Translating a Clinical Workflow into a Computer-executable Model User Needs Discovery, Challenges and Lessons Learned

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Abstract:

Getting to technical requirements from user input is already a hard task in an environment where the workflow processes are very well defined. When trying to extract a unique process from the users of such a variable work environment such as a healthcare institution can be very challenging. In this paper, we share our experience with extracting user requirements from clinical users by presenting the specific example of transforming workflows into models that can then be used as part of an IT solution to support workflow guidance. Here we present not only some of our main challenges when approaching different institutions and professionals with different roles, but also some of the methods we find most useful to establish communication and extract as much relevant information possible. In the end we explain some of the differences between a workflow as explained by the users and a computer–executable model and how to make the connection between the two.

1 INTRODUCTION

In 2004 Ash et Al. said that "we should strive to have a national system of Electronic Health Record (EHR) that can share information on any patient in any health care setting". While some institutions have the financial capabilities to have the latest technology which allows them to automate and make a wide range of tasks digital, there are still institutions who depend very highly on paper, especially when it comes to documenting clinical processes and pathways.

From our learnings this persistence on the use of paper to document clinical processes and pathways within a hospital is not only driven by lack of resources and financial capabilities to go digital but in many cases, paper is seen as an easier alternative to implement than modifying the IT system to support such tasks. Also, the IT systems are still having negative impact on the work of the clinicians by increasing the documentation time and being incompatibility with clinical workflow. This leads to a higher amount of interruptions in the medical work and system-introduced errors in patients care. (Ologeanu-Taddei, R. et al., 2015; Jamoom, E. W. et al., 2016)

Another limitation of paper supported processes is that although this may make the administrative task of collecting most relevant information in one location easier, they generally do not aid the clinical users to adhere to the recommended steps in a pathway in real-time - they mainly serve as a reminder of which data to collect so that the management can at a later date evaluate how well the care was delivered. And while with an EHR this collection of information is easier and more automated, there are still gaps on the usage of these that limit the step by step tracking of clinical events. One of our research aims is to investigate how we can proactively support the clinical staff to adhere in realtime to clinical pathways, with a greater focus on delivery of care than on care delivery documentation. We want to do this by going beyond the simple digitization of the paper process.

Even though it is possible to identify processes in healthcare, these are different from the ones that could be found in an industrial manufacturing environment (Mans et al., 2015). In the healthcare environment, users are dealing with the care of patients, who are not predictable machines with predictable failure modes. Therefore enforcing a process can be an extremely challenging task, let alone having a system trying to follow the steps making up that process. It is extremely difficult to identify all the steps healthcare professionals follow in a process performing retrospective data analysis

since EHRs are rarely pre-programmed to support clinical workflows in a structured manner. Therefore any evidence we collect from these, represent point measures of the process either indicating partial activities in the process or post-documentation information. Our research challenge was therefore to understand how the users incorporate the clinical processes in their routine, how they interact with the systems, and how they could optimally be supported with technology in the future to support them in realtime to adhere to clinical pathways as they deliver care to patients. There are no specific guidelines to support extraction of requirements from end-users in such situations, with most publications in the area focusing on modelling of clinical processes, but not giving insights onto the differences one might expect across hospitals or recommendations how to translate user specifications to technical requirements. (Böckmann and Heiden, 2013; Dadam et al., 2000; Latoszek-Berendsen et al. 2010; Staccini et al. 2001; Oosterhout et al. 2005)

In this article we share some of our experiences and methods used to go from an expressed wish from users to actual user and technical requirements, using the specific example of transforming workflows into models that can then be used as part of an IT solution to support workflow guidance.

In the specific study that we are using as example we have confronted 4 different institutions with different levels of understanding and complexity regarding the same type of care delivery pathways and associated workflows. We had a total of 51 participants in which 13 where physicians, 21 where nurses (some with coordination roles within the departments), 11 where quality staff and 6 had other roles within the Hospitals. The Hospitals involved have between 200 and 350 beds each and cover most specialties inside the institution. Associated to this they all have implemented an EHR but only one was considered a paperless Hospital. Our expectation is that models can allow us to create a unique translation of realities, bringing together the workflows of the different institutions. Therefore, we focus on the specification of requirements for a technology solution to assist the adherence to a Clinical Pathway that involves multiple stakeholders, sometimes across departments; and for a variety of care settings.

2 USER CONFRONTATION

2.1 Preparation Phase

Our team conducted user confrontations to validate hypotheses, developed from literature reviews and existing knowledge on the topic, on what users would want in a workflow product. When researching how to design these products to fit the needs of a specific population of healthcare professionals, doing many iterations of user confrontations is important. The aim with the first user confrontations is to understand what aspects of the problem cause the user the most hindrance, and from there prioritize aspects of the future product and create a research roadmap. For each iteration after this, the scope of the confrontations becomes more granular to specify wishes for components of the proposed product. Preparation for these confrontations consists of 3 phases: (i) identifying the activities to be done with the clinicians and what type of professionals need to be included, (ii) preparing legal and regulatory documentation with our company and the hospitals with which we will collaborate, (iii) contacting hospitals and agreeing on an agenda.

- (i) Identifying activities and participants: For every round of user confrontations, we need to identify:
 - a. What information we need to retrieve from the activities (proving or disproving our hypotheses) [more on this topic in the next sub-section]
 - b. Who we should involve in the confrontations in terms of professional roles

Then, we plan activities that help us gather this information. For each activity, we usually assign 2 researchers per activity, for 1-4 participants. This way one person is able to take notes and another leads the exercise. When performing user confrontations, a risk that is run is that of collecting the opinion of too few users and using these opinions to generalise to the overall population of users. One way to address this, if resources are limited, is to organise group activities which enable multiple users' viewpoints to be collected in one session.

(ii) Legal and Regulatory: For conducting user confrontations, there are legal and regulatory agreements that need to be made on the institutions involved, covering the interviewers and the interviewees. It is important to keep this in mind when planning the confrontations. Translating the relevant documents such as Non-Disclosure Agreements and Consent

- Forms into the local language and allowing time for reading and signing by the institution could take several weeks. We strive to send the Participation Information Letter and the Informed Consent in advance of the visit, to ensure the participants have had time to read it and consider their involvement.
- (iii) **Preparing the agenda:** When planning the activities it is important to keep in mind time. Healthcare professionals will typically have 30-45 minutes to spend in the activities. Lastly, the agenda request must be made to the hospital. In this request, there should be an overview of the project, goals of the interviews, and request for specific users for specific amounts of time (for individual interviews and group exercises).

2.2 Exercises Used by the Team

In this paper, we focus on the exercises carried out in the first round of confrontation sessions with the users. For this round, our main aim was to derive the users' main needs and challenges when it comes to supporting the implementation of Clinical Pathways in practice. As we were still in our project definition phase, our scope was large: we wanted to learn more about the topic from the users (general information on how this is done in practice), from a variety of users (from administrative to clinical and managerial staff) and from all phases of Clinical Pathways (from the creation of pathways, the use at the point of care to the evaluation reporting). With this in mind, we devised a number of activities:

- Interviews to understand the users' and institutions' realities and scope the landscape of Clinical Pathways as it stands today in clinical practice
- A model building exercise, where we asked the participants to build a pathway of their choice and take us through their routine to help us identify elements common to various pathways as well as routine bottlenecks and deviations from the set pathway
- Confrontations of our work and assumptions:
 - Review of a generic model we created, to get some validation on the modelling of the pathways
 - Feedback on user interface designs for use in supporting clinical and administrative workflow to verify some assumptions we made on information needs for clinical users when it comes to needing to track and care for a patient on a pathway

- Interactive activity enabling participants to prioritise importance of pre-assumed needs, as well as creation of unthought-of needs
- Questionnaires to derive quantitative results related to the concepts explored with the users.

Whenever possible, we asked the users to walk us through their way of working, showing us how they interact with the clinical systems and indicating when they would do this at various points of the care.

We had a variety of one to one and group settings. Considerations when setting up group confrontations are the following:

- Size of group: 4-6 participants for 2 facilitators is an appropriate size, larger groups may have to be separated in sub-groups
- Roles within group: hierarchy and personality may influence the interaction dynamics within a group, for overall opinion on a concept, we prefer to separate the groups according to role; mixing of roles can work well when complimentary perspectives about different aspects of a topic are sought
- Facilitation skills: the facilitator of the activity should direct the involvement of participants when necessary, to ensure a fair representation of all participants in the discussions
- Discussion material: having material to discuss (such as a concept video, screen designs, a conceptual poster) can help the conversation along, as a starting point or as a way to focus the participants on the topic matter.

Overall, we derived a lot of useful information from the users, which ranged from scoping a landscape of realities and challenges from various hospitals with varying levels of maturity when it comes to implementing Clinical Pathways; all the way to having a much clearer picture of the roadmap we needed to create in order to meet the most pressing needs of the users.

Some pitfalls we encountered were:

- Broad scope and limited time meant that some topics could not be deeply explored
- Tight planning meant that not all exercises could be conducted with all users
- Questionnaire not specific enough to provide significant added value on top of qualitative results
- Unexpected changes in times and personnel available for participation in the activities.

Our recommendations include:

 Be clear within the team on the objectives of each exercise

- Dry-run the activities with colleagues or proxy users not involved in your project to ensure instructions and questionnaires make sense before finalisation
- Double check translations (back translation if possible) to ensure that the meaning is retained.
 This might seem quite obvious but it is often dismissed specially when using official translators. It is important to make sure the interpretation is the same for all readers no matter the language.
- Perform debriefing within the team as frequently as possible, at least at start and end of each day, and if possible, in between activities especially in the first days to ensure that the activities can be refined as the interviews progress.

Finally, keep in mind that structured activities and questionnaires are important to ensure focus is not lost, but ability to improvise and follow the participants' train of thought in a semi-structured interview format can often be invaluable to discover user needs the team had not thought of or planned for.

2.3 Challenges of Interaction with the Users

The first challenge of interacting with users on an international level is communication. It is imperative that the professionals that are participating in the discovery activities, fully understand what is presented so that your questions can be answered in the end of the exercises.

To facilitate the understanding and better communication we try to provide all the material and conduct all the activities in the language of the users, whenever possible.

Also, it is important to keep in mind that the realities differ among institutions so the speech should be adapted to the reality of each institution and professional. You should always take into consideration the following factors:

■ Technical resources. Not all institutions have the same resources, such as, imaging machines, beds or medications. This has a very high impact on how the tasks are done, meaning that the same step in a process can be executed in different ways and sometimes even include a third party institution who provides the resource. A good model based system can help not only to optimize the existing resources but also to find the best workflow using the resources available at each institution.

- People. Not only is there variation in the availability of staff, but also in the interaction between different types of professionals among the different institutions. As an example, in some hospitals strict hierarchy may be the norm (e.g. in one institution nurses may be empowered to put a patient in a clinical pathway whereas in another this may only be done by a clinician). This has a big impact not only on the identification of who should be involved in a task but also on the attribution of authority and permission for decision making. This is so far the hardest factor that can affect not only the way the exercises are done during the user interactions but also can have a big impact on how an IT solution will be used in the institution. If you are looking to create a solution which could be used in different institutions it is important to identify all the potential users, how they interact and who will be the potential main users (which can include different type of professionals)
- Impact of geographical, organisational and legislation factors on the level of maturity of clinical processes. By association, institutions that are involved with certification organizations and medical societies usually have very clear ways of working which are based on best practices. This is also very closely related to differences in implementation of health services between different institutions, regions and countries. In countries where there are little or no public healthcare institutions except for the primary care facilities, most Hospitals and private institutions will rely on certifications to distinguish themselves from others. In the case of countries where the Healthcare service is very well managed by the government and advances, chances are that standardization and certification processes are stimulated if not required by the government to guarantee the minimum quality of services.
- Knowledge. It is easy to assume that different types of professionals have different levels of knowledge. While that is true on a high level and most people have greater knowledge on their roles rather than on that of others, it is good to not only explore their roles, but also how they interact with and perceive the roles of others in the organisation. When approaching users from different institutions, cities or even countries, we must take in consideration their knowledge not only regarding technology (how

familiar are they with the latest technology and how they use it in their work) but also on the content level. As mentioned before, the involvement of the professionals with the latest news on best practices will also define how prepared they are to understand the concept to be discussed during the user interactions. And as rewarding as it may be to involve Key Opinion Leaders who are very much up to date with state of the art and best practices in the area you want to discuss, it can be even more insightful to talk with users who have less or little knowledge of the theoretical aspects so that you can understand the real practical issues the end-users are actually confronted with. Nonetheless, it is good practice to assume the users know very little about the topic, and be prepared with a good but not restrictive definition of the concept you want to present.

3 FILTERING KNOWLEDGE INTO REQUIREMENTS

The main challenges we have had are:

- How to transform information collected from users into requirements usable by the technical team?
- How to ensure that the collected needs and corresponding requirements are in some way weighted to reflect the input from the variety of users we interacted with?

To address the above, we employed a number of methods, which included use of:

- Raking/Rating systems where possible, e.g. when confronting 3 user interface designs, beyond asking for specific feedback, we also asked the users to classify the designs from their preferred one to least preferred one; for the pre-assumed needs list, we asked the users to rate each requirement as necessary, nice to have, or not necessary
- Quantitative data analysis wherever possible; e.g., for the pre-assumed needs list, we calculated a weighted average across the groups and used this to rank the requirements in order of importance, which gave an objective perspective on the relative importance of the rated requirements
- Consensus technique whereby we analysed the results of the interviews by first having a round of insights extraction from our notes at an individual interviewer level, before coming

together to share findings and debate if the insights resonated with one or more interviewees before including this as relevant insights for our results.

Concerning Clinical Pathways, a main insight that was drawn from our study with users is how to bridge the technical viewpoint and the user viewpoint: there are really two aspects to workflow modelling. One level are the workflow elements needed for user interaction to support them in their daily work; the other level are those workflow elements which are essential to the user to follow a Clinical Pathway, but may not be relevant to model in technical terms, either because it is not measurable or is difficult to model, e.g. due to lack of evidence in the clinical IT systems.

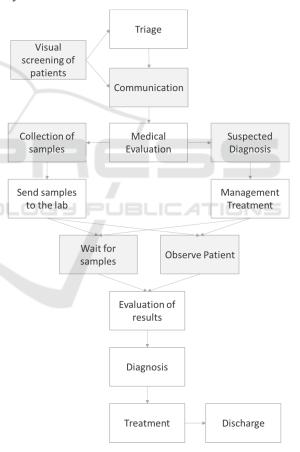


Figure 1: Simplified clinical process example as it would be described by the user. The boxes in grey represent the activities in the clinical process which are essential for the users to carry out the process but only essential to the people carrying out the task and not the model; or not captured in the IT system because non-measurable or not included in the IT documentation of the process.

Taking the example of a high level description of a clinical process as described by a user such as the one in Figure 1, we can identify 5 steps identified in grey, of such type, e.g., the communication interaction whereby the conversation process is more important than the actual data exchanged. In the same example we have the visual triage which is not measurable since it is done mostly following the professionals' instinct and experience and it is not associated with any record in the EMR; or activities such as "collection of samples" which are not captured in the EMR because so far, when the EMR is used mainly for documentation of patient medical data, there was no need to capture such process-related information.

The same model can be translated into a machine executable model, including only the steps that can be found or recorded using the EMR, which would look more like the model presented in Figure 2. Here we can see loops appear in the place of a step by step flow. While the user feels the need to represent every step of the process as being unique, when mapping these to the EMR the distinction loses relevance. For example we can say that "Medical Evaluation" and "Evaluation of results" are the same task since these are represented by a new iteration of a clinical note in the EMR.

Another big difference between a model described by a clinical user and a technical model as the one of Figure 2 is the detail and grouping of steps. We can, for example, remove the "Suspected Diagnosis" step described by the user as this is usually included only as part of the clinical note. Also, steps that are in distinct areas of the EMR and can be done in different contexts outside the flow described by the user can be represented as sub-processes. For this we have the example of the "Diagnostic sub-process" or the "Treatment sub-process" which can be done in a different order or sequence than the one of Figure 1 when used in a different patient or clinical context.

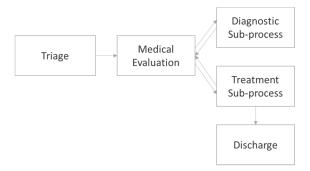


Figure 2: Simplified clinical process example as it would be used in the backend.

In the end we are left with only the steps which can be detected from or triggered using specific activities of the EMR. And while this might bring some value in terms of process evaluation using the EMR, it is not so useful if we are trying to support and stimulate the users to follow guidelines or processes using an abstract process model where the same type of task can have different meanings and relevance.

We believe that a model that reflects the habits and routines of the professionals and not just the steps / recommendations of the protocols / guidelines / pathways is the key to make a process support tool operational and usable in clinical practice. That is, a model which guides the users into doing the right thing using more than just the steps that are recorded in the EMR but also including those necessary for their own routines. Such an ideal model based solution would be the one that is capable of providing the support for the human only tasks mentioned in Figure 1, that usually have no place for representation in the EMR (e.g. nurse calls the lab to check status of sample analysis), even if they are not driving the reasoning of the process. This support can be given not only by making the association between the modelling tools with Clinical Decision Support Systems (CDS) but also organizational tools just like communication, schedule assistance tools or others. A severe limitation of modelling clinical processes (whether prospectively or derived from process mining) is the ability to derive representative models despite some essential activities not being represented in the event dataset.

Concerning those activities that are not possible to model due to lack of evidence in the IT system, these are essential to be aware of as this may imply:

- an incorrect (incomplete) representation of the process when performing process discovery. Which consists in applying process mining algorithms to an event log based on the information from the Hospital's EHR database, to discover a process model. (van der Aalst, W., 2016)
- a necessary change to the IT system which may have an impact on the workflow when trying to derive a process model for real-time tracking of process activities.

The latter has implications that go further than the mere addition of a few requirements to the IT solution: if the additional events cannot be captured automatically, this will imply additional input from the users affecting their workflow and potentially adding burden to the overall process. If the workflow is affected, this would also call for other

measures such as co-creation with the users and change management leading up to and during introduction of the technology to ensure acceptance and good uptake of the solution.

4 CONCLUSIONS

Deriving clinical processes based on data available in EHRs is a challenge for a number of reasons: different hospitals are likely to implement similar processes in different ways due to different resources available and local constraints; not all process activities may be directly extractable from the data, due to lack of documentation or impossibility to capture in a structured format; any additional process-related data which needs to be acquired may be seen as an additional burden on the users and may impede the actual process we are trying to support. When extracting knowledge from users to determine relevant events from data or to derive process models, one must be aware of the different realities of each setting and user's role, and try to capture the overall process by approaching the various stakeholders that often work together to make the entire clinical process a reality.

It is really important to find a balance between the tasks that need to be represented and shown to the user and the tasks that can be automated relieving burden from the user. For a good workflow support system we do not necessarily need to present all the steps of the process to the user nor represent in the model all the intermediate steps that are taken by the user. More than a good model, you will need extra support systems that can fill the gaps and fix the bottlenecks of the workflows.

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