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DESIGN AND EVALUATION OF A FLEXIBLE WEB-BASED SCREENING SERVICE FOR CLINIMETRICS

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ABSTRACT

Clinimetrics is gaining significance in health related and clinical disciplines. However, obtaining and accessing outcome measures in a flexible manner is an issue because of difficult-to-use programs, fixed instruments and poor access to tools and results.

Hence, we developed and evaluated a novel Software-as-a-Service to create, share, conduct and manage clinical screenings and tests.

The service supports a wide variety of screening instruments. These instruments can then be used in a wide variety of ways: online and offline; on smartphone, tablet and computer; guided by a professional, or self-assessed. Both tests and results can be managed and shared among peers and patients. New screenings can be designed based on standardized instruments or tailored to outcome measure requirements.

The service, called ReQuest, was successfully implemented in multiple research projects. Evaluation results show good acceptance in elderly asked to use the system for self-assessments. Researchers who use the service to conduct and manage screenings, value (i) secure on-site storage, (ii) the flexibility in which they can create or reuse screenings and (iii) sharing screenings with others.

KEYWORDS

Clinimetrics, screenings, clinical research, evaluation tools

1. INTRODUCTION

Clinimetrics focuses on the development and application of assessment methods and measurement instruments to describe or measure symptoms, physical signs and other clinical phenomena. Since the introduction of clinimetrics in 1987 by Alvan Feinstein, adoption and usage has increased significantly in clinical research and practice.

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Nowadays, such clinimetrics systems should be well accessible, easy to use and adaptable towards increasing numbers of tests and patients. In their review, Terwee et al. (2010) demonstrate the importance of standardization in clinimetrics. De Vet et al. (2003) emphasize technical advancements in clinimetrics as crucial towards the future. Not only 'these data still have to be interpreted', also 'their origins should be evaluated and interpreted.' Tomba & Bech (2012) discuss the issue of clinical judgment analysis. To this end, the ability to share and compare *results* and the *screenings* themselves is key.

For individual health indicators, public health and policy, systematic screenings are commonsense (Giard, R. W. M., 2005). In the recent years, many hospitals and health centers saw themselves confronted with an ever-increasing demand of health figures, to be provided for reasons of quality control, benchmarking and comparison. The increasing number of tests, test formats and data points however, raise the demand for clinimetrics support that allow to manage both different screenings and screening results. Meanwhile, this process is facing barriers in logistics of acquisition, distribution, collection of forms; difficulty understanding and completing surveys by patients; the potential disruption of workflow; difficulty scoring and interpreting results; clinical relevance; and cost (Williams, Templins and Mosley-Williams, 2004).

This indicates the need for clinimetrics services that offer 24/7 availability, interoperability, means to access and compare patient results (both inter-subject and between subjects) and safely share them across stakeholders. Data security is a crucial factor in clinimetrics, i.e. knowing the medical data is in safe hands (Institute Of Medicine, 2009).

Research projects increasingly demand development of screenings and self-tests, sometimes including multimedia instructions to clarify the tasks at hand. Finally, we see increasing patient numbers in longitudinal multi-cohort studies requiring effort in screening management.

To sum up, data security, adaptability, availability, easy-to-create screenings with rich content, interoperability, sharing of screenings, management of studies and flexibility for accommodation of screenings are important *criteria* in clinimetrics services.

Current services that fulfill these criteria to a certain extent are given in Table 1. In general, they lack functioning on tablet or smartphone (important for on-the-go usage), media support, connectivity, and sharing options. Besides, costs and data security can be an issue when general available services are used. So the question arises how to address these demands, especially in a reusable and flexible manner.

To be able to fulfill the mentioned criteria, it was necessary to develop our own clinimetrics service. This service is called ReQuest. It is a web-based program (SaaS service), available for clinical research, education, and commercial use.

The service is presented in this paper as follows. Section 2 present the process of executing a screening. In Section 3, the design and implementation approach are discussed. The service is evaluated among users and patients. This is discussed in Section 4. Finally, Section 5 discusses conclusions and Section 6 plots the future work.

Table 1. Comparison of screening programs: RRD ReQuest, VitalHealth QuestManager, SurveyMonkey, Nedap Ons

Heading level	ReQuest	QuestManager	SurveyMonkey	Ons EHR
Target market	research, clinimetrics	surveys, care	surveys,	patient
			general	administration
			purpose	
Measurement instruments				
Number of questions	20	10	15	11
Media	video, photo	-	-	-
Standard database	yes	yes	no	yes
Screenings extensible	yes	yes	yes	yes
Instruction necessary	no	yes	no	yes
Measurement results				
Security	on-premise secured database	cloud database	cloud database	cloud database
Media	video, photo	-	-	-
Result fetching	all, per patient	all, per patient	all	all, per patient
Availability				
Online available	yes	only via EHR	yes	only via EHR
Works on tablet	yes, responsive	yes, limited	yes, responsive	yes, limited
Works on smartphone	yes, responsive	no	yes, responsive	no
Result fetching	all, per patient	all, per patient	all	all, per patient
Sharing				
Share/reuse instruments	on-premise secured database	cloud database	cloud database	cloud database
Personalize instruments	video, photo	-	-	-
API	yes	yes	yes	yes
Connect to EHR	yes	no	no	yes
Technology	very modern	modern	modern	very modern
License	Free for research / education	paid	paid (free trial)	paid
Validation	clinical research	practice	practice	practice

2. SCREENING PROCESS

We define the process of executing a screening by performing the following 4 steps.

- 1. Analyse phenomenon to be screened.
- 2. Design a fitting screening to investigate the issue.
- 3. Gather results through ensuring that the screening is filled out.
- 4. Analyse the results.

Before starting to work with a screening tool, one should analyse the issue at hand one want to investigate. The outcome measures desired should be made clear.

Once analysed, an appropriate design of a screening must be made, or an existing instrument can be used or extended with additional parameters.

The screening can then be filled out to gather results. These results should be analysed with an external analysing program. This can be either aimed at a population or aimed at an individual, based on the task at hand.

3. DESIGN

In order to support the abovementioned steps, a tool was created to support these steps. In this section the main design considerations are presented. It includes its data model, question types flexibility, sharing options, and security aspects. Then briefly the implementation is discussed.

3.1 Data Model

The main point of designing a flexible screening service is choosing a data model that supports a variety of screenings. A *screening* consists of parts and questions. A *part* consists of questions. Each question has a label, optional explanation and uses a question type, such as a Likert scale, multiple choice, stop watch and different numeric / text / decimal types. In this design, many different screenings can be modelled. Currently, ReQuest has over 80 standardized and widely used screenings available, mainly in rehabilition, physical exercise, physiotherapy and evaluation domains.

Questions are stored within each answer, such that should a question definition change over time, the original question text answered is always available. Results are modeled as shown in Figure 1.

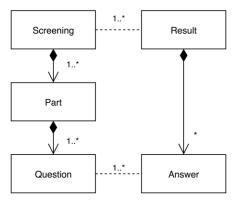


Figure 1. Nested modeling of screenings, screening parts and question, and results with answers. Left column: a Screening consists of one or more Part(s). A Part consists of one or more Question(s). Right column: whenever a Screening is answered it is stored as Result. A Result consists of zero or more

Answer(s) to modeled Questions

3.2 Question Types

Question types refer to a kind of question. E.g., a *numerical question* is a question that should be answered by a number; a *boolean question* should be answered by either yes or no. We made 20 question types are available, including numeric, decimal, date and multiple choice. The full listing is shown in Table 2. In each question, multimedia (images, movies) can be added to explain or illustrate the item. By defining multiple choice options, many discrete questions more can be formulated.

Table 2. Question types available in ReQuest

#	Question type	Explanation of rendered answer field(s)
1	STRING_SMALL	Small text
2	STRING	Text
3	TEXT	Large text
4	NUMERIC	Numeric
5	DECIMAL	Decimal
6	LIKERT_1_5	Likert 1-5
7	LIKERT_1_7	Likert 1-7
8	SCORE_1_10_DECIMAL	Score 1-10 (Decimal)
9	SCORE_1_10_NUMERIC	Score 1-10 (Numeric)
10	BOOLEAN	Boolean question
11	MC_SINGLE	Multiple choice, 1 answer
12	MC_SINGLE_HORIZONTAL	Multiple choice, 1 answer, horizontal
13	MC_MULTI	Multiple choice, multiple answers
14	DATE	Fillout with date (shows date picker)
15	TIME	Fillout with time (hh:mm)
16	EMAIL	Fillout with email address
17	PICTURE_SINGLE	Image, 1 point to be selected
18	PICTURE_MULTI	Image, multiple points to be selected
19	EXPLANATION	Just an explanation label, no answer
20	STOPWATCH	Stopwatch (shows a timer)

3.3 Sharing

Once a screening is created, sharing of screenings is available in three different ways:

- 1. The screening can be added to a publicly available catalogue. This means each other user of ReQuest can reuse the screening. This is useful for standardized tests that are used frequently.
- 2. Besides that, the screening and its results can be shared with a specific number of other users. These other users can access the screening and its results.
- 3. The final way of sharing is to allow a specified number of other users to access the screening and its results, and also allow them to change the screening or manage it. Again, this full-access way of sharing can be set up regardless of whether the screening was added to the catalogue.

3.4 Security

As indicated by a.o. the Institute Of Medicine (2009), a major issue in using publicly available questionnaire services for clinical research, is the fact that the medical data collected is stored in places not controlled or operated by the responsible organization itself. We overcome this issue by using on-site storage. In the case of the implementation at Roessingh Research and Development, it means that the ReQuest databases are protected in dedicated server areas owned and controlled in their own premises.

Moreover, in ReQuest only the owner of a screening is allowed to define who may access either the screening or the screening results, allowing for fine-grained access control to possibly sensitive information.

3.5 Implementation

Ruby on Rails (Ruby on Rails, 2015) was chosen as the framework to implement ReQuest due to its suitability for fast web application development. Moreover, it stimulates convention-over-configuration dictating a clear Model-View-Controller (MVC) separation, support for agile development and good support for automated code testing. Main highlights of the MVC levels are discussed below.

3.5.1 View

Vitannen (2011) concluded a survey stating that usability is among the large points for improvement in clinical software for physicians. We addresss this issue by using a well-known templating format. In this way, the user interface is very recognizable. Twitter Bootstrap (Bootstrap, 2016) is used for the View. Bootstrap enables responsive design and allows a wide-spread layout of the various screens of the service.

Rails' built-in localization functionality is used to provide versions in English, German and Dutch. New screenings can also be designed in other languages.

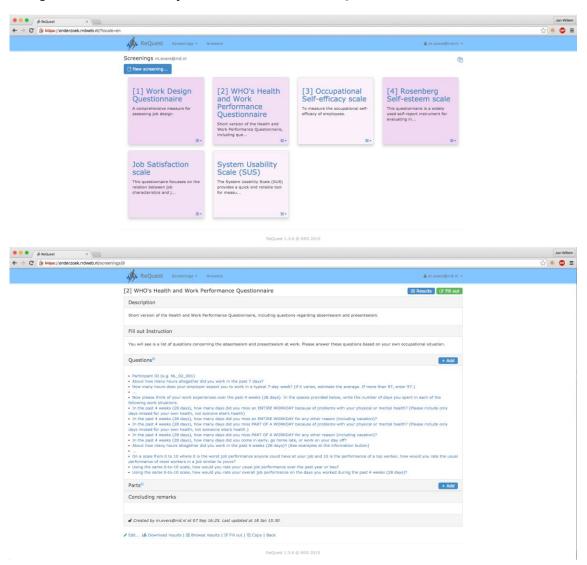
To be able to integrate with other healthcare services or electronic patient records, an API is inevitable. The ReQuest API is currently used to access screenings, questions and results.

RABL (RABL, 2016) is used for API templating, as shown in e.g. Listing 1. It defines the JSON or XML structure and allows CRUD operations in this format consecutively.

Listing 1. RABL templating for retrieving screening by textual identifier

```
collection [@screening] => :screenings
attributes :id, :name, :description, :text id, :created at, :updated at
child :parts do
  attributes :name
    child :questions do
      attributes :id, :name, :description, :question_type, :position,
:greyed out, :required, :default answer, :render instructions, :condition,
:regexp, :options, :media_link, :image_link, :created_at, :updated_at,
:multiple_choice, :text_id
          child :multiple_choice do
        attributes :name, :description, :inactive, :created at, :text id,
:updated at
        child :multiple_choice_options do
          attributes :name, :description, :score, :inactive, :created_at,
:value, :updated_at
        end
      end
    end
end
```

Figure 2 shows the most important interface screens of ReQuest.



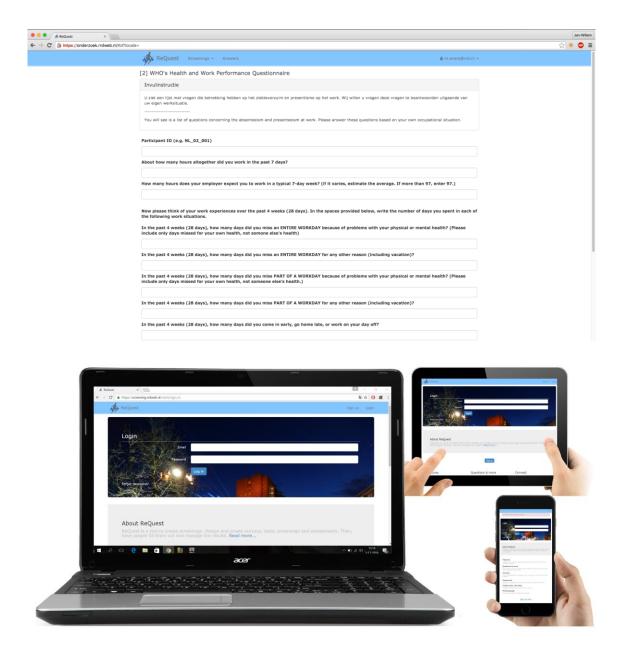


Figure 2. Starting from top: (i) a set of personal screenings, (ii) creating a new screening, (iii) filling out a screening, (iv) responsive design

3.5.2 Model

The models shown in Figure 1 are all backed by means of the ActiveRecord Object-Relation Mapping (ORM). Decoupling the structure of screenings and their answers allows for a wide

variety of screenings to be modeled, while at the same time leaving the screening result modelling relatively easy. When this model is exposed using APIs, other services benefit from a reusable ease to use data format.

The library (in Ruby called gem) deep_cloneable was used for data manipulation tasks related to the nested models of the screenings. I.e., copying of screenings requires deep copies of items from different tables. For performance reasons, this is preferably done using native SQL queries. An example use of this gem is showed below.

```
clazz = self.deep clone include: [:questions, {parts: :questions}]
```

This method takes care of all necessary SQL copying instructions under the hood of a simple statement telling what part of a screening to clone for another use case. It consecutively takes care of referential integrity of the new instance. The model shown in Figure 1 is implemented and backed by MySQL. There are separate databases for test, staging and production deployments.

3.5.3 Controller

Controllers in Rails define the soul of the system. They are at the core of the functionality, relying on the model and represented by the views. To prevent access of screenings patients don't have to do with, hashed id's are used to expose the fillout url to the user. E.g. https://screening.rrdweb.nl/eFHxaz. Json or Xml can be produced for a plethora of read and write operations. This can be used in the API to access screening definitions and to access screening results given a specific screening identifier. Also, complete screening results can be browsed through. Alternatively, it is downloaded in .csv file format for future data processing in e.g. R, SPSS or Matlab. Controllers for the API layer include a before filter to check for valid API calls, to prevent unauthorized access to screenings and results.

The software is hosted on GitHub and tested on CircleCI using RSpec unit and integration tests. ReQuest uses the semantic versioning convention for new releases. At the webpage http://roessinghresearch.github.io/request/ technical documentation is given, the service itself is available at https://screening.rrdweb.nl.

4. EVALUATION

4.1 Method

Currently, researchers working on a.o. FP7 Perssillaa, AAL Pearl and ZonMW Life use the service in longitudinal studies. We set up an evaluation to evaluate usage systematically in 3 ways:

- 1. ReQuest is designed to allow participants, especially elderly, to fill out screenings themselves. Hence, the System Usability Scale was used to find perceived usability among 8 elderly filling out a screening on a laptop in their own home. The screening-of-interest was the SF-36 (Ware et al., 1992) as it used in multiple European prevention projects RRD participates in.
- 2. <u>Screenings can be created and managed with ease</u>. To validate this, it is also evaluated with 7 different researchers that use the service already to create and conduct screenings for their daily work using the System Usability Scale (SUS)

(Bangor, 2008). Then, a semi-structured interview, incorporating questions regarding the specific properties of the service, is conducted to further assess perceived usefulness. Finally, their opinion regarding ReQuest as compared to other screening services was enquired.

3. The service should respond quickly and be 24/7 available. Thus, we monitored the performance of ReQuest using NewRelic application performance monitoring.

4.2 Results

By the end of November, 2016, over 100 screenings were made and over 10.000 questions were answered in over 1000 results. ReQuest has about 3400 pageviews per month. It performs fast: 99,7% of requests are handled within 0,5 second; 0,3% within 0,5-2 seconds based on end-to-end measurement.

The SUS delivers a single number on a scale from 0 to 100. The elderly filling out the SF-36 assessment in their own home using a wifi-connected laptop. They reported a score between 75 and 97,5, resulting in an average benchmark score of 84,4 (sd 6,51).

The researchers also filled out the SUS based on their experience in creating and managing screening using the service. They reported a score between 70 and 85, resulting in an average benchmark score of 78,9. Note that creating a screening is a more demanding task than filling out an already created screening.

The researchers consulted value the ease at which it is possible to create and conduct screenings (n=3).

'It is just that what I need', one researcher said. 'Commercial alternatives may provide more functionality but are often not as intuitive or as trustworthy.' Another said: 'It's easy to create screenings in a fast way. It offers the necessary options that are needed when developing a screening. Furthermore, it's possible to add media files in the screening'. This allows to design screenings with images and videos.

They valued the possibility to discuss program improvements with the designers of ReQuest (n=5) and access to technical support. One other researcher saw it as a must:

'Without ReQuest it would not be possible for me to create self assessments.' One researcher said. 'It was explained clearly to me and allows me to process results easier than on paper as I did beforehand.'

'Especially for healthcare, it is important that we know where the data resides and who has access to it.' was mentioned regarding data security. Since ReQuest allows on-site storage, this crucial aspect can be guaranteed if needed. All interviewees agreed on this being an advantage.

Five out of 7 interviewees said their study participants did not face substantial problems in filling out screenings. Two did not know.

Sharing of screenings is not used by all. Those working in European projects valued screening sharing, as it allows them to share and conduct screenings in multiple centers. Sharing of screening is favored slightly over sharing results. 'If I want to share results, I may as well email the data file' one researcher said, denying need for built-in support.

The responsiveness (it works on all screen sizes) was received positively as well as the user interface.

The number of question types is sufficient, yet 3 researchers would have been better off with even a few more. In most cases they work around missing types. E.g., selecting an answer from a dropdown list can be replaced by using a multiple choice question.

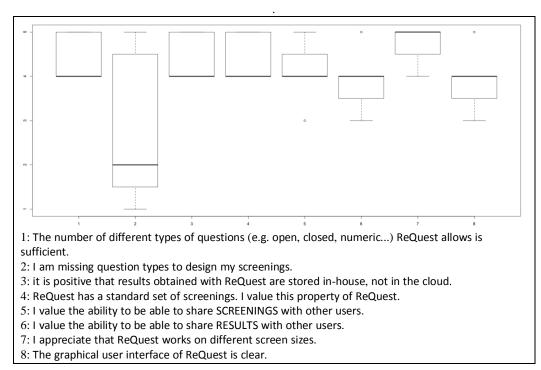


Figure 3. Likert-Based Evaluation (1 (Bottom) – Strongly Disagree ... 5 (Top) – Strongly Agree) For 8 Questions (Left To Right)

5. CONCLUSIONS

In this article we presented a web-based screening and clinimetrics service. Using this service, it is possible to conduct existing screenings as well as new screenings. The service has over 100 screenings with over 1000 results currently.

The service allows a variety of assessment to be conducted on different screen sizes such as smartphone, tablet or laptop. Currently, ReQuest is used in national and European research projects FP7 Perssillaa and DECI, AAL Pearl and ZonMW Life. The current work shows that safeguarding data, sharing of screenings and results for cooperation purposes, and the ability to manage a study process are key factors for researchers in such a tool.

Seven screening designers were interviewed. They are satisfied with the process of offering and improving ReQuest continuously. They value on-site data storage that safeguards their measurements and the possibility to share and reuse screenings. New screenings can be created quickly according to the users. SUS indicated good usability in elderly filling out self-assessments as well in researchers using ReQuest.

The limited numbers of respondents available (related to the novelty of the service) prevents bold statements about the outcomes. When evaluating usage of such a flexible tool in patients, is that the usability of the system itself is blurred with the usability of the screening created with it. I.e., end users evaluate the overall perceived screening, and not only the program that allow to conduct a to-be-configured screening. Of course, such scoring is dependent on the actual screening. For that reason we choose a common standardized test.

6. FUTURE WORK

ReQuest is being used in different national and European projects. Recently, efforts were made to support large data sets in these projects, including the functionality to indicate key answers to be shown in result overviews. A current topic of interest is the possibility to perform functional tests such as the Timed Up and Go test as a self assessment, using instructions and videos presented on screen.

More work is needed in the future especially to support cohort studies. Then, partial result sets can be obtained and cohorts can be managed with more ease. We are also developing manuals and video instructions to increase self-support when using ReQuest. Finally, the flexibility of the service makes it worth to investigate its applicability to more practical areas outside clinimetrics research, such as physiotherapy.

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