Standardized Process Models for Applying Artificial Intelligence to High-Risk Decision-Making: A Pediatric Neuro-Oncology Perspective

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ABSTRACT

Research and deployment of AI in high-risk decision-making environments often focuses on specific components of the AI process, such as the users, models, or data, as a means to successfully apply AI. We propose a shift towards a more holistic approach that requires a comprehensive focus on all involved components and more importantly the integration of the complete environment. In high-risk decision-making environments, there are a number of stakeholders who play various roles. When we integrate AI into such a setting, we are adding even more stakeholders (e.g, AI and UI researchers). Each of these stakeholders tend to work in silos with their own nomenclature and culture. Careful integration of these roles is critical to develop and apply trustworthy AI in high-risk decision-making contexts, like cancer care. Historically, a similar situation occurred during the evolution of enterprise software that led to the creation of a standards consortium and the development of a standardized process model ecosystem. Here, we argue that a standardized process model should be formally defined for high-risk decision-making, using pediatric neuro-oncology as an example application. Using standardized models could lead to a development environment which engenders trust through transparency and social capital.

INTRODUCTION

Artificial intelligence (AI) is increasingly being utilized to support high-risk decision-making, for example in medicine [15–17, 30]. However, this application has been limited so far due to a lack of model interpretability and overall perception of trustworthiness.

Methods developed in the emerging explainable AI (XAI) research area, at the intersection of human-computer interaction (HCI), visual analytics (VA), and artificial intelligence (AI) research, aim at addressing these issues. These methods seek to explain AI model behavior using specialized network architectures or surrogate modeling approaches. One major but currently underappreciated consideration within XAI is *who* is the explanation for?

Understanding the perspective of the recipient of an explanation is critical because decision makers with different roles and backgrounds vary in their perception and interpretation of information. VA methods are increasingly being developed using human-centered design principles, with an emphasis on creating a mutually intelligible channel of communication between humans and machines to improve decision-making capacity [31]. For example, Wang and colleagues developed user-centric XAI solutions that take into account the users' AI literacy as well as the subject domain [30].

Real-world development and application of XAI to high-risk decision-making involves a large number of contributors and/or stakeholders from a diverse set of backgrounds and varied expertise. Because successful high-risk decision-making requires risk mitigation, each of these stakeholders will perform their relevant contributions according to a specific and well-defined workflow. We argue that the application of AI to high-risk decision-making requires careful integration of these workflows. Importantly, like XAI, we emphasize the need for asking *who* is the workflow for?

Process Models (PMs) are abstract representations of the steps needed to complete a workflow. These can be applied to concrete tasks like manufacturing as well as philosophical notions like sense-making [3, 11, 35]. PMs are utilized fairly independently in the fields of visualization and software development, healthcare, and business. To our knowledge, there currently exist no approaches to blend these workflows from different fields in a way that can standardize a pipeline for the development and deployment of XAI-enabled tools in a transparent and reproducible manner.

In this paper we first provide an overview of and discuss PMs in different fields and then make an argument for why a standardized PM framework should be developed for the high-risk decision-making context of pediatric neuro-oncology care.

OVERVIEW OF PROCESS MODELS (PMS)

PMs are languages defined by elements and relationships, and give a means to measure progress in a specific task. For example, when you are hungry you can eat food and become satiated.

PMs can be defined using a declarative or imperative notation. Declarative PMs define the desired outcome of a process but not the steps to get there. Using our example, this is easiest to observe in 'eat food'; it tells you *what* to do. In contrast, imperative PMs define *how* to reach a goal. In this case, 'eat food' could become a highly intricate process for sourcing and preparing food. Figure 1 displays a toy example of an imperative PM describing a patient going to a doctor for receiving medicine using the Business Process Model Notation (BPMN).

Benefits of declarative PMs include that they are deterministic, structured, and repeatable. This class of PMs requires comprehensive definitions of activities and relationships up front. Therefore, these PMs are not well suited for environments that routinely change, like that of cancer patient care. A second disadvantage of declarative models is that every time a redesign is required, there are significant information security concerns [12]. Imperative PMs are performed *ad hoc* and are not repeatable, but they are dynamic in nature and can have much longer life cycles [28]. Because of lack of repeatability, imperative PMs have an intrinsic problem related to benchmarking and evaluation. Overall, there are strengths and weaknesses related to each methodology and a general consensus is to utilize both in an integrated fashion [28].

Processes can be categorized as knowledge-intensive (KiP) or non-KiP; KiPs are tasks that depend on knowledge and human expertise, often in contexts like creative tasks or unpredictable decisions [7, 24]. An example of a KiP is the step in Figure 1 that states *Receive Symptoms*. These processes are particularly difficult to model and automate. Importantly, there are numerous KiPs involved in the development and application of AI tools for high-risk contexts like cancer care. This is confounded further because these KiPs can be subclassified by the kind of knowledge worker the process is for. For example, clinicians, AI and VA developers, and regulatory specialists all have prominent and interconnected roles in

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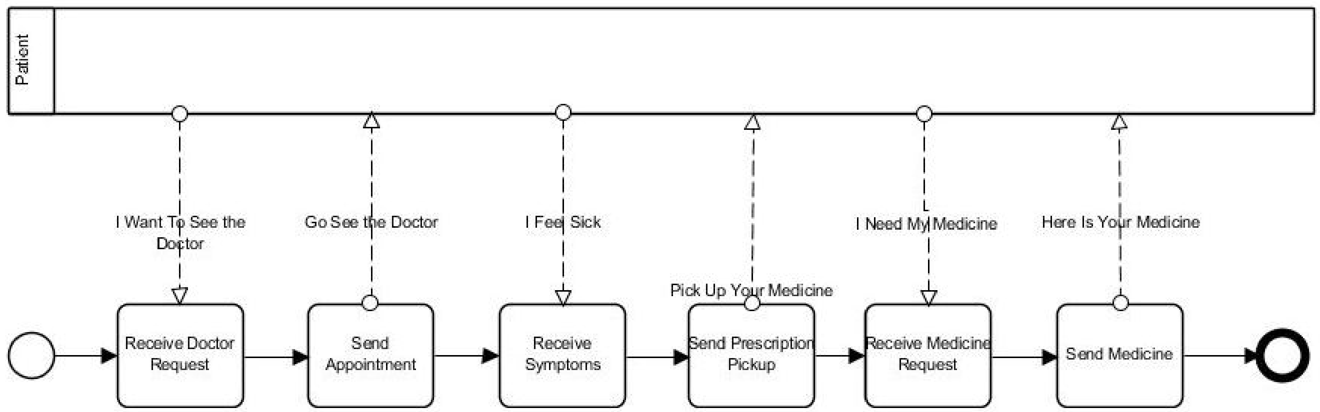

Figure 1: Example of a patient being prescribed and receiving medication from a doctor. The top row represents a *lane* for the patient timeline, and the bottom row represents the clinic timeline. Steps are represented as boxes and activities are shown as arrows. The image is taken from bpmn.org and is in the public domain.

the successful application of AI tools in the cancer clinic. Because each of these roles comes from a different cultural community, they will have different nomenclature and problem-solving strategies.

PMs can be developed both manually and using automated methods. Various guidelines for PM development exist (e.g., 7PMG [21]) for manual generation relying on human knowledge and expertise. An example of an automated method for PM development is process mining, a technique for designing business PMs automatically using retrospective inference [1]. There exist also methods for explicitly considering relationships with uncertainty in the PM, such as trust-aware process design [26].

PMs are often evaluated based on the quality and flexibility of the model. Quality measurements can be subdivided into process-oriented (i.e., quality of the workflow) or product-oriented (i.e., quality of the output) [9]. Quality measurements are defined by the International Standards Organization (ISO) according the Systems and software Quality Requirements and Evaluation (SQuaRE; ISO/IEC 25000:2014). The flexibility of PMs can be determined using methods like counting the number of insertions and deletions to translate one PM to another (i.e., editing distance) or measuring the number of alternative contexts within which a given PM can be validly utilized [20]. Flexibility can also be considered in terms of build-time (i.e., development) or run-time (i.e., implementation) flexibility.

Integration of PMs is critical and difficult. PMs that have different levels of granularity and vocabulary can be mismatched between process model design for use within the same application domain [29]. This issue arises due to the fact that a given pair of activities (from the pair of PMs to be integrated) can have a ranging degree of equivalency [29]. Nonequivalent pairs are activities that have distinct objectives in each PM. Equivalent pairs are considered to be trivial or non-trivial. Trivial pairs are those that have similar or identical labels. The major issue is created by non-trivial pairs which are activities which have the same objective but have dissimilar labels [29]. The reconciliation of non-trivial pairs is an open area in PM research. Another common example of PM misalignment can be found in commercial software development [4]. In this context, it is common for business leadership to define their goals and PMs using BPMN. Next, software developers implement their skill set by defining development PMs, often using UML. Unfortunately, these individual groups operate independently of one another and the result is PM misalignment.

AN ARGUMENT FOR DEFINING A STANDARDIZED PROCESS MODEL (SPM) IN PEDIATRIC NEURO-ONCOLOGY

Neuro-oncology is a field in which AI is expected to provide significant benefit, yet adoption of the technology remains minimal [18]. Modern cancer care protocols involve several care "touchpoints" where groups of individuals with diverse expertise intersect to make a clinical decision (Figure 2) [17].

Stakeholders for this environment include patients, their families, physicians, advanced practice providers, therapists, social workers, students/trainees, hospital administration, pharmaceutical companies, and the broader community [17]. This environment is further tailored to whether the patient is a child or an adult. The relationship between who the primary decision-maker is depends on the patient's age and psychosocial status. The application of XAI adds a range of additional stakeholders: AI developers, UI/UX designers, system administrators, and web developers.

Figure 2 displays a coarse and imperative PM from the intersected perspectives of a clinical provider and software developer. The actual process is comprehensive and requires the perspectives of other direct contributors like systems, and VA and AI developers. Each of these groups utilize PMs in order to develop the infrastructure, models, and interfaces needed for explainable AI enabled clinical decision support systems (XAI-CDSS).

There are a variety of examples of PM usage in healthcare and in the development of technology for healthcare. We provide one example of how PMs are currently utilized in pediatric neuro-oncology, and two examples of how PM-based approaches have been employed in the human-centered development of XAI-CDSS. However, each of these examples utilize a unique PM and therefore are not immediately interoperable, which ultimately hinders progress towards real-world deployment. As a final example we present a historical analogy from the business sector in which defining a SPM led to increased interoperability of software and significant advances in information technology.

RAPNO: Response Assessment in Pediatric Neuro-Oncology

RAPNO is a working group consisting of an international panel of experts in the medical treatment of pediatric central nervous system tumors. As a group, they have defined a set of assessment criteria for understanding patient response to treatment in a standardized way. Example of assessment criteria include clinical imaging, molecular, and patient performance evaluation (e.g., psychosocial and quality of life measures) [5, 8, 10]. Unified consensus recommendation

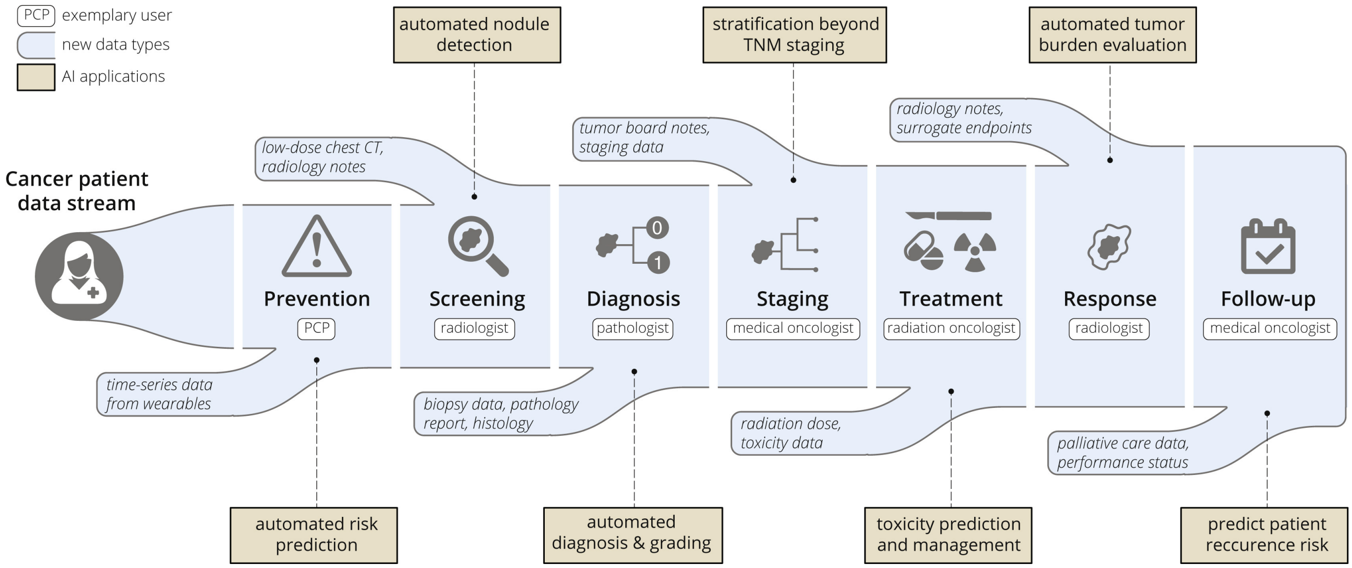

Figure 2: Example of cancer patient data stream overlayed with cancer care "touchpoints". Exemplary user, data type, and AI applications are labeled in the top left of the figure. The image is taken from [17].

tools like the RAPNO assessment criteria represent an initial effort towards improved understanding of treatment response across groups of patients. In addition, approaches like RAPNO are readily available solutions to make interpretable clinical decision support systems. For example, Peng *et al*. leveraged this PM to develop an automated pipeline (AutoRAPNO) powered by deep learning models to assess tumor burden [25].

DoReMi: Designing Patterns for Explanations of XAI in Clinical Decision Support Systems

Schoonderwoerd *et al*. presented a human-centered design approach for AI-generated explanations in CDSS for diagnosing ADHD in children [27]. The approach, DoReMi, is comprised of three modules: (1) domain analysis, (2) requirements elicitation and assessment, and (3) multi-modal interaction design and evaluation. The group performed a domain analysis through literature review on clinical diagnosis of ADHD and curated 20 information elements that can be utilized for XAI in this task. Using their defined PM and information elements, they created a set of explanation design templates which were used to generate prototypes for user studies. DoReMi enabled developers to prototype customized multidisciplinary explanations more rapidly with fewer end-users needed throughout the iterative design process.

XAI User Needs Library: Towards Standardized Explanations of Artificial Intelligence in Medicine

He and colleagues systematically developed an XAI User Needs Library for the medical domain. Their focus was on explanation content, and not explanation techniques, algorithms, or design methods [13]. The library was developed as a collaboration between engineers and AI experts and the end-user as a consumer. This library is comprised of numerous factors grouped based on Input, Output, and Performance of the AI model. In addition, there are a set of more abstract factors (e.g. how, what, and why) and other broad concepts like 'What is the information on impact on existing legal liability?' and 'What does this AI/medical terminology mean?' Using this library, they developed specific design components and a prototype which was evaluated by a study group. Their results suggest to focus on managing the level of detail within an explanation and making explanations personal to the end-user.

Standardized Process Models in Information Technology – A Historical Example

During the 1980s, computers were increasing in popularity but the expected benefit was not being realized because components and software were unique to each manufacturer and developer. Although each manufacturer produced a computer, their individual process models were unique and not interchangeable. This resulted in limited performance from computers using different software and essentially threatened the ability for software to improve.

A response came in 1989, when eleven companies including IBM, Hewlett-Packard, Sun Microsystems, Apple, as well as end-users, academic institutions, and government agencies founded the Object Management Group (OMG). Accordingly, the goal of the OMG was to develop an interoperable object model, set of methods, and data to be used for the definition of specifications needed for enterprise integration of the computer industry.

Since then, the OMG has adopted a set of standards for declarative (Business Process Model Notation; BPMN 2.0), imperative (Case Management Model and Notation; CMMN), and decision-making (Decision Making Notation; DMN) PM notation. These three standards are specifically designed to be comprehensive and complementary to one another and to be capable of integration.

These standards have been previously utilized in healthcare. In 2019, a community of academic and industry leaders along with OMG began a collaboration known as BPM+ Health. The group has created Shareable Clinical Pathways (built on BPMN, CMMN, and DMN), which are machine readable healthcare practice patterns designed to create automated healthcare solutions. In addition, these PM languages have been used in independent studies for operating room management and demonstrated beneficence for translating patients into clinical pathways [2, 14, 33]. However, there is no inclusion of PMs for software developers and no standardized PM for the development of XAI-CDSS for pediatric brain tumor care. We propose to adapt methodology like BPM+ Health to also include PM components for visual analytics and XAI developers.

How Will SPMs Improve Development and Application of XAI?

Practical application of XAI in pediatric neuro-oncology is complex. Improper follow-through during the design process can lead to systems that have the opposite effect of what is intended, resulting in difficulty obtaining sufficient buy-in from stakeholders in the process (e.g., patients, patients' families, clinicians, hospital administrators, designers, and the broader community). Moreover, failure to identify systemic biases can lead to greater divergence of groups of individuals, which greatly decreases medical trust [32]

Defining a SPM allows for a perspective to ensure comparison of different methods will scale to the broader community, or if a given tool is not appropriate to dispatch to a new context. Notably, the majority of FDA-approved AI devices have only been evaluated retrospectively and not across multiple sites of deployment [34]. One such case, IBM's Watson for Oncology, did not have strong concordance with clinicians in China due to differences in preferences between Eastern and Western cancer care [36].

Observations like these lead us to consider the importance of defining an explicit and comprehensive PM for applying AI in a setting, so that we can understand if a given tool is suitable for a given context. Specifically, **we hypothesize that a team of non-clinical XAI and visual analytics developers can create more usable XAI-CDSS at a faster rate if given a standardized process model**. This can be tested through a user study in which teams of developers are tasked to develop XAI-CDSS and are randomly given a SPM for the task, or not. This hypothesis could also be test longitudinally through literature, given adoption of a SPM by the community.

Like all models, numerous variations of SPMs can be applied to a given context; no SPM generally outperforms all others. Instead, SPMs can provide a new ecosystem within the clinic for XAI-CDSS deployment (maybe similar to the R tidyverse). Meaning, by explicitly defining our task ecosystem, we could have independent research groups working within the same SPM leading to tools that are immediately capable of interacting. Along these lines, **we hypothesize that developing XAI-CDSS based on a standardized PM will result in more interoperable components across tools, compared to tools that are not built upon a SPM**.

SPMs should be exhaustive and explicit regarding application domain, stakeholders, requirements/assumptions, etc. **SPMs can and should engender an environment of trust**. For example, defining human-centric PMs in virtual learning environment led to trust through the accrual of social capital [6]. Meaning, by having a direct involvement of stakeholders in the PM generating process, there was established credibility. In addition, trust mining is an automated method to quantify and interpret uncertainty related to process models [22]. This approach first defines relevant stakeholders and specifies their trust tolerance profiles. Trust mining then generates a set of pertinent trust issues centered around questions related to where uncertainty is present, which types of uncertainty are present, how can uncertainty be represented to process engineers, and how is each individual stakeholder impacted by each uncertainty issue [22].

Clinical decision support software built upon SPMs also provides a solution to issues related to implementing multi-institutional XAI. For example, blockchain technology (i.e., distributed ledger systems) provide an interesting solution for minimizing uncertainties and vulnerabilities related to data integrity and a process in general [23]. Specifically, the explicit use of blockchain within a policy-based process model (e.g., a Petri net) can create situations where mutual trust between two given parties is not required prior to data sharing [19]. Enhancing trust and reducing regulatory restrictions (i.e., material transfer or non-disclosure agreements) in these areas can foster growth of multi-institutional federated databases, which will lead to improved AI model performance.

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