

Requirements for a Patient Recruitment System

Björn SCHREIWEIS^{a,1} and Björn BERGH^a

^a*Center for Information Technology and Medical Engineering, University Hospital Heidelberg, Germany*

Abstract. Computerization and increasing need for evidence based medicine are not stopping at biomedical research. Clinical trials need participants and the problem of matching patients with eligibility criteria to support clinical trials has many different solutions. A detailed analysis of stakeholders' requirements would help implementing better patient recruitment systems (PRSs) in the future. Thus we decided to analyse the requirements in literature and talk to stakeholders what they feel the features of PRSs should be. Including patients and data privacy officers as stakeholders gives a holistic overview. Requirements are overlapping between different stakeholders with each stakeholder adding a different view on PRSs. Requirements implemented in current PRSs overlap mostly with requirements expressed by physicians and researchers. Especially patients' requirements (e.g. not having to enter medical data themselves) on PRSs give the impression that PRSs need to integrate with EHR systems or even PEHRs.

Keywords. Clinical trials as topic, patient recruitment system, EMR, EHR, requirements.

Introduction

Clinical research relies on sufficient data and research subjects. Introducing new drugs, medical devices or therapies hence requires a certain number of study participants or patients. But clinical trials often fail recruiting a sufficient amount of participants at least within the time planned in trial protocols [1]. Patient recruitment systems (PRSs) to improve the process of recruiting a sufficient amount of patients/participants are starting to be introduced more widely [2-9]. Studies show that PRSs can improve patient recruitment (e.g. [10]). However, the stakeholders' requirements and patients' perspective are not yet fully presented and analysed. Thus we decided to research and analyse the requirements of patients, physicians, data privacy officers, researchers and hospital administration.

1. Methods

An unsystematic literature analysis was performed to get an overview of existing PRSs implementations and the requirements that led to these PRSs. Search terms were

¹ Corresponding Author.

“patient recruitment”, “clinical trial” and “software tool”. The search was performed on the PubMed database. The requirements were not weight on the number of appearances of a certain requirement but put on the list of requirements after the first appearance. Additionally the German data privacy laws were analyzed to find legal requirements a data privacy officer would have on a PRS.

Further unstructured interviews were performed to allow for the stakeholders’ to mention their requirements unbiased. The interviews were conducted in form of focus group meetings and face-to-face interviews. Patients, medical phd students, study nurses, physicians, principal investigators (PIs), data privacy officers and researchers were identified as possible stakeholders. Medical phd students, study nurses and PIs are seen as a subset of researchers.

2. Results

2.1. Literature

Literature [2, 3, 5-26] revealed functions the PRS implemented instead of requirements by stakeholders. Functions implicitly mention basic requirement, e.g. a function to search for patients matching eligibility criteria fulfills the requirement to match patients and eligibility criteria. Many systems in literature (e.g. [8, 22, 24, 25]) integrate the PRS into the EMR or EHR System implementing the requirement for prevention of extra documentation. Current PRSs notify physicians or PIs by generating trial worklists, messages via phone or email or popup notifications [3, 23, 26]. The requirement implemented by this feature is the physicians or PIs want to know when patients match the eligibility criteria of their trial. Some PRSs (e.g. [2, 8]) implement the functionality to document the inclusion of patients into trials. Participation in another clinical trial is often an exclusion criterion from other trials and thus the documentation of a patient’s inclusion an important requirement for PRSs. (see Table 1)

Table 1. Requirements on PRS independent of implementation as described by different stakeholders and derived from literature

Requirement	Patients	Physicians	Data privacy officers	Researchers	Hospital management	Litera- ture
Trials a certain patient fits	X		X			
Patient allows for contact with principal investigator	X		X			
Manage informed consents	X					
Information whether informed consent available or not		X	X	X	X	
“Physician cannot see if I fit or not”	X		X			
See all patients that fit “my trial”		X		X		X
Get notified when new patient match for “my trial” is found		X		X		X

Documentation of trial inclusions		X		X		X
Implement trial protocol				X	X	X
Execute patient – eligibility criteria match		X		X	X	X
No extra documentation required	X	X			X	X
Data integration with EMR/EHR	X	X		X	X	X
See all trials in institution					X	

2.2. Interviews

Physicians want to know whether a patient they are treating is included in any kind of clinical trial because that usually means a certain protocol has to be followed. Also physicians are interested in knowing whether one of their patients matches the eligibility criteria of a trial they are supporting. Additionally physicians want an overview of patients fitting or already included their trial. Another requirement of physicians is that the information whether informed consent by the patient has been obtained is available to them. Because physicians only use a PRS if it prevents extra documentation for them, the PRS has to integrate data from the EMR/EHR system.

Researchers have almost the same requirements on PRSs as physicians. One exception is researchers want a PRS to implement the trial protocol for automatic matching of patients with eligibility criteria. The other exception is that researchers don't require PRSs to prevent them from extra documentation.

Patients want to know which trials they fit, especially if they have a severe medical condition. Also privacy is an important requirement for them. Patients want to decide themselves if a physician should know about them matching the eligibility criteria or not, so the physician or PI cannot talk them into participating so easily. That means patients have the requirement to manage their informed consents themselves. Existing documentation should be used, because patients don't want to enter their medical history into a portal just to find out whether the match with trials or nor. Preventing data entry for the patients requires integration with the patient's EMRs and EHRs.

Data privacy officers emphasize on patients' privacy. Important for them is that patients have the opportunity to manage their informed consents on their own. From an ethical point of view data privacy officers encourage PRSs to allow for patients to decide whether physicians or the PIs can know about the patient herself matching the eligibility criteria. This way the patient explicitly allows for the PI to contact her. Another requirement mentioned by data privacy officers is that the informed consent be documented and enforced by the PRS.

Hospital management wants to know about all trials being performed within the institution for monetary reasons. Also they want to reduce workload regarding documentation and search for patients, resulting in requirements as the trial protocol needs to be implemented in the PRS and an automatic patient – eligibility criteria match is executed. Further requirements by hospital management are preventing extra documentation for physicians by data integration with the hospitals EMR. The documentation of patients' informed consent is a legal requirement by hospital management.

All results are summarized in table 1.

3. Discussion

3.1. Methods

Literature search was performed to get an overview of already implemented PRSs and the functionality such systems provide. Requirements were implicit in the functionality and thus had to be derived from features of the PRS.

Unstructured interviews were chosen to allow for unbiased input on what stakeholders and patients require to improve patient recruitment. Structured or semi-structured interviews would have biased the interviewees through direct questions. Thus only the topic 'patient recruitment' was pre-defined for the interviews.

The combination of literature and interviews helped to find more requirements than literature only could find. This seems to improve the quality of the results as the requirements from literature and interviews are overlapping.

3.2. Results

The results show on the one hand that physicians and researchers requirements are the requirements mostly implemented in solutions described in literature (see table 1). On the other hand patients' requirements and wishes regarding PRSs are not well represented in current solutions. The results also show overlapping requirements between the different stakeholders. So talking to different stakeholders helped in finding more reliable results and a holistic view on requirements for PRSs.

3.3. Outlook

Further research is required on how a PRS implementing all requirements can be successfully designed. The results could recommend an analysis of integration of PRS with different record types usability. EHRs, PEHR and PHR tend to be an option at least for implementing the patients' requirements.

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