On the "pathway" towards ICT-support for a better and sustainable healthcare

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Abstract: This paper focuses on clinical pathways, a tool that physicians are introducing to support the management of patients' illness trajectories. We undertook a six months long observational study in an intensive care unit of an important Italian teaching hospital and we acknowledged with physicians the importance of relying on well-agreed and properly defined clinical pathways in daily care practice. As a result of this study, we propose a roadmap on how to participatorily design a computer-based system supporting practitioners' decisions on the basis of the integration between clinical data and the indications reported in clinical pathways.

1 Background and motivations

In this paper, we focus on a new tool doctors and nurses are beginning to become familiar with: clinical pathways (CPs)¹. Often, this tool is given to clinicians by the management of the facilities where they work for the same purposes underpinning the introduction of clinical records almost one hundred years earlier: i.e., legal accountability, medical evidence retention, quality management, resource planning and smoother coordination [Ber03]. Indeed, CPs are tools that even doctors propose themselves as result of an intrinsic drive towards better quality of care, continuous learning and improvement, and need for better coordination with heterogeneous actors involved in the same clinical case.

Although there are several definitions for the term *clinical pathway*, in the following we will adopt what stresses their representational and descriptive nature. A clinical pathway is a "map" — i.e., a schematic representation of a plan — of preferred activities to undertake for the management of a homogeneous population of patients associated to a specific diagnosis from start to finish of their episodes of care (cf. [Poh05, Uls05]). Several studies (e.g., [ANQ05, KC06, dL00]) from the medical specialistic literature have been providing evidences that developing and adopting CPs can be useful towards (a) the improvement of patient care by encouraging patient involvement and by identifying and measuring improvements in patient care and outcomes; (b) the maximization of the efficient use of resources by reducing unnecessary documentation and overlap and reduced length of hospital stay for particular conditions; (c) the improvement of clinical effectiveness in terms of better clinical outcomes and less adverse events; (d) the increases in the collaboration between the disciplines, professionals and agencies. The latter has been seen as a pivotal condition

¹Other authors refer to CPs as critical pathways, care maps, care programs, integrated care pathways and other similar expressions.

to ensure continuity of patient care by reducing unnecessary variations in the management of the clinical case and to enhance both the extent and the quality of interaction between the involved professionals [AC02].

We began addressing this topic during the field studies we were undertaking for the development of an electronic clinical record that would not disrupt traditional coordination patterns and care practices. To this aim, we have been collaborating since spring 2006 with doctors and nurses from the Neonatology Intensive Care Unit (NICU) of a big teaching hospital of Northern Italy (the Alessandro Manzoni Hospital in Lecco) [CSST06, CSST05]. During these studies, several doctors, and especially their head-physician, told us that pathways should have been used to improve quality of care and facilitate the extraction of scientific evidences from daily clinical practice. Clinical pathways were advocated as the main tools that should provide unambiguous and precise indications about "who is supposed to do what and when" with respect to a specific health problem. Consequently, our interest grew upon these open research questions: how are CPs designed and for which underpinning purposes? How are they then put at work, shaped and adopted within a local community of practitioners? And, above all, how could CPs be augmented with useful computational functionalities to make them powerful and context-aware tools to increase comparability, quality management and clinical research, while keeping the doctors' status of autonomous and creative problem solvers preserved?

2 Bringing together pathways and records

Clinical pathways are representations of a process that *can* occur either within single or across multiple facilities under given and precise circumstances. Each pathway represents a path that a patient can undertake if and only if her conditions are associated with a routinary series of interventions. These interventions can be either oriented to the confirmation of some diagnostic hypothesis or to the resolution of a patient's health problem according to the related diagnosis. At each step of the path, or better yet, in any moment of the care process, clinicians can decide whether the patient must keep following the initial pathway, exit it, or begin a new one towards her recovery and discharge. For this reason, the link between the application of any pathway and the clinical data that are recorded within a clinical record (CR) is indissoluble: clinical data give evidences by which clinicians can choose a track among all possible paths that a pathway suggests them; the pathway gives data scattered on a network of documental artifacts a sense for afterhand interpretation and a rationale for beforehand planning.

In order to focus on this manifold tie, we undertook several interviews with the head-physician that advocated the intensive and daily use of CPs in his ward. As a result, with him we identified a number of requirements to integrate the computer-based clinical record and the digitalized counterpart of clinical pathways. Also other physicians that we interviewed advocated the CR-CP integration: they shown appreciation for a computer-based support that could be provided "at the point of care", i.e., at the time and place where care is provided, and that could help them managing multiple cases unfolding at the same time by reminding them what to consider next at each step.

The integration of clinical record and CPs is important for at least two reasons: support to decision making and support to proper documentation of care. Doctors can be supported while they read and write clinical data in becoming aware – or just be reminded — of those data that from the overall record must be considered at a certain point in the routinary management of a disease. Consequently, the theory behind a consolidated best practice can "be reminded" in the very moment it should be enacted, applied, i.e., made *current* practice. The tight mapping between sections, tables and single fields of the clinical record and expected activities encompassed by a CP in use can help doctors in consuming and producing information from and into the record properly. On the one hand, they are supported in considering all and just those relevant pieces of information that can influence their autonomous decision positively, so as to make faster and apter decisions and avoid the risk of unnecessary information overload and relevant data dispersion. On the other hand, clinicians are also supported in documenting decisions taken and care provided at the right time, in the right way and in the right records with respect to both next consultations during the hospital stay and later use of clinical data for statistical research and clerical administration: i.e., for what have been called the primary and secondary uses of clinical records, respectively [Ber99, CS06].

3 A roadmap for pathway integration with clinical work

In order to facilitate the explicitation of CP-related aspects of routinary care and the integration of CPs into the current clinical record architecture and its electronic implementation, we propose to limit the question of developing and using CPs in clinical practice within two orthogonal classes of problems. In these two classes, CPs are seen either (a) as tools for the contextual management of a current and still-open case; or (b) as tools for auditing and quality improvement over trajectories previously documented into the CR, respectively. Focusing on these two different classes of CP-based support circumscribes what computer-based functionalities can be feasibly conceived and designed. While the former vision calls for functionalities aimed at supporting direct care (i.e., the primary purpose of recording care), the latter calls for functionalities that support either primary and secondary users of clinical data for the incremental tuning of CPs as well as for the extraction of insights and indications for further clinical research from their corresponding outcomes.

With specific respect to the field studies we conducted in our reference setting, the requirements we collected about the preliminary integration of clinical data and processes shed light on a steplike roadmap where pathways are defined and applied in the respect of the peculiarities of the situated practice they spring from and they are intended to be applied to. This roadmap encompasses (a) the proper representation of CPs; (b) their integration with the CR by defining data-process interdependencies and correlations; (c) the detection, characterization and management of variances between the best intended practice fixed in the CP structure and the situation in which the CP is applied. In the following sections, we briefly outline our first findings on each of these research threads and how we aim at integrating them in a more comprehensive framework.

3.1 Proper representation of pathways

The first requirement to work with pathways is to rely on a proper representation of them. Here, we consciously leave aside the important, yet very subtle, issue whether CPs are a proper representation of the intended reality. The requirement we express about this representation is twofold. On the one hand, the most suitable notation must be able to depict them as naively and simply as clinicians and health practitioners conceive them. We call this a "front-end requirement" and formulate it as: the language by which pathways are represented must be easily comprehensible even by laymen, so that it can be used to communicate with the real users and stakeholders of any CP-centered application. In doing so, discussions about and over specific pathways can be fostered both between clinicians and between clinicians and the process analysts that work in the further design phases of the computer-based integration between CP and CR. On the other hand, this notation must be also able to be "translated" into more formal internal representations that could make the pathway computable, i.e., object of formal validation and simulation. We call that a "backend requirement" and formulate it as: the language by which pathways are represented must be capable of undergoing a process of normalization so that their representations can be formal enough to allow their computable interpretation.

With normalization, we refer to a process by which a pathway, which is conceived and envisioned by clinicians as naively as it must be, is then transformed into a more formal representation that can be used to enable process analysis and the deployment of the computer-based support for the application of pathways to single clinical cases. This normalization address problems related with ambiguities and inconsistencies and is aimed at avoiding and reducing the former ones and at detecting and correcting the latter ones. Ambiguities can be hidden within pathways that are represented with loosely defined notations, especially when they are used by different actors over time; inconsistencies can be detected in terms of either unintended or senseless behaviors, e.g., as infinite loops and medical or physiological non-sense, respectively. We do not specifically address the problem of either necessary or unintended underspecification of process descriptions. The latter issue, which is tightly related to the understanding which is the right level of description and detail for a given problem and community of users, has been convincingly treated in the case of communities of practice [BCC+03] but it could arise again in the scenario in which CPs are used to mediate communication and articulation between actors of different and distributed communities around the same clinical case.

The fact that we advocate that the representation language at the *front-end* and at the *back-end* be the same or closely related could lay itself open to the objection that in this way the compromise notation could fail at both ends: i.e., at being accepted and fully understood by the clinicians involved in the preliminary CP conception and at fulfilling more strict and formal requirements on CP computation. Nevertheless, our point is that the requirement of relying on a common notation that could be used to *mediate* and facilitate communication both between clinicians, their representatives and the analysts involved in the study at hand is the most important, especially in a scenario where CPs are the *object* of, as well as a *medium* for, the discussion between members of different communities of practitioners, with their own jargon and idiosyncrasies, on how to articulate their interventions and

shared responsibilities over the same illness trajectories.

As a first endeavor in probing the feasibility of this scenario, to represent CPs in our field studies, we are adopting the Business Process Modelling Notation (BPMN), although with a slight modification in the semantics of one of the control-flow patterns defining the elementary aspects of process control [WfM99]. BPMN provides a graphical notation for expressing business processes in a Business Process Diagram (BPD); this notation has been developed by an independent consortium of standardizing bodies and industry partners with the explicit aim to bridge for the gap between the business process design and the process implementation. For this reason, BPMN aims at providing both a comprehensible description of the process, which is based on a comprehensive review of the best ideas from previously developed notations (e.g., UML Activity Diagrams, Event-Process Chains and Activity-Decision Flowcharts) and its formal analysis and verification, which draws on the principles of formal mathematical models, such as pi Calculus and Petri Nets. While we are well aware that BPMN cannot be considered the best tool for every domain and application requirement, we observed that its *flow-charty* resemblances had a role in making it appealing for clinicians as a working tool for their own description of clinical processes. Besides the characteristic of being a suitable tool "at the front-end" with practitioners, we have also considered its agreed-upon formal semantics be sufficiently suitable to unambiguously express the main patterns that are likely to occur in a CP formalization [WvdAD⁺06] and can be expressed in BPEL constructs [Whi05]. Whether this will be enough to fulfill our formal requirements "at the back-end" on data-activities integration and variance management will be object of further investigation in the very next phases of our field study.

3.2 Integrating clinical data and activities

In order to integrate data from the clinical record with the activities encompassed by CPs, we proposed in [CSS07] an approach based on the Inputs, Outputs, Pre-conditions and Effects (IOPE for short) notation. The IOPE conceptualization dates from the very first works in computing semantics (e.g., [Hoa69]) and it has been recently adopted in the definition of modelling languages and related standards for the Semantic Web (cf. e.g., [CDM+04]). We also adopted it in a design-oriented framework, called WOAD, which we developed for the provision of awareness information in computer-augmented documental domains [CS07]. The main idea is to consider the whole CR as a rooted tree and the documents that compound it as nodes of the tree. Single fields are represented as terminal leaves of the tree (see top of Fig. 1).

In order to address the integration between CR data and CP activities in a participatory process of co-design, we propose a sort of four-step methodology: (i) for each single activity referenced by a CP, detecting all those document-based sub-activities that can be traced back to the execution and proper documenting of that clinical activity (e.g., reading a report, writing into a form, sharing data with colleagues and gain access to particular artifacts); (ii) characterizing the document-based activities in terms of relationships with the documental context, i.e., detecting *input* and *output* relationships at the proper level of

data granularity, in order to identify which documents are used or produced by an activity, respectively; (iii) distinguishing² between decisional points that can be considered akin to complex medical assessments – and hence requiring physicians' direct involvement - and points where the pathway branches off to strictly alternative paths according to specific guard conditions. A guard condition is a true/false conditional expression that is evaluated according to few and well specified clinical values: e.g., the condition hyperpyrexia is true whenever body temperature is higher than 39 degrees, false otherwise; (iv) characterizing the main clinical activities, the assessment decision points and the activity ordering in terms of preconditions and post-conditions. Both hold on specific data values, events and other contextual elements that are deemed relevant to be represented into the computational system and are expressed on clinical data either represented in the clinical record or more broadly in the Hospital Information System (HIS). Pre-conditions are conditions that trigger, or better yet, enable a pathway activity: e.g., the existence (i.e., arrival from the testing facility) of a test report triggers a new clinical assessment. *Post-condition* (or effects) of an activity are those conditions that hold upon relevant aspects of the "state of the world" occurring because of the completion of that activity. (v) assigning a criticality weight to the clinical activities, assessment decision points and their preconditions and post-conditions. Criticality indicates how important it is for doctors to follow the indications of a CP, e.g., how critical it might result to deviate from the related process schema and to have a variance occur in its application to a clinical case.

3.3 Functionalities of awareness provision on variances

One of the problems related to how formal representations of work are used to indicate due actions is that human performers need to be left free to decide wether to strictly adhere to these representation or to act autonomously from them according to the situation at hand [Suc87, Sch97]. Freedom from strict adherence to formal representations of work according to the contingent needs of the field of work is seen as an important requirement by health providers in order to avoid the pitfalls of the so called "cookbook medicine" [Hol89]. Yet, this requirement necessarily collide with some of the tenets by which these representations had been introduced in clinical settings and CPs are not exception. One of the main aims underlying the introduction of CPs regards the identification and valorization of the current "local practices" used within a single ward or hospital and their validation with respect to the evidences provided by the international medical research community, in accordance with the Evidence-Based Medicine movement [Jen03]. Pathways are hence the result of a twofold synthetic process: routinary instances of local practices are fixed into some template in a bottom-up fashion; then in a top-down fashion, this template is either corroborated by scientifically-grounded recommendations or amended with respect to regional policies, quality standards and organizational constraints. Hence, the rationale of CPs is to support physicians during their daily work in adopting and making "highly recommended" practices their own in order to reduce variance. Variance

²Notice that decisional and branching points within a CP are graphically represented as diamonds and are then different from activities that are rendered as boxes.

reduction can enable further rationalization of medical practice and guarantee compliance to established standards of quality of care.

It is then worthwhile to try to understand whenever the differences between what suggested by a CP and the current practice are *justified* (by a specific condition of the patient), *unjustified* or, even worse, *undesired*. For this specific reason, to integrate clinical data with clinical *intended* processes (as they are represented in CPs) requires the need to document variances from intended processes also in terms of data, or, at least, to trace back variances to objective data that document the interventions accomplished. To this aim, *variance records* are the specific artifacts where there are recorded "all the unexpected events which occur during patient care events which are different from those predicted in the pathway" [dL00]. Variance recording and its post-hoc analysis represent an opportunity to let the pathway become a dynamic tool that is continually refined so that clinical and organizational practices can be reviewed, updated and improved [dL00].

In the traditional approaches to variance management that are based on variance recording, variances are related to either outcomes that had not been achieved or reasons why the care had not been performed according to the care pathway [MFB+06]. For this reason, these approaches can act only afterhand the caring process and do not give any direct support to physicians during their work. We acknowledge the effectiveness of these approaches to variance management, but we also want to extend them with a more direct and interactive support that could be conveyed to physicians whenever a variation occurs during the course of their work with respect to the clinical pathway currently in use. Our point is that this can be done on the basis of the modelling effort described in Section 3.2. Once the interdependencies between CP activities and CR data are explicitly expressed in terms of IOPE relationships, practitioners can be provided with timely and apt awareness information [DB92] on 'what it's important to consider', 'what they should/shouldn't do', and 'what deviations from routine are occurring'. The former two aspects of contingent clinical work refer to what in a previous work [CSS07] we defined as criticality and pertinency, respectively. While criticality is assigned at compile-time and is a characteristic of the process at schema level, pertinency relates to how coherent it is the accomplishment of an activity with respect the current work context (expressed in terms of clinical data within the CR and HIS). In regards to the best ways to render these two dimensions in the graphical interface, we tested some solutions with the physicians and had them interact with a simple graphical representation of the CP. In these mock-up sessions, criticality was expressed in terms of intensity, i.e., of thickness of lines and borders of the CP elements. Pertinency was expressed in terms of color tones: from red to green. The first color would hint to practitioners that at least a precondition of the activity is false and that hence the activity should not be started. Conversely, a green box would hint that all the preconditions of the activity are true and that hence the activity is enabled to start. Pertinency and criticality were obviously combined in order to express how much an activity was enabled and how much its enabled/inhibited accomplishment was critical, respectively.

The focus to variance management leads us to think of a third dimension that could be combined to the former two: *variability*. It expresses "what deviations are occurring" *right* while clinical data are recorded in daily practice. Variability awareness could be conveyed to hint clinicians whether they are accomplishing an activity *when* and *how* they are ex-

pected to, according to the CP; or, conversely, to make them aware of the fact they are *diverging* from the activity proposed by the considered CP. This functionality was advocated by physicians especially to support novices, but also to improve the effectiveness of CPs as work references and to support even expert practitioners whenever some unusual or unexpected situation or exception occurs.

We designed a system that is able to detect variability at three levels: variability on start, variability on execution and variability on completion. In the first case, the system can recognize variances regarding the starting of activities which are not yet enabled, i.e., when at least one of their preconditions is false. In the second case, the system can convey awareness about variations occurring during the accomplishment of an enabled activity, in terms of different inputs or outputs, i.e., elements of the CR that are either read or written, respectively. In the third case, the system detects variations occurring in terms of the effects that the activity produces in the environment. When a variability on start occurs, the variation is detected whenever a doctor starts another activity instead of on an enabled activity (i.e. an activity whose preconditions are all true). This can be detected either because the doctor declares explicitly what activity she is going to perform next (e.g., by clicking on the related box in the graphical interface); or because the system detects that a document that is input/output of the alternative activity (and not of the suggested enabled one) is read/written. In case of variability on execution, the variation occurs whenever doctors engaged in a given activity end up by reading or writing data that are not indicated in the IO(PE) schema for the related activity. Variability on completion regards conditions other than those holding on data within the CR after activity's completion. We experimented variability conveyance in terms of winking of the CP element related with the varied activity. Also variability and criticality can be combined together: the more critical it is an activity that is either bypassed or executed unexpectedly, the more serious the related deviation is rendered in the graphical interface through the frequency of blinking. In the case the variation is critical, the physician is also asked to justify the need for variation briefly for the sake of better accountability.

To illustrate our approach, we consider a fragment of the clinical pathway that physicians at the NICU designed for the treatment of neonatal infections due to the beta hemolytic streptococcus group B, i.e., the so called GBS pathway. This CP was chosen since GBS infection is the leading cause of death in newborns and the NICU felt the need to address this problem in a more systematic and effective way. As a first example of support for clinical awareness provision, let us consider the left side of Fig. 1. The CP suggests that doctors should administer to every newborn suspected of GBS an antibiotic drug for at least two days (AT box in Fig. 1) and no longer than than unless an assessment is accomplished (BCA). This is because to give antibiotic to non-infected newborns can be dangerous for the risks of creating drug-resistant bacteria and of endangering their delicate metabolism. For this last reason, doctors must also get the informed consent from parents before prescribing this treatment to their newborn. This requirement has been modeled in terms of a critical precondition of AT activity holding on the existence of the informed consent sheet within the CR (see the P relationship and the IC node depicted in Fig. 1). Yet, sometimes physicians could have to prescribe the therapy without the related consent in order to save time in life-threatening situations. In these cases, the system reminds them that the

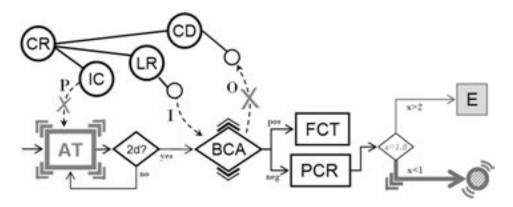


Abbildung 1: An exemplificatory excerpt from the GBS CP as the prototype would modulate its representation in terms of pertinency (color tone/pattern) and criticality (intensity, line thickness).

started activity is not enabled (rendered by the red borders for AT box in Fig. 1) and that this represents a variation from what should be accomplished; this variability on start is rendered by winking the AT box. Moreover, since the precondition of informed consent is modeled as critical in the CP, lines are rendered in bold and doctors are asked to justify their decision into the variance record.

Now, let us consider the medical assessment based of the "blood culture test" (BCA diamond in Fig. 1) that is prescribed to decide whether to accomplish a full cycle of antibiotic treatment (FCT box) or prescribe a Polymerase Chain Reaction (PCR box), i.e., a more expensive test that is usually used to evaluate GBS infection. As input, the BCA receives the report from the lab (LR document). As one of its outputs, the BCA activity is expected to produce a new entry into the clinical diary (see the O relationship), by which physicians exchange their remarks with the colleagues of the next workshifts. In our example, the newborn is on the brink of death but the blood culture test is negative. Therefore, the doctor decides to prescribe immediately the PCR test, before wasting precious time in recording her assessment into the clinical diary (CD node in figure). In doing so, the system recognizes that the BCA is over and that it did not produce any output. The system detects that a variation*on execution* occurred and, after that the PCR prescription has been committed, it reminds the physician unintrusively to comply with hospital policies and write her assessment remarks into the clinical diary, so that the rationale behind the choice related to the blood culture test assessment can be documented properly.

Let us go ahead with the example. The right side of Fig. 1 gives us the opportunity to illustrate how the awareness provision could be useful to support physicians in making decisions even in complex situations. The availability of PCR results in the clinical record establishes a branching point where two alternative paths can be chosen according to the test results. As PCR test outcome, the examining facility provides a report in which numeric values are used. The CP encompasses clinical knowledge by which values greater than two are clearly associated with a positive outcome, while values minor than one must be usually interpreted as a clear negative outcome of the test. The former case calls for a

further battery of tests (activity E in Fig. 1), which are more expensive and also potentially more dangerous for the infant but also more powerful in detecting GBS. The latter case means "exit from the GBS CP", since no clear diagnosis of GBS could have been made that far and other hypotheses must be entertained (eventually with the support of other pathways). Each of the two branches has been associated with a different criticality weight during the modeling phase. In fact, the lower branch is rendered as thicker (see Fig. 1), since the choice of exiting from the CP implies to exclude the GBS infection and this was deemed as more critical by the interviewed physicians. A more difficult case occurs when the result value is between one and two, say 1.8 (see Fig. 1). In this situation, it is not straightforward for the doctor on-duty to assert test either positive or negative, although she can give the positive option a slight preference. In this specific case, the system identifies that at least a precondition of both the activities following the PCR decisional point are false. Accordingly, by displaying both the positive and negative branches in red, the system suggests that both positive and negative branches have the same pertinency and that neither of them should be undertaken, "rebus sic stantibus". In this case, either activity is chosen, the doctor is making a variation from what suggested as *pertinent* by the CP in use (variability on start). The awareness information conveyed by the winking of the chosen activity is then combined by the system with its criticality weight. If the doctor rejects the more critical branch (i.e., the lower branch depicted in Fig. 1), that branch will flash at a high rate and the doctor will be asked to justify her choice. Conversely, if the doctor rejects the less critical branch, she is noticed of the variation (on start) by means of a low-rate flashing and explicit justification is prompted either.

4 Conclusions and Future Works

Our interest in the potentiality of clinical pathways relies on a major consideration: healthcare has always been a tough and yet very challenging application domain where to deploy non-disrupting computer-based technologies (cf. [Ber03]). Our preliminary studies on clinical pathways suggested us that in settings where CP introduction is either advocated or already a reality, software analysts and designers find a rich common ground to conceive and develop applications. In these domains, information, work processes and artifacts are integrated with respect both to the operative and coordinative requirements of all the involved users and of the secondary goals that managers and administrators must pursue for achieving the goal of a better and sustainable healthcare [CS06]. Currently, we are following the steps of our pathway oriented research: so far, we have designed the WOAD framework [CS07]; adopted a comprehensive and feasible notation to represent CPs; defined a methodology to model the CP-CR interrelations; and we have undertaken a field study on hospital practices in order to understand the role of CPs within routinary care practices. This agenda is aimed towards the implementation of a computer-based solution integrating electronic clinical records and the computable and digitized counterparts of clinical pathways. In particular, we are still testing with the NICU physicians and other intended users the interactional mock-ups that we intended as proof of concepts to understand the feasibility and usefulness of the awareness-oriented functionalities. The current

ways we employ to render criticality, pertinency, and variability awareness are under user evaluation to see if unobtrusive graphical representations that flank traditional electronic clinical records can be feasible and effective ways to facilitate the integration of clinical pathways into the physicians's daily practices. In addition, we are investigating more advanced functionalities about variance management beyond mere variance detection. These functionalities would take the history of previous cases into account to have the system provide a more active support for clinicians in knowing what colleagues did when similar variations occurred.

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