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A Workflow-Driven, Formal Methods Approach to the Generation of Structured Checklists for Intra-Hospital Patient Transfers

Areti Manataki, Jacques Fleuriot and Petros Papapanagiotou

Abstract—Intra-hospital transfers are a common but hazardous aspect of hospital care, with a large number of incidents posing a threat to patient safety. A growing body of work advocates the use of checklists for minimizing intra-hospital transfer risk, but the majority of existing checklists are not guaranteed to be error-free and are difficult to adapt to different clinical settings or changing hospital policies. This paper details an approach that addresses these challenges through the employment of workflow technologies and formal methods for generating structured checklists. A three-phased methodology is proposed, where intra-hospital transfer processes are first conceptualized, then rigorously composed into workflows that are mechanically verified, and finally, translated into a set of checklists that support hospital staff while maintaining the dependencies between different transfer tasks. A case study is presented, highlighting the feasibility of this approach, and the correctness and maintainability benefits brought by the logical underpinning of this methodology. A checklist evaluation is discussed, with promising results regarding their usefulness.

Index Terms—checklist, formal methods, intra-hospital transfer, process model, workflow.

I. INTRODUCTION

Intra-hospital patient transfers are a common and important aspect of hospital care, but they are known to pose potential risks to the critically ill patient [1], [2]. A recent analysis of incidents in Australia revealed that, in over a third of the reports regarding intra-hospital transportation, the patient suffered serious adverse outcomes [3]. Safety issues pertaining to intra-hospital transfers have received some research interest over the past few years [4], [5], and there is agreement in the research community over the need for the development of guidelines and protocols [5].

Checklists are regarded as a promising solution to this problem, as they ensure that all important tasks are carried out in the correct order and they improve communication between cross-functional teams that need to coordinate [6]. A checklist is an organized cognitive tool, often in the form of a list of things that need to be checked or done, that guides users through accurate task completion [7]. Despite the strong potential of checklists for improving patient safety, there is a lack of standardised methodologies for designing and developing medical-specific checklists [6], [7].

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Recently, there have been some efforts towards developing checklists for intra-hospital transfers [2], [3], [8]–[11]. However, the majority of these seem to be devised in an ad-hoc fashion, based primarily on the experiences of hospital staff. This raises the significant issue of correctness, as it cannot be guaranteed that the checklists are error-free or do not contain redundancies. It also poses the challenge of adapting the checklists to reflect different hospital environments and maintaining them as hospital policies change over time.

This paper addresses these issues by employing a computer-based formal methods approach to the generation of structured checklists for intra-hospital transfers. A three-phased methodology is used, in which intra-hospital transfer processes are first conceptualized, then workflows are composed and rigorously machine-checked via theorem proving, and finally translated into structured checklists. We posit that the employment of formal methods and verified workflows can ease the process of developing checklists and deal with the correctness and maintainability challenges discussed earlier. A real-world application of the proposed methodology to intra-hospital transfers of tracheostomy patients at St Mary's Hospital, London, is also discussed in this paper, demonstrating the feasibility of our approach.

We note here that the research described in this paper significantly extends our previous work on intra-hospital tracheostomy transfers [12] by going beyond modelling to deal with the systematic generation of checklists and by providing some preliminary evaluation of the potential usefulness of said checklists to medical staff.

The rest of the paper is organised as follows: in the next section, we briefly describe our recent work on formal workflow verification. We then introduce the proposed methodology (Section III), and describe our case study, discussing the lessons learnt (Section IV) and the results from its preliminary evaluation (Section V). We conclude with a summary of some related work (Section VI) and with an overview of our plans for future research (Section VII).

II. BACKGROUND: FORMAL FRAMEWORK FOR RIGOROUS WORKFLOW COMPOSITION

In recent work, we developed a rigorous framework for the formal verification of healthcare process models, which describe the series of tasks for achieving a particular goal. This utilizes a fully visual tool that enables the development of diagrammatic process workflows [13], which are both machine-readable and human-understandable. An underlying theorem

proving engine formally verifies the correctness for the developed workflows so that they are *correct-by-construction* with respect to the consistency of the information flow.

In particular, the engine is embedded within the modern proof assistant HOL Light [14] and implements a rich theory involving Classic Linear Logic (CLL) and the proofs-as-processes paradigm [15]. The use of CLL as a process language, enables the explicit recording of resource dependencies and outcomes (inputs and outputs) of each process, including composite resources and optional ones. The latter can be used to describe exceptional events that may occur so that contingency processes can be implemented. The formal CLL inference rules help connect processes together to form workflows with the following unique advantages:

- All the involved resources are systematically tracked so that repetitions and redundancies are minimized and process dependencies are enforced (e.g. availability for the necessary resources is checked before a process starts).
- Resources connected to adverse events or obstacles that may occur are accounted for to ensure that such cases will be handled (or reported) explicitly and maximize resource reuse.

The proofs-as-processes paradigm ensures that CLL workflows are translated to executable procedures where individual processes are automatically organised in an efficient way, maximising concurrency and avoiding deadlocks [16].

The benefits of our correct-by-construction workflow modelling framework are particularly important in the context of healthcare processes, where resources are costly, enforced policies are directly connected to patient safety, and efficiency is key.

III. METHODOLOGY FOR DEVISING INTRA-HOSPITAL TRANSFER CHECKLISTS

A. Phase 1: Conceptualizing transfer processes

Intra-hospital transfers include a variety of processes that can be satisfied either by automated procedures or human provided services. We focus on facilitating organizational rather than medical decision-making tasks, as they have a direct effect on patient safety but, nevertheless, are often neglected. These processes may require significant resources and are often interrelated in non-obvious ways. For this reason, we specify the following three principles for conceptualizing transfer processes:

- 1) In order to capture the entire transfer lifecycle, we focus on the pre-, during- and post-transfer stages of processes [11]. The processes' scope and granularity levels can be decided by the modeller although typical transfer tasks (e.g. setting up equipment), as well as processes that influence or justify the progress of the transfer (e.g. review patient for transfer) should be captured.
- 2) For each process, we define its set of inputs and outputs, including those for alternative or exceptional outcomes such as unexpected results, failures or obstacles. Inputs and outputs related to patients, equipment and information are important since they are crucial for the transfer progression.

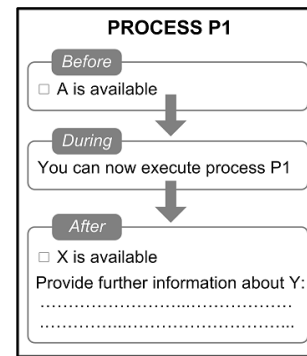


Fig. 1. Abstract example of structured checklist

- 3) Resource-based inter-process dependencies, which indicate logical interrelations between the execution of processes, and time-based dependencies, which indicate temporal constraints on process execution, are identified.

The outcome of the conceptualization phase is an informal textual or graphical model of transfer that captures its salient aspects but provides no guarantees regarding its mathematical consistency. The next phase of our methodology tackles precisely this issue.

B. Phase 2: Formally verifying transfer workflows

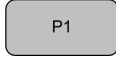
In this phase, the specification, composition and verification of clinical workflows are carried out with the use of our tool. The user specifies transfer-related processes and composes them purely diagrammatically, while the corresponding CLL specifications and proofs are constructed automatically in the background. All resulting workflows are visually inspectable and can be trusted as a sound basis for generating structured, consistent checklists, free of logical errors.

C. Phase 3: Generating structured checklists

The final phase of our methodology involves the systematic generation of structured checklists based on the formalized workflow obtained from the previous phase. Fig. 1 presents a template for a structured checklist for a human provided service, consisting of three sections: before, during and after. The before-section contains elements that need to hold before the health personnel proceed to satisfy the corresponding process. Once all required before-elements are provided, the health personnel can move to the during-section, and thus carry out the task. After completion of the task, the after-section is to be filled in, at which point the checklist is considered to be completed, and the health personnel can proceed to the following checklists, as prescribed by the workflow. Different design elements can be used for the checklist, such as checkboxes, textboxes and radio buttons.

In our current work we focus on the generic design of such structured checklists that can serve both paper- and computer-based checklist implementations. We note that, in our examples, we focus on the key information and resources of each process and omit metadata, such as the date and the names of the involved patient and hospital staff for simplicity.

TABLE I
TRANSLATION GUIDELINES

Workflow element	Checklist element
	<p>Checklist</p> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">PROCESS P1</p> <p><i>Before</i></p> <input type="checkbox"/> A is available</div>

We provide guidelines for translating the formalized workflow into a set of checklists. An extract is presented in Table I, reflecting individual transfer-related processes, their inputs and outputs, as well as their dependency-based arrangement in the verified workflow. For instance, it can be seen that sequentially composed processes are translated into sequential checklists, i.e. checklists that are filled in one after the other. So, for instance, the checklist for P_1 is filled in before P_2 and all of

TABLE II
CONCEPTUALIZED PROCESSES FOR THE PRE-TRANSFER STAGE

Process	Input	Output
Decide on tracheostomy	ENT review Patient requirement	Decision for tracheostomy
Document decision	Decision for tracheostomy	Decision documentation
Refer patient	Decision for tracheostomy Timing	Referral
Document referral	Referral	Referral timing Consent form 4
Review patient	Referral	Patient fit for procedure OR Patient unfit for procedure

P_i ($i \leq N$). Note that all elements within the before- and after-sections of a checklist need to be filled in, except for the case of alternative elements, highlighted by the ‘or’ keyword.

Finally, we propose distinguishing elements in the before-section of a checklist that are provided by previous checklists, as opposed to elements that are new, for example by marking the former in italics. This differentiation can help healthcare practitioners better track the requirements of their tasks, as well as highlight elements that can be automatically propagated in a computer-based implementation.

IV. CASE STUDY: INTRA-HOSPITAL TRANSFERS FOR TRACHEOSTOMY

We now examine the application of our methodology to tracheostomy transfers, which did not have well-defined guidelines or checklists at St Mary’s Hospital.

Data was collected through the shadowing of a consultant anesthetist, semi-structured interviews with nurses, doctors and porters, as well as Skype meetings and frequent email exchanges with clinicians.

A. Conceptualizing the processes for a tracheostomy patient transfer

Our medical collaborators first provided us with hand-written notes on general intra-hospital transfers and then notes on transfers specific to tracheostomy. Following our request for them to consider the flow of tasks, the medics devised a set of hand-sketched flowcharts, an extract of which is depicted in Fig. 2.

Utilizing these flowcharts, we manually identified the main processes involved in tracheostomy transfers, along with their inputs and outputs. We also analyzed the process dependencies and the exceptions involved. The final process conceptualization was validated by the clinicians, and an extract is presented in Table II, which accounts for all main items of the top part of the flowchart in Fig. 2. Some of these items are represented as processes (e.g. “Review patient”), while others correspond to process inputs/outputs (e.g. “Consent form 4”).

B. Composing and formally verifying the workflow of tracheostomy transfer

The conceptualized model was then formalized and automatically verified. For more details regarding the processes’

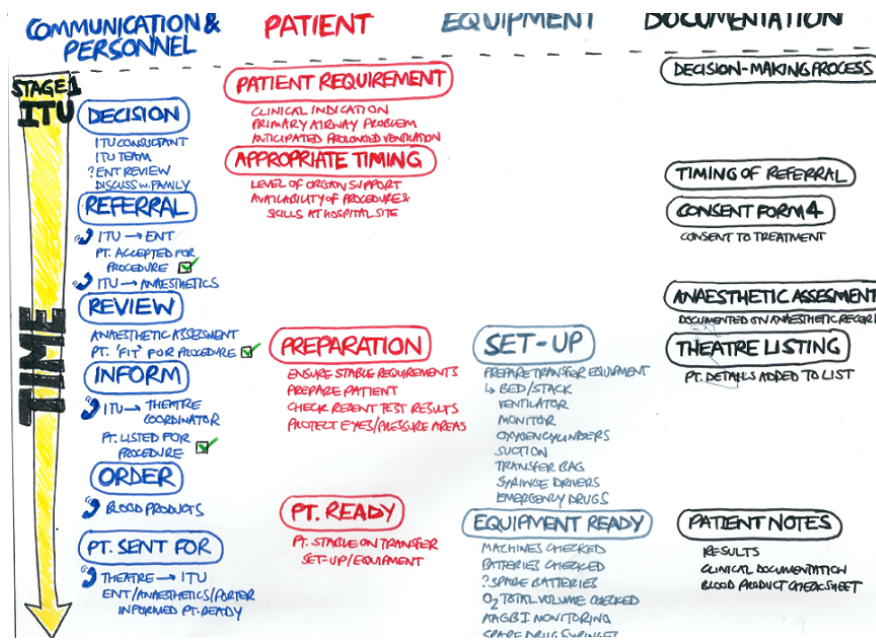


Fig. 2. Extract of pen-and paper flowcharts for tracheostomy transfer provided by medics. This extract corresponds to the pre-transfer stage at the ICU.

specifications, refer the interested reader to our recent paper on the formal modelling of tracheostomy transfers [12].

We visually combined the formally specified processes to obtain the overall workflow. An extract is shown in Fig. 3, clarifying the progression of the pre-transfer stage: A decision is first made for tracheostomy, and the patient is next referred and reviewed for the procedure. These processes are followed by a set of preparation tasks, while, in the meantime, several documentation tasks are carried out. All preparation and documentation processes need to have completed execution before sending the patient for the transfer. In the case where the patient is assessed as unfit during the review, the preparation and documentation processes do not need to be carried out, except for “document anesthetic assessment”, after which the transfer is aborted.

The workflow makes evident the process dependencies and the order in which they should be performed. For instance, it can be seen that “review patient” and “document referral” depend on the successful execution of “refer patient”, and thus they should be carried out strictly after it. They are, however, independent of each other and, thus, they could be performed simultaneously or one after the other, in any order. The flow of resources during the transfer is also visualized. For instance, it can be seen that the decision for tracheostomy is transformed in a sense into a referral and next into a review of the patient as fit or unfit.

The use of formal methods for representing the tracheostomy workflow allowed its rigorous verification and accounted for all resources, including exceptional cases. This is visualized in Fig. 3, where the two groups of outputs of “send patient for transfer” refer to the two different cases of termination of the pre-transfer stage: it is either successfully completed (with the patient, personnel, equipment and documentation ready for the transfer) or it is unsuccessfully stopped due to the patient being unfit for the procedure (with

documentation-related outputs being available).

C. Generating structured checklists for tracheostomy transfer

Finally, the formally verified workflow for tracheostomy transfers was manually translated into paper-based checklists by following the translation procedure introduced in Section III-C. Fig. 4 shows the structured checklists for the sequentially composed processes “refer patient”, “review patient” and “document referral”. The three sections in each checklist can guide the health practitioner towards satisfying the corresponding processes in a structured way: To refer a patient, given the first checklist, a decision for tracheostomy needs to have already been made and the health practitioner needs to verify that the timing is appropriate. Once information on these requirements is provided, a decision can be made on referring the patient and the outcome is then recorded. As soon as the checklist for “refer patient” is dealt with, the health practitioner can proceed to fill in the checklists for “review patient” and “document referral”. Note that, as prescribed by the workflow in Fig. 3, there is no constraint on the order in which these two checklists are filled in, except that they should follow the completion of the checklist for “refer patient”.

Fig. 5 presents the checklist generated for the process “send patient for transfer”, which takes place before the physical transfer of the patient. Checking the availability of resources and confirming that all requirements are satisfied through the use of this checklist ensures that a “mobile ICU” is in place for the transfer and eliminates any related delays or mistakes. This checklist can be further specialized via appropriate modelling decisions at the workflow level, for instance to include the exhaustive list of specific transfer equipment.

As demonstrated by this case study, the workflow-driven and logical foundations of our approach for systematically devising intra-hospital transfer checklists bring four valuable characteristics:

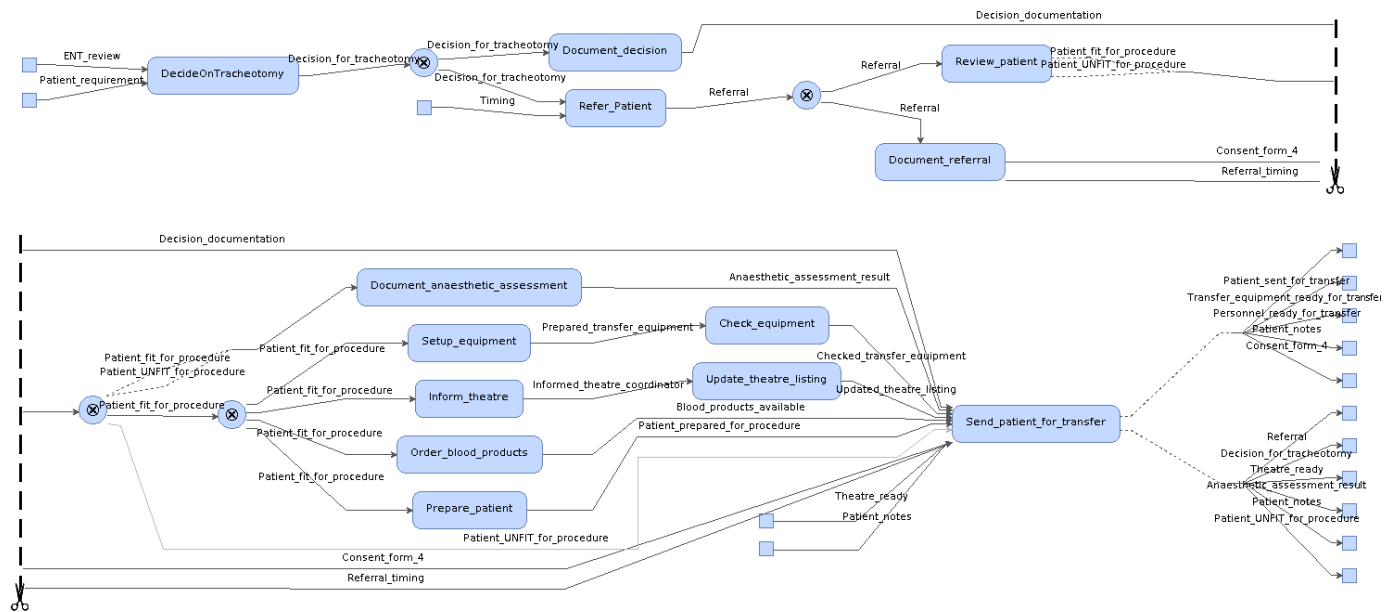


Fig. 3. Example of mechanically verified workflow of tracheostomy transfers. This workflow corresponds to the pre-transfer stage at the ICU.

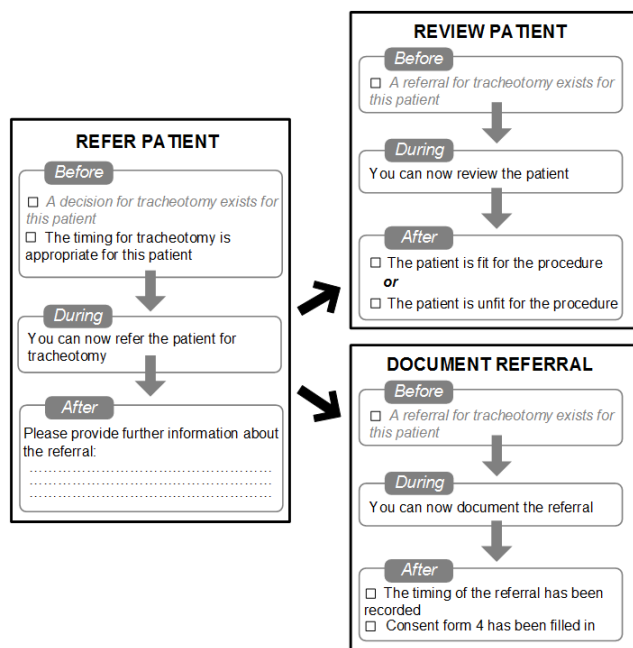


Fig. 4. Example of devised structured checklists for tracheostomy transfers

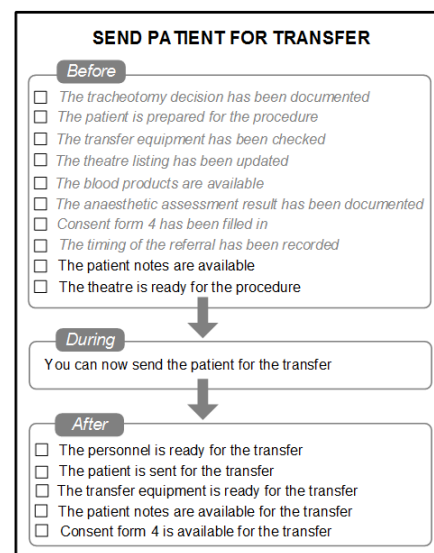


Fig. 5. Structured checklist for “send patient for transfer”

- **Structured:** The checklists have a clear structure with respect to both their sequence and the arrangement of their fields. There is, thus, no ambiguity with respect to the series of steps to be followed or the requirements for carrying out a task.
- **Consistent:** The devised checklists are consistent with the specified workflow, which means that no assumptions need to be made about the clinical path followed, and hence no irrelevant information will be asked.
- **Correct:** The checklists can be trusted to be error-free with respect to the formalized workflows. This is achieved

- **Maintainable:** The checklists can be easily tailored to different hospital settings, as well as adapted to changing policies and practices, in the sense that minimal checklist modifications can be applied in a methodical way. For instance, given a change in transfer practices, the related conceptualized process(es) will be modified accordingly and the workflow will be updated in a verified way. Since only the modified elements of the correct-by-construction workflow will translate to modified checklist elements, the maintenance effort and its associated risk of error will be minimized (see Fig. 6 for an illustrating example).

We regard these characteristics as considerable strengths, especially when comparing them to checklists that are created in an ad-hoc way. The latter may not be fully consistent with the transfer workflow, and hence could skip necessary steps or include irrelevant questions. They could also involve logical inconsistencies, possibly leading to redundancy or mistakes. Furthermore, maintainability aspects are not easily ensured, potentially leading to confusion when hospital policies are changed. We should emphasize that we are not claiming that ad-hoc checklists always have these flaws. Adept checklist designers could potentially develop structured checklists and achieve correctness, consistency and maintainability, but this is a non-trivial task in general.

V. EVALUATION

A preliminary evaluation has been conducted for the tracheostomy transfer checklists, with promising results. This was carried out with the participation of 6 clinicians (4 critical care physicians and 2 nurses) with extensive experience in intra-hospital transfers. The clinicians were based at the Royal Infirmary of Edinburgh, rather than St Mary's Hospital, to provide an independent evaluation of the merits of our approach and of the resulting checklists.

Evaluation sessions of at most 45 minutes were run separately for each participant and with a member of our team being present. Interaction with the participants was kept at minimal levels through the use of appropriately designed evaluation resources. In particular, participants were provided with a scenario of tracheostomy transfers and a set of corresponding checklists, developed using Google Forms for them to go through. As a side-remark, we note that having the checklists in an electronic form allowed for the straightforward propagation of information for the before-sections in some cases, e.g. as depicted in Fig. 7. However, both this instance of the "review patient" checklist and the one in Fig. 4 are faithful realisations of the templates arising from the process described in Section III-C.

Once the participants completed the checklists, they were asked to fill in a questionnaire consisting of 10 scale questions ranging from 1 to 5, where 1 is "strongly disagree", 3 is "neither agree or disagree" and 5 is "strongly agree" about checklist properties. All participants gave a score of 4 ("agree") or 5 for policy adherence, consistency and appropriate granularity level. Similarly, they all agreed or strongly agreed that the scenario given was representative of their experience of intra-hospital transfers. The average score for the question "I would consider the use of the checklists provided in my practice" was 4.5, and all participants found that the checklists would be useful or very useful if applied in their practice. Questions around the potential of the checklists for training new staff, managing resources and reducing the occurrence of errors during intra-hospital transfers got an average score of 4.8, 4.2 and 4.5, respectively. Finally, all participants agreed or strongly agreed that the checklists can support hospital staff.

In addition to the 10 questions, the questionnaire included an optional, free-text field for providing further comments. Some participants highlighted differences to their local practices (e.g. around ordering blood products) and the need to

Tracheostomy Patient Transfer

*Required

Review Patient

The following information is available:

- Patient Referral details (includes patient details, decision for tracheostomy details, ENT review)

Is the patient fit for the procedure? *

Patient is FIT for procedure.

Patient is UNFIT for procedure.

BACK

NEXT

before-section
(information propagated)

after-section

Fig. 7. Checklist for "review patient" used at the evaluation

adapt the checklists accordingly if these were to be employed at their site.

We regard these results as very encouraging, especially given that the value of the checklists was perceived as high by an independent group of clinical experts. Furthermore, by observing participants use the checklists, we can confirm that there was no uncertainty regarding the series of steps to be followed or the prerequisites for different tasks.

VI. RELATED WORK ON WORKFLOW-BASED APPROACHES IN HEALTHCARE

Workflow technologies are widely used in healthcare, as they can enforce clinical guidelines, while supporting team communication and care coordination [17]. Representative examples include the following:

- PROforma [18] is a logic-based language for the modelling of clinical processes by specifying a wide range of clinical tasks, medical knowledge, and patient data associated with the management of medical procedures and clinical decision making. It is used within the Tallis [19] software kit that supports authoring, publishing and enacting web-based clinical knowledge applications.
- EON [20] is a framework comprising of models and software components for the creation of guideline-based applications, focusing on patient-specific decision support, time-oriented patient data, and knowledge-engineering for guidelines.
- Asbru [21] is a language for the representation of clinical guidelines and protocols as time-oriented skeletal plans.
- GLIF3 [22] is an executable language for clinical practice guidelines, supporting multiple system platforms and integrating ontologies for medical guidelines, data, and concepts.

These technologies make use of formal representation mainly to provide guideline-based decision support for diagnosis and treatment, while in our case, we focus on organizational support for intra-hospital transfers. Process modelling techniques commonly used for such organizational optimisation [23] lack the rigour and reasoning capabilities of our framework.

VII. CONCLUSIONS AND FUTURE WORK

This paper presented a systematic, computer-based approach to supporting patient safety during intra-hospital transfers

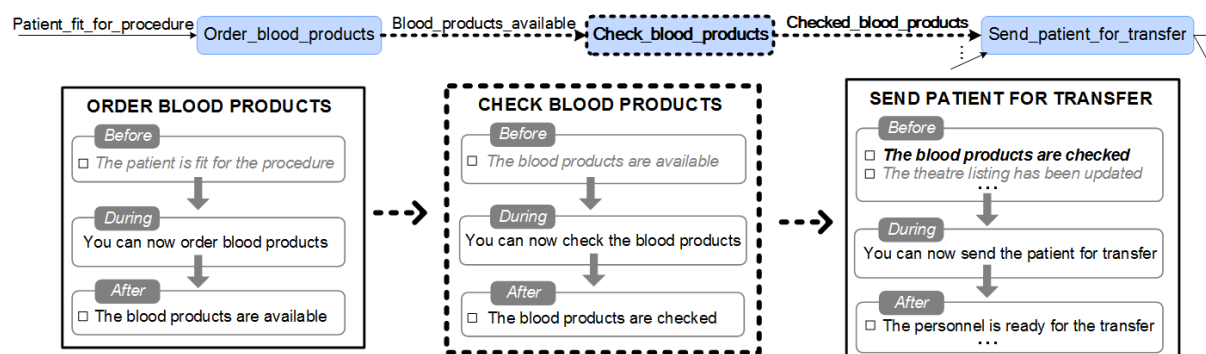


Fig. 6. Example of workflow and checklist modification in the hypothetical case where St Mary's Hospital changed their policies to introduce a check of blood products before sending the patient for transfer. The modified elements are highlighted in bold and dashed lines.

through a three-phased methodology that utilizes formal methods and workflow technologies for generating checklists.

The checklists, which are guaranteed to be free of logical errors, can support health practitioners throughout the transfers, guaranteeing that clinical pathways are accurately followed and that all resources required are in place before performing any safety-critical task. Moreover, they can be modified in a systematic way to fit different hospital environments or changing hospital policies. We believe that these are considerable strengths not found in other approaches, and preliminary evaluation by clinical experts shows promising results.

However, a thorough clinical evaluation is needed to investigate the impact of the checklists on clinical practice and patient safety. Another constraint of our approach is that it can be time and labor intensive, especially for people that are new to workflow modelling.

To help address this, future work will involve the automated generation of structured, *electronic* checklists from the workflows. As fully automating this translation process may prove difficult, we are exploring the possibility of a semi-automated process. We also plan to enhance our modelling tool to make some of the visual aspects more specific to healthcare and, based on some preliminary study, it seems clear that our approach can be readily extended to inter-hospital transfers.

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