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Original Article

Development and usability testing of Riyadh Mother and Baby Multi-center cohort study registry

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ABSTRACT

Rational and objectives: A medical registry is a software application that gather and keep clinical and non-clinical data to serve as recording tool for a specific disease longitudinally. In this study, Riyadh Mother and Baby Multicenter was designed as longitudinal study to understand the effect of non-communicable disease on mothers and their babies. A registry was built for the study; to improve data collection process thus enhance the data analysis and to enhance quality of healthcare provided by timely improvement of the services. The objective of this study is to test the usability of the cohort registry developed for clinical research and service improvement.

Methods: Think aloud method, a qualitative approach was employed to elicit behaviors of participants while interacting with the registry interface prototype while the focus group session was conducted in order to understand the participants' insights and how participants reach consensus on the functionality and user interface design. Both deductive and inductive thematic analysis were performed on the qualitative data. After two iterative design cycles, improvements were made to the registry prototype.

Results: The registry was found to be efficient, easy to learn, satisfactory, and easy to remember, and resulted in fewer errors. Major design features such as font size and colors were improved based on participants' feedback. In addition to the tested attributes, additional themes of design and benefits were found inductively.

Conclusion: Usability testing of the cohort registry showed that the system was easy to use due to its simple and custom- made design. Improvements of the registry based on the participants' feedback helped in enhancing its usability attributes.

Introduction

The use of information technology in healthcare is an integral part to the reform of health systems in many countries [1]. Although, many health systems are yet to incorporate more sophisticated applications in different aspects of patients' care and health research, the implementation of such technology may prove to be challenging to the users [2–5]. Based on failures of adoption of some high-cost national electronic systems, early usability testing and sharing of technology with end-users and stakeholders is of paramount importance and may prove to be vital in overcoming challenges and barriers [5,6]. Registries are software programs that collect and store data and serve as a recording tool [7]. A registry is a type of clinical research informatics (CRI) system, defined as a health information technology intervention, that enables the computerized collection, storage, a processing of data specifically for clinical research [8–10]. Registries in medical research help to explain the history of a disease, to inform the clinical and cost effectiveness, and to determine the risk factors and measure health outcomes [7]. Such features are important especially for longitudinal studies, which investigate the effects of exposure in more than one generation of the population. Furthermore, registries can be used as audit tools for improving the quality of healthcare.

A user-centered approach is employed to measure human interaction with computer in work settings [11,12]. Usability testing

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examines how users interact with a system in the work environment and evaluates the capacity, performance, and ease of use of the system. Users are included during the early design phases and an iterative development process is employed to ensure the final system will be well suited to the users' needs. Multiple data collection methods, such as "think aloud" and focus groups, are used in user-centered approach. They enable triangulation and inform the iterative process so that users' needs and opinions could be incorporated throughout the development process. Usability attributes that can be measured through user-centered approach include; efficiency, learnability, memorability, error rate, and satisfaction.

In Saudi Arabia, there is still a gap in medical research technology development thus understanding how registries can be used for research is an innovation [13,14]. A recent work on registry in biomedical devices was published in the past year to show there are efforts in registry development in Saudi Arabia [15,16].

The objective of this study is to test the usability of the cohort registry developed for clinical research and service improvement.

Methods

RAHMA registry development

The subject of this registry is Riyadh Mother and Baby Multicenter (RAHMA) Cohort Study which was conducted in three major hospitals in Riyadh, the capital city of Saudi Arabia, to investigate the effects of maternal non-communicable diseases on newborn and child [17]. The study recruited more than 14,000 participants using paper-based data collection. The participants will be followed for several decades to come. The study had noticeable impact on clinical practice as analysis of the data from the study was used as an audit tool to improve screening and management of pregnant women for gestational and pre-gestational diabetes [18,19].

RAHMA registry was custom-made to overcome medical research challenges specific to Saudi Arabia, such as difficulties in recalling participants due to duplication of family names, insufficient contact information and lack of national medical records. RAHMA registry was developed in-house to reduce the cost of data collection. It was designed and developed using Visual Basic and ASP.NET. The database underlying the system is Microsoft SQL Server 2005. There are four sections in the registry:

Dashboard: dashboard where users can access specific patient record in the registry, log management and user management (See Appendix A)
User management section which can be accessed through the dashboard from where administrator can create access for users for clinicians and researchers.

RAHMA Registry data collection section: contains 13 forms with a total of 256 fields to collect all maternity and newborn clinical information. The forms allow data to be collected longitudinally through pregnancy and postpartum period. To reduce duplication and the possibility of errors when entering participants' names, the system offers fields for all Arabic name components (first name, last name, grandfather's name and tribe name). For contact information, both cell and home phone numbers for the participants and husbands were included. In addition, the system incorporates automated features such as calculation of BMI, expected delivery date, and validates data entered into fields as being the correct range and type (numerical vs. text). The user can navigate from one form to another using the quick link menu. Users can export data into text (csv) or spreadsheet (Excel) format for data analysis purposes.

Log management section: allows users to view and track all system-related activities, such as the latest accessed records and changes made to records.

Setting and participants

We adopted a user-centered approach; where users were part of the early stages of system design and their feedback was elicited during development of the system through think aloud sessions and focus groups [11,12]. The feedback directly resulted in changes to the registry followed by re-testing (iterative approach).

The qualitative research study was conducted at King Khalid University Hospital (KKUH) which is part of King Saud University medical city. The hospital was one of the centers where the cohort study was conducted [17]. Data collection was conducted between April and May 2015. Purposive sampling technique was used where we recruited participants who were researchers or potential researchers including; nurses, physicians and researchers working in the maternity or pediatric departments in addition to public health and family medicine specialists. Based on user interaction experts, 85%of the usability problems can be discovered by four or five participants while 100% of usability problems can discovered by 15 users [20]. Thus, in this study, we recruited 15 participants.

All participants signed a consent form and agreed to be tape-recorded during data collection. The sessions were conducted in computer laboratories, offices or clinics that were equipped with internet access computer and offered a quiet and private environment conducive for think aloud and focus group session.

Qualitative research: Think Aloud and focus group

A qualitative design was employed to explore users' experience in depth. This method was chosen to elicit the shortcomings of the registry design and to improve the contents and design of the registry [21,22]. For triangulation, we employed two data collection methods which were, think aloud and focus group [21].

Think aloud is a qualitative data collection method where participants think and talk out loud while performing usability testing of software [20,23,24]. A few studies in healthcare, employed think aloud technique to capture user's thoughts, and also behavior of interaction with a bed side systems [25] and one study for a nursing scheduling system [26] explained how think aloud provide an insight how user behave when using the system.

In this study, before the think aloud sessions, participants were briefed on usability testing of the registry then each participant was asked to perform specific tasks using RAHMA registry based on the protocol (Appendix B.1 and B.2). One of the authors observed the participant's interactions with the system and audio recorded the process which was later transcribed for data analysis. A total of 15 participants took part in the study; four physicians, four researchers and seven nurses. Ten were females and three were males. Participants came from different departments in KKUH.

Following the think aloud sessions, a focus group was conducted. From the 15 participants participated, 11 of participants attended the focus group session. The purpose of the focus group was to stimulate group discussion about the registry and reach a consensus on its usability attributes. Three facilitators were present to run the session, which lasted for 70 min. Questions on specific usability attributes were used to stimulate the discussion based on the focus group guide (Appendix B.2). RAHMA registry was projected on the screen during these sessions so that participants could refer to the actual system while discussing design and functionality issues. During the focus groups we observed agreements and disagreements among participants. For this study, we tested the following usability attributes:

Learnability, how quickly users become comfortable working with the system) is an important factor in measuring the usability of health information technology which explains the relationship between humans and computer [27,28].

Efficiency is a broader aspect of usability meaning that the product is easy to use and not annoying.

Error rate is defined in terms of the accuracy of data entered, calculated as the number of mistakes committed when users use the health registry program [21]. Memorability is defined as how easily the user can remember the features of the program [27]. Satisfaction is the only usability component that is subjective and pertains to the fulfillment of the user's expectations derived from using the program [27].

Besides the common usability attributes above, we anticipated that other new usability issues would emerge from the data.

Data management and analysis

All data, including think aloud and focus group recordings, were stored in the researchers' computers which were password protected. Audio recordings were transcribed and analyzed using Atlas.ti, Mac version 7. Once all transcriptions were imported into Atlas.ti, thematic analysis was conducted.

Validity of data and analysis was confirmed by discussion among researchers. Each theme and sub-theme was supported by meaningful quotations (verbatim). Reliability was achieved by researchers' agreements on themes and sub-themes for consistency. Credibility is reached by member checking process where participants themselves confirm their response during focus group sessions [24]. After the focus group, we confirmed all data were able to support each sub-themes and saturation is achieved.

Ethical consideration

This study was approved by the Institutional Review board for King Khalid University Hospital with permission number E15-1440.

Results

Thematic analysis of the think aloud data yielded five sub themes:

Efficiency

The first usability measurement, efficiency indicates that the prototype is easy to use and not cumbersome to the users. All of the participants reported that RAHMA registry was easy to use for all tasks that they were asked to perform. For example, this physician find the registry is easy and straightforward to use where he said

> "I think using with this program was easy although it was my first time it. I don't think it was complicated"
>
> (Doctor 1).

Learnability

Learnability measurement can help to show the learning behaviors among participants. Many participants agreed that the system was easy to learn and straightforward in terms of guiding them to put the right information in the right place. They were able to follow the instructions easily without asking for help. The system has a function that highlights any empty required fields in gray to guide the users to the required.

> "I think the example written in "gray" inside the boxes are very useful to show what kind of information is needed." (Doctor 2).

However, one participant could not figure out how to change her password:

> "I cannot change my password, I tried many times to change it, it keeps telling me the old password was wrong" (Researcher 1)

Memorability

A few of the tasks during the think aloud require participants to repeat some task in order to measure the memorability dimension. The phrase "easy to remember" how to navigate were repeatedly mentioned by many participants, reflecting positive memorability of the system. They also mentioned that they would remember how to navigate between system pages next time they used it.

> "It is easy for me to look for the page that I would like to find." (Nurse 1)

However, one participant mentioned that it took her some time to find her name when she wanted to edit her profile:

> "It took a while to find where I should go to find my name" (Doctor 3)

Coping with errors

Participants reported very minimal errors when using the registry and they praised the accuracy of the system. The majority mentioned that the registry was accurate when they found that the patient's data matched the patient's name.

> "I didn't encounter any errors." (Nurse 2)

One particular feature of the registry is that it validates numeric entries carefully.

> "The registry will only accept digits within the correct range. It did not accept when I entered mother's weight to be 170 kg instead 70kg" (Nurse 3)

Only one participant mentioned making errors while using the system:

> "The system is complicated and it caused me to commit many errors and I spent a long time completing one form, I keep having errors". (Nurse 3)

Satisfaction

Many participants expressed satisfaction with the system. For example:

> "Overall, I found it user friendly and I am pleased to use it". (Nurse 3)

Participants also felt that the program contained enough information about the patient:

> "I think the patient information is very comprehensive" (Nurse 4)

However, the data also revealed that some of the participants found the form of the registry too lengthy to complete.

> "Although most of the information is useful, it so much information to fill up and takes a lot of time to complete." (Nurse 5)

Design

The design sub-theme was elicited inductively through evidence that describes the overall design and functionality during the focus group. The majority of the participants agreed that the design was acceptable:

> “I think the program as a whole is unique and very easy to use; the access was easy and I hope it would work.” (Doctor 1)

Benefits

Many of the participants said that the system was beneficial for use in research.

> “This system can help for easy information retrieval for research purposes.” (Nurse 5) One participant said,

> “I think if we immediately enter the data into a system like this, it will be much better than the paper-based data collection” (Doctor 1)

Major improvements

A few design suggestions were discussed during the focus group and major improvements were made where necessary.

Font size of logout button was enlarged so it would be more visible to users.

> “I could not see the logout button on the dashboard page, but after exploring the page, I could see the logout button was at the far-right corner, but the size is not visible” (Nurse 3)

Often times, some field cannot be filled up as information cannot be completed at the point of patient recall.

We decided to add a “Not applicable” button to some fields to allow users to skip some fields or text box. “Sometimes, I do not have information for some fields in the form, it would be nice that if the registry can allow us to ignore the field and go to the next form” (Nurse 2)

Added a calculator for expected delivery date and body mass index.

> “I wish the registry can automatically calculate the BMI and expected delivery date based on the information given in the form, i.e. weight, height and last day of period” (Doctor 2)

Added the option to choose “Save” or “Save and next” for those who want to continue to the next page.

> “It will be great if a user can choose to save and go to the next form or return to the dashboard if needed”

(Nurse 3)

There was a feedback on navigating from one form to another form in the registry. For an example, one participant mentioned this

> “There are many forms need to be filled in the registry, it would be nice if we can skip some form and go to the form that we want” (Doctor 1)

Our team decided not to address this feedback as the forms in the registry are arranged based on the natural history of pregnancy with childbirth and postpartum period. We could not introduce the feature of skipping some forms to avoid risking the possibility of incomplete data in the registry

Discussion

The results of this study showed that participants found the RAHMA registry usable in terms of; efficiency, satisfaction, learnability, memorability, error reduction, and overall design. The usability factors and subthemes found in this research enable us to improve the usability of RAHMA registry to be deployed in clinical settings. Usability testing is an economical way to improve a system before it is placed into general use. Past studies indicated that a single cycle of evaluation results in a tenfold reduction in usability problem [11,27]. In this study, we made improvements to the registry while the usability testing was conducted based on a user-centered approach. In addition, by using triangulation we ensured an iterative design process using multiple data collection techniques. The use of the think aloud technique gave us an in depth understanding of the participants' responses to and feelings about the registry, while the focus group made it possible to get confirmation and consensus from the participants regarding how the registry could be further improved.

The use of information technology (IT) in the medical field to share and coordinate data is still in its infancy in the Middle East [14]. Only a handful of health organizations are using electronic health records (EHR) to collect and store data in Saudi Arabia, which is a problem because EHR can be a powerful vehicle for clinical care and research. In the capital city of Riyadh, only two hospitals have achieved Stage 7/Meaningful Use of Electronic Health Record [29]. There are few notable work that have been published in registry development in Saudi Arabia involving Saudi Food and Drug Administration (SFDA) in biomedical devices that can help us to learn and improve our registry development process. The published work in Medical Device National Registry based in Saudi Arabia discussed the idea conception of a registry [30], the data elements needed for a registry [31], the registry development process [31], the readiness study before the cloud-based registry across organization in Saudia Arabia [15], the policy development process for a registry [16] and most importantly the overall experience of designing and developing a national registry [32].

Although many developed nations have been using EHR for years, the literature indicates that IT is not regularly used to link clinical care with research [33]. Many institutions even in developed countries are still struggling to integrate clinical care with research from the data model perspective [34]. RAHMA registry is one of the examples of a clinical research informatics [10,35]. The registry provides data warehousing, data management, participant recruitment, collaborative teamwork, and integrative data mechanisms.

The registry was custom made to be used in the same environment in which data collection took place. Health researchers/clinicians often resist complex systems as they are working in a busy environment with limited time to learn new systems [34,36]. In addition, the research culture is still new in the Middle East including Saudi Arabia, thus a system that is simple and easy to use will encourage and promote research by saving time, effort, and cost [37,38].

RAHMA registry has a great potential as source of valuable information to improve maternity services in the hospital and in the Kingdom if implemented as a national registry, however such implementation faces few challenges. One of the most important challenges is to link the registry to the hospital electronic or the national health record, which will save staff time and efforts in dual entry of clinical data, furthermore it will improve the healthcare quality by providing regular reports which can feed into key performance indicators (KPI).

Longitudinal cohort registry requires patient contact information to be accurate and complete in order for patient recall process to be done in a timely and orderly manner to avoid large dropout of patients and invalid data for follow up. Maintaining the contacts with the patients' in the registry may prove to be another challenge because the postal addresses of many patients are inaccurate and change frequently as well as their telephone numbers. To overcome this problem, the registry was designed to require users to identify patients with their first and last name (the father's and grandfather's names), the husband full name and the tribe name. In addition to the mobile phone numbers for the mother and her husband and the email addresses if available.

Strength and limitations

RAHMA registry is a new health informatics innovation in Saudi Arabia created in a teaching hospital to provide clinical data for research. The research in this study has evaluated the usability aspect of the registry which can be of value for researchers and policy makers.

RAHMA registry will have significant impact on the maternity clinical services, research and teaching. The information collected by the registry can be used to improve the quality of healthcare provide by red-flagging and bench-marking the rate interventions such as cesarean section delivery rate in addition to vital statistics such as preterm birth and perinatal mortality rate. The registry is a valuable data for research on the immediate effects of many maternity problems such as pre-gestational and gestational diabetes on the newborn and the mother as well as the future child and adult. The integration of the registry in the hospital IT system will provide a valuable subject for teaching undergraduate and postgraduate students the importance of registry as source of data for research and clinical practice. RAHMA registry will have significant impact on the maternity clinical services, research and teaching.

The usability study run using RAHMA registry is amongst the few study in Saudi Arabia that apply usability testing during the development phase. The expertise and experience gained in conducting such methodology can be valuable for the research community in Saudi Arabia to exchange ideas on such methodology. Consequently, workshops and training in usability testing in healthcare environment can be organized to create awareness and understanding of such methodology.

We acknowledge the limitations of this study including all participants were from one center despite the fact this cohort study itself is a multi-center study. Other participants from other centers were not able to join the study, thus we may have missed some valuable feedback. Another limitation was that we did not include the opinion of other end-users such as statisticians and senior researchers due to time constrain to develop the registry.

Conclusion

In-house built cohort registry was found to be users friendly, learnable and efficient by the participants. The employment of the user-centered approached in the evaluation of RAHMA registry was proven to efficient and cost effective.

Competing interests

The authors Nasriah Zakaria, Hayfaa Wahabi and Mohammad AlQahtani declare that they are the investigators in RAHMA cohort study.

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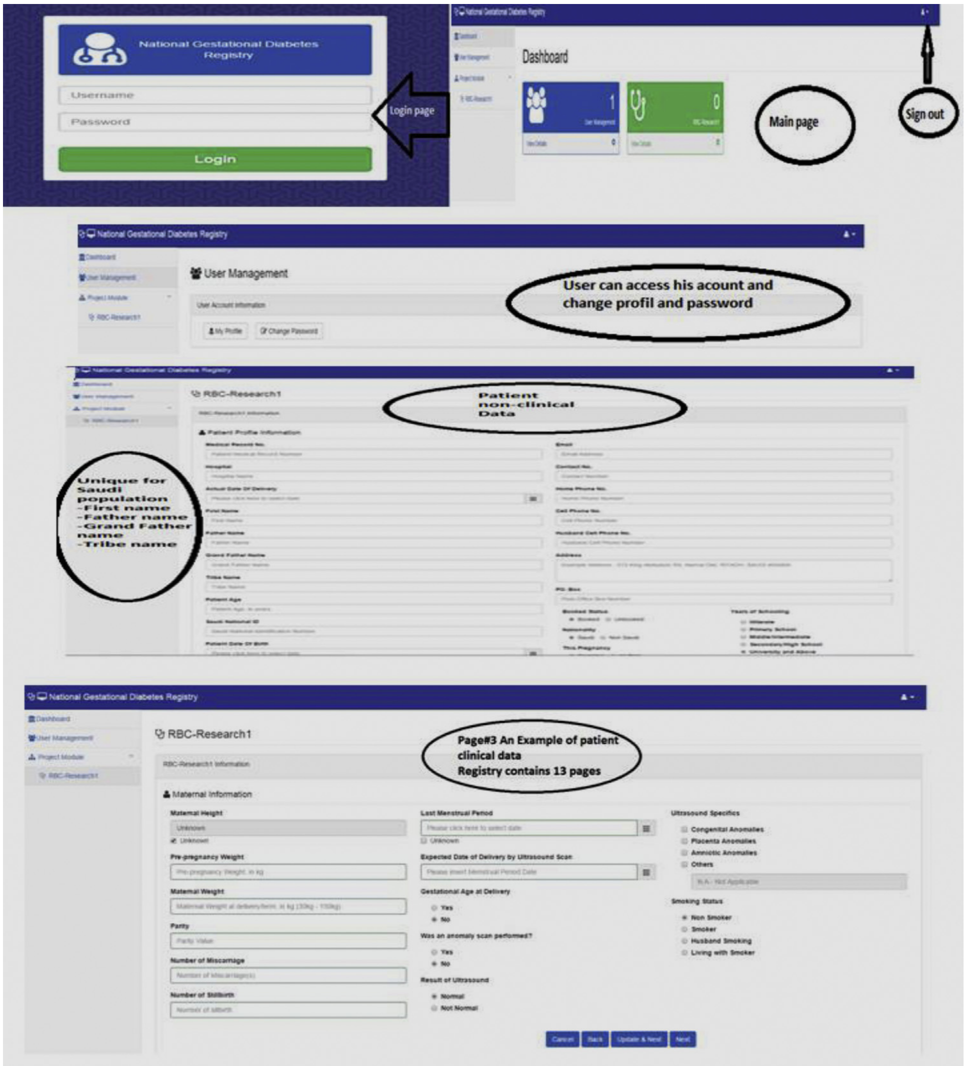
Appendix A. Screenshot of login, dashboard and login information



User can access his acount and change profil and password

Patient non-clinical Data

Unique for Saudi population
-First name
-Father name
-Grand Father name
-Tribe name

Page#3 An Example of patient clinical data
Registry contains 13 pages

Appendix B

B.1 Think aloud questions

Task Questions

Login: please log-in to the system using your username and password as given **Doctor1**

Abc123

User management: please click on user management icon

a. Change your name and update
b. Change your password and update c. Logout and re-login with your new password

Creating new record:

a. Please go back to the dashboard and click on RAHMA Registry data collection formicon then create a new record
a. Fill up Page 1–3
b. Check each page by clicking“Back”.

Data retrieval from patient medical record:

a. Please go back to the dashboard and click on the RAHMA Registry data collection formicon. Go to medical record 12345, change Age, Years of Schooling and Update
b. Put characters only in Cell phone field and update
c. Double check by going back to RAHMA Registry data collection form, and find and verify medical record 12345

a. How easy were you to access the main page?
b. How fast were you able to access the page?
c. What do you feel when you accessed the main page?
d. Do you think that your username and password is safe when you accessed the page?
e. What do you think should we add or delete to improve the main page?

a. How easy was it to navigate from the main page to the user profile page?
b. What can you say about the way you were directed from the main page to the user registration page?
c. Do you think that you can access the user page easily the next time you log-in?
d. What can you say about the complexity or simplicity of the program for a user like you?

e. Are you satisfied with the way the program is set-up for you?

a. How easy was it for you to learn how to navigate between pages of the system?
b. What can you say of the ease in using the system?
c. Did the page open-up to the page that you wanted?
d. Is it easy for you to remember how to navigate through the pages the next time you will use the system?
e. What can you say of the system design and do you have any suggestions to improve the system?

a. How easy was it for you to navigate from the dashboard to the patient medical record system?
b. What can you say about the items on the RAHMA Registry data collection form page?
c. Did the page give you sufficient information that you needed accurately? Did the entries in the patient's information correctly matched the medical record number?
d. How did you feel over the details of how the patient's information pages created?
e. Do you have any suggestions to improve the page? What are those?

Log out: Please terminate all the activities and log-out from the program

a. How easy was it for you to log-out of the system?
b. Do you think that by logging-out from the system, that your username and password is protected?
c. Did you encounter any errors in logging-out?
d. What can you say about the logging=out system of the program?
e. Do you have any suggestions to improve the logging-out system of the program?

B.2 Focus group protocol

Interviewer Questions

Introduction Could you please introduce yourself? Briefing of the participant
Background questions Have you ever been involved in any research work or data collection? (Paper based)
What was your role?
Do you enjoy the process?
Do you have experience using computer at your workplace, please tell me what are the advantages and disadvantages of using computer instead of paper?

Remind the participants that they had logged-in, change name and password, filled- up three pages of the form, updated some information on the system, checked updates and logged-out

Main questions:

(a) What is your first impression about the system design? Interface, color?
(b) Is the language, clear and easy to understand?
(c) Are you satisfied with the design of the program?
(d) Do you have any suggestions to improve system design?
(e) Do you think this program is useful for you as a data collection tool?
(f) How did you find the comfort and ease of using the program?
(g) How easy to navigate from one page to the next?
(h) Does the system help you to learn how to use it?
(i) What are the problems you faced in using the program?
(j) Do you see any benefit from this registry?
(k) How did you evaluate the time consumed to fill system pages? Do you have suggestions to reduce time taken?
(l) How much time do you think you will spend for each patient?
(m) In the future, we will need some clinicians to help with data collection for RAHMA registry. If you are involved in this research, can you discuss how much should a data collector be paid for each patient?
(n) Can each of you give comments about the RAHMA registry?

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