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IntegrIT - Towards Utilizing the Swedish National Health Information Exchange Platform for Clinical Research

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Abstract. This paper describes how the Swedish national Health Information Exchange platform can be used to facilitate clinical research in the future. Different e-services for different user groups are being developed using a usercentered design approach. The main user groups are study participants, clinical researchers and healthcare professionals. The different e-services are based on an in-depth analysis of the clinical research process, and the main identified needs relate to recruitment of study participants, access to clinical data from different sources as well as improved tools for patients' self-reporting. The national Swedish HIE platform has the potential to enable a seamless connection between patients/citizens as study participants, health care professionals and everyday clinical work and clinical researchers in both academia and industry.

Keywords. Clinical Research Informatics, eHealth, User-Centered Design

1. Introduction

Clinical research is an important part of healthcare and clinical research informatics provides essential tools to support and reshape the landscape of clinical research [1][2]. Clinical research informatics is a relatively young field of research, and there are many challenges that need to be addressed, whereof data access and recruitment issues are often mentioned as some of the most important ones [3][4]. Many international studies are focusing on addressing the challenges of gaining access to clinical data, from e.g. the electronic health records (EHR), for research purposes [5][6].

In parallel with the progress within clinical research informatics, participatory health is a growing area in which individuals are using health social networks, smartphone health applications, and personal health records to achieve positive health outcomes. In Sweden, a national eHealth infrastructure [7] is currently being implemented enabling health data to be accessible across care providers and to patients.

Mobile technology and self-tracking devices are also radically impacting the way we collect, use and share health related data, and when patients pool their data together powerful data sets are created that can be of great importance to clinical research. In the

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US, the Precision Medicine Initiative is aiming to explore how such large data sets capturing can help create treatments that are adapted to individual variability in genes, environment, and lifestyle for each person [8]. In Sweden, several initiatives are exploring the opportunities of utilizing the national eHealth infrastructure for secondary purposes, e.g. to support clinical research. In this paper, we aim to describe how the Swedish national Health Information Exchange (HIE) platform can be used to facilitate clinical research in the future.

2. Methods and Materials

IntegrIT is a 2-year project with the goal to develop new services and improve routines for patient recruitment to clinical research projects, systematic, ongoing collection and analysis of structured clinical data for research directly from medical records, and integration of clinical data with patients' self-reporting and data from biobanks and registries. To be able to access data from many different EHR systems currently used within Sweden, the solutions are based on the national HIE platform and will be part of a new national research infrastructure. The infrastructure will be integrated with the already available national virtual patient portal 1177 Vårdguiden (http://www.1177.se/) and the corresponding portal for healthcare professionals. The purpose is to promote clinical research in daily care while reducing administrative time for both researchers and study participants.

2.1. The Swedish National Health Information Exchange Platform

Sweden has chosen to implement a national HIE platform to facilitate the communication between different health information systems and eHealth services. The national HIE platform enables a single point of connectivity for client applications, making all Swedish EHRs appear as a national, virtual EHR. Client applications may be targeted for patients, professionals, researchers, payers, byers and follow-up. The national HIE platform allows exchange of health care data between different health information systems (HIS) according to nationally defined *service contracts*. Rather than having direct integration between HIS, all integration is with the national HIE platform which then redirects requests for information and transactions to the appropriate system. In summary, the national HIE platform forwards the request message from a system or a service to the appropriate source systems, often e.g. EHR systems used by different care providers and returns the response, which may be aggregated from multiple sources [9].

2.2. User-Centered Design

A user-centered design approach [10] has been applied in the IntegrIT-project to ensure that the solutions are usable and adapted to the context of the different user groups. The main user groups were identified as study participant, clinical researchers and health care professionals, and an in-depth analysis of their needs was performed using qualitative methods; interviews [11] and contextual inquiries[12]. Based on the contextual inquiries with clinical researchers, a hierarchical task analysis [13] was performed which formed the basis for the proposed functionality for different user groups.

3. Results

In this paper we provide an overview of the e-services developed in the IntegrIT project. As an important part of the context description, we first present the different user groups, and then continue to describe the services proposed in the project.

The stakeholders are many in clinical research, and there is great interest in a clinical research infrastructure. Within the IntegrIT project we have chosen to focus on 3 main user groups which are described further in table 1.

 Table 1. Description of IntegrIT's main user groups.

User group	Description
Clinical researchers	Clinical researchers (physicians, nurses, physiotherapists etc). Work situation
	and incentives differ a lot between researchers in the hospital and primary care
	contexts, as well as clinical researchers in industry.
	Research nurses is a specific sub-group of clinical researchers who work almost
	exclusively with clinical research but rarely as Principal Investigator (PI)
Study participants	Patients are the main type of study participants in clinical research, but we also
	include next-of-kin in this category (e.g. parents of children participating in
	clinical studies). In addition to patients, healthy volunteers are also an important
	sub-group that could have an interest in IntegrIT's e-services.
Health care	In many clinical studies that are performed in daily care, health care
professionals	professionals are required to contribute to the study by e.g. recruiting study
-	participants and collecting study data.
	In this category we also include healthcare managers who need to approve the
	participation of staff as well as access to clinical data.

As part of the user needs analysis, a hierarchical task analysis was performed based on the contextual inquiries made with clinical researchers. The activities or tasks researchers go through within a clinical study was identified and broken down in several layers. Here, we only present the top layer which corresponds to the overall phases in a clinical study, figure 1. Whereas there were many tasks identified in all phases, the analysis indicated that IntegrIT's e-services could be most useful in phase 3 and 4 – preparing and conducting the study.



Figure 1. Top layer of the hierarchical task analysis

The analysis of activities in the clinical research process formed the basis for identifying the core functionality needed to create useful tools to support different users through the clinical research process (figure 2).



Figure 2. An overview of the services proposed by IntegrIT

In the first stage of the project, an initial set of e-services was developed based on the main needs identified as well as the feasibility of providing the functionality through the national HIE platform.

Table 2.	Description	of IntegrIT's	main	e-services
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e-service	Description
Study Guide	A study guide was developed based on the need to support less experienced
	researchers in planning and preparing a study. The study guide e.g. describes
	what approvals are needed, as well as where and how to obtain them.
Study service –	Clinical researchers can log in to register their studies. Current functionality
Researchers	includes support for recruiting participants through the national patient portal
	and to set-up recruitment rules for matching with EHR data, to handle study
	participants from first contact to inclusion, to handle informed consent
	(electronically or manually) and to collect data from EHRs (with patient and
	care provider consent). Researchers can also invite other investigators and add
	further study sites.
Study service -	The study service for citizens/patients is intended to be reached through the
Study participants	national patient portal with secure log-in. After log-in, the user can search for
	available research studies in a study catalogue, use an EHR matching service to
	find studies that could be relevant based on the information in the EHR, contact
	studies that are interesting with a request to participate, receive information and
	provide informed consent (and have access to consents given and study
a. 1	information in retrospect).
Study service –	This service contains two main functions; (1) to approve that a study can gain
Care provider	access to EHR data, and (2) a matching function similar to the one used by the
	patients themselves but intended to be used by healthcare professionals together
	with the patient during an encounter. A so called Clinical Trial Alert [5]
	function is also under development in collaboration with EHR vendors.

In addition, an iPhone app for self-reporting of study data has been developed based on the Apple Research Kit [14], for study participants to be able to report their allergy symptoms on a daily basis during the allergy season. The app was used in a study during the summer 2016 and evaluation from a user perspective is ongoing. The app is not yet integrated with the study services described above.

4. Discussion and Conclusion

The national Swedish HIE platform has the potential to provide not only useful tools for clinicians (e.g. the national patient overview) and patients (e.g. online access to one's own EHR) but also to enable a more seamless connection between patients/citizens as study participants, health care professionals and everyday clinical work and clinical researchers in both academia and industry. In this paper, we have presented the initial steps of developing a national clinical research infrastructure based on the national HIE platform. The e-services developed in the first stage of the project have undergone formative evaluation through usability testing, however further pilot testing in clinical studies is required to ensure that both infrastructure and e-services are sufficient to support clinical research in the future.

Acknowledgments

The project "IntegrIT" is supported by VINNOVA – Swedish Agency for Innovation Systems (2014-00736).

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