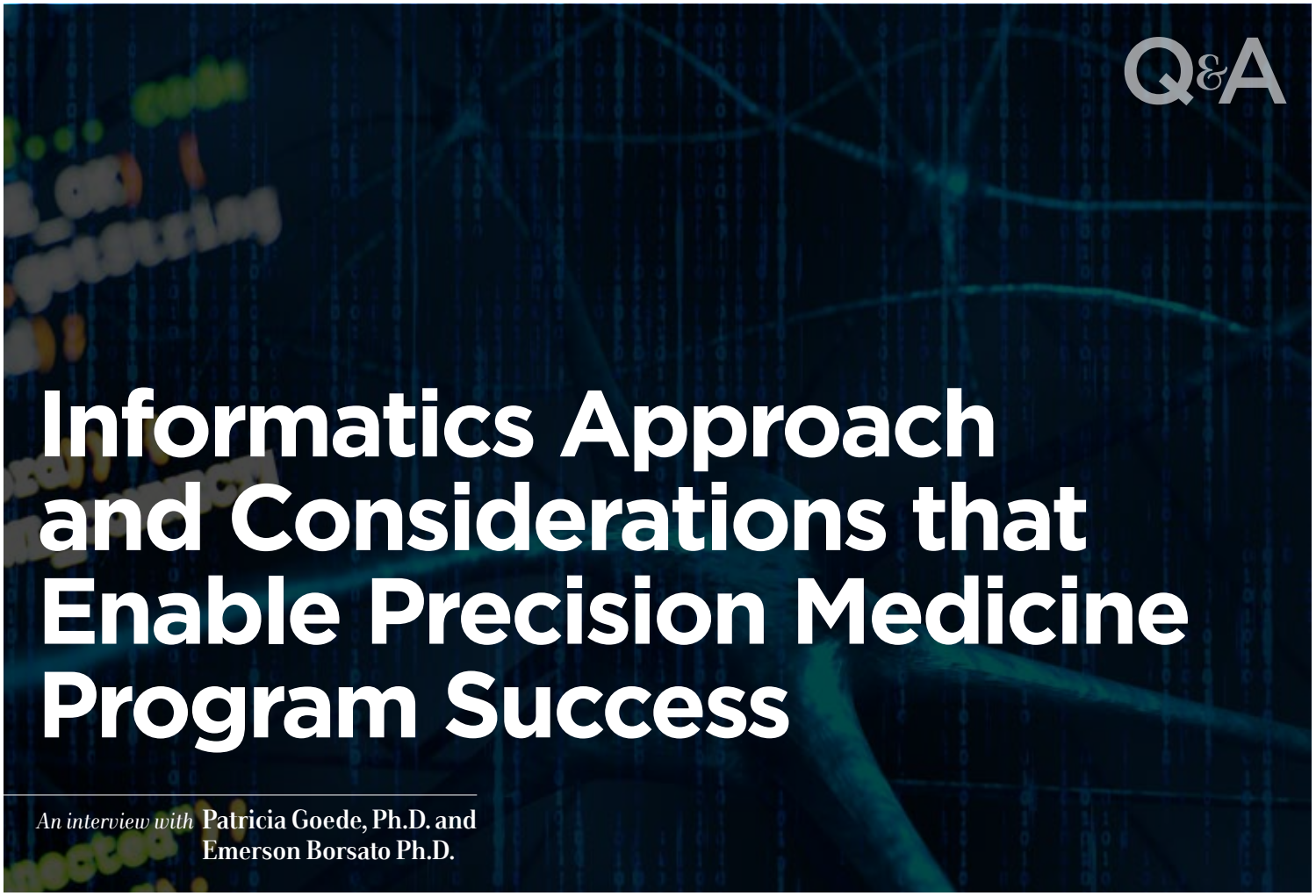

Q&A

Informatics Approach and Considerations that Enable Precision Medicine Program Success

An interview with Patricia Goede, Ph.D. and Emerson Borsato Ph.D.

Precision medicine program success is dependent on healthcare providers' timely access to the patient data that is used to guide clinical decisions so that patients can receive the best possible treatments, based on their unique diagnostic biomarkers, lifestyle and personal preferences. For a variety of reasons, the majority of today's health systems have not yet adopted health informatics technologies specifically designed to meet the complex challenges presented by precision medicine programs. In conjunction with the Journal of Precision Medicine, XIFIN, Inc. conducted a research study to better understand the value, adoption, challenges, and use of precision medicine informatics solutions.

The Co-founder and President of The Journal of Precision Medicine, Nigel Russell, had the pleasure of moderating a jointly hosted June 2019 webinar entitled *Precision Medicine Informatics: Key Research Findings and Emerging Best Practices*. During the webinar, Sandra Greefkes, AVP of Product Marketing at XIFIN revealed the top-level research findings and a live Question and Answer (Q & A) session was conducted with Patricia Goede, Ph.D., VP of Clinical Informatics, XIFIN Inc., and Emerson Borsato Ph.D., Principal Informaticist and Knowledge Engineer, XIFIN Inc.

The feedback from webinar attendees was very positive, and we wanted to share several excerpts from the live Q&A portion of the webinar.

Q Trish and Emerson, could you describe for us how you define an "informatics approach" as well as "knowledge management" and explain why these types of approaches are necessary for precision medicine?

A Informatics is all about using information technology (IT) to build bridges that connect

data, systems, and people, so that data and information are exchangeable between groups, is accessible to individuals in a timely fashion and fits into their workflow. The data becomes more meaningful because it not only fulfills the purpose of its original intent such as reporting a test result, but the accumulation of different and related data points allows analysts to discover new relationships and gather new information within a much broader data system. This information can be used for multiple purposes, including gaining new knowledge and understanding, and for guiding decision making.

In precision medicine, the volume and complexity of data has grown exponentially, making it critical that healthcare providers have ready access not only to the data but also to the healthcare experts that can explain what the data means in the context of treatment planning for any particular patient. In other words, a system that can integrate multi-modal data and foster multidisciplinary team collaboration is essential for providing the very best patient care.

Q To what extent do current healthcare IT systems, such as Electronic Health Record (EHRs) and Electronic Medical Record (EMRs), fulfill the informatics and knowledge management needs of precision medicine programs?

A Almost 60% of participants in our Precision Medicine Informatics research reported that their current EMR or EHR did not, or only partially met their precision medicine needs. This high figure was not completely unexpected since these systems were not designed to meet the increasingly complex needs of precision medicine programs. A major hurdle to EHR/EMR systems is their lack of connectedness or interoperability within any given healthcare environment. Particularly challenging is when data is generated outside of the health information technology (HIT) system, a very common scenario in precision medicine. An example is genomic test results and other biomarker data that is often provided by a reference laboratory that is outside of the health systems IT environment. Another concern is that these systems are often not capable of absorbing and storing new kinds of data including complex imaging files because they were not designed or implemented to support the ever-changing data mass or data structure that is being generated in the precision medicine field today. EMRs and EHRs serve the purpose of delivering the functionality that they were designed for, but they have not yet caught up with the increasingly complex functionality requirements needed for precision medicine programs including integrating multiple disparate data systems so that all of the data is readily accessible in one place.

"Knowledge management, informatics, and data analytics all go hand in hand"

Knowledge management, informatics, and data analytics all go hand in hand. Knowledge management, or knowledge engineering, involves developing the integrated systems, infrastructures, and the processes for maximizing the appropriate use and storage of data, information, and knowledge across the organization. For precision medicine, which relies on data-driven treatment planning, it is important to develop not only the types of tools that can deliver actionable data to clinicians but also a tool that can document the entire patient journey. These types of systems allow the healthcare team to use data to "see" what is going on with their patients, are searchable, and allow the healthcare team to learn from previously treated patients that have similar characteristics. This is where the analytics come into play. Analytics enables us to query and learn from retrospective data so that we can make better-informed decisions in the future. This is the key to fulfilling the promise of precision medicine since even with targeted therapies, some patients may not respond as expected or may experience unintended side effects. Collecting, storing, and analyzing patient treatment and outcomes data over time has the potential to explain these unexpected and unintended results so that even more precise treatments can be developed.

Q What is your recommended approach for communicating across systems, and how does that approach overcome the obstacles to interoperability?

A The world is gravitating towards the adoption of Fast Healthcare Interoperability Resources (FHIR) interfaces or FHIR services. That's a step in the right direction. However, just using FHIR doesn't solve the whole problem since there is always going to be a heavy lift in terms of using a common semantic ontology and data mapping that needs to get resolved for systems integration. While it is still challenging to do this, it is much easier today than it was 20 years ago because now we have better tools to overcome these challenges.

Adoption of standard communication protocols will be critical to overcoming the longstanding interoperability obstacles. Historically, HIT systems are not friendly to each other, and they are not open to data exchange by default. A concerted effort is necessary to break down barriers to achieve interoperability. This is so important that the Office of the National Coordinator of Health has developed a ten-year roadmap defining the learning health system and how to achieve interoperability. It is also a requirement of the 21st Century Cures Act, and the Federal Health Information Technology Standards state that HIT vendors must become more interoperable. Standardizing on something like the FHIR interfacing over a Representational State Transfer (REST) web services approach in architecture will help make interoperability a reality.

Q Based on the research results, participants indicated that they could not easily access diagnostic and biomarker data from their EHR in a simple-to-use interface. Why is that important, and what is the best approach for achieving this?

A It's important because it's about patient care. Patient care is facilitated through quality data, which in turn is facilitated by timely access to data. In cancer care, the users of this data are the oncologists. They're the ones who, when putting together a treatment plan, need to get real-time access to all sorts of information. Their EHRs don't store the information in a readily accessible way or at all, so they routinely have to go searching for it. It is critically important to bring various bits and pieces of discreet patient data together into a synoptic timeline so that it is available and presentable to the oncologist. That way, when they're with their patients, they're not wasting time hunting through the EHR trying to find information. Ready access to the relevant information provides more time for the oncologist to spend interacting with his or her patient. It also becomes more efficient when it comes time for them to do their charting.

The best approach to achieving access to

biomarker data from a simple-to-use interface is to build the system using a knowledge management approach with standardization in mind for pulling the data in. The first problem to solve is the lack of interoperability. The second problem to solve is the workflow. The workflow designed into an EHR doesn't necessarily represent the true workflow, particularly in precision medicine where many subspecialty physicians and providers interact with the data and each other. However, EHR vendors are starting to realize that there's a lack of workflow alignment and are starting to partner with companies that can seamlessly integrate with their systems to provide the tools and functionality that their customers are starting to demand. It's really important that the integration is seamless to avoid imposing an additional burden on the end-users. Already, significant physician and other healthcare provider burnout has been attributed to the increased documentation demands imposed upon healthcare providers because of EHRs. Thus, the logical solution is to integrate EHR with external applications, by leveraging HL7 SMART on FHIR, to facilitate data availability from different sources and enable the decision making process. As an example, the generation of a synoptic report containing pertinent information for decision making in precision medicine is viable. Thus, HL7 SMART on FHIR apps can bridge the gap to provide very granular and detailed information that EHR alone does not support.

Q What do you perceive are the biggest gaps in the current precision medicine workflow, and what is the best approach to addressing those?

A The biggest gap for clinical teams is the lack of access to the data. We know that EHRs are not known for being able to consume biomarker results in a structured way. Instead, biomarker results are predominantly generated from an external entity that's not part of the network of a hospital system. These results are often received as a PDF report that contains unstructured data. To transform this data into a structured format that is readily accessible and searchable in the future is often a time consuming, labor-intensive manual process. Leveraging a system that can ingest, compute, store, and display biomarker data in a meaningful, accessible way, would be a huge benefit.

Another gap in current HIT systems that would provide benefit to users and ultimately to the patients is the lack of collaboration tools such as a virtual molecular tumor board. Precision medicine is all about collaboration around genomic and other biomarker results and being able to understand how to use test results. The best approach is to, first, find ways to get the information into the EHR and second, to provide a framework for collaboration with peers and other subject matter experts that can help guide therapy decisions.

Q When data from various health information systems is brought together in a meaningful way into a single system, what else can the data be used for?

A The data can be used to build knowledge. Collecting all this information into a carefully thought out architecture requires structured and searchable data that can be used for many different purposes, including disease insights, patient cohort studies, and outcomes research. Financial data is another data point that can be leveraged to understand the total cost of care for every patient, paving the way for value-based care. Real-world evidence development, clinical trials, treatment safety, and effectiveness studies, and business intelligence are all mechanisms for building knowledge. Machine learning and artificial intelligence (AI) are just two of the many tools that can be applied to this type of data. What many people in the precision medicine space have started to realize is that high-quality data is key to maximizing the benefits of AI. So, systems that don't organize relevant data in a structured way are limited in their ability to leverage AI tools and machine learning. There are almost endless future possibilities of bringing all this data together to advance human health and to truly achieve value-based care.

Q Final question, and a nice segue since you brought up AI. What are the foreseeable roles of AI and blockchain in handling big data sets for precision medicine development?

A AI can be an overloaded term. If you don't have good quality, structured data with rules, and you can't apply or leverage those rules, then you don't have the ability to plug in machine learning. Machine learning actually feeds AI, starting with good clean data and working forward. First, tackle the problems of interoperability; get good high-quality data in your system, and make sure it is available so that the care teams can collaborate. Next, look at different trends, different outcomes, and patient populations, from the discreet data, then start to apply machine learning and AI techniques.

With precision medicine today and the precision medicine informatics approach, especially with bioinformatics, the amount of data that we have now is much larger than what we had before. Thus, with structured data sets, AI techniques, and classification methods, clusters of data can be identified. That's the key for precision medicine, and that's where AI, the patients, and the providers would benefit from this type of quality data.

Blockchain is another very important emerging technology. Blockchain is a distributed ledger that is designed to manage transactions, not necessarily to handle distributed data. When it comes to big data—something that is routinely generated in precision medicine—blockchain currently may not be sufficient to address the handling of complex heterogeneous datasets. Blockchain could possibly be used by patients to give permission to a treating physician's office to view parts of their records. Probably the best application for Blockchain today is to manage data access. IoPM

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Patricia Goede has more than 20 years' experience developing biomedical imaging informatics solutions to facilitate multi-modality and multi-specialty image-based exchange, collaboration and management. Dr. Goede was a research professor at the University of Utah, founder and director of the Electronic Medical Education Resource Group (EMERG) before founding VisualShare, which was acquired by XIFIN in 2015. She holds a an MS in Computational Visualization and a PhD in Biomedical Imaging Informatics.

Emerson Borsato has over 20 years' experience in healthcare IT with a focus on Medical Knowledge Engineering. Prior to joining XIFIN, Dr. Borsato was the technical lead and architect for knowledge integration at Intermountain Health while maintaining the role of integration architect for Cerner Millennium Solutions. He earned his PhD in Medical Informatics from the Federal University of Parana, Brazil.

Further information

The Journal of Precision Medicine and *XIFIN* are further studying the approaches of precision medicine informatics to uncover which technology investments, data integration, and best practices lead to the greatest value and outcomes. Share your experience with us at **www.visualstrata.com/pmisurvey**

For our readers that are interested in getting a copy of the research results or viewing the entire on-demand webinar, both are available at **www.visualstrata.com**