

Declarative Workflow Supported Collaboration Based on Clinical Practice Guidelines

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Abstract

Objective: The aim of this paper is to present a flexible and dynamic approach to collaboration support for clinical work based on a declarative workflow model and an observation study of the use of Clinical Practice Guidelines (CPGs).

Methods: An observation study of clinical work focusing on the application of clinical guiding artifacts was conducted. Based on the findings in the observation study a formal declarative workflow process notation was applied to a case leading to further development of the notation. An activity-based presentation of the computerized guiding artifacts based on the workflow model and potentially other involved HIS applications is briefly discussed.

Results: CPGs and protocols were found to be rarely applied in clinical practice, while application was perceived as interruption of workflows. Instead a wide number of *Second Order Guiding Artifacts* (SOGAs) were applied, as they were activity specific, present at the point of care, embedded in the clinical work practice and supporting coordination and collaboration. The SOGAs were locally transformed from CPGs and protocols according to a standard operating procedure to fit the local organization of clinical work. Notably, many crucial aspects of the flow of control were left implicit in the SOGAs, which could lead to serious errors. We demonstrate how a simple, yet expressive declarative workflow process notation based on condition and response relations can add control flow in a flexible way. In particular it avoids the introduction of explicit and rigid control flow graphs. We briefly discuss how the workflow model could enrich the current SOGAs with control flow, which could strengthen the collaboration support.

Conclusion: The functionality and features of the currently applied SOGAs should be taken into account when computerizing CPGs. A declarative workflow model can be embedded conservatively in the current artifacts, thus avoiding the need for a completely new way of controlling the collaboration, e.g. as required by standard approaches based on explicit control flow graphs.

1 Introduction

It has long been realized that there is a global need for making clinical work practice safer and more efficient based on the best available scientific evidence [1]. The most promising way to achieve more efficient collaboration and increased level of safety is by the use of clinical workflow management systems and decision support based on up-to-date clinical practice guidelines (CPGs) [2, 3]. To be able to do so will require the establishment of efficient support methods for collaboration based on CPGs [4].

Using CPGs as a foundation for workflow engines is however a challenge for several reasons. First it is well known that CPGs are currently not widely applied in clinical practice [5, 6]. A reason for this may however be that CPG's are not embedded in the clinical work practice and in the technology available in clinical settings today. Secondly the lifetime for CPGs is short [7] implying frequent updates that have to be manageable in the applied system. Finally there are no standard patients, so there is a need for the

systems to be flexible and adaptable to the individual context and patient [8]. Although computerized CPGs have proven beneficial both on process outcome [9] and patient outcome [10, 11], the systems are not yet widely applied in clinical practice. We argue that a reason for this is that CPG computerizations pre-dominantly has been accomplished from a technology perspective rather than from a computer supported cooperative work (CSCW) perspective.

In the present paper we discuss design principles for computerization of CPGs and describes the first results obtained within a research project (the TrustCare project) pursuing an inter-disciplinary collaboration approach between universities and an industrial partner on innovation of effective and trustworthy IT support for clinical practice based on computerization of CPGs.

The paper presents a case where participatory design methods [12] have been applied for uncovering demands from clinical collaboration. We have chosen to make the case study within the field of oncology since the specialty is known to have a high CPG compliance [13], thus not confounding our findings with the problems of CPG non-compliance. The results from the field study constitute the basis in the development of a formal declarative workflow model which generalizes and formalizes the model employed by the industrial partner in the TrustCare project, and allows to extend the current guiding artifacts used in the case study with control flow information while maintaining the required flexibility in the work process.

1.1 Demands on computerized collaborative tools

Based on activity theory three hierarchical levels of collaboration can be distinguished [14]: coordination, cooperation and co-construction. Until now most focus in design of Hospital Information Systems (HIS) has been on support of coordination among actors based on integration of various information sources [15]. In coordinated work the actions of the individual actors are coordinated according to explicit or tacit rules but the actors do not have to actively interact in the execution of the activity. In cooperative work the actors are interacting in the execution of actions for which the aims are agreed upon. In the co-construction the actors is focusing on re-conceptualizing the aims and the work practice. Co-construction is a prominent part of a design process.

When designing collaboration support for the healthcare sector it further has to be taken into account that health care work is characterized by being very complex [16], mobile [17] and ephemeral [18], and based on an ever growing source of medical knowledge [19]. Further it has to be taken into account that the majority of communicative exchange of clinical information is oral [20], leaving no trace to act upon.

2 Methods

One of the authors – a physician - and an anthropologist conducted an observation study in three Danish oncology clinics, all in all twelve days of observations were carried out. The clinics all belong to the same public hospital corporation established one year before study start by a merger of three counties. Two clinics (UN1 and UN2) were situated in large university hospitals, and one clinic (CH1) was situated in a big regional hospital. The observations were supplemented by ad-hoc interviews whenever feasible and collection of guiding artifacts. The observations took place in 2008.

Patients were referred to the oncology clinics from other hospital clinics with a diagnosis of cancer. Close to 100% of patients were treated according to a treatment protocol (either a standard treatment protocol (75-80 % of the patients) or a research protocol (20-25% of the patients). Patients were seen by a physician either for planning or monitoring of treatment or due to deviations from a planned pathway. Nurses provided care in relation to the encounters and were responsible for administration of chemotherapy. Patients with severe complications either in relation to the primary disease or to the treatment were taken care of in the bed wards.

Protocols are a specific type of CPGs originally developed as a formal description of a scientific clinical study including a standardized patient pathway for a specific disease. Within oncology, it has become a tradition to remove research specific parts of research protocols when the study is over and the protocols are passed on as standard treatment protocols. A protocol holds 20 - 100 pages (research protocols being the most comprehensive), each protocol describes in detail how to carry out and monitor a specific chemotherapeutic cure for a specific disease. Protocols are usually applied by several clinics and may be national or even multinational. In the observed clinics, approximately 50 - 110 protocols were applied at any time.

All the hospitals used computerized patient administration systems (PAS), computerized provider order entry (CPOE), laboratory information systems (LIS), radiology information systems (RIS) and picture archiving and communication systems (PACS). Further, they all had intranet portals that hold several hundred local and regional CPGs. In UN1 and CH1, an electronic patient record application for physician notes has recently been introduced. The same system is soon to be introduced in UN2. In CH1, a medication order and administration system was in use, the system could however not handle individually produced drugs like chemotherapy, they still had to be ordered and otherwise registered manually. The IT systems were not integrated, and consequently the health professionals had to apply several log-on's and passwords on a daily basis to access the various systems. The hospital cooperation's IT-unit had plans for further consolidation and integration of the IT systems in the region to support coordination and information integration.

Based on the findings in the observation study the two other authors of the paper applied a recently developed formal declarative workflow process notation to the case study, which lead to a revision of the formal model making it possible to describe the control flow in a simpler and also more compact way. The next step, which is left for future work, will be to prototype the workflow based collaboration using an activity-based presentation of the computerized guiding artifacts and get feedback from the participants in the original field study.

2.1 Data collection and analysis

A clinician: a registered nurse, junior house officer or senior consultant¹ was shadowed for 2-6 hours during daytime of a normal working day. The researchers kept a structured log on when any clinician requested clinical guidance, when or whether a CPG was used, or whether other kinds of guidance were applied. Beside the log the researcher kept a diary of the observations. Examples of guiding artifacts were sampled during the observations. Observation notes and interviews were transcribed immediately after the observations and

¹ Subsequently the general term "clinician" is used when referring to health professionals who take care of patients.

a preliminary analysis were made. The preliminary analysis was presented at staff meetings at the clinics. Afterwards, workshops with clinicians (physicians and nurses) were held in UN1 and UN2. A brief summary of the preliminary results as well as a prototype of a CPG based declarative workflow model [21] were presented to initiate discussions of how computerized CPG based cooperation tools should be designed.

The workshops and interviews were taped and immediately transcribed. Analysis of the material was divided into two parts: the observations study, ad-hoc interviews and collected artifacts were analyzed together as they all provided information on present practice. The workshops were subsequently analyzed focusing on requests for future clinical guidance. The analysis of both data sets was carried out applying a grounded theory approach [22]. This included familiarization with material, identification of key issues, indexing of data, charting and mapping and interpretation [23]. A single researcher applying manual coding performed the analysis. Validity of categorizations was ensured by (a) critically examining and re-examining analytical decisions, making changes when analysis of subsequent data sets challenged past coding decisions; (b) by presenting and discussing the preliminary results of the analysis of present practice in the staff meetings and workshops with clinicians from two of the observed clinics to refine the categorization; and (c) validation of final results by two clinicians from two of the participating clinics.

3 Results

In this part we first present the results of the field study, in the second part we present the flexible declarative notation for workflow, and finally we discuss how it could be used to computerize the current guiding artifacts using an activity-based approach.

3.1 Application of guidance in clinical practice

All the observed clinics had a wide number of standard treatment protocols and research protocols in use. Although nearly all patients in the clinics were treated according to a protocol, we only observed a few cases where a question of doubt was actually checked in a protocol. We were frequently met with comments like “*You are wasting your time, we do not use guidelines*” or “*You will not see much, as we are not using the guideline portal*”. In fact it was true, we did not observe any comprehensive use of textual CPGs.

We however, observed an extensive use of what we have conceptualized as second order guiding artifacts (SOGAs). SOGAs are forms that locally have been transformed from a protocol or textual CPG (primary guiding artifacts) according to a standardized operating procedure. There was a set of 7-10 standard templates for SOGAs that were applied whenever a protocol was transformed. The SOGAs were characterized by being: locally developed (although close to similar in all the observed clinics), activity specific, in a format that was suitable for being present at the point of care, able to support coordination in clinical practice and, embedded in the work practice – presenting room for input and output of relevant data. Each SOGA had its own characteristic layout making them recognizable at a glance. All the clinics had drawers and cabinets filled with SOGAs.

followed the process and it served as a coordination tool indicating workflow progress by its physical presence.

3.3 Conclusions of the field study

Several characteristics of the clinical work were elucidated in the field study:

- There were several clinicians involved in even rather simple workflows like the ordering, preparing and administration of chemotherapy. The clinicians were concurrently involved in several workflows.
- Most workflows were distributed, with the various clinicians located in different places.
- Most workflows were guided by a SOGA. SOGAs served as a token in the workflow as well as a way to present relevant existing data and document occurring data.
- Only the clinician possessing the SOGA knew the state of the workflow. It was observed that much time was used waiting for and controlling the status of the workflow. Knowledge about the workflow status was a prerequisite for prioritizing and planning of the clinicians work activities.
- Checkpoints were frequently occurring. Failure at checkpoints could lead to a reiteration of previous verification or a repetition of the activity.
- Exceptional events like timing-out of prepared chemotherapy also led to repetition of previous activities.
- Only the state (information) and the actors are explicit in the SOGAs. The control flow/ordering of events (i.e. transfer of the SOGA from one clinician to the subsequent clinician), handling of exceptions and recurrence/validation of calculations are implicit.
- The current hospital information systems (HIS) were composed by several legacy systems and did not provide any kind of cooperative support.
- The major reason for not applying the existing CPGs and protocols was that it was perceived as time consuming and required interruption of the workflow.

4 Clinical Treatment Process as a Declarative Workflow

In this section we introduce our declarative workflow process model Strong Condition Response Structures (SCRS) and describe how the chemotherapy treatment workflow can be represented in SCRS. The SCRS model is a variant of the model of Dynamic Condition Response Structures (DCRS) presented in [26], which has both a formal mathematical model generalizing the fundamental model of Event Structures [25] and a graphical notation looking similar to flow charts, but preserving the flexibility of the declarative model. For the full details of the formal semantics and description of the graphical notation we refer to [26]. In this paper, we limit our discussion to the graphical notation to model the chemotherapy treatment workflow model.

The SCRS graphical model has three basic relations between activities, namely: *condition*, *response*, and *strong condition*. The *condition* relation imposes precedence between the activities in a workflow, whereas the *response* relation imposes a follow-up relation between the activities. For example, if we have two activities 1) “*prescribe medicine*” and 2) “*sign prescription*” related by a *condition* relation from activity 1) to 2),

then we say that activity 1) is a condition for activity 2), which means that it must have been executed at least once before activity 2) can be executed. Dually, if we have a *response* relation from 1) to 2) we say that activity 2) is the response for the activity 1), which means that whenever activity 1) is executed, then activity 2) must be executed at least once at some later point. The *condition* and *response* relations are the core relations of the DCRS model presented in [26]. The DCRS model also has the relations *include* and *exclude*, which allow for activities to be respectively included and excluded dynamically from the process. These relations complicate the semantics, and we found that they were not needed in the present example if we instead introduced the simpler *strong condition* relation as a new basic relation. The *strong condition* like the *condition* relation enforces a precedence condition between the activities, but it also enforces that the predecessor activity must not have been required to be re-executed (as a response) since its last execution. This relation will be explained in the example of the chemotherapy treatment process shown in Table 1 below as a SCRS workflow model.

| Activity number | Tasks | Roles | | | | Relations | | |
|-----------------|--------------------------|-------|---|--------|--------|-----------------|------------------|-----------------|
| | | D | N | C P | P A | Condition | Strong condition | Response |
| 1 | Protocol assignment | √ | | | | | | |
| 2 | Patient history | √ | √ | | | | | |
| 3 | Read lab results | √ | √ | | | | | |
| 4 | Prescribe medicine | √ | | | | 2,3 | 1 | 5 |
| 5 | Sign doctor | √ | | | | 4 | | 7 |
| 6 | Don't trust prescription | | √ | √ | | 5[CP], 11[N] | | 5 |
| 7 | Accept prescription | | | √ | | | 5 | 8 |
| 8 | Make preparation | | | | √ | 7 | | 11 |
| 9 | Sign PA | | | | √ | | 8 | |
| 10 | Don't trust preparation | | √ | √ | | 9[CP], 11[N] | | 9[CP], 11[N] |
| 11 | Sign CP | | | √ | | | 9 | |
| 12 | Sign nurse 1 | | √ | | | | 5,11 | |
| 13 | Sign nurse 2 | | √ | | | | 12 | |
| 14 | Administer medicine | | √ | | | 13 | | |

Table 1 Chemotherapy treatment workflow in tabular format

Each row of the table represents an activity of the Oncology workflow. The columns are divided into four major parts: The first two are the activity numbers and names. The next column describes the access rights for the different roles: Doctor (D), Nurse (N), Controlling Pharmacist (CP), and Pharmacist assistant (PA). The √ sign indicates that an actor with this role can execute the activity. The fourth column represents the relations

between activities. As explained before, the oncology workflow contains three basic relations: *condition*, *response*, and *strong condition*.

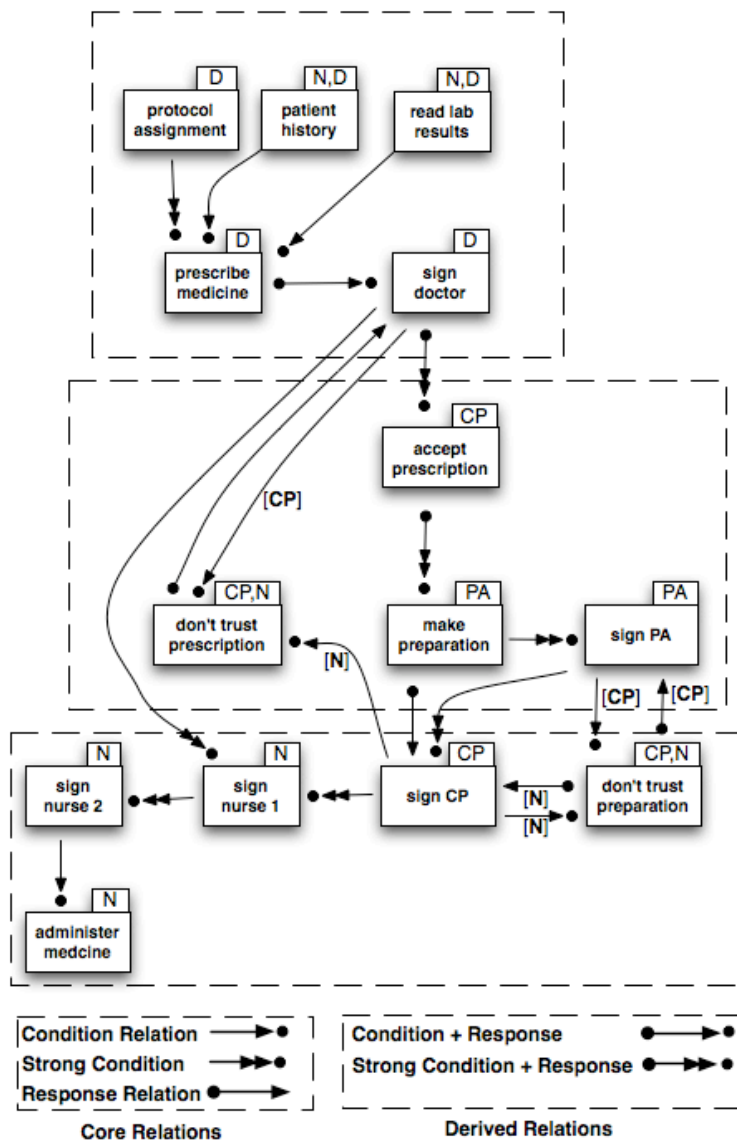


Figure 2 Oncology workflow in DCRS graphical notation

The oncology workflow can also be represented graphically using the SCRS graphical notation shown in Figure 2. The figure represents activities and relations between them listed in Table 1. The roles that can execute an activity are marked on the activity. For example, the activities 'patient history', and 'read lab results' can be executed either by the role 'doctor' (D) or 'nurse' (N), whereas the activity 'protocol assignment' can only be executed by the role 'doctor'. The strong condition and condition relations between the activities 'protocol assignment', 'patient history', 'read lab results' and 'prescribe medicine' indicates that the activity 'prescribe medicine' can only be executed after all the three predecessor activities has been executed at least once. Additionally, the strong condition between 'protocol assignment' and 'prescribe medicine' entails that the activity 'prescribe medicine' must not have pending responses on it, that implies that it must not have been set to be re-executed (as a response).

Note that we use a derived graphical notation combining *condition* and *response* in one arrow, as used between 'prescribe medicine' and 'sign doctor'. Having both relations ensures that the activity 'sign doctor' cannot be executed before the performance of 'prescribe medicine' that entails that whenever the doctor prescribes the medicine, subsequently at a later point of time she will have to sign the prescription. Note that the doctor can prescribe the medicine, as many times as she want, but she has to execute the sign activity authorizing all the prescriptions.

After the doctor has signed the prescription, the control flow enters into the pharmacy department, which is the dotted middle portion of the workflow. The 'Control

pharmacist' (CP) will then have two options, either to accept the prescription or to say that he/she does not trust the prescription.

In the chemotherapy workflow, we have also introduced parameterized relations as a compact way of representing relations between some of the activities which are only required for some of the actors. That is, in case an activity has a parameterized relation, then the role executing the activity will determine if the relation is enforced. By default if a relation does not have any parameters, then it will be enforced for all the roles that can execute the action. For example, the condition relation between '*sign doctor*' and '*don't trust prescription*' is parameterized with a parameter [CP] and also the condition relation between '*sign CP*' and '*don't trust prescription*' is parameterized with a parameter [N]. Now note that the '*don't trust prescription*' activity can be executed by two different roles control pharmacist (CP) and nurse (N). In this case, if the role CP is executing the '*don't trust prescription*' activity, then all relations with [CP] parameter and relations with no parameters (by default) will be enforced, there by enforcing a condition saying that the activity '*sign doctor*' must have been executed before but the activity '*sign CP*' does not need to have been executed before. On the other hand, if an actor with a nurse role wants to execute the '*don't trust prescription*' activity, then '*sign doctor*' is not required to have been executed, but the '*sign CP*' activity must have been executed before. Also note that, in both the cases, executing the '*don't trust prescription*' activity will create a pending response on the '*sign doctor*' activity. This is irrespective of who is executing the '*don't trust prescription*' activity, since the response relation between '*don't trust prescription*' and '*sign doctor*' does not have any parameters.

Coming back to the discussion on what the CP can do after the doctor has signed; he can either accept the prescription if he trusts it or he can execute '*don't trust prescription*', if he believe that the prescription must be reviewed/re-checked by doctor. In the latter case, a pending response will be created on the '*sign doctor*' activity, the strong condition between '*sign doctor*' and '*accept prescription*' will further prevent the '*accept prescription*' activity being executed accidentally/erroneously (by himself or by any other person in the CP role) before the doctor has been checking the prescription and re-executing the '*sign doctor*' activity. Then, the doctor can either re-do the '*prescribe medicine*' if necessary (if she thinks that the prescription should be changed) and/or re-do the signing activity subsequently to proceed in the flow. Also, the response relation between '*sign doctor*' and '*accept prescription*' will ensure that the '*accept prescription*' activity will be executed after the doctor has signed the prescription. In this way, by having fine-grained relations such as *strong condition* and *response* one can prevent occurrence of medical errors in a workflow guided clinical treatment process.

Similarly, there exist parameterized relations: between '*sign PA*' and '*don't trust preparation* ([CP])', between '*don't trust preparation*' and '*sign CP* ([N])' dependent on the role executing the '*don't trust preparation*' activity the necessary relations will be enforced. At different points in the control flow, either nurse (N) or control pharmacist (CP) can raise a flag saying that they '*don't trust the preparation*' thus enforcing the pharmacy assistant (PA) to check the preparation. Notice that in this case, the role (CP or N) executing the '*don't trust the preparation*' activity will decide on which activity ('*sign PA*' or '*sign CP*') the pending response will be raised.

Finally, after the '*sign CP*' activity the nurse can execute the '*sign nurse 1*' activity if she/he trusts both prescription and preparation and proceed further. Conversely, the nurse will not be able to execute the '*sign nurse 1*' activity if there is any pending response on either the '*sign doctor*' or '*sign CP*' activities. The logic behind having both '*sign nurse 1*' and '*sign nurse 2*' is that the activities are to be executed by two different persons having

the nurse role. This could be enforced by the formalism, e.g. by introducing a richer notation for access rights allowing to express that the person executing the second signing must be different from the first. We leave this for future work.

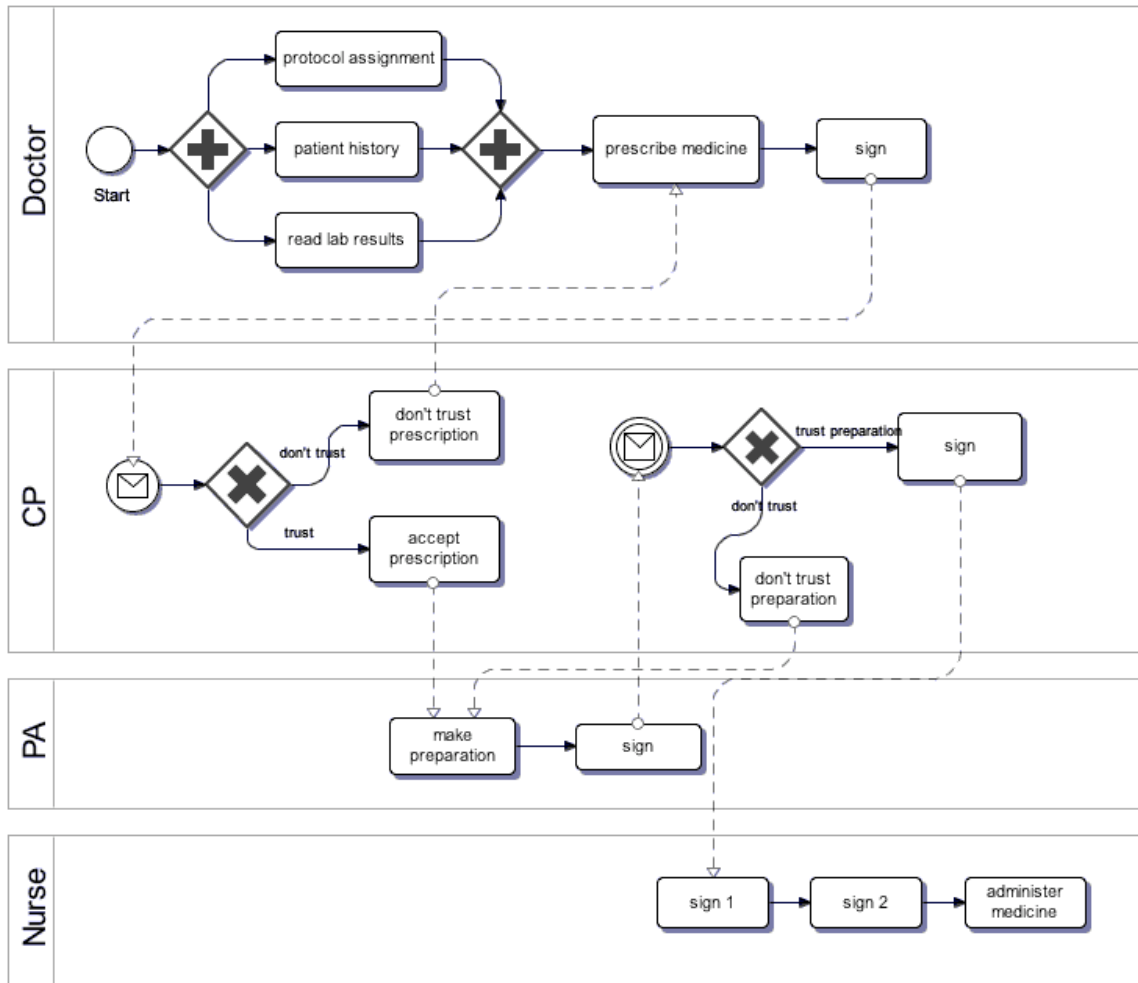


Figure 3 The chemotherapy workflow in Business Process Modeling Notation (BPMN)

The tabular form of the process corresponds very closely to the paper based SOGAs used in the workflow showed in Figure 1. A key difference though is that the control flow (condition, response, strong condition) was not made explicit in the paper-based SOGAs, what occasionally may be a source of errors.

A simple graphical user interface (GUI) could make the workflow supported by the form in Figure 1 digital, blocking the fields that are guarded by a *condition* or *strong condition* relation and putting a warning sign on fields that are required to be re-executed as a response to another action. Further, the user may get the detailed reason (i.e. the relations in the model), by right-clicking on the field.

5 Discussion

The issue of computer-supported cooperation is about more than just computerizing workflows. To provide genuine cooperative support based on CPGs it is essential to provide efficient process support that is not perceived as an interruption of the workflow by the clinicians. In our observation study we found that even a rather simple process such

as managing chemotherapy involved several clinicians with conditional relations, had an extension in time and space and, required access to input/output of relevant data. To support such a process there in a smooth way may be accomplished by a declarative workflow presented in an activity-based GUI providing access to existing HIS.

Even though clinical work is carried out according to a standardized process described in CPGs and/or protocols alterations occur frequently based on clinical judgment of the patient and/or the context. The applied SOGAs were found to support collaboration among the actors as they in a simple way outline the subsequent process steps and mediate access to input/output of relevant patient data. The SOGAs has continuously been developed over the last decades to match the clinical work practice thus they are deeply embedded in the clinical work. The SOGAs however also have some major limitations by only being present in one place, by not making the control flow dependencies explicit, and by not being integrated to existing HIS. Moreover, they are cumbersome to update when the underlying scientific knowledge is updated.

The clinical process support should not mimic the SOGAs however it should be able to substitute the functionality and features in a mode that fulfill clinicians requirements on support for smooth and efficient workflows both in their own work and in the individual patient's pathway, this put high demands on flexibility of the solution.

Computer executable CPGs should be designed in a flexible format that can be changed by local clinicians when the collaborative practice is redesigned as part of co-construction. CPGs and protocols serve merely as resources for planning, thus the applied notation should be dynamic and flexible. These requirements are accomplished with the presented notation. The conceptual distance between the SOGA and the presented workflow table (Table 1) is limited, making it possible for a clinician with limited computer skills to actively apply the table when re-constructing work processes. Also, as pointed out by van der Aalst and Pesic [24] the declarative approach promises more flexibility than traditional imperative approaches based on flow-graph notations such as BPMN, Petri-Net, and WSFL, which often lead to over specification, i.e. impose too many constraints on the workflows. As an illustration, it is worth briefly comparing the declarative approach to a more typical approach based on a flow graph notation such as BPMN, which is shown in Figure 3. The main problem with the BPMN approach is that the diagram has to be followed in exact order. For instance, after the doctor prescribes medicine the next step must be signing. In the declarative model, the doctor may go back and check lab results again, or perhaps re-do the medicine prescription before signing. Even worse in the BPMN notation; if the nurse does not trust the prescription then the entire process has to be re-executed, even if the prescription is correct and the doctor could verify this and simply sign again. In the declarative model, the doctor can simply sign, and the flow can continue by the nurses signing and administering the medicine. This could be modeled in BPMN, but would require a complex diagram with plenty of loops.

By presenting the process support in an activity and role adapted computer application it will be possible for the individual clinician to attain an overview of his/her current tasks and concurrently having access to input/output of relevant data in the original HIS-application. In this way there is no need for profound integration of the various applications, although they all have to be integrated to the activity-based framework. Applying an activity-based approach [25], the GUI should present the part of the workflow relevant for the current activity and users concurrently with the other relevant HIS applications for the current activity. In future work we plan to explore a prototype of an activity-based GUI and evaluate it in collaboration with participants from the field study.

6 Conclusions

The comprehensively guided work processes within oncology provides an excellent source for studying the possibilities and challenges in computer supported clinical cooperative work. Even rather simple work processes are distributed in time and place, involve several clinicians and are reliant on access to input/output of relevant clinical data.

To be able to provide efficient clinical process support we recommend a declarative notation approach, as it provides the flexibility and dynamics required by clinicians. To achieve this an inter-disciplinary approach is needed, including the collaboration between researchers in computer-supported cooperative work, workflow systems, and human computer interaction, as well as domain experts.

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Summary Points

What was already known on the topic:

- Collaboration within clinical practice is very complex.
- Application of computerized CPGs has been shown to improve quality of care.
- Computerized process support is not widely applied in clinical practice.

What this study added to our knowledge:

- In a specialty where most patients are treated according to a protocol, it is not the protocols but SOGAs that are applied in clinical practice. Sagas are besides providing activity specific guidance, serving as cooperation support and providing data representation and documentation at the point of care.
- Clinicians are striving for smooth workflows supported by tools that provide all relevant information and try to avoid any interruptions in the workflow.
- Replacing the functionality of SOGAs by a declarative workflow enriched form presented, as part of an activity-based-computing framework could be a feasible starting point for computer supported cooperative work in clinical practice.

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