy for research data lifecycle management, which may eventually span all of the affiliated HES-SO institutes. This includes the definition of guidelines and foundations for a potential service for research data management, including a medium and long-term vision, support and maintenance plan, feasibility analysis and inter-relationships with other existing services.

Such a strategy will allow integration with the MedRed platform with open data services, link with open access catalogues, create potential open innovation opportunities, etc.

Related work and services
Up to now there has not been an initiative for establishing a comprehensive research data management solution in the scope of the HES-SO. Currently, each research group handles the acquisition, storage and analysis process of research data independently through ad-hoc combinations of paper-based forms, scanned documents, excel files, etc.

However, the introduction of the proposed platform into the workflow of the different research groups at the HES-SO Institute of Health requires careful consideration of everyday practices in order to avoid intrusiveness, and in such a way that existing protocols and norms are respected. While in the past, manually filled forms were the norm for acquiring data in this context, nowadays the use of electronic data capture (EDC) solutions have been shown to improve the efficiency of the process, while maintaining quality and accuracy standards [1, 6]. In particular, EDC helps to increase the efficiency of the entire data management process, reducing and/or eliminating data transcription and transmission times, providing data validation and input enforcement, or helping to schedule the site visits [2, 3]. Furthermore, EDC is expected to provide faster access to data, which can help to perform live analytics and decision making on the existing acquired datasets. Due to these benefits, clinical research organizations, pharmaceutical companies, and university hospitals, among others, make use of EDC and related clinical data management systems such as OpenClinica, REDCap, TrialDB, InForm, Medidata Rave, and Datatrak [5].

Given the large number of clinical studies that are performed worldwide, and their complexity, there is now a need to share results as well as research structures and metadata. This would make it possible to perform tasks such as validating existing protocols, reusing and refining clinical research instruments, extending previous studies, and performing surveys and systematic analytics of clinical trials, etc. Significant efforts have been made to agree on standards for clinical studies, and the ODM (operational data model) [4] proposed by CDISC has been adopted by several regulatory bodies and also EDC software tools such as REDCap.

Although there are other data management systems for electronic data capture, the proposed REDCap solution has the advantage of being provided at essentially no cost for academic purposes, even if it is not open-source software. Furthermore, it has an active and well-established community of users, as well as a large number of partner institutions, including several universities and institutes in Switzerland (e.g., HUG, CHUV, Lausanne, CTU Bern, etc.) None of these institutions belongs to a Swiss University of Applied Sciences. Thus, there is a clear need to establish in Switzerland such a platform to support data research in professional health sciences (e.g., nursing, physiotherapy, ergotherapy, etc.).

Sustainability, outreach and discussion
We have presented the MedRed project for data acquisition in health-care studies, implemented for the entire network of HES-SO researchers, institutes and schools. This initiative aims to constitute a first-of-a-kind service that supports scientists in the health domain, not only with technological but also methodological tools that will help to facilitate common tasks in research workflows, while raising the quality of research outcomes.

We have outlined in this paper the different advantages of such approach, but we have also analysed the costs of...
maintaining such an infrastructure. While in the current pilot phase there is direct support from external funds (Swiss Universities CUS-P2), the platform will continue working as a service available to the whole HES-SO. Maintenance and support will be assured through a medium-term contract with the chancellery of HES-SO and a business plan that relies on mandates for the participating schools, similar to the setup of a clinical trials unit.

Finally, we think that this initiative would pave the way for a future creation of a dedicated centre for data lifecycle management for the HES-SO, which would cover not only data acquisition and storage but also other additional services, such as data policy regulations, ethical committee submission support, data reuse best practices, etc. This would help to unify research data strategies, which are essential for today’s requirements in project fund-raising and for data quality assessment.

Disclosure statement
No potential conflict of interest relevant to this article was reported.

References

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Figures (large format)

Figure 1: REDCap deployed at HES-SO for MedRed. REDCap users can create their own projects, define their instruments, and collect the data using the provided functionalities.

Figure 2: MedRed project organization: All HES-SO researchers as well as authorized external partners can access the REDCap infrastructure through the SWITCH authentication. MedRed also coordinates the different support services described in this paper.
Figure 3: REDCap instrument designer: The user can customize the questionnaire items as desired, including branching and validation rules.