Modeling Evidence-Based Medicine Applications with Provenance Data in Pathways

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***Abstract*—Clinical Pathway Management Systems have emerged as promising methods and tools in clinical care automation as analogous to workflow management tools in business process management. Nevertheless, they are not fully appropriate yet to model and express the complex and non-deterministic clinical phenomena in which clinicians are interested. In this paper, our overall goal is to contribute to the automation of clinical pathways with the use data provenance methods and tools. In contrast to commonly developed methods for clinical pathways, we claim that the specification and execution of pathways should include not only a description of structural aspects, but also a description of what a clinician needs to know about the execution when the outcome is produced. Consequently, this requires clinicians to communicate their knowledge, ideas and requirements on data provenance at the modeling phase or execution of a clinical pathway. With this recognition of clinician participation in development, we will develop a new conceptual modeling process for clinical pathways in which clinicians can express their data provenance expectations.**

***Keywords*—provenance; workflow; ehr; evidence based medicine; pathways**

I. Introduction

The last ten years have seen a dramatic rise in the studies of process and workflow management solutions in healthcare[1][2][3]. While the research projects differ in their particular concerns, they share a common goal that takes on the challenge of bringing the advantages of automation in healthcare and related business areas[4]. There has been a steady consensus among healthcare experts that automation can significantly contribute to improve healthcare quality, at reasonable cost, by addressing clinical needs such as accurate diagnosis and treatment, ensuring timely interventions for both preventive and ambulatory care, and finally, making the relevant medical knowledge accessible at the point of care. Outside of traditional business process management solutions employed in healthcare such as insurance claims or appointment scheduling, processes associated with the clinical dimension of healthcare differ interestingly in many ways from traditional processes, in that they have a distinctive life cycle and involve in the decisions of different caregivers and other clinical evidences[5]. From text-based Clinical Practice Guidelines (CPG)[6] to computer-supported Clinical Decision Support Systems (CDSS)[7], they can be implemented in different ways with or without software applications. Clinical Pathway Management (CPM) systems have emerged as promising methods and tools in clinical care automation as analogous to workflow management tools in business process management. In contrast, the structural natures of clinical pathways are more complex than their business homologous. They are composed by activities that deal with multiple aspects of complex diagnosis or treatment procedures, each formalizing a specific advice related to a patient characteristic or medical condition. New diagnostic and therapeutic procedures, changes in operational procedures of a healthcare facility might add further complexity to the successful implementation of a clinical pathway system. The lack of clinician adherence to implemented techniques and applications is a consistent criticism of clinical pathways[8][9]. The multifaceted criticisms include, but are not limited to: lack of familiarity with tools, lack of information and awareness of complex pathways, lack of design and sub-par performance of tools [10][11][12]. Moreover, the contradictory pathways for a specific medication condition also lend to the further criticism. Clinicians, albeit reasonable, often do not rely unconditionally on the outcome of clinical pathway applications for diagnosis or treatment. As such, a more suitable and appropriate modeling and awareness methodology must be implemented to address the efficient integration of CPM applications into clinical care lifecycle. Data provenance has long been acknowledged as a successful implementation of a system in which the value of an outcome of a process rests upon the combination of the outcome itself with the track record of the process that produced it[13]. In our discussion of the clinical pathway case, we claim that a data provenance model and management engine integrated with clinical pathway framework will be the most important contribution to the future of automation in clinical healthcare processes. Thus, the primary role of clinical pathway would no longer automate (speeding up on existing tasks); rather, it would inform (redefine work using provenance as an enabler) the clinician about how the automation had been completed. With this approach, we develop a framework in which a clinician can model a clinical pathway with the associated data provenance model. This will provide the clinician with the information necessary to evaluate the outcome of pathway.

II. Clinical Pathway Management and Data Provenance

In the use of clinical pathways in clinical care, it is very common that two different automated prescription orders

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results could be totally unrelated for two patients with similar demographics, symptoms and medical stories. One of the principal reasons of these differences is that they relate to the computation of a large of number properties in patients EHR and in prescription pathways. Pharmacogenetics is the study of inherited genetic differences in drug metabolic pathways that can affect patient responses to prescribed drugs. Pharmacogenetics is one of the special fields in which pathways need to take several different parameters in order to formalize their outcome[13]. Pathways can be conditionally routed by several different pharmacogenetic tests:

- Genetics tests to identify heritable disease-related genotypes, mutations, phenotypes, or karyotypes to route clinical treatments (e.g. evaluating a patients family history for Huntingtons disease is an example of pre-symptomatic genetic testing. While there is no cure for this disease, a positive result can be used for life planning, including reproductive planning, as well as potential treatment [14])
- Pharmacokinetic genetic markers tests to determine the enzymes that might involve in drug metabolism in order to identify drug dose and drug choice (e.g. evidence indicates that genetic factors can account for an estimated 20% to 95% of drug metabolism and response [15])
- Pharmacodynamic genetic markers that are able to predict either the positive efficacy of a drug (e.g. IL28B as a marker for response to interferon- in hepatitis C) or predisposition to an adverse reaction (e.g. HLA-B*57:01 and the risk of hypersensitivity to abacavir)[13].

The use of aforementioned tests, among others, is tightly coupled with the evidence that justify their use in the pathway. In [13][5], it is argued that before the selection of a clinical intervention, four types of evidence can be evaluated: *(i)* analytic validity that might be related to similar pathway cases measuring the tests ability to predict a genotype *(ii)* clinical validity measuring the ability of the test to accurately predict a clinical phenotype *(iii)* clinical utility evaluating the appropriateness of provided information in clinical decision making and finally, *(iv)* consideration of the ethical, legal and social implications. The involvement of these evidences in the pathway can be under different forms depending on the clinical pathway structuring. The computation of evidence could be selected by user (*i.e.* clinician), defined by automation steps pre-programmed in clinical pathway, defined by automation wrt patients EHR or consolidated analyze of related populations EHRs. Furthermore, the result of test selection can be reported with possible results along with the evidences used for the computation of tests. The type of evidence discussed in pharmacogenetic tests and similar evidence exist also in different parts of clinical care such as diagnosis, procedure or routine controls. The large amount of the above health information libraries involved in clinical pathway implementation requires the integration of appropriate execution modules that can help clinicians to evaluate the pathways result along with the evidences and critical steps used in the computation. This involves the tracing and recording of the origins of data such as the computational steps and decision points that led to the current state of pathway and its intermediate states[13]. The concept of provenance, its characterization, modeling and implementation has reached a level of maturity in databases and scientific workflow research. The elements necessary to characterize the information that the clinicians need to ascertain the quality of a clinical pathway outcome exist, at least in large parts, in the data provenance frameworks: *(i)* the ancestral and evidences data products, *(ii)* the transformations that they underwent to produce that data.

REFERENCES

[1] P. Dadam, M. Reichert, and K. Kuhn, "Clinical workflows - the killer application for process-oriented information systems?" in *4th International Conference on Business Information Systems (BIS 2000*, 1997, pp. 36–59.

[2] P. Gooch and A. Roudsari, "Computerization of workflows, guidelines, and care pathways: a review of implementation challenges for process-oriented health information systems," *Journal of the American Medical Informatics Association*, pp. amiajnl–2010, 2011.

[3] Á. Rebuge and D. R. Ferreira, "Business process analysis in healthcare environments: A methodology based on process mining," *Information Systems*, vol. 37, no. 2, pp. 99–116, 2012.

[4] R. Hodach, *Provider-Led Population Health Management: Key Strategies for Healthcare in the Next Transformation*. AuthorHouse, 2014.

[5] G. J. Kuperman, A. Bobb, T. H. Payne, A. J. Avery, T. K. Gandhi, G. Burns, D. C. Classen, and D. W. Bates, "Medication-related clinical decision support in computerized provider order entry systems: a review," *Journal of the American Medical Informatics Association*, vol. 14, no. 1, pp. 29–40, 2007.

[6] J. M. Grimshaw and I. T. Russell, "Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations," *The Lancet*, vol. 342, no. 8883, pp. 1317–1322, 1993.

[7] R. B. Haynes, N. L. Wilczynski *et al.*, "Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: methods of a decision-maker-researcher partnership systematic review," *Implement Sci*, vol. 5, no. 1, p. 12, 2010.

[8] S. A. Flottorp, A. D. Oxman, J. Krause, N. R. Musila, M. Wensing, M. Godycki-Cwirko, R. Baker, and M. P. Eccles, "A checklist for identifying determinants of practice: a systematic review and synthesis of frameworks and taxonomies of factors that prevent or enable improvements in healthcare professional practice," *Implement Sci*, vol. 8, no. 1, p. 35, 2013.

[9] D. E. Casey, "Why dont physicians (and patients) consistently follow clinical practice guidelines?: Comment on worsening trends in the management and treatment of back pain," *JAMA internal medicine*, vol. 173, no. 17, pp. 1581–1583, 2013.

[10] M. D. Cabana, C. S. Rand, N. R. Powe, A. W. Wu, M. H. Wilson, P.-A. C. Abboud, and H. R. Rubin, "Why don't physicians follow clinical practice guidelines?: A framework for improvement," *Jama*, vol. 282, no. 15, pp. 1458–1465, 1999.

[11] R. Grol, "Improving the quality of medical care: building bridges among professional pride, payer profit, and patient satisfaction," *Jama*, vol. 286, no. 20, pp. 2578–2585, 2001.

[12] J. Grimshaw, M. Eccles, R. Thomas, G. MacLennan, C. Ramsay, C. Fraser, and L. Vale, "Toward evidence-based quality improvement," *Journal of general internal medicine*, vol. 21, no. S2, pp. S14–S20, 2006.

[13] P. Buneman, S. Khanna, and T. Wang-Chiew, "Why and where: A characterization of data provenance," in *Database TheoryICDT 2001*. Springer, 2001, pp. 316–330.

[14] E. McPherson, "Genetic diagnosis and testing in clinical practice," *Clinical medicine & research*, vol. 4, no. 2, pp. 123–129, 2006.

[15] K. R. Crews, J. K. Hicks, C.-H. Pui, M. V. Relling, and W. E. Evans, "Pharmacogenomics and individualized medicine: translating science into practice," *Clinical Pharmacology & Therapeutics*, vol. 92, no. 4, pp. 467–475, 2012.