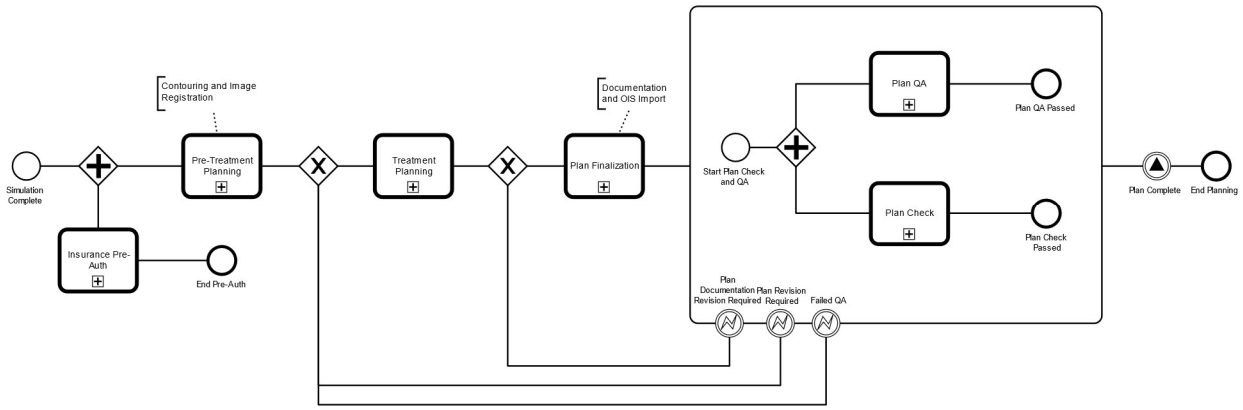

The Need For Shareable Clinical Pathways

By Quantek Systems Founder Gabe Colburn M.S., DABR

Introduction

Across the world, and particularly in America, healthcare cost and complexity has increased dramatically. This creates an unsustainable burden on both health care providers and patients. How do we decrease cost, manage or reduce complexity, and simultaneously improve quality and patient safety? Unfortunately, there are no simple answers to these multifaceted issues. It will take many individuals, organizations, companies, and governments to roll up their sleeves and work hard to solve the problems collaboratively. There is one aspect of healthcare in particular that we at Quantek Systems are passionate about and strive to improve: the implementation of shareable clinical pathways in healthcare. This is why we built the RO Dynamics platform. In this paper we will look at some of the challenges facing clinicians and how shareable clinical pathways based on existing standards can improve patient care. Furthermore, we will introduce the BPM+ Health community, which we encourage individuals, clinicians, vendors, professional organizations, providers, and government agencies to get involved with.

Challenges in Health Information Technology and Workflows

Throughout the patient care process and across all specialties, information needs to be obtained and communicated between patients, diagnostic laboratories, doctors, and electronic health information systems to provide high quality, safe, diagnosis and treatment. While information technology has provided some automation and communication improvements, it has created its own complications as there are a range of software options to choose from, in some cases resulting in high vendor lock-in and increased cost. One of the key challenges is to develop software that enables care teams to focus on treating patients with best practice guidelines and minimal clicks. Additionally, the software needs to provide interoperability of core information between other systems a provider may use, reduce duplication of information, increase efficiency, and provide the key information that is needed from various data sources.

We will always have a need for multiple software solutions from different vendors in healthcare. No single piece of software will ever meet all of the needs of clinicians. If we

must live in a multi-software and vendor environment, how do we prevent becoming stuck with poorly connected data silos? The answer lies in wide-spread adoption of data exchange specifications such as Fast Healthcare Interoperability Resources (FHIR) (FHIR Overview, 2020) from Health Level 7 (HL7), and Digital Imaging and Communications in Medicine (DICOM) (DICOM, 2020). While DICOM has been around much longer and seen wide adoption for medical imaging, FHIR is a newer specification to supersede older HL7 standards for exchanging patient health information that largely predate the modern web. FHIR was designed based on years of learning from experiences with implementing older HL7 standards and is based on emerging recommended industry approaches. While FHIR solves a significant part of the data exchange issues to reduce data silos, there are other issues that are not intended to be addressed by the specification. How do we prevent clunky workflows from emerging between multiple software systems that prevent clinicians from efficiently implementing recommended best practice guidelines for their specialty? How do updated best practice guidelines get adopted more rapidly by providers with existing software once they are released? Part of the solution is vendor-neutral shareable clinical pathways.

What are Shareable Clinical Pathways?

Clinical pathways are often referred to as Care Paths, Clinical Workflows, Multidisciplinary Pathways of Care, and other terms. In general, a clinical pathway consists of 1) a structured multidisciplinary plan of care 2) a channel to support implementation of guidelines, protocols, or evidence 3) detailed steps along a timeframe in a course of treatment or care in a plan, and 4) standardized care for a specific population (OMG Healthcare Domain Taskforce, 2020), (Kuntz, 2019). While clinical pathways may be documented in unstructured formats such as text documents and PDFs, the full extent of their value can only be achieved if they contain a structured aspect enabling software to extract and act on key information. They should also be executable in health information technology systems to combine orchestration and choreography of clinical workflows. One might ask if this is even feasible given the current landscape of software in healthcare, but we at Quantek Systems believe it can be achieved through combining existing solutions from the business world and healthcare. Furthermore there is an existing community and standards body working toward this goal: BPM+ Health.

BPM+ Health

Perhaps the best description of the BPM+ Health community is directly from their website: “BPM+ Health was launched as a community of practice in September 2019 by the Object Management Group® (OMG®), an IT standards development organization. The objective of the community is to develop and pilot standards-based healthcare automation techniques, specifically the application of Business Process Management (BPM) and related standards to clinical care pathways and workflows. By applying IT standards to healthcare, practitioners are able to leverage and disseminate evidence-based best practices at the point-of-care to save time, reduce error, and produce better outcomes” (BPM+ Health FAQ, 2020). This community consists

of software/IT engineers, doctors, professional organizations, clinical societies, vendors, business process management experts, and healthcare providers working together to apply existing standards from both the business and healthcare worlds to create shareable, executable clinical pathways in healthcare.

How can Shareable Clinical Pathways be Implemented?

The BPM+ Health community's goal is to produce standardized style and implementation guidance, as well as reference implementations and tooling for shareable clinical pathways. One of the key references is the Field Guide to Shareable Clinical Pathways Version 2.0 (OMG Healthcare Domain Taskforce, 2020), which applies proven standards for business process modeling and decision modeling to healthcare workflow and decision making.

A primary set of existing standards are combined to make this possible: Business Process Model and Notation (BPMN), Decision Model and Notation (DMN), and Case Management Model and Notation (CMMN). Supplemental health care standards may be integrated as well, such as Clinical Quality Language (CQL) and FHIR which are both standards from HL7. The combination of these standards enables implementation of shareable clinical pathways. Next we shall provide an overview of these standards in more detail.

BPMN

BPMN is well known and adopted in the business world, but those in the healthcare world are typically not familiar with it. The latest major version (2.0) was released in 2011. One of the challenges in business software is creating transparent, automated workflows that can be customized while software is running in production, without having to make changes to software code that few people can see or understand. To solve this, the BPMN standard defines standardized symbols and connections to create visual diagrams that look like flow charts to describe business processes. They have well defined meanings both to people that read and create them, as well as computer software that can execute them. The goal is to be vendor-neutral and simple, yet allow expressive, precise modeling when needed. They should also enable process automation by software systems.

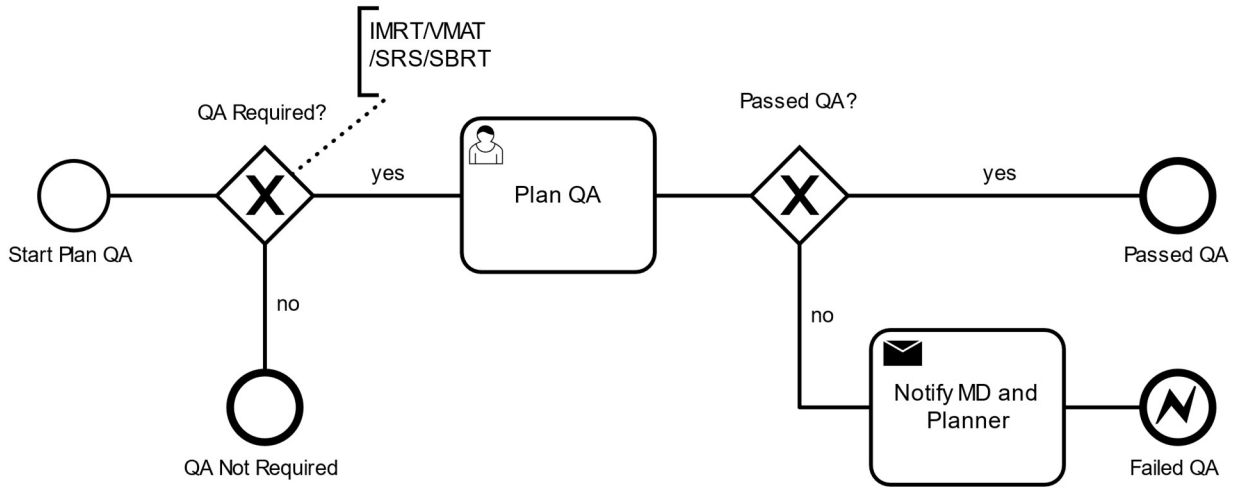

Figure 1 Plan Quality Assurance Workflow

As an example, we will reference Figure 1 Plan Quality Assurance Workflow. In this example a start event depicted by a circle denotes the start of a Plan QA process in radiation oncology. In BPMN the term "process" is used, but in healthcare the term "workflow" may be more commonly understood. At the start of the process, we must determine if a Quality Assurance (QA) task must be performed for the radiation treatment plan, for example using diode detectors. The workflow branches using an exclusive (XOR) gateway indicated by a diamond shape, depicting the possible flows. In this example, QA is required if the radiation treatment plan technique is IMRT, VMAT, SRS, or SBRT. If the plan is one of these techniques, a user task is created to perform Plan QA, which is depicted as a rectangle with the icon of a person. The process will be stopped if QA is not required. When the plan is one of the techniques requiring QA, the user completes the Plan QA task and selects if it passed or failed. It is possible to make this automated if the QA measurement result is accessible by software, for example in a file or database. In this case we just use a user task to decide the result. Once the result is determined, the next XOR gateway directs the flow based on if it passed or failed. If it passed, we end the process successfully with a standard end event symbol, which is a circle with a bolder outline. If it failed, an email is sent to notify the medical doctor (MD) and the treatment planner that the plan failed QA. This is accomplished using a BPMN send task, denoted by the rectangle with an envelope symbol. Finally, the process ends with an end error event, which signifies a business error has occurred. In the healthcare setting we can just as easily take this as an important healthcare workflow event that needs to be reacted to. In this case, a separate process could listen for the Failed QA event, and redirect the workflow for the plan to re-do the treatment plan and re-run the quality assurance process. A full overview of BPMN is beyond the scope of this paper, but the example should provide an idea of what BPMN diagrams look like, how they can be understood by people, and how they can be automated with software.

DMN

DMN is a relatively new standard compared to BPMN with the first 1.0 release occurring in September 2015. The latest release is 1.3 from March 2020. It was created from the expertise of the authors in the decision modeling space to create a single standard notation for decisions that is easily understandable by business users, business analysts, technical developers, as well as software. Additionally, DMN models are intended to be interchangeable across organizations via standard XML files. While originally developed from the business world, there is nothing inherent in the standard that restricts it to business use cases. It can be applied just as well to healthcare. To get a better understanding of DMN, let's look at the example in Figure 2 Patient Cardiac Implanted Electronic Device Risk Level Decision Requirement Diagram. The goal is to document and implement the decision logic for the risk level of a patient with a cardiac implanted electronic device undergoing radiation therapy. The risk is if the device could malfunction due to interactions from the radiation such as ionization. The elements required to make the risk level decision are encapsulated in a decision requirement diagram (DRG). The final decision we intend to make is the risk level, which is depicted in the top rectangle "What is the Patient CIED Risk Level?". The logic for the decision is embedded in a decision table consisting of rules to

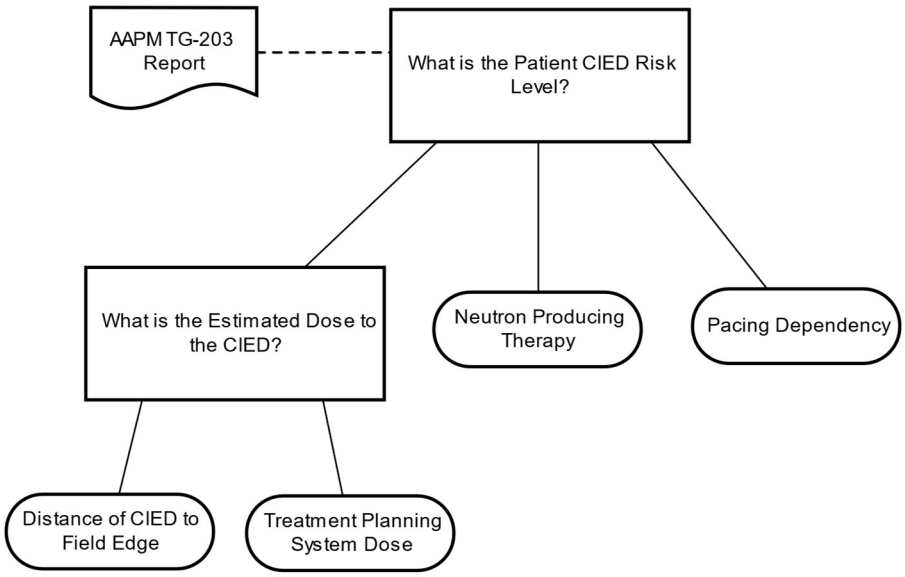

Figure 2 Patient Cardiac Implanted Electronic Device Risk Level Decision Requirement Diagram

determine the output decision from inputs. The AAPM TG-203 report icon that is depicted is called a knowledge source in DMN, and defines the authority, domain experts, or source documents which the decision is derived from. In this case, it is a report from the American Association of Physicists in Medicine task group #203 which provides guidance on the management of radiotherapy patients with implanted cardiac pacemakers and defibrillators. In order to determine the risk level, input information is required, depicted using rounded rectangles. In order to determine the risk level, one needs to know if the radiation is neutron producing, if the patient is pacing dependent, and the estimated dose to the device. To determine the dose to the device, another decision is required, which evaluates whether the treatment planning dose is likely a reliable estimate of the actual dose to the device, or if a measurement is required. This is determined based on the distance of the device to the field edge. This information is used to determine the estimated dose, either from the treatment planning system or through measurement, and ultimately used to determine the patient risk level. Once the risk level is determined (low, medium, or high), specific recommendations are made from the task group report to manage treatment of the patient and reduce risks of adverse effects. One of the benefits of DMN is to enable easy understanding of the decision-making process and what input information and knowledge sources are required. Furthermore, these are potentially executable by software as decision services. Required data may either be entered by a user, or automatically queried from various data sources. Further details of DMN such as decision tables and friendly enough expression language are beyond the scope of this paper, but this example should serve to give an understanding of the purpose and strength of DMN.

It is worth noting that while the DMN standard was created after BPMN, it is often used in conjunction with BPMN, being commonly implemented in a BPMN process using a business rule task.

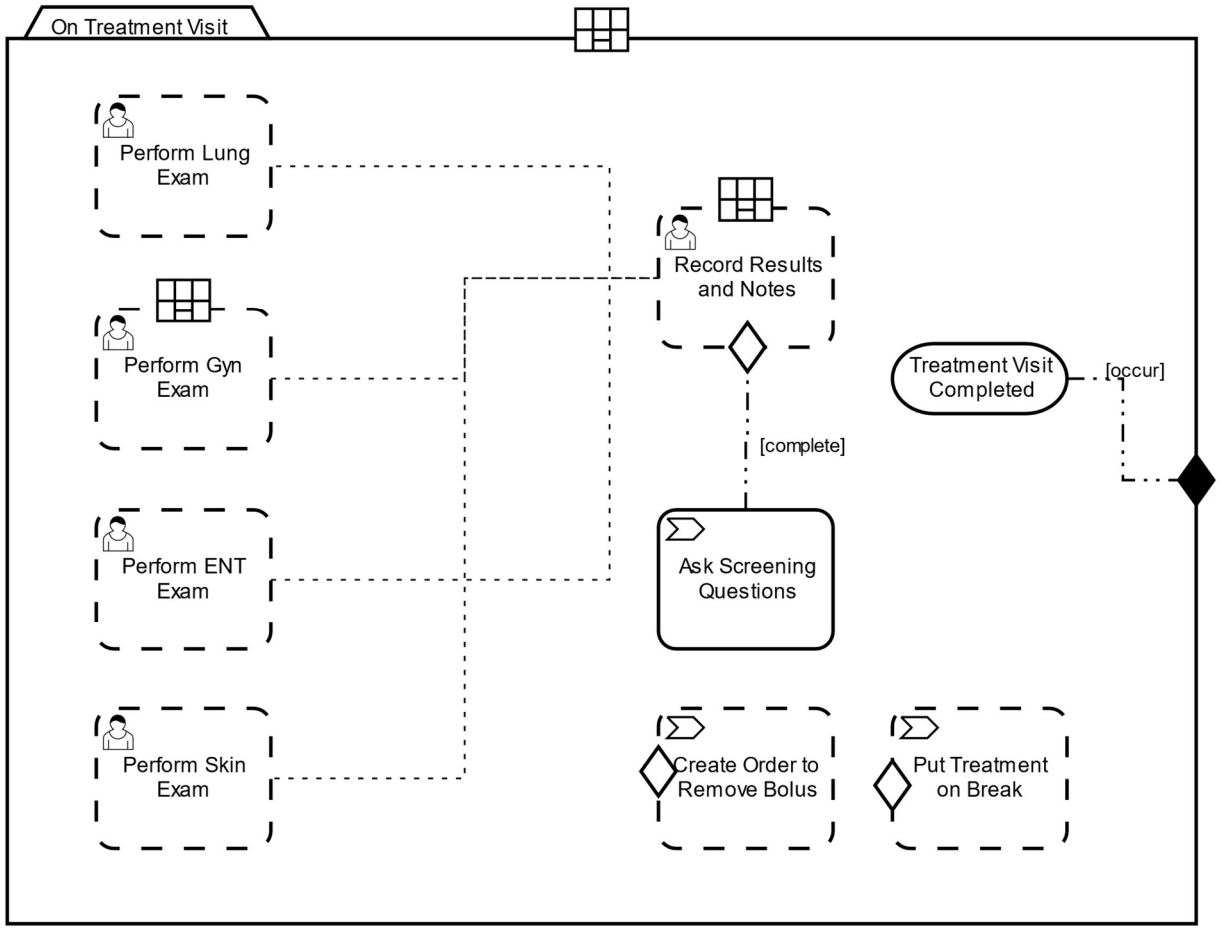

Figure 3 On Treatment Visit Case Model

CMMN

In many healthcare situations a workflow is well defined with a sequence of activities. In these cases, BPMN is the ideal modeling choice. In other cases, it is not known exactly which activities will need to be performed in advance for a patient and cannot be guided by a more rigid workflow. In these instances case management model and notation (CMMN) may be more appropriate as it is designed to support ad hoc workflows. CMMN is a relatively newer standard than BPMN and may be useful for many situations in healthcare that require more ad-hoc workflows. As an example in Figure 3 On Treatment Visit Case Model, a radiation oncologist is performing a regular on treatment visit. Depending on the type and location of the cancer(s), the MD may need to perform various types of optional examinations and record the results and notes. For various reasons they may decided to remove bolus currently placed on the patient's skin if applicable or put the treatment on break. In these cases, they start a process to ensure that the appropriate care team executes the appropriate tasks. While the details of all that can be done with CMMN is beyond the scope of this paper, one can see that it supports the dynamic nature of some aspects of healthcare that require a knowledgeable person to determine what does and does not need to be done in a patient's care. Rather than hardcoding software to provide limited

options, CMMN models may be created and shared to support different cases without having to re-write the software.

FHIR

BPMN, DMN, and CMMN provide a whole new paradigm for implementing shareable clinical pathways in healthcare. These standards alone however are not sufficient to enable efficient workflows since information needs to be integrated into the workflows from health information systems to provide automation and efficiency.

The new FHIR standard is an important enabler of this in healthcare. It defines a standard set of clinical, diagnostic, medication, workflow, and financial resources that are well defined, enabling any system implementing this standard to exchange information. Already the top electronic health record vendors have FHIR services available, with adoption rapidly increasing. For more information visit hl7.org/fhir/index.html.

Vendor Lock-In

One of the challenges within healthcare is the barriers to switching or adding software vendors. The reality is that software often dictates clinical workflow, rather than being customized to reflect the ideal clinical workflow. Where there is customization it is typically proprietary due to lack of standards, increasing the barrier to switch vendors should the need arise. The result is high risk and cost to switching vendors both on the implementation side, as well as the clinical workflow side. It is not easy for clinicians to be forced to adapt to brand new workflows that are dictated by the software. Shareable clinical pathways present a unique way to reduce the implementation costs to interchange and integrate health information systems, while largely preserving clinical workflows between vendors and enabling implementation of best practice guidelines.

Conclusion

With the large adoption of electronic health records, there is an opportunity for higher quality care than in the days of paper charts. However, the full value has yet to be realized due to the costs and challenges of implementing interoperable health information systems. Adoption of business and healthcare standards such as BPMN, DMN, CMMN, and FHIR enable the creation of shareable clinical pathways, to support clinicians in efficiently implementing the latest best-practice guidelines, increasing continuity of care, and reducing healthcare costs.

References

BPM+ Health FAQ. (2020, 30 6). Retrieved from BPM-Plus: https://www.bpm-plus.org/faq.htm

DICOM. (2020, 6 30). Retrieved from https://www.dicomstandard.org/

FHIR Overview. (2020, 30 6). Retrieved from HL7 FHIR: https://www.hl7.org/fhir/overview.html

Kuntz, G. (2019). What Do We Mean When We Talk About "Clinical Pathways"? *J Clin Pathways*, 5(1):36-39. doi:10.25270/jcp.2019.02.00060.

OMG Healthcare Domain Taskforce. (2020, 06 30). *Field Guide to Shareable Clinical Pathways Version 2.0*. Retrieved from BPM+Health: https://www.bpm-plus.org/healthcare-and-bpmn.htm