VOLUME 28, NUMBER 2 / SPRING 2014 *A HIMSS Publication*

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JOURNAL OF HEALTHCARE INFORMATION MANAGEMENT

FOCUS

Big Data and Population Health Management

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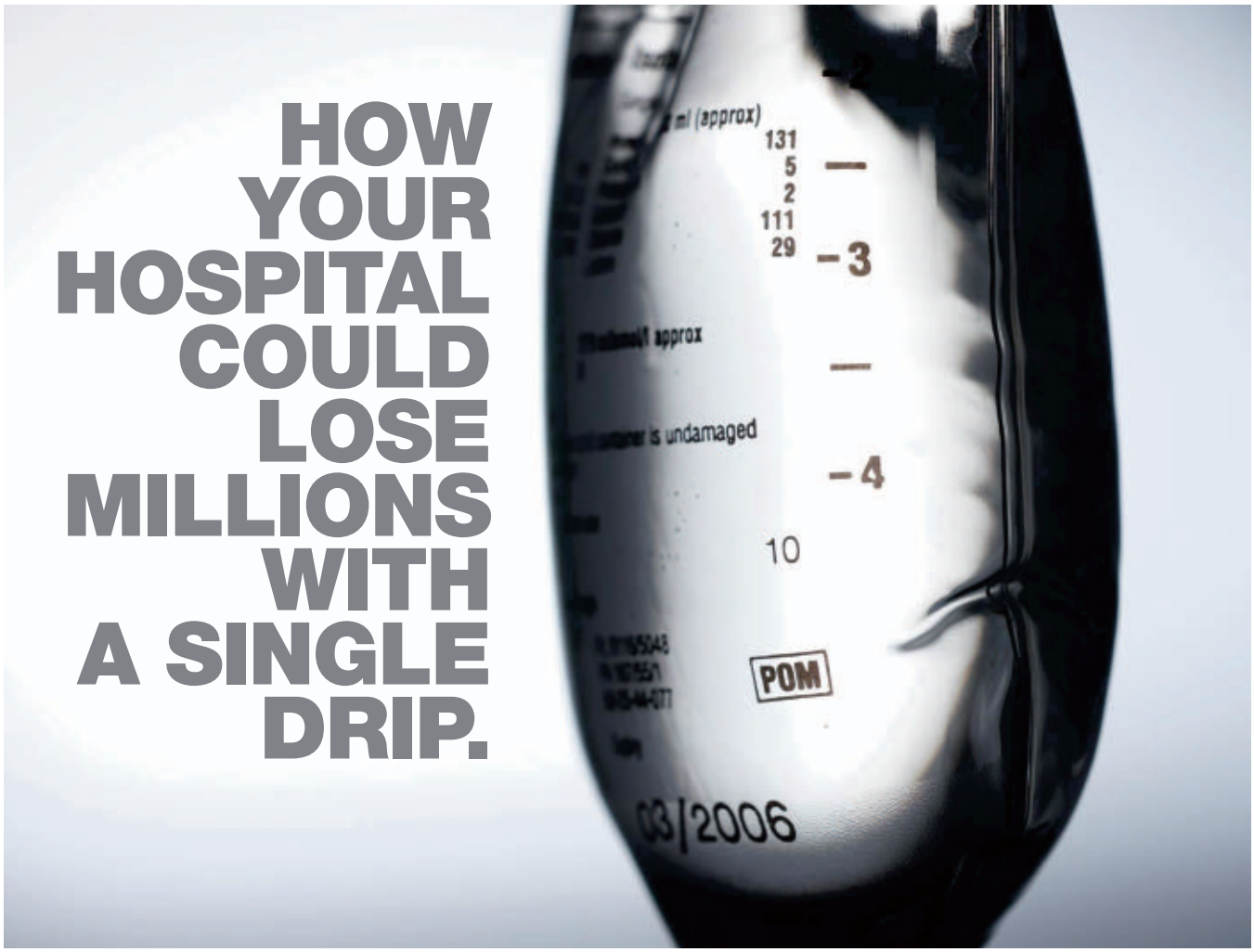

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VOLUME 28, NUMBER 2 / SPRING 2014 A HIMSS Publication

JHIM

JOURNAL OF HEALTHCARE INFORMATION MANAGEMENT

COMMENTARY

FOCUS: BIG DATA AND POPULATION HEALTH MANAGEMENT

FEATURES

EDITOR'S REPORT

By Mary Alice Annecharico, MS, RN, FHIMSS

'Big Data' and Population Health Management

Data-Driven Decisions Will Shift Organizational Culture

THE THEME OF THE Spring 2014 edition of *JHIM* is Big Data and Population Health Management. We can be encouraged from the recent HIMSS14, and the emerging interest in data analytics and the early wins seen by a growing number of healthcare organizations. Advances made in structuring the all-important data governance model encourages us feel as if the industry is beginning to make progress toward value based healthcare reform. The ability to make data driven decisions will shift organizational culture. Case studies of successfully managing at-risk populations are emerging through the uses of aggregated data and predictive analytics to model improved outcomes and to control costs.

A major objective of HITECH is to use data meaningfully to improve outcomes of care. The patient care can represent an individual patient or a cohort of patients across a system or across diverse populations. Healthcare organizations have long known that the driver to invest in and utilize comprehensive electronic health records is to create an integrated source of truth about a patient population. Yet, as the EHR vendor tools continue to evolve, organizations are compelled to invest in or create clinical and business analytics services to enhance and improve their data management and analytics capabilities.

The healthcare industry is seeing the practical application of using data analytically in the tenets of the Affordable Care Act. It forces organizations to broaden the view of care to include quality over quantity for at-risk populations. The shift away from fee-for-service and acute-care settings toward ambulatory management drives primary care into more closely aligned relationships with patients and care teams. Population health management compels organizations to appreciate the provider to provider, patient to provider, family to provider, as well the provider to health plan relationships. By being able to correlate the intersections of how data relates to other internal and external sources of data, the clinical decision making capabilities, plans of care, and the cost efficiencies will become more structured and predictive and less accidental in patient care settings and in clinical research.

As more care moves away from the acute care setting into the community and the region, a greater emphasis is being placed on registries and interoperability standards to aggregate, normalize, summarize, and transport data to broader and broader relevant audiences outside the traditional care settings. At HIMSS14, Karen DeSalvo, National Coordinator for Health Information Technology, describes interoperability as "the elephant in the room". [Key Takeaways from HIMSS14, Santosh Mohan, March 13, 2014]. Over the next 10 years, "data needs to move freely and bi-directionally, and ONC should help build a platform that includes information from outside of the EHR sphere, to include Big Data such as genomics, social determi-

THE HEALTHCARE INDUSTRY is seeing the practical application of using data analytically in the tenets of the Affordable Care Act.

nants of health, and patient or consumer-generated data."

For most healthcare organizations the struggle in getting started is three-fold:

- **Strategy**—Closely relating business intelligence to the delivery of the organization's business strategy.
- **Governance**—Defining the membership and roles, the decision making hierarchy, the data model attributes.
- **Cost**—Creating a comprehensively tailored plan that outlines all the resources, investments and timelines. I suggest that the greatest of these challenges is Governance discipline.

Of the greater than 60 maturing commercial big data vendors, many organizations are faced with finding solutions that work. Many seek options to leverage internal EHR clinical and business data to create external aggregation points for comparing cohort data. This is a big and lucrative business for the vendor industry and can facilitate access to the critical information needed to support an organization's strategic positioning and market growth.

In discussing data-centric high value care, Michelle Blackmer states, "Aggregated data, not electronic health records alone, will be the engine of innovation, built through information management that spans domains where patients or providers are engaged. How stakeholders behave in this new ecosystem is critical. It will drive how organizations engage consumers, employers, payers and providers. It will determine how high-value, high-quality healthcare is delivered and the ways in which wellness promotion and sickness prevention are addressed across a very fragmented technology-enabled environment. [Michelle Blackmer, Director of Healthcare Industry Solutions, Informatica, "Unlocking the Potential of Data Healthcare Transformation", Informatica and HIMSS Media 2014.]

We are beginning to make relevant decisions based on data driven outcomes and quality.

- It is about measuring value and monitoring clinical outcomes and costs
- It is about partnering with and educating patients through the uses of data to change wellness behaviors
- It helps to improve compliance and understanding of existing conditions
- It is about the partnership relationships that influence patient choices and obligate responsible behaviors for all members of the patient's care team

In this issue of *JHIM*, the reader will experience a series of peer reviewed articles and case studies that demonstrate the strides being made in planning, executing, and transforming behaviors in an increasingly data driven and competitive healthcare environment. We welcome and encourage your feedback and your contributions to the upcoming editions. **JHIM**

Mary Alice Annecharico, MS, RN, FHIMSS, is Senior Vice President and CIO of the Henry Ford Health System, Detroit. Ms. Annecharico recently transitioned from a similar position at University Hospitals, Cleveland, where she was responsible for the implementation of an integrated EMR with an 87 percent physician CPOE adoption rate.

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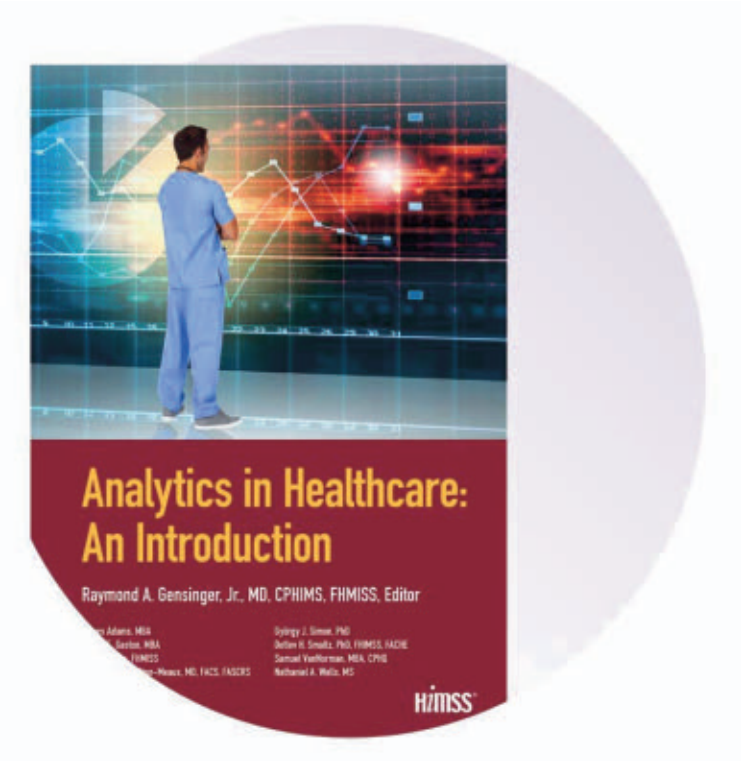

NEW - Analytics in Healthcare: An Introduction

This book provides a clear, straightforward roadmap to achieving your goals within the domain of healthcare analytics. Building on chapters that describe the evolution of healthcare analytics, others then address current and upcoming challenges including productive data mining from electronic health records, data governance, and the DELTA analytics maturity model. An appendix with learning modules for healthcare providers on secondary use of data and a comprehensive glossary are unique features of the book. The authors' varied experiences and perspectives demonstrate the range of opportunities where healthcare analytics can be applied to make a difference in the current healthcare climate.

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HIPAA

Gerry Blass and Susan A. Miller, JD

HIPAA Compliance

The Ever-Changing World of Information Privacy and Security

THE COMPLIANCE DATE FOR THE Health Insurance Portability and Accountability Act (HIPAA) Omnibus Rule has come and gone. Yet, HIPAA compliance continues to have as many questions as answers as technology changes and payment models evolve.

NEW RULES

Six new HIPAA rules were published in the Federal Register in less than 45 days, from December 2013 through February 2014:

- Physicians' Referral Exception and Anti-Kickback Safe Harbor for EHRs; Final Rules - December 27, 2013
- Administrative Simplification: Certification of Compliance for Health Plans; Proposed Rule - January 2, 2014
- Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the National Instant Criminal Background Check System (NICS): Notice of Proposed Rule Making - January 7, 2014
- Clinical Laboratory Improvement Amendments (CLIA) Program and HIPAA Privacy Rule; Patients' Access to Test Reports; Final Rule - February 6, 2014
- Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements; Proposed Rule – February 26, 2014

In addition, there is an expectation that the U.S. Department of Health and Human Services (HHS) will publish the HIPAA Privacy and Security Rules Accounting for Disclosures modifications sometime in 2014. It will be interesting to see the scope of the changes and how reasonable the requirements will be for covered entities and vendors to comply.

ENCRYPTION NOW MANDATORY FOR VULNERABLE ELECTRONIC PROTECTED HEALTH INFORMATION (EPHI)

The HIPAA security rule did not make encryption mandatory, but the Accountable Care Act of 2009, Centers for Medicare and Medicaid Services (CMS) Meaningful Use Rules mandate encryption for providers receiving federal funds for Electronic Health Records (EHRs).

We all also know that the HIPAA Breach Notification Final Rule in the preamble guidance states that there is a safe harbor if the entity uses the National Institute of Standards and Technology (NIST) encryption for special publications to secure their protected health information (PHI) that they store, maintain and transmit. This is one step closer to mandatory encryption for HIPAA Covered Entities and Business Associates, plus subcontractors.

In addition, the "Patient Access to Test Reports Final Rule" published in the *Federal Register* on February 6, 2014, states on page 7302 in the preamble:

"As a security measure, the Security Rule requires encryption when transmitting electronic protected health information where it is reasonable and appropriate to encrypt the information. In general, encryption is a reasonable and appropriate measure to safeguard email transmissions." (Emphasis added by authors)

Yet, we still see an increasing number of breaches discussed in the trade press and on the HHS's Office of Civil Rights (OCR) wall of shame that are due to lack of encryption.

For more than 10 years now, both authors have been out preaching that encryption makes good business and economic sense. We recommend that covered entities and business associates conduct a PHI vulnerability assessment by documenting where their PHI (hardcopy and electronic) exists (e.g. mobile devices, servers, multi-user workstations, backup tapes, wireless transmission, email, etc.), and then document their current controls, future plans, gaps, risks and action items, if necessary, to reduce risk to an acceptable level.

PAYMENT AND DATA SHARING MODELS

The world of HIPAA in 1996 when the law was passed by Congress and signed by then President Bill Clinton was mostly a paper environment for medical records, and most PHI was not transmitted to the open internet, but rather point to point.

Organizational and technological changes and advancements can increase vulnerabilities that can succumb to new and existing threats to the confidentiality, integrity

THE COMPLIANCE DATE for the HIPAA Omnibus Rule has come and gone. Yet, HIPAA compliance continues to have as many questions as answers as technology changes and payment models evolve.

and availability of PHI. So when they occur and when subsequent changes in regulations occur, covered entities and business associates need to re-evaluate their risk and perform due diligence and compliance activities such as workforce training, etc.

The world of HIPAA today includes EHRs, health information exchanges (HIEs), accountable care organizations (ACOs) and credit card payments. Today's world has increased the scope of what covered entities of all sizes need to do to properly protect both PHI.

Here are a few examples to consider:

- If an entity is using an EHR, it must consider additional privacy and security requirements, such as having updated firewall capabilities. In addition, traditional one-to-one electronic transmissions are now one-to-many electronic transmissions. Covered entities need to consider this as part of their ePHI vulnerability assessment.
- If an entity is participating in an HIE, it needs a participation agreement along with considerations for breach responsibilities and prevention outside of their own organization.
- Similar in theory to multi-organizational HIEs, ACOs are also complex entities that have privacy, security and standards impacts regarding notice of privacy practices, breach mitigation, risk assessments and overall governance and policies. For example, how are information privacy and security violations and sanctions handled?
- The payment card industry (PCI) security standard is a proprietary information security standard for organizations that handle cardholder information for the major debit, credit, prepaid, e-purse, ATM, and point of service (POS) cards defined by the Payment Card Industry Security Standards Council. If an entity is accepting credit card payments (and who isn't), do they have policies and procedures for the PCI security standard? Are they including PCI compliance audits to their organizational HIPAA privacy and security audits?

These few examples only scratch the surface. The authors plan to devote a future column specifically covering information privacy, security and breach notification and mitigation considerations for HIEs and ACOs. We plan to research and then consider who is typically responsible, what requirements are there for participation and what periodic risk monitoring is being done from a change management and due diligence standpoint, and report our findings.

CONCLUSION

The world of HIPAA-HITECH (Health Information for Economic and Clinical Health) Act and Meaningful Use keeps changing due to changes in regulations, organizations and technology. Covered entities and business associates therefore need to continually re-evaluate their programs for HIPAA-HITECH Privacy, Security and Breach Notification due diligence and compliance. While this has always been the case, what makes it more difficult today is the multi-organizational environments that exist with HIEs and ACOs and the ever growing web of where ePHI can exist in transit and at rest. **JHIM**

Gerry Blass has over 35 years of experience in healthcare IT and compliance. Blass provides IT and compliance consulting services and software called ComplyAssistant that automates the management and documentation of healthcare compliance activities. Blass is President & CEO of Blass Consulting and Compliance LLC.

Susan A Miller, JD, has 40 years of professional leadership experience spanning college teaching, biochemistry research and law. Since 2002, Miller has provided independent consultation and legal services to numerous healthcare entities including NIST and HHS. She has co-authored two OCR audit protocol prep books, HIPAA Security Audit Prep Book, and HIPAA Breach & Privacy Audit Prep Book. Published at http://www.malverngroup.com/New_Publications.html.

Blass and Miller are co-founders of HIPAA 411, a linked-in group.

VENDORS CONTRACTS

Robert Doe, J.D.

Software Delivery Models

An Update on Protecting Your Interests

In the fall 2008 JHIM, I wrote an article called "Negotiating Application Service Provider Agreements: Understanding the Upsides and Downsides of ASPs." While a lot has changed since that time, including the fact that application service providers (ASPs) are not utilized with the same frequency as they may have been previously, many of the considerations that laid out in that article still apply to the more frequently used models of today, such as software as a service (SaaS) or services provided by way of the "cloud."

ASP VS SAAS VS CLOUD

While I am by no means an expert on the technical distinctions (and I am sure there is room for some debate), I will point out some of the differences between these terms, especially as they relate to contract issues. For the purposes of this article, the most significant differences will be with regard to the location and treatment of the user's data. With regard to the distinction between an ASP model and SaaS, one significant difference is that, in an ASP model, the vendor is generally running the user's application for the user, but the application is not made available to other customers of the vendor. With the SaaS model, the vendor still hosts the application, but makes it available to multiple customers in what is commonly referred to as a multi-tenant arrangement. As such, SaaS software is generally configurable, but not customizable. Cloud differs from these two models in that it covers a broader scope of services delivered. While a software application could be delivered via a cloud model, the cloud model could also be used to deliver various computing resources and infrastructure management, such as outsourced hardware or file storage, giving it a much more broad array of offerings commonly referred to as computing as a utility (although some of these offerings may have their own acronym, such as Infrastructure as a Service (IaaS) or Platform as a Service (PaaS). In addition, there is no guarantee that a cloud model of delivery includes multiple users/multi-tenants (as in a SaaS model), and all the benefits that go along with the multi-tenant arrangement (e.g. lower implementation costs). Because of the breadth of the offerings, the term cloud has become a popular way of referring to anything that does not occur inside of one's own firewall, whether it is computing resources or a software application. However, in the world of application software procurement, there may not be much difference when it comes to delivery by way of SaaS or cloud, as SaaS seems to be a subset of cloud's offerings.

If you're an ASP/SaaS/cloud application software customer, be sure to ask questions when selecting your vendor about how your vendor delivers its application. The answers may be important to how you structure your contract and what provision you include with regard to data security.

DATA AND DATA SECURITY

Regardless of what model you utilize for your software application, treatment of your data still remains an issue. You still must make it clear that you will continue to own your data during and after the term of the agreement and be clear about how the vendor can use your data (increasingly, vendors want to be able to use data, both performance and de-identified PHI, for a variety of purposes that may not be related to providing you the services).

In addition, data security and access continues to be a concern. In the *JHIM* article, I noted "Depending on the importance and sensitivity of the data, the user can include specific language regarding the particular obligations of the software vendor with regard to keeping the data secure. For example, the user can specify in the agreement which individuals will have access to the user's data, where it will be stored and how it can be accessed." In

addition to these contractual provisions to help ensure the security of your data, it is also advisable to have a third party perform an audit of your vendor's operations. At the time the article was published, many organizations required their vendors to be SAS 70 certified. However, this has since been replaced by the Statement on Standards for Attestation Engagements No. 16 (SSAE 16) put forth by the Auditing Standards Board of the American Institute of Certified Public Accountants. The SSAE 16 includes the more expansive requirement that the service organization provide a description of its "systems," whereas the SAS 70 only required a description of its "controls." The SSAE 16 also requires a written statement of assertion that is created by management of the service organization that includes a number of important declarations. Keep in mind that SSAE 16 is not a certification. A better term might be SSAE 16 compliant, meaning that the service organization has undergone attest procedures resulting in the issuance of a service auditor's report.

There are also different reports under SSAE 16. A Type I report covers one specific point in time and is commonly used as a starting point, whereas a Type II report covers a specified range of time, such as an entire year. There are also SSAE 16 SOC 1, SOC 2 and SOC 3 reports, each with their own areas of concentration. The SOC 2 report is likely the most relevant to IT vendors. It focuses on a service organization's controls over its system relevant to security, availability, processing integrity, confidentiality or privacy.

A SSAE 16 report could be required in the preliminary contract negotiation phase (e.g. as part of the RFI/RFP, request for information/request for proposal, process) to gather information about the systems of the various vendors being considered and/or as a contractual provision requiring a periodic report be produced for the user. In the event the report identifies any significant issues, the contract provision should require the vendor to submit mitigation plans, including a schedule for completion. If the vendor does not correct the noted exceptions in the report by the scheduled date for completion, the user may want to include the right to terminate the agreement.

In addition to the SSAE 16 report, a user can require a vendor to allow vulnerability scans and penetration testing of the service provider on a periodic basis. Once again, if any issues are identified, the vendor should commit to correcting the issues within a specified period of time.

If the vendor will be storing the user's only copy of the data at the vendor's site, these issues become even more significant. The user should consider including language in the agreement that requires the vendor to provide a periodic copy of the user's data to the user so that in the event of a loss of data at the vendor site, the user has only lost the data entered after the date the last copy was provided.

Most of the remaining issues from the 2008 article (i.e. disaster recovery, transition services, uptime/response time and requirements regarding the service provider's system) would still be applicable to today's SaaS/cloud service agreements.

One thing that we can count on is that things will always continue to change in the world of healthcare IT. Delivery models will continue to change over time, and with those changes, healthcare IT users will need to continue to re-evaluate the best ways to protect their interests, especially as they relate to data use, disclosure and security. **JHIM**

Bob Doe is a founding member of Context Law (www.contextlaw.com), an information technology law firm located in Minneapolis, Minnesota. Doe has extensive experience preparing, reviewing and negotiating healthcare-related information technology contracts and can be reached at rdoe@contextlaw.com or (952) 548-6064.

BIG DATA

Ray Hess, RRT, MSA, FHIMSS

The Search for Excellent and Timely Healthcare Intelligence

Is Big Data a Big Deal?

THIS QUARTER'S JOURNAL is dedicated to *big data*. The term is the latest in big hype, but is it real? What does it mean to the average clinical and business intelligence professional? What should it mean to you and me?

When I saw the *JHIM* themes for 2014, I came up with the idea for this particular column. Since then, my stand-alone community hospital became part of Penn Medicine, the University of Pennsylvania Health System. Penn is one of the most prestigious academic medical systems in the world. They are actively developing their big data repository called PennOmics. This is a example of big data at its finest. It merges genomic, clinical trial, registry, bio, and clinical data into a massive data store where complex processes are being developed to take us to the next evolutionary level of intelligence-driven personalized medicine. Big data is real and happening in major academic medical centers. So I revise the question: because big data is real, how do those of us who work in non-academic, community and rural healthcare settings prepare for its use?

I have been in healthcare IT long enough to have seen a lot of change. Kilobytes became megabytes, megabytes went to gigabytes, gigabytes grew into terabytes and terabytes are now becoming petabytes. I remember when we first started relationally querying data and linking disparate systems. Adding clinical content was an enormous challenge, as was adding ambulatory and benchmarking data. I submit to you that in their day, the additions of each of these steps in our history could have been called *big data*.

Wikipedia defines it this way: "Big data is the term for a collection of data sets so large and complex that it becomes difficult to process using on-hand database management tools or traditional data processing applications. The challenges include capture, curation, storage, search, sharing, transfer, analysis and visualization. ...."

This definition could easily be applied to what we experienced when we first tried to bring clinical data into our warehouses. I feel that I have walked through many cycles of big data. Every time I thought my warehouse system was at equilibrium, there was a new larger and more complex data source that needed to be pulled in. Solomon wrote that "Nothing under the sun is truly new." (*Bible* (NLT) Ecclesiastes 1:9). I believe that big data fits into his wisdom. It is not truly new. The challenge keeps getting bigger and more complex, but so do our knowledge and the tools available to us.

The big data challenge should drive us back to the basics. The bigger the data, the more we need to focus on the details of data governance, data integrity, data management and end user involvement. Each of these components is foundational to clinical and business intelligence. As with any building, the larger the structure the firmer the foundation needs to be.

Data Governance. As data grow, the definition of each element must be crystal clear. A schematic of each piece of data and how it can and cannot be used is vital. Data governance is difficult and gets harder as the number of systems and inputs increase. Often it is impossible to dictate how data are set up when it comes from external

sources. With big data, you must understand the foreign definitions completely and develop rules carefully for how the outside data can be used and linked to data that are in the warehouse.

Data Integrity. The integrity of the data is key to everything a clinical and business intelligence professional produces. The bigger the warehouse, the more important it becomes to know exact details about the integrity of the data. An integrity analysis includes quality, completeness, accuracy, consistency and timeliness. Data integrity checking should be a way of life for us. As the industry moves to merging bigger and bigger disparate data sets, the integrity checking process needs to ramp up commensurately. When data integrity is suboptimal, the analysis and reporting teams need to determine and communicate how reliable the data are so users know the confidence that can be put into informational output.

Data Management. As a data integration project grows, the process to manage how the various data sources are pulled and linked needs to become more precise. Solid extract, transform and load (ETL) methodology, data mapping and referential integrity are not new concepts. The big data management scope may be broader, but the approach is the same as we use today. There are many newer tools on the market that help perform ETL tasks. Find the right one for you. Like all building projects, make sure you have the proper tools and know how to use them.

End-User Involvement. End user involvement has always been a key to clinical and business intelligence success. This does not change with big data. Big data will have more stakeholders and therefore need more deliberate communication and feedback loops. Many of us tend to pull away from feedback as projects get bigger. Feedback can complicate and slow down the process, but it is necessary for success. Our data projects are for our customers, and they will only be successful if we know and meet their needs.

The requirements listed here are not anything new to the clinical and business intelligence professional. It is a continuation of what we do every day. The level and complexity may be greater but not the concepts. Unfortunately, human nature often leads people to back away from tasks when they become more daunting. This can be a temptation when working with big data. The amount of foundational work to be completed and managed is so great that some might decide to cut corners with these difficult challenges. Taking that approach is a recipe for disaster. The more complex the task, the more we must apply diligence to the details.

Big data is real. If we know the basic tenets of data stewardship and have consistently applied them to our processes, we should be ready to take the step into bigger data. If not, we need to get back to basics and clean up our shop before expanding into this new world. Big data is the next step in emerging clinical and business intelligence capabilities. If we have managed our current environment well, this will be nothing to fear. We really have been here before and know what we need to do. **JHIM**

Ray Hess, RRT, MSA, FHIMSS, is Vice President for Information Management at The Chester County Hospital in West Chester, PA. Hess' experience includes having overseen Decision Support Services, Health Information Management, and Workflow Automation/Clinical Decision Support. Hess has more than 25 years of hospital management and administrative experience.

LEADERSHIP

Jack Hueter

Big Data and Population Health Management

Healthy Outcomes with Lower Costs

As we continue to look at how we can lower the trillion dollar cost of healthcare in our nation, the topic of population health management is growing like the weeds in my lawn (that is once we thaw out from this horrific winter). Big data is a term I have grown to hate as I think it is so overused but has become one of the buzz words in health IT. Let's dissect Population Health Management and Big Data so we can apply practical and useful opportunities for our already overburdened roles as healthcare IT leaders.

It is a known fact that Population Health Management works when there is a focused attention on health management and prevention, that health improves. This also lowers the costs of healthcare and improves outcomes. Numerous studies on chronic health conditions such as high blood pressure, high cholesterol and diabetes to name a few have shown significant health benefits to individuals combined with overall lower costs related to healthcare when closely managed. In a provider world where getting paid for taking care of sick patients has been the norm, the focus now to keep the patients out of our provider institutions and keep them healthy is contrary to our status quo mindset in healthcare. However, CMS, our biggest payer has realized that aligning incentives and payments to keeping people healthy is actually a lower cost than continuing to treat people when they are sick. As healthcare leaders we all know that the focus on our initiatives will follow where the dollars are being paid. How we can transition to the focus on population health management? We have to figure this out while we are also being paid for treating episodes of care. Many providers are juggling this today but see the change on the horizon. The recent focus on readmissions is a perfect example.

So where are our providers moving to population health management without bankrupting our organizations? Some large health systems and provider groups are focusing population health management on their own employee populations. As a large employer, they recognize that keeping employees healthy lowers their own employer healthcare costs and also improves productivity. This is one area we follow the dollars by lowering our internal costs. Another area providers are pursuing is venturing down the Accountable Care path. The feedback from the early ACO pioneers is coming in with mixed results. Several ACO pioneers have realized the costs to develop and support an ACO outweigh the savings and have dropped from the program. Others have shown that the ACO savings and incentives are worthwhile. They all have provided the feedback that going at risk with populations by becoming an ACO is not a venture that should be understated. Almost all have spent a significant amount of dollars and resources in putting in place the supporting IT and data systems required to manage populations. The last report I saw noted that the typical starting cost for IT to support and ACO is close to $2 million.

Big Data plays a critical role in population health. According to Wikipedia the definition of Big Data is as follows:

IT IS A KNOWN FACT that Population Health Management works when there is a focused attention on health management and prevention, that health improves.

"Big Data usually includes data sets with sizes beyond the ability of commonly used software tools to capture, curate, manage, and process the data within a tolerable elapsed time.[1]" Gartner likes to associate the 3Vs with big data – high volume, and high variety. As organizations determine which opportunity they want to pursue with population health, the amount of data that needs to be analyzed can be staggering. Data will reside among the various sources from hospital EMRs, physician practice EMRs, Home Health agencies, Long Term Care facilities, Specialty Clinics, Personal Health Records, Health Information Exchanges, CMS – Medicare and Medicaid, and other private payers. Having worked with ACOs in NJ and the required reporting, I can vouch for the fact that not everything is electronic and even if it is electronic, it needs to be interpreted correctly for the quality reporting requirements. In a number of cases, data needs to be abstracted manually from paper and electronic records by a knowledgeable clinician to provide the necessary data requirements for ACO reporting. The ability to consolidate the data, that is not standardized, and link it to the health of a patient population can be a significant effort and cost. Many software companies are coming to the forefront to offer various big data solutions.

As healthcare IT leaders, we need to filter through the glossy sales brochures and determine solutions that integrate well with our current systems and provide flexible solutions that work.

As we summarize our health IT focus on population health and big data, we can see how these play out to help us analyze the next wave of analytics. Data sources will be from within and outside our internal IT systems. The ability to extract and interpret the data can be enormous. Accountable Care Organizations are a good example of where we see this playing out. The ultimate outcome of the transformation of healthcare to provide better care and outcomes while lowering costs is where we all want to go. Data will be critical to help us measure how we get there. As health IT leaders, we have a strategic role in population health management and big data will be one of the strategies. **JHIM**

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Jack Hueter is the CEO of Digital Health Consulting LLC, a provider of Healthcare IT consulting services for healthcare providers. Jack is also currently under contract with the New Jersey Regional Extension Center as the South Jersey Regional Director. His consulting experience includes leading the East region Provider Services as a Partner with IBM and as a management consultant with Ernst and Young. Jack has over 20 years as a Health System CIO for Catholic Health East, Mercy Health System and Franciscan Health System.

MOBILE HEALTH

Rick Krohn, MA, MAS

mHealth Innovation

Lightning in a Bottle

FOR THE PAST 100 YEARS, the U.S. healthcare system has been constructed around the hospital as its central figure—a care model that has been a study in inefficiency. Reactive, waste-ridden, insular and economically nonsensical, we are now faced with a stark truth: the U.S. healthcare system in its current incarnation, a system of facility-based, wildly expensive, hopelessly fragmented, episodic care is insufficient to the task of improving, much less sustaining our nation's health. Under present conditions, the outlook isn't encouraging, and healthcare's intractable issues - access, uneven quality and spiraling cost, can only get worse.

The solution set to our predicament features a healthcare delivery system with a greater array of provider-patient engagement; with consumer empowerment; with efficient processes and better care coordination; with a bias toward wellness and prevention; with tools for patient accountability; with a recalibration of financial incentives and with the capability of achieving behavioral change across the spectrum of healthcare stakeholders.

And the headliner for this brave new world of healthcare: *mobile healthcare*. At incredible speed and with an uncharacteristic display of industry innovation, mobile healthcare has within a few short years been catapulted to healthcare's center stage. As a class of technologies, mHealth is an anomaly within health IT solutions – it is affordable, scalable and accessible, it is highly configurable and endlessly adaptive, and most importantly, it is a lightning rod for process innovation. mHealth is premised on the notion that healthcare is not restricted by its traditional boundaries and that technologies, processes and roles in healthcare can be architected in wholly new ways. In an industry that has been hidebound, literally for decades, in an antiquated pattern of healthcare delivery, that is a truly novel idea. Few technologies have the potential to radically alter the processes of healthcare in so many areas—clinical workflows and service efficiency, care coordination, patient engagement and consumerism among them. mHealth is inserting itself into ever-more-granular aspects of everyday living, with healthcare providing a seemingly limitless template for industry transformation. And we have only scratched the surface of mHealth's potential.

So why is mHealth percolating to the top of must-have industry solutions? For the most part, mHealth solutions don't rely on expensive proprietary technology, sourced from a single vendor – so they do not require a sizable, irreversible capital investment. And unlike other technology solutions whose foremost purpose is to digitize manual processes, mHealth is oriented around re-engineering processes with technology acting as an enabler. That's a critical distinction – mHealth is not about technology as the solution – it is about technology as the engine of a process solution.

mHealth innovation is being driven by two of its foundational attributes—connectivity and communication. Whereas many technology solutions are stand-alone or M2M, mHealth is unique in its capability to create connectivity among healthcare's stakeholders, for care coordination, for patient engagement, for resource allocation, for chronic disease management, for self care, for population health and wellness, for event response –the list keeps growing. It creates channels of communication that are pervasive and persistent and removes the silos of information, silos of care and silos of access as barriers to efficient service delivery.

mHealth innovation is also defined by several guiding principles: coherence; convenience and cost – that make the user experience engaging across the spectrum of healthcare services. It is endlessly adaptive, which makes solution development possible (and comparatively cheap) from the most discrete app to a global solution. It leverages complimentary technologies like real-time locating system (RTLS), speech recognition and video. mHealth solutions get an image bump from the larger world mobile attributes: reliability, familiarity, personalization and, in the case of the healthcare consumer, instant gratification. And in comparison to "big box" healthcare technologies, cost-wise mHealth is a steal.

mHealth is all about data. It is uniquely positioned in its ability to capture, store, interpret and communicate healthcare information at the point of care, across platforms, among a host of devices and all in real time. It makes healthcare an ongo-

ing process, removes barriers to provider/patient communication and collaboration and democratizes both access to and management of care. With access to on-the-fly patient data, providers can make informed treatment decisions. With actionable data, patients and consumers can effectively act as stewards of their own care, in concert with the provider community, with affinity groups and with family members. As patients and consumers take ownership of their care via mHealth tools, they become more accountable for their health management – propelling them toward the center of the mHealth ecosystem, a remarkable recasting of roles in healthcare.

Finally, mHealth leverages existing consumer electronics, public communication and network infrastructures. It makes use, efficient use, of affordable devices, most notably mobile phones, whether they are smartphones or feature (text and voice) phones. It communicates with people where they are, with tools they can use, at an acceptable cost. And it taps into the widespread development of mobile networks – even in the poorest countries – to make broadcast engagement a realistic prospect.

That combination of availability and affordability makes mHealth solutions viable, in terms of cost and access, to entire populations, regardless of economic strata, geographic isolation or technologic sophistication.

It is these *brand identifiers* of mHealth that make it such a rich template for innovation. And because the universe of healthcare services is so broad, and the gaps in care so great, there is an elegant need-meets-opportunity aspect to mHealth's growth and diversification.

Innovation in the mHealth space is proceeding at amazing speed. mHealth solutions can be conceptualized, developed, pressure tested and commercialized within a matter of months. Often these solutions are developed outside the mainstream of health IT, on a shoestring, by entrepreneurs with little direct healthcare experience. These start ups – or upstarts – have brought fresh thinking, inter-industry and interdisciplinary experience to the task of making healthcare transactions – knowledge, education, treatment, prevention and finance – more efficient. It is this wellspring of new thinking being applied to old problems that is making mHealth the rising star of health IT.

And the result: mHealth innovation is emerging as the single most transformative force in healthcare today. It is reshaping healthcare delivery, already having established a firm foothold in areas like wellness and chronic disease management and growing organically into more diverse areas such as remote patient management, telepresence and mobile wallet. It is forward reaching in areas such a imaging, augmented reality and body area networks. And the application of mHealth to gaps in care – from engaging the underserved and treating tertiary health issues to population health and education – is allowing us to apply fresh, unstructured thinking to healthcare's problems. **JHIM**

Rick Krohn is an expert in healthcare corporate strategy and strategic marketing, business development, technology development and commercialization and corporate communications. He has served as President of HealthSense (www.healthsen.com) since 1998. Krohn's consulting experience spans the healthcare, telecommunications, education and technology fields. He is the author of more than 100 articles on a wide range of technology topics and has written three industry texts – most recently mHealth Innovation: Best Practices from the Mobile Frontier (HIMSS, 2014).

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GOVERNANCE

By Roger Kropf, PhD and Guy Scalzi, MBA

Physician Leaders' Role in IT Governance

How Can CMOs, CMIOs and Other Physician Leaders Help Secure Physician Involvement and Support in IT Governance?

For our HIMSS book on IT governance,[1] we interviewed chief medical information officers (CMIOs) and chief medical officers (CMOs) to understand what they saw as their role in the IT governance process. In this article, we present their responses along with insights from interviews with other physician leaders.

THE UNWRITTEN ROLE OF PHYSICIAN LEADERS IN IT GOVERNANCE

In addition to their formal roles, physician leaders have roles that aren't written down anywhere.

Erik Steele, CMO of Eastern Maine Health Systems (Brewer, ME) believes the role of the CMO is to "make it work." "You are the utility infielder and your job is to make it work, whatever that takes," he said. He suggested talking directly to physicians. "Push through a process for tracking concerns and getting them resolved. Good governance isn't a random event."

According to Christopher Barrilleaux, CMIO at East Jefferson General Hospital (Metrairie, LA), the CMIO needs to be a leader, cheerleader and salesperson. The CMIO needs to use the system, which means practicing medicine, and be willing to say when the system needs improvement. The CMIO also must be willing to tell project sponsors what reality is. "The CMIO has to be ready to say 'We can't do it because it's not for the greater good, or we can't do it because of budgetary reasons.'"

Carl Dirks, CMIO, St. Luke's, Kansas City, MO, closely focused on implementation from the end user's point of view. "That includes closely monitoring implementation down to the level of identifying users who are struggling."

COMMUNICATION

The physician leaders stressed the importance of communication with other physicians in the success of IT governance.

Back to Steele who believes that to keep physicians engaged you need to provide multiple modes of communication. CMIO and Meaningful Use reports were formally on the agenda of medical staff meetings. Reminders were built into the electronic medical record (EMR). "You may need to call physicians, as well as send materials to emphasize the importance of what they should be reading," he says. "If they miss a meeting, a staff member needs to follow up with them and tell them what happened to issues they care about. Their performance needs to be monitored. If they are not showing up for meetings or repeatedly approving changes that their group later objects to, they need to be approached and asked to change behavior or be replaced."

C.T. Lin, CMIO of University of Colorado Health, stresses listening and repeating what is heard. "Sometimes just verbally repeating a frustrated physician's concerns can re-start a stuck conversation. The CMIO has to be seen as a physician advocate, but also a steady hand and voice of reason." Lin added " Help establish and hold to the guiding principles of the project when situations get muddy. Sometimes a physician's voice stating both sides of an argument and returning to general principles can help clarify difficulties."

STRUCTURES TO FACILITATE PHYSICIAN INVOLVEMENT AND SUPPORT

The role, authority and influence of physicians need to be considered in determining a committee structure. Many physicians are interested in attending a meeting where a project of personal importance is being discussed, but participants in the governance process need to commit to working on a whole range of projects. Multiple perspectives are needed to make good decisions. All three organizations had a high-level committee to make decisions that were then forwarded to the CEO and board, as well as to advisory committees. Decisions had been made on whether the CMO or CMIO would serve on each committee.

The CMO at St. Luke's Health System (Kansas City, MO), a member of the man-

agement committee, chairs the clinical applications prioritization group and is also a member of the business applications prioritization group. The system's management committee had delegated the function of assessing and prioritizing clinical applications to the clinical applications prioritization group.

Dirks, as discussed earlier, co-chairs the Information Technology User Group and is a member of both the clinical applications and business services prioritization groups but is not a member of the system management committee. This provides the CMO and CMIO the opportunity to discuss and vote on both types of applications before they are sent to the management committee. Dirks noted that most applications, with a few exceptions such as revenue cycle management, affect clinical care.

Because so much money is being spent on clinical systems, many hospitals and health systems have established specific structures and processes for clinical IT governance. The need for clinical IT governance is made even more important because of the key role that physicians play in the governance and success of health organizations.

East Jeffferson General Hospital (EJGH) has a clinical operations committee (COC) chaired by the CMIO and includes the chief nursing executive, the medical director, the chief of staff, nursing vice presidents, other physicians and IT staff. Under the COC are three subcommittees. The first is the physicians advisory committee, chaired by the CMIO. The second is the meaningful use steering committee. The third is the COMPASS advisory committee (COMPASS is EJGH's EHR system), which is composed of nurses.

Eastern Maine Health Systems (EMHS) has a clinical coordinating committee composed of the CMO, chief nursing officer (CNO) and the president of the medical staff of each member organization. There is a subcommittee of the clinical coordinating committee, the clinical systems steering committee, delegated to make design decisions about the EMR. There is also a decision support work group composed of physicians that makes decisions on order sets and clinical pathways.

KEYS TO SUCCESSFUL PHYSICIAN ENGAGEMENT

We asked physician leaders to describe the important factors in engaging physicians in the governance process. As noted earlier, they stressed the importance of their active engagement and constant communication.

In addition, they suggested:

Keep Governance Simple and Transparent:
"Physicians want to know how decisions are made. They want some processes embedded in policy. Physicians and nurses can go online and raise an issue about the EMR and that issue will be tracked until it's resolved. Others will go to the CMIO and CMO and raise the concern directly."
– Erik Steele, CMO, Eastern Maine Healthcare Systems, Brewer, ME

Physicians and CNO input into prioritization and configuration of applications:
"Physicians need to feel they are just as important as the business side. If there are templates, physicians need to know what they are, agree that they will be functional and have significant input on configuration."
– George Pagels, CMO, St. Luke's Health System and chief executive officer (CEO) of Saint Luke's East, Kansas City, MO

Personal Involvement of Physician Leaders:
"The personal investment of the CMO in the process is key. The CMO has to understand how decisions are made. CMOs have to make sure that issues get tracked and resolved. The loop has to be closed back to the initiating physician. The CMIO and the CMO have to be partners. The CMO needs to be involved in key discussions to make sure that the physician perspective is represented. You have to make sure the physician's voice is effective in decision making."
– Erik Steele, CMO, Eastern Maine Healthcare Systems

Engaging the Critics:
"Remember that the people who don't agree with you are not your enemy. Bring the people who are the loudest critics into the process."
– Christopher Barrilleaux, CMIO, East Jefferson General Hospital, Metairie, LA

THE FORMAL ROLE OF THE CMIO IS CHANGING

Hospitals have frequently sought out members of their medical staff who would be willing to take on a part-time CMIO role. They would serve as advisors and work with the medical staff. Sheryl Bushman, CMIO at New York University Langone Medical Center in New York, believes the HITECH Act and the timeline for complying with meaningful use requirements is increasing the need for full-time CMIO involvement. CMIOs are moving into implementation and supervisory roles they did not have before. Bushman now has three full-time physicians working for her and works full-time as CMIO. She believes that the importance of experience in implementation is making CMIOs more mobile. Hospitals and health systems are seeking experienced physicians regardless of whether they have been part of the medical staff.

CONCLUSION

We agree with Lin that the physician leader "... has to be seen as a physician advocate, but also a steady hand and voice of reason." Effective governance requires careful thinking and discussion regarding the role of physicians and physician leaders. That dialog should result in structures and processes that encourage physician involvement and support. As our interviews suggest, not all organizations will make the same choices, but the final objective remains an engaged and supportive physician community. **JHIM**

Roger Kropf and **Guy Scalzi** are the authors of IT Governance in Hospitals and Health Systems, published by HIMSS in February, 2012. Kropf is a Visiting Professor in the Executive MBA in Health Administration Program at the University of Colorado, Denver Business School. Scalzi is a Principal in Aspen Advisors, a professional services firm that works with healthcare organizations to enhance processes and streamline operations through the strategic and effective use of technology.

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FOCUS

BIG DATA AND POPULATION HEALTH MANAGEMENT

Using the Patient Centered Medical Home Model to Effect Population Health Management

Demonstrated Success in One Western New York Community

By Jeanette Ball, RN, PCMH, CCE, and Linda Lockwood, RN, MBA

ABSTRACT

It is one thing to say the healthcare industry needs to shift from a fee-for-service to an outcomes-based model. It is quite another to develop a viable path to get there.

Population health management (PHM) shows great promise for improving quality of community care while reducing costs. Yet there are many barriers to PHM, especially for independent practices lacking the broad patient base to create statistically valid cohorts to inform their decisions.

These were the issues facing providers who participated in HEALTHeLINK, a health information exchange (HIE) that serves eight counties in Western New York. These practices, which range from rural sole providers to large urban practices with more than 25 clinicians, had very familiar challenges—financial concerns, resistance to change, fear of new IT adoption and a lack of internet connectivity in rural areas. Yet more than 100 of them committed to adopting the Patient Centered Medical Home (PCMH) model for standards of excellence in primary care.

This article presents how one Western New York community shared resources, technology and data to create a PHM initiative for diabetes that yielded results effecting enhanced quality care at the community level, including:

- 77.4 percent of patients sampled were at or below HgbA1C of 7.0 or showed improvement
- 80.3 percent were at or below LDL of 100 or showed improvement
- 78.6 percent had systolic blood pressure (BP) at or below 130 or showed improvement
- 83.7 percent had diastolic BP at or below 80 or showed improvement

Two examples of PCMH being used in PHM initiatives and the conclusions to be drawn will be further explored in this article.

KEYWORDS

Population health, population health management, accountable care, accountable care organization, patient centered medical home, National Committee for Quality Assurance, electronic health record, EHR.

IT IS ONE THING to say the healthcare industry needs to shift from a fee-for-service to an outcomes-based model. It is quite another for a community to develop a viable path to get there. Western New York (WNY) did in fact develop that viable path! During 2010 to 2012, the WNY payer community and HEALTHeLINK, the WNY HIE, united to effectively influence and clear barriers for practices to be more outcomes-based in a two-prong approach.

The initial step was the introduction of technology with the Payer Electronic Medical Records (PEMR) program. PEMR offered funding for EMRs and implementation consulting services to primary care offices. This fund provided the necessary technology and clinical transformation consulting services for practices to move from paper-based systems to fully integrated electronic systems connected to the HIE.

The second prong to this program was a New York State Grant administered by the HIE and executed concurrently with the PEMR program. The grant was designed to affect the WNY diabetic population and Diabetic Outcomes in Western New York using the Patient Centered Medical Home (PCMH) model of care. These two programs together provided an outstanding pairing of resources to drive not only technology, but also the means to apply that technology with a proven framework using the NCQA PCMH model of care, including the establishment of diabetic registries and measures.

The approach theorized that participating practices would immediately benefit from a consultant not only assisting with the implementation of the EMR but providing practice transformation services in line with PCMH principles and effecting diabetic health by setting up registries and PDSA cycles to effect health. The practices would begin to see the power technology provided in improving health outcomes, and how PCMH principles can be applied to drive improvements and efficiencies with the care delivered. The EMR and HIE technology, coupled with the consulting services and PCMH model, drove amazing outcomes over a two-year period.

The contracted consulting firm assessed multiple EMR vendors and selected a list of those preferred. The EMRs were selected for their ability to appeal to a large demographics and interact with the HIE. A marketing campaign was launched and practices were enrolled.

The demographics of the practices consisted of adult primary care offices, which ranged from small rural sole practitioners to large urban practices with more than 25 clinicians. Though these practices were vastly different in demographic makeup, they also had very common challenges, which included financial concerns, resistance to change, fear of new IT adoption, and in some rural areas, a lack of internet connectivity.

In addition to technology and geographic-specific barriers, achievement of PCMH recognition is no small feat. It takes significant foresight, planning, dedication and commitment to make it a reality. Despite these challenges, more than 300 providers committed to adopting the NCQA PCMH model for standards of excellence in primary care and creating diabetic registries coupled with improvement strategies for their diabetic populations.

A segment of the 300 providers were stratified and defined as those practices without an EMR and not having begun any PCMH activities. These were termed the "C practices." That is the segment this article will focus on. This group of practices received the full gamut of services including clinical transformation and implementation of an EMR, PCMH consulting services, and mandatory diabetic measurement population performance quality measures. These practices had the longest and hardest road to travel and created the most challenges.

WHY PCMH?

The NCQA Patient Centered Medical Home model was selected for this program because it shows great promise for advancing the Triple Aim in healthcare, that is, improving quality and decreasing cost, all while improving patient experience. The NCQA PCMH model has gained increased attention across the nation as communities look to improve the quality of care and, ultimately, the outcomes of their patient populations. The PCMH model of a coordinated, patient-partnered approach to healthcare has the ability to transform how care is delivered and was selected as a framework for this project.

In addition to technology and geographic-specific barriers, achievement of PCMH recognition is no small feat. It takes significant foresight and planning among healthcare members across the community, and administrative dedication and commitment to make it a reality.

STANDARDS, ELEMENTS AND FACTORS

The PCMH model focuses on building a patient-focused, quality-driven organization. The NCQA governs this recognition for primary practices and has defined several criteria that help to ensure that a practice is acting as a medical home, with care being delivered by a compassionate team of healthcare providers. The PCMH standards guide a practice to be focused on quality and continuous quality measures. By the nature of the standards, it forces a practice to "inner-reflect" and examine changing their paradigm from reactive fee-for-service to becoming a proactive, outcome-driven organization. Critical to PCMH success in any practice is a clearly-defined organizational vision that is supported by strong leaders, has the buy-in of physicians and has the required technology to connect care across the continuum.

The NCQA PCMH program requires a level of strict adherence to excellence in care for which many organizations are not prepared. The NCQA PCMH program standards provide measurable criteria that help guide the transformation efforts of communities on their journey to PCMH. Level 1, 2 and 3 recognition is granted based on the achievement of predefined standards (6), elements, (28) and factors (152) demonstrating that systems and processes are in place to meet nationally recognized care delivery standards.

PCMH philosophy and rigorous standards provided a methodology and framework to move the whole community forward with outcome-based care. The approach and criteria were able to be reproduced across multiple practices,

with variable demographics, which drove WNY along a guided path. For the participating practices, diabetes was required to be at least one of the chosen diseases to be measured. Mandating diabetes and specific measures met the New York state population health objectives of effecting diabetic health in a standardized model.

The PCMH standards also lay the foundation for organizations to need to meet healthcare reform requirements due to the inclusion of the MU objectives within the PCMH standards. This inclusion also provided the consultant with a means to assist the practices on their MU journey.

PCMH AND POPULATION HEALTH APPLIED WITH SUCCESS IN WNY

Affecting and improving population health takes community-wide commitment and determination, as demonstrated in WNY. Three payers, the region's entire hospital network and New York state worked together using the NCQA's PCMH model to successfully complete the journey from paper to electronic health record (EHR) to PCMH, resulting in positive, measureable results today.

HEALTHeLINK's objectives to expand technology overlaid on NCQA PCMH recognition standards—with all driving toward diabetes health—made for an ambitious set of goals. The vision was to increase the use of technology and EMR use within the practices, optimize the use of technology for chronic disease management through the HIE, and increase the number of PCMH-modeled practices to improve overall population primary care across the region.

The use of multiple EHR vendors across the various practices, coupled with some practices still operating in a paper-based environment, only served to compound the existing challenges to PCMH deployment. These barriers made it imperative for HEALTHeLINK's leadership to partner with an experienced advisory service company who could bring forward a team of consultants able to provide:

- Objective EMR selection consulting services to assist practices in choosing an EMR that met their individual ROI and goals.
- Consultants versed in EMR implementation services and operational practice management transformation services.
- Content experts on NCQA PCMH recognition standards.
- Population health and analytics for overall outcomes.
- Project management and administration of New York state grant execution.

A methodology framework template was created including a set of 45 reproducible tools providing consistency and standardization. A baseline PCMH assessment was conducted for each practice to assess the practice's operational needs and measure a PCMH score. Tools were created to help practices launch PCMH in their organizations including: sample policies and procedures for the practices, clinical guidelines examples and sample practice tools for referral logging, call monitoring, diabetic outcomes and clinical surveys. Visio workflows were created that identified potential process/workflow enhancements as the practices began to transition to the EHR. These workflows could be customized to meet the unique needs of each practices' patient populations, while also retaining industry best practice principles for operational excellence.

One objective that that this region defined as a measure of PCMH program success was to demonstrate chronic disease can be managed at the population level, as well as at the individual patient level. In this case, the region chose to look at the diabetic population. All practices were assisted in setting up registries of diabetic patients who were 75 years of age or younger.

For consistency, all practices used the following three measures:

1. Number of diabetic patients seen with HgbA1C lower than 7
2. Number of diabetic patients seen with LDL lower than 120
3. Number of diabetic patients seen with BP under 130/80

A baseline measurement was collected using NCQA-defined sample methodology and repeated after PCMH and transformation activities were completed. The consultants worked with each practice to not only set up the registries but to assist the practice in affecting the health of their specific population demographic. This additional effort demonstrated to the practices how to set up population health performance management and continuous quality improvement activity.

For example, one of the practice sites enrolled in the program was a large urban primary care clinic. A closer examination of the community's demographics revealed some staggering facts:

- The average household watches 56 hours of television each week and consumes more than 13 meals per week from a fast food restaurant
- 84 percent of the adult population has less than an associate's degree
- 31 percent live below the federal poverty level, and only 60 percent of the available workforce is employed
- 16 percent of homes lack basic kitchen facilities and almost 10 percent lack proper plumbing

The practice set out to address the socioeconomic barrier that this demographic presented to diabetic health. This practice began activities such as: Starting a farmers market in the neighborhood where fresh vegetables and fruits could be purchased with food stamps. Another is working on launching a safe environment for walking in the facility.

Each practice was coached on how to affect their individual baselines using technology workflow enhancements and community involvement. Consultants demonstrated to practices how a chronic disease can be managed at both the population and patient levels by including template EHR changes coupled with team practice involvement and organized primary care teams. The groundwork was laid for empowerment, and practices embarked on a journey toward continuous quality improvement, pay-for-performance and MU.

Collaborating with the advisory services company produced excellent results in meeting HEALTHeLINK's goals.

- 100 percent of participating C practices demonstrated an improvement in the PCMH standards from baseline.
- NCQA PCMH practice assessment results improved from 13.4 percent to 81.1

FIGURE 1: Diabetic Patient Outcomes

Population Improvement	Result
Overall improvement in HgbA1C	77.4%
HgbA1C at or below of 7.0 or showed improvement	77.4%
LDL at or below of 100 or showed improvement	80.3%
Systolic BP at or below 130	78.6%
Diastolic BP at or below 80 or showed improvement	83.7%

Diabetic patient outcomes showed marked improvement after initiation of the PCMH program.

FIGURE 2: Measurable Results – January 2013 to October 2013

Mammogram Rates	15% improvement
DM Pts. Not Receiving HgbA1c	Dropped by 13.2%
DM Pts. With LDL <100	7.1% improvement
ED Utilization	Dropped by 16.95%
No Show Rate	Dropped by 4.1%

These figures show significant gains in health across the community.

percent of completed work from baseline to remeasurement. They achieved an average increase of 52 points (of 100), demonstrating a 40.9 percent overall improvement in PCMH standards.

- 18 practices achieved full level 3 NCQA PCMH recognition – above and beyond the grant requirements.
- 61 percent of practices showed improvement in all NCQA PCMH standards from baseline.

Having established quality metrics reporting, practices also showed significant positive outcomes in managing three identified diabetic measures for chronic disease management goals. These include:

- 77.4 percent of patients sampled were at or below HgbA1C of 7.0 or showed improvement.
- 80.3 percent of patients sampled were at or below LDL of 100 or showed improvement.
- 78.6 percent of patients sampled had systolic BP at or below 130 or showed improvement.
- 83.7 percent of patients sampled had diastolic BP at or below 80 or showed improvement. (See Figures 1 and 2.)

These results illustrate a stunning transformation from paper-based practices with limited quality measures to an EHR with an active quality monitoring and measuring process. To improve the overall health of their diabetic populations, practices now routinely intervene at the point of care to proactively treat borderline patients and have established outreach programs such as family-centered wellness programs offered at local schools to re-engage and empower patients to manage their own care. Access to care has also increased patient involvement with such programs as a mammography bus, which has screened more than 2,000 women since June 2012.

CONCLUSION

Changing the way primary care practices administered care using the PCMH framework and philosophy in Western New York, and the measurable outcomes it achieved, serves as a roadmap for healthcare organizations facing similar challenges. While the journey ahead may appear daunting, the obstacles are not insurmountable.

The willingness of highly involved key stakeholders – payers, providers and the health information exchange and state funding – are key factors to success in moving community technology advancement implementation in the right direction. PCMH at the practice level takes active leadership committed to PCMH transformation. The likelihood of staying focused on the end goals can easily be overthrown in facing the required PCMH measures, time and effort to get there.

Bringing in experienced project consultants to assist easing providers' transition to the rigors of PCMH recognition, creating a population health management strategy and a culture of continuous quality improvement is recommended. Consultants can shortcut the process of redesign and reengineering that is often necessary when planning your evidence-based, systematic path to PCMH program recognition.

Most importantly, no single formula for PCHM works universally. PCMH program principles include examining the patient population demographics in depth, determining its specific challenges, and developing a patient engagement program that promotes and simplifies self-care adherence to clinical recommendations.

Achieving a PCMH care delivery model initiative requires significant investment and the yield, as demonstrated in this case study, is excellent. Western New York resident are benefitting from better quality care and access, and community practices are now in a better position to compete in a pay-for-performance world. **JHIM**

Jeanette Ball, RN, PCMH, CCE, Advisory Services Principal Consultant, CTG Health Solutions, has experience in executive healthcare administration and health IT consulting. Ball is one of the nation's first 100 recognized NCQA PCMH experts.

Linda Lockwood, RN, MBA, Advisory Services Solutions Director, CTG Health Solutions, has over 40 years' experience leading a wide variety of healthcare initiatives, including Meaningful Use readiness and program management.

FOCUS

BIG DATA AND POPULATION HEALTH MANAGEMENT

The New World of Population Health

How to Get to Good … and Then Beyond to Great

By Gregg Mohrmann, MPA, PMP; Claudia Blackburn, MBA, PMP, CPHIMS; and Vincent D'Itri, BS, PMP

ABSTRACT

Numerous models for value-based healthcare exist, yet all of them have at least one thing in common: population health management (PHM). There have been several approaches to PHM, and some have demonstrated results while others have yet to do so.

In practice, five pillars form today's PHM model and transform organizational vision into action and results: the business model, financial model, clinical integration, member and community engagement and technology. Sound business goals and financial backing provides direction and funding to launch the endeavor, respectively. Clinical integration efforts identify and optimize key processes that span the care continuum to achieve the clinical outcome objectives. Member and community engagement captivates members as constituents in accountability for their own care. Technology forms the underpinning with a solid, integrated, platform to address interoperability, cross continuum care management, data analytics and quality and financial outcomes and risk sharing.

This article will describe the five pillars of PHM and outline a maturity model that can be used to define the roadmap to population health. It will identify what separates the PHM programs producing results from the others. Using a case study from a major health system, it will also highlight typical organizational challenges, key activities and supporting structures within the pillars necessary for effectively implementing PHM across a healthcare enterprise.

KEYWORDS

Population health management, PHM, accountable care, clinical integration, ACO, value-based care, accountability, risk, care management.

THE CURRENT HEALTHCARE environment is transforming from a reactive, volume-based care model to a proactive value-based model because of a myriad of challenges including unsustainable rising healthcare costs, the goal to have healthier populations and the need to further integrate siloed care environments.

Efforts are focused, pilots are underway, full-scale programs have been launched and some results have been achieved. In a recent College of Healthcare Information Management (CHIME) focus group, the number one funded priority over the next two years is population health and/or initiatives supporting population health management. As healthcare organizations put a greater focus on providing high quality care at a lower cost, this will require a business model, payment mechanisms, clinical integration processes, engagement tactics and, in some cases, new technology to provide better visibility to care across the continuum, improved analytics, protocols and transitions, and quality, financial and risk sharing systems that support the new payment model and incentives.

To make these changes, it is essential that healthcare organizations have a good understanding of the core competencies of population health management (PHM), an awareness of how mature the organization is with respect to these core competencies

and insight into how to move along the maturity curve.

UNDERSTANDING PHM CORE COMPETENCIES

PHM is viewed by many in differing ways. However, no matter the view, there are seven main core competencies that an organization must have. These should be understood and applied throughout the planning and deployment of an organizational PHM initiative:

Business Planning: Program executives and physicians jointly develop the PHM business plan to define goals, vision, target populations, associated budget, staffing models, technology plans and clinical integration assumptions.

Member Engagement: Members must be actively involved in the maintenance of their health and wellness, which requires them to be educated on tools and methods in order to take control of their health.

Cross-Continuum Care Delivery and Management: PHM requires consistent care planning and monitoring, consolidated clinical data views, different modes of communication and seamless hand-offs among care settings.

Quality Outcomes Reporting and Management: While quality reporting is not new, the difference for population health is the need for measuring and monitoring across the continuum of care. It includes all participating entities and should support a number of health reform programs. This will require thinking "outside the box" of traditional quality reporting, which focuses primarily on the inpatient care setting. There will be a need for cross-continuum measurement and reporting that is timely and enables practitioners to make proactive decisions while reacting to updated information on a regular basis. This reporting should review individual providers, centers of care provision and specific established key performance indicators (KPIs) to ensure quality is in line with organizational benchmarks and evidence-based medicine guidelines.

Operational Performance Reporting and Management: To deliver great care at lower costs, constant monitoring of performance to KPIs is inherent. Like quality outcomes reporting, this reporting will need to review individual providers, care teams, centers of care provision and specific established KPIs to ensure costs are in line with organizational benchmarks, via real-time access to cost per procedures, encounters, etc.

Accounting and Payment Structures: The revenue cycle is a critical element of the PHM program, as knowing the true cost of care supports the fundamental shift to value-based care and risk-shared savings. A focus on new payment and incentive structures will enable an organization to reward those practitioners who are providing high-quality care while lowering the overall costs of the provision of that care.

Integration, Infrastructure and Systems: Technology to support PHM programs must keep track of members, providers and encounters, ensuring the right information from one system goes to the right destination (system) for the right individual with appropriate data transla-

FIGURE 1: Population Health Management Maturity Model

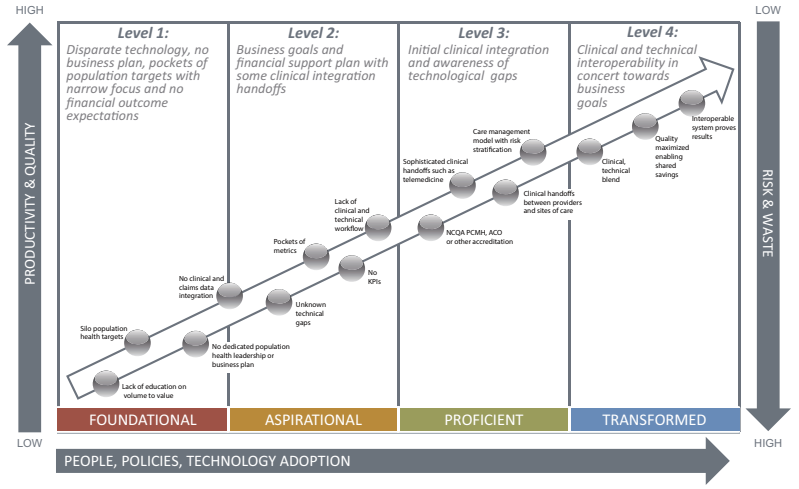


FIGURE 2: Five Pillars of Population Health Management

Business Model	Payment Models	Clinical Integration	Member & Community Engagement	Technology
Business vision, population definition, policies, modeling, financials, contracts, procedures, market analysis, and value proposition	Risk, incentives, payment management, shared savings	Workflows, role changes, people, care coaches, wellness program development, heath risk assessment process, population engagement	Active and engaging patient portal, self-service kiosks, telemedicine-home monitoring, CRM/ patient outreach, social networking, outreach marketing	Integration and interoperability including HIE, patient portal, analytics, coaching tools and health risk assessment

tion and data security. Every time a new entity or technology is added, it must be integrated into the enterprise IT solution. While many organizations take an integrated system strategy, their application portfolios typically are complex. System integration is essential to enable key decisions on behalf of providers, practitioners and organizational leadership.

A MATURITY MODEL FOR POPULATION HEALTH MANAGEMENT

Often healthcare providers ask "Where am I with regard to my PHM maturity?" It is valuable to understand the current state when it comes to planning and implementing PHM. By understanding the organization's capabilities in the seven competency levels previously outlined, then you can plan and implement key strategies and tactics to enhance those competencies and get to the next level. The ultimate goal: effectively and efficiently support the PHM business goals and achieve better health for populations, better provision of care and lower per capita costs.

There are four levels in the PHM maturity model. With advancement across the levels, organizational risk and waste is decreased, along with more productive and quality care.

1. Foundational. This level is characterized by an organization that has not spent a lot of time putting a PHM business plan together. Any PHM-supporting technology is typically disconnected and siloed between ambulatory, inpatient and ancillary systems. The organization may be struggling with defining which populations to prioritize to drive down overall costs and which metrics to use operationally and clinically to support PHM.

2. Aspirational. At this level, organizations typically have developed a business plan that incorporates some financial outcomes, as well as clinical outcomes. Clinical integration is in its infancy, and technological gaps still persist but are identified.

3. Proficient. Organizations in the proficient level have developed some mature clinical integration with care coordination and transitions of care—all while using technology to accomplish these transitions. Additionally, there are some initial KPIs to measure how the organization is doing from an operational, financial and clinical perspective in support of the overall PHM business plan, strategy and vision.

4. Transformed. At this level, the organization has developed sophisticated clinical integration at all levels of the organization; handoffs between care givers are seamless from the hospital all the way to the individual's home and the follow-up care required. Robust real-time KPIs have been established for measuring and making operational, financial and clinical decisions. The organization is truly harnessing its technology and patient-centered focus to drive down costs, maintain high quality care and keep the populations they serve healthier through proactive care management. Every level of the organization understands the PHM goals and objectives and is working to achieve those goals. The technology platform is fully integrated and consistently supports the need for real-time information for decision making, care coordination and management of members and providers.

Assessing and knowing where the organization is along the maturity continuum provides a starting point. To move along the continuum, focus on the five pillars of PHM.

THE FIVE PILLARS OF PHM

There are five distinct pillars to consider when planning and implementing a PHM program: the business model, financial model, clinical integration, member and community engagement and technology.

Pillar 1: The Business Model

The business model pillar forms the foundation of an organization's PHM planning effort. This pillar comprises the strategy, planning and vision for PHM. It includes the business plan, financial plan, staffing needs, target populations and key processes that are needed to effectively launch a PHM initiative.

The following are the high-level components that need to be addressed as part of the business model pillar:

- Defining the business vision and strategy, including a market analysis and value proposition;
- Determining what type, if any, will be the PHM partnership model (e.g. accountable care organization ,ACO, payors, employers, etc.);
- Identifying the target population(s), strategic objectives, partnerships and operational and quality metrics of success;
- Defining key program policies, including security and privacy provisions;
- Describing external marketing and communication for strategic reach;
- Creating and maintaining a budget, financials and master agreements with partners and providers (including a proforma that outlines how PHM will affect the organization's financials);
- Developing legal and compliance structure and policies; and
- Determining optimal staffing structure and needs to support PHM efforts.

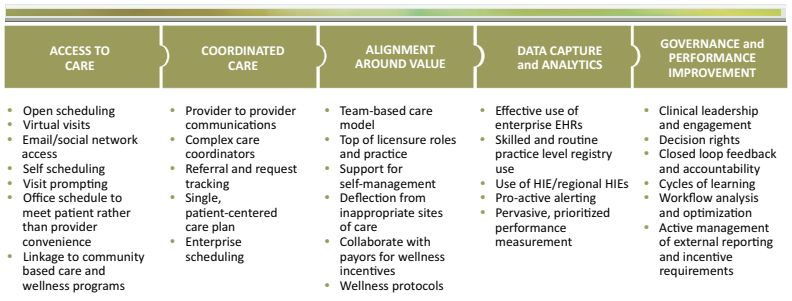
The typical outcome: the overall business plan that incorporates these high-level components. Defining the PHM model is not a small task and requires the organization stakeholders, who may have varying perspectives, to work through the plan that will propel the organization's transition to PHM forward. A steering committee is an effective tool to support this process. Start it early and include the right representatives to ensure the business plan/model is complete and actionable.

We cannot iterate this enough: it is important that none of the other pillars become a primary focus until the business model is completed and the organization has signed off on the strategic plan and vision. Many times organizations embark on the PHM journey without a fully-developed business model. This leads to miscommunication, unclear goals and objectives, and ineffective efforts across the other pillars.

Pillar 2: Financial Model

The second pillar is the financial model pillar. This is also sometimes referred to as the payment model. This is one of the more complicated pillars, because payment models are still evolving. Most systems and data repositories do not support these new payment models, which makes planning and managing the components under this pillar problematic. Additionally, managing risk sharing

FIGURE 3: Five Population Health Management Clinical Integration Areas



and incentives needs to be closely tied to the overall compensation model for providers.

The key components that comprise this pillar are:

- Performing complex risk management with partners;
- Planning and implementing structures in systems that track, manage and report on incentives for patients, consumers and providers;
- Aligning structured payment management and distribution with complex risk and incentives that can change on a regular basis;
- Systematically and operationally managing contracts that support the new shared risk/accountability models; and
- Tracking and managing true cost of care for shared savings of bundled services.

To effectively manage the new payment model, refine and evolve the revenue cycle model to address risk sharing, incentive management and new payment distribution models. Ensure the financial system is flexible enough to manage these new complex risk/financial-sharing rules, contracts and relationships. Lastly, make real-time data available for decision making and incenting the right people for the right behaviors.

The challenge around the payment model is how to best hedge the risk-sharing contract because many population risk characteristics are unknown. Several organizations are estimating a per member per month (PMPM) risk baseline for members year one on a small population to learn competencies around risk stratification and management to prepare for a renegotiation on that contract year two. This includes being aware of members whose health acuity begins to trend toward a high risk/high cost-of-care state and preventing the trend at the earliest onset of symptoms. The analytics behind this just-in-time monitoring can be challenging, as there are multiple risk stratification methods (e.g. Adjusted Clinical Groupings, Episode Treatment Groups, CMS Hierarchical Condition Category, Charlson, etc.). Additionally, many revenue cycle systems do not produce cost data (not to be confused with claims reimbursement).

Pillar 3: Clinical Integration

A fully-integrated clinical environment is the lynchpin of delivering care in this new value-based world. Support this by effectively planning and managing a clinical integration strategy and tactics across the care continuum – from the hospital to primary care locations, as well as specialty locations such as long-term care, home health, and so on.

We define clinical integration as improving the health of an entire population by coordinating services across people, functions, activities and sites over time to maximize the value of services delivered to all the individuals in a population over time and across the continuum of care. By essence of the definition, our hope is to help address many challenging components that healthcare organizations have been stretched to address with regard to clinical integration in the past. For PHM to effectively work, everyone has to work together, including the healthcare consumer.

The key components that comprise this pillar are:

- Delivering safe and effective care, coordinated across all sites and providers, following best practices based on sound evidence;
- Reducing error and inefficiency in care delivery processes, including transfer of care, providing maximum value from the perspective of the consumer;
- Achieving real-time knowledge about individual and cohort health status and trends, as well as identifying opportunities for timely interventions that increase quality and decrease cost; and
- Providing the highest level of safe, effective and efficient care in the lowest intensity site of care, reducing demand for expensive, complex hospital-based services.

PMH clinical integration is a family of organization skills, competencies and behaviors that form a fabric of awareness and support to achieve the overall goals of PHM. PHM clinical integration includes five distinct areas to be incorporated when planning and managing cross-continuum integrated care.

The challenge we have seen with clinical integration is around acceptance of the new way to provide care as a care team. A proactive approach requires a focus on change leadership, PHM education to all staff and constant communication as processes evolve for best care, while supporting a standard of care. Do not make the mistake of buying a technology product first and then attempting to retrofit it to a clinically integrated workflow. It is essential that the workflow of the care team be defined before the technology is designed to support it.

Pillar 4: Member and Community Engagement

The whole premise of PHM is around members becoming accountable for their care along with the provider. Gone are the days when the provider is reactive to a member coming in for a visit; providers must now proactively reach out to assure the member is following a care plan.

The key components that comprise this pillar are:

- Engaging consumers as active partners in their care planning and encouraging personal ownership of health decisions and behaviors;

- Implementing a consumer portal to link consumers to the provider network with the ability to push and pull information, as well as enter and validate consumer data;
- Installing kiosk technologies that support self-scheduling, previsit data collection and account management;
- Providing telemedicine that offers real-time monitoring from the home to enable early intervention for complex and high-risk conditions;
- Doing member outreach and cohort-specific engagement and providing wellness messaging and alerts for overdue interventions;
- Delivering consumer education and enabling feedback via social networking, as well as consumer-driven support and interest groups; and
- Developing outreach marketing to educate population members of program benefits.
- The challenges with engagement revolve around how to reach the members through the best route of communication. In the CHIME focus group mentioned earlier, the most effective tool for engagement cited was the telephone. Other avenues include the internet and mobile devices for surveys, member-reported outcomes, provider messaging, alerts and fitness tracking.

PILLAR 5: TECHNOLOGY

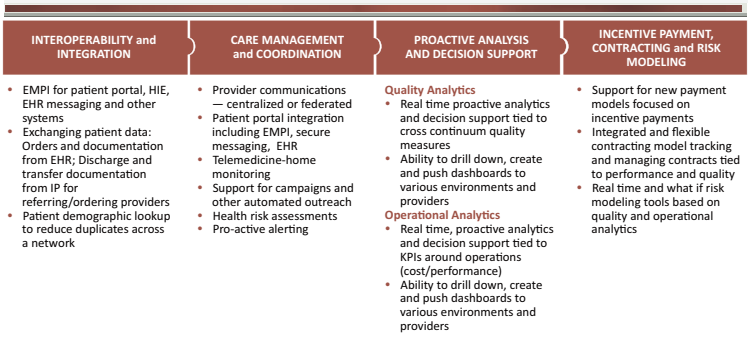
The fifth pillar is technology—specifically, the technology that forms the underpinning of a PHM strategy. PHM cannot be undertaken without a solid, integrated and robust technology platform. This platform needs to address interoperability, messaging, cross-continuum care management, protocols and transitions, data analytics for operations and quality, financial and risk-sharing systems that support the new payment model and incentives.

There are over 150 vendors in the marketplace today providing PHM solutions for healthcare providers. It is no easy task to figure out which tools are most effective in filling the holes in the current portfolio and what current vendors can do or will soon be able to address. Most organizations choose, and rightfully so, to make the most out of their core clinical and financial systems. However, some core systems today lack robust analytics to support a patient-centered medical home and are not yet able to incorporate the financial and risk functionality outside of the traditional ambulatory/inpatient payment models.

A good first step is to review, assess and determine the organization's technology maturity in the following four areas depicted in **Figure 4.**

We have identified over 250 technology requirements that fall into the four areas outlined in this chart. Assess the requirements; determine what is needed, when it is needed, and where to find it within or outside the organization. It is important to know the business and clinical integration strategy before you determine what technology is needed. Otherwise, it can be overwhelming and costly. As mentioned earlier, try to accomplish as much as you can with the existing systems rather than go out and purchase net new systems that have to be integrated back into an already complex environment.

FIGURE 4: Technology Areas of Focus for Population Health Management



PHM IN ACTION: A CASE STUDY

In 2011, a multistate health system changed focus to address accountability. Under the framework of the PHM Maturity Model, they would have been considered in the foundational category at the time. Care teams were siloed, only existing for episodic care. Multiple EHRs were used across care sites (some with patient registries) and not coordinated into an overall care system. No leader was responsible or accountable. Stakeholders were not aligned on how to make the shift from volume to value.

APPLYING THE FIVE PILLARS

The health system made significant strides in developing their business and financial models, evolving clinical integration, engaging members and communities in the effort and advancing their technology to support the PHM goals. Some examples across the five pillars are shown next:

Business Model: A business plan was created which defined the vision, mission, goals and initial structure for the business unit, with a two-year roadmap. A medical director was identified to lead the program and given responsibility and accountability. Initial financing for the office, staff, systems and other expenses was approved. The initial target population was defined. In this case, the definition was any member who was paneled to a primary care provider (PCP) within the health system. The enterprise definition of a panel was not yet standard, but many individual facilities limited the population to those with a visit in the last 3.5 years.

A market analysis showed that a focus on complex care was needed, defined as those with more than one disease state. The value proposition was focused on reducing emergency department visits, inpatient admissions and readmissions. This standard model of care would be created and rolled out to each primary care practice across the enterprise.

Financial Model. The health system

Challenges and Lessons Learned

Organizations working to get to good and then beyond to great with regards to their population health management initiatives have discovered insights valuable to others at varying points in their journey. Keep these in mind as you build and implement the program:

- Evolve the business plan to adjust to market and population changes and define return on investment (ROI) to support increased resource requirements;
- Consider an HRA tool to understand and stratify risk to better bear the risk given the number of members without claim data to evaluate the risk;
- Define incentives for value-based compensation;
- Provide oversight required to assure a consistent care team role definition, protocols, policies and IT use;
- Invest in effective change leadership to support the rollout of the new model, new roles and the new care team approach;
- Evaluate workflow and technology gaps and build the roadmap;
- Get stakeholder alignment for volume to value shift;
- Achieve seamless integration between the EHR and the care management module;
- Report on the care management assessment and protocol answers that are needed to trend behavior; and
- Don't forget training and education.

accepted a per member fee, bearing risk on an insurance plan membership pool. No other contracts have been implemented.

Clinical Integration. There has been a concerted focus on standardizing care across care teams. There were leaders and teams defined for focus areas such as prevention, access, chronic condition management, team-based care, care transitions, care coordination, palliative care, community engagement, wellness and member engagement. These teams defined standards and measurements, staff was trained and the standards were implemented at pilot sites. As an example, for the team-based care area, initiatives included development of oversight structure for protocols and nursing education, team care model development, communication improvement among team members, role definition, ensuring clinicians operate at the top of their licensure and nurse-only visit support.

Standardization has focused on several objectives including promoting self-management skills, shared decision making and wellness; creating a team-based, navigable, coordinated care system that promotes the right level of care at the right time and using automated tools within the care team to promote proactive management of patients with chronic conditions.

Member and Community Engagement. The standardization efforts extend to engaging communities and public health organizations to help address social determinants of health that have a disproportionately large impact to the overall health of the population and the cost of healthcare. Specific initiatives have been funded and launched for shared decision making, patient-reported outcomes, telemedicine and eHealth. Examples include a patient portal and enhancements to the existing mobile phone app. Health risk assessment tools are used to obtain health status for possible care team management.

Technology Integration. The organization implemented a population analytics system with integrated claims, EHR lab and other results, risk stratification and robust dashboard capabilities. A care management system has been implemented in pilot sites. Because of the lack of closed loop between the population health analytics and care intervention documentation and the EHR, the organization has three pilots to test approaches.

ACHIEVING RESULTS

Initial results are trending positively in the pilot sites. Some results include:

- Increased overall PCP assignments, as well as PCP assignments for individuals with high emergency room utilization;
- Launch of a wellness navigator program;
- Improved care team understanding of prevention requirements;
- Decreased 30-day readmission rate; and
- Improved quality outcomes for hypertension.

The benefits include not only achieving these goals, which show progress to improved care and standardization, but also increased awareness of the paradigm shift within the pilot sites.

NEXT STEPS

In just two years, the health system now has KPIs, supporting technology systems, and some clinical integration, which has moved them along the maturity continuum. In order to achieve the next level on the population health maturity model, they are working toward sophisticated handoffs between not only the care team members but also different sites of care.

CONCLUSION

Implementing a PHM initiative can be a daunting task, and many organizations waste time, money and resources on processes and systems without moving from good to great. Fortunately, as described in this article, by understanding the seven PHM core competencies and following the five pillars of PHM to move across the maturity continuum, the resources applied can result in measurable value and new behaviors in alignment with the paradigm shift from volume to value. **JHIM**

Gregg Mohrmann, MPA, PMP, Six Sigma Green Belt, is a principal with Aspen Advisors, a leading national healthcare consulting firm. Mohrmann is the head of Aspen's Population Health Management Center of Excellence (COE), as well as a regular contributor to JHIM. He can be reached at: gmohrmann@aspenadvisors.net.

Claudia Blackburn, MBA, PMP, CPHIMS, has 15+ years of experience directing healthcare technology projects in health system and physician practice environments. Blackburn's PHM involvement includes serving as System Director to create an accountable care initiative at a Gulf Coast health system. She co-developed Aspen's PHM framework and co-leads the PHM COE.

Vincent D'Itri, BS, PMP, draws on his healthcare operations, project management, business analysis, implementation and analytics experience to serve health plans, health systems and ACOs. D'Itri is an active contributor to Aspen's PHM COE and co-developed a vendor matrix that catalogs vendor capabilities to the 250+ PHM technical requirements.

FOCUS

BIG DATA AND POPULATION HEALTH MANAGEMENT

Mind the Gap

Identifying Critical Data Quality Gaps to Unlock Population Health Management

By Michael A. Simon, PhD; Zachary Baum, MSc; Lindsay Lebel, BS; Leanne Harvey, MBA; Bill Gillis, MS

ABSTRACT

Improving the health of at-risk, vulnerable and chronically sick populations remains a daunting challenge for the healthcare community. Social, cultural, hereditary, economic and geotemporal issues stymie traditional approaches to care and complicate efforts at controlling medical costs. Management of complex populations requires comprehensive and reliable data on patient health and demographics. However, many of the actors in the healthcare ecosystem possess only an incomplete or imprecise picture of the populations in their care.

We present a study by Arcadia Healthcare Solutions and Beth Israel Deaconess Care Organization on data fidelity showing that, while there is profound variation between the sources of data gaps, the flaws leading to these gaps can be classified along three axes: Capture, representing the accurate acquisition of the desired data elements into storage; Structure, representing the storage of the information in a format appropriate to its use; and Transport, representing the means by which data are transmitted and reported. Using this model, our gap analysis identified several clusters of data integrity issues based on a set of nationally-accepted standards.

Our analysis revealed that a targeted effort to improve transport mechanisms would have the most profound and broad-reaching impact on these providers' ability to understand and treat their sickest patients. Further analysis on this dataset reveals additional actionable, targeted, and timely interventions that can improve provider quality reporting and population management. By highlighting data gaps in a targeted fashion, this model provides the key to focused population management, leading to improved quality measures and incentive revenues.

KEYWORDS

Data quality, electronic health records, health information exchange, medical informatics.

In the face of dramatic upheaval in the delivery of healthcare – from fee-for-service to value-based-payment, independent providers to clinically integrated networks and payer-based risk to risk-sharing contracts – the importance of population health management (PHM) has become evident to all stakeholders in the healthcare marketplace. Yet successful PHM is not dictated by a provider's ability to manage a single population. Successful providers will demonstrate themselves by their ability to manage multiple populations on differing levels and timescales of risk. As providers transition to EHR systems – in 2013, 78 percent of office-based physicians used an EHR system, up from 18 percent in 2001[1] – the population health planner is within reach of copious and diverse sources of healthcare data. Health IT is on the cusp of Big Data.

The power of Big Data applications to drive effective healthcare analytics has the potential to revolutionize population health management.[2] Health care informatics could very well be the poster child for the five 'V's of Big Data: Volume, Velocity, Variety, Value and Verification. The sheer quantity, heterogeneity and speed with which new healthcare data are generated certainly fit the requirements,[3] and the potential value of these data for healthcare stakeholders, and to the challenge of pop-

ulation health management, in particular, has not gone unnoticed.[4]

Verification, the fifth 'V' in that list, requires some additional scrutiny. As millions of health-related records are generated every day from diverse sources – EHR, claims, billing, appointment and customer relationship management systems, just to name a few – the trustworthiness of the data held within these systems has been called into question,[5,6] and a standard for the verification of the quality of these sources has yet to emerge. Despite no lack of attention to the challenge of identifying data quality gaps, data quality analysis remains an ad hoc process, subject to local pressures and tendencies.

Even defining a data quality gap properly presents an analytic challenge.[7] All of the following qualify as data quality issues one might encounter in an EHR:

- Erroneous patient identifiers, including a missing social security number, misspelled name, incorrect sex, or transposed date of birth.
- A standard numeric metric, such as blood pressure, written in text in encounter notes or medical history rather than in appropriate structured fields.
- Generic diagnosis codes entered quickly or out of habit instead of more specific and actionable diagnosis codes appropriate to the patient.
- Crucial radiology images absent from reports, resulting in insufficient information to consult or verify a diagnosis.
- Inconsistent entry of standard codes, such as National Drug Catalog (NDC) and Logical Observation Identifiers Names and Codes (LOINC) codes, derailing bulk analysis.

All of these cases involve very different causes and data sets, and result in different types of gaps. Some arise as a result of standard reporting configurations that fail to transmit crucial information. Others are the result of clinical practices, which may stem from EHR configuration, organizational workflow or even user personalities.[8] Regardless of the cause, concerns about the quality of healthcare data generated in the clinical environment threaten to derail efforts to derive organizational and public value from healthcare data sets.[6]

The diversity of quality gaps has made the challenge of addressing them ever more complex, splintering these issues across different areas of the clinical workflow (i.e. who enters the data) and different components of the healthcare IT environment (i.e. which system captures the data). There have been a substantial number of efforts to quantify data quality in EHR systems,[7] often in the context of a particular need,[9,10] and typically with a focus on correctness and completeness of data entry.[11]

While errors and gaps in data entry are demonstrably harmful to the mission of population health management,[12,13] the attention paid to the capture of information may have come at a cost to consideration of data quality degradation following entry. The effects of clinical workflows and system configuration can have an equally deleterious effect on the *fitness for use* of an EHR system, to paraphrase a classic definition of quality.[14] This will likely become especially critical for large organizations with multiple, diverse systems and spread across numerous organizational entities with different habits and cultures.

To address the challenge of quantifying and qualifying EHR data quality gaps, we developed a model capable of identifying a wide range of data quality gaps and assigning specific impacts based on independent factors. Here, we describe that case study exploring data quality gaps, as well as the model that emerged from that process. We also describe how these results can be applied in a practical setting to create targeted and effective plans for data quality improvement and discuss the impacts of such improvements on clinical and operational effectiveness.

CASE STUDY

Beth Israel Deaconess Care Organization (BIDCO), a physician and hospital network with over 2,000 providers in the Northeast United States, sought assistance from Arcadia Healthcare Solutions in identifying sources of flaws in an existing clinical measure reporting infrastructure.

To assist BIDCO with its reporting requirements, each practice EHR system transmitted a data feed nightly to a third-party analytic tool, which would calculate a set of quality measures for reporting. These data feeds were formatted according to vendor-defined Coordination of Care Document (CCD) Specifications v.C3216, which were the only source of clinical data for the analytic tool. BIDCO analysts had identified inconsistencies in the measures reported and, due to the number of systems involved in data storage, transmission and analysis, were unable to identify the source of the data quality issues.

For the purposes of this study, Arcadia consultants and BIDCO subject matter experts (SME) examined four practices with a total of 5,800 patients served by 50 providers. Of those 50 providers, all use the eClinicalWorks (eCW) Electronic Medical Record platform. Although model parameters were chosen to fit the configuration of the eCW platform used at these practices, our consultants report similar types of quality issues with other platforms, as well.

DATA QUALITY ANALYSIS

Data quality can mean many things, ranging from predictable data encoding errors to complete corruption or even absence of data. In their review of EHR Data Quality Assessments, Weiskopf and Weng[7] proposed a mapping between dimensions of data quality – How do we define the function of quality? – and methods of assessing data quality – What criteria do we test data against? This case study focused on processes that would cause reported measures to fail to correspond with the captured data. Therefore, we were primarily focused on dimensions of Concordance, Plausibility and Currency: Does the EHR offer a valid, plausible and relevant representation of patient state at the time of reporting?

QUALITY MEASURES

For the purposes of studying potential data quality gaps, we tested existing EHR data against a subset of ACO quality measures issued by CMS[15] (Table 1). These standards are nationally recognized clinical indicators, with corresponding indicators in other standards sets, such as the Health Effectiveness Data and Information Set

(HEDIS) from the National Committee for Quality Assurance (NCQA).[17] Each measure was defined by a set of metrics (e.g. How many male patients 45 and older?), which were the basis for calculation of a measure denominator (number of patients applicable to the measure) and numerator (number of patients compliant with the measure).

TIERED CRITERIA

To isolate the sources of the measurement reporting errors, we calculated metrics using three tiers of inclusion criteria meant to simulate available clinical data at each step in the data flow (**Figure 1**). These tiers, or "cuts", were based on previous data quality assessment experience, manual examination of patient records and interviews with clinical staff (Figure 2):

The Reported Cut only included data elements that would be available for external reporting. In this case study, the criteria were based on the vendor-specific CCD feed, which was the primary mechanism for populating external analytic and reporting tools. Although CCD feeds follow a standard specification,[16] vendors may define how the CCD feed is populated. Because the existing analytic platform was limited to clinical data from the CCD feed, the Reported Cut was the most limited dataset.

The Structured Cut included only structured data elements. In this case study, the criteria for structured data elements included any elements represented by a code (e.g. NDC code, International Classification of Diseases (ICD) code, vendor-specific code), number or date. This level of inspection added patients for inclusion or compliance whose data were mapped to structured fields that would not normally be captured for reporting by the CCD feed. Although the identity and storage location of structured fields varies by EHR vendor, the data elements identified in this tier are represented as a structured field in most EHR platforms.

The Unstructured Cut included all available, appropriate data elements, both structured and unstructured. Unstructured data elements included free-text and note fields and contained data in the form of a known pattern (e.g. "'mammogram' NOT 'ordered'") or an incorrectly formatted string (e.g. "7.6%" instead of 7.6). For any data to be included in a measure calculation, the data: 1) must have been entered in some form by clinical staff; 2) must have been entered in a known location 3) and must have been entered in a predictable format or phrasing. Nonetheless, cases that do not meet these criteria may exist and would have represented data quality gaps that this study does not quantify.

TABLE 1: Case Study Measures

Measure	Measure Description
14	Influenza Immunization
15	Pneumococcal Vaccination
17	Tobacco Use: Screening and Cessation Intervention
19	Colorectal Cancer Screening
20	Breast Cancer Screening
22	Diabetes: Hemoglobin A1c Control (<8%)
23	Diabetes: Low Density Lipoprotein (LDL-C) Control
24	Diabetes: High Blood Pressure Control
25	Diabetes: Tobacco Non-Use
26	Diabetes: Aspirin or Antiplatelet Medication Use
27	Diabetes: Hemoglobin A1c Poor Control
28	Hypertension: Controlling High Blood Pressure
29	Ischemic Vascular Disease (IVD): Complete Lipid Profile and Low Density Lipoprotein (LDL-C) Control
30	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic
32	Coronary Artery Disease (CAD): Lipid Control

DATA EXTRACTION AND ANALYSIS

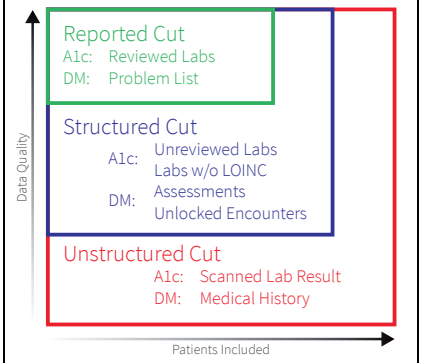
For each tier, metrics appropriate to the measure were calculated based on the criteria for inclusion in that tier. Data were extracted directly from provider EHR platforms using Structured Query Language (SQL) interfaced with a database running MySql (Oracle Corporation). Measure calculations were based on ACO Narrative Specifications from CMS.[15] Initial aggregation was conducted using SQL and measures calculated from aggregated data using Microsoft Excel (Microsoft Corporation). All activities were conducted according to HIPAA regulations and best practices for preservation of patient anonymity. The model presented here is based entirely on previously collected aggregated data and required no involvement from patients.

DATA QUALITY MODEL

The Data Quality Model was based on a need to identify data quality gaps anywhere from capture to reporting. The model was intended to specifically highlight the sources of compromised data quality and their impact on measure calculations.

When are data quality gaps introduced into the system? Some of the most prevalent data gaps were identified between the Reported Cut and the Structured Cut. Two measures – Colorectal Cancer Screening and Breast Cancer Screening – were reported as 0 percent compliant using the Reported Cut, whereas the Structured Cut revealed compliance between 80 and 95 percent. This failure to report information that was clearly properly structured in the system indicated that this class of failure represented an issue with data transport.

FIGURE 1: Patient Health Information Data Flow



However, there were also significant data quality gaps between the Structured and Unstructured Cuts. Influenza vaccinations were underreported by 20 to 30 percentage points in both Reported and Structured Cuts compared to the Unstructured Cut. This failure represents an issue with data capture and storage that inhibits future options for reporting and analysis.

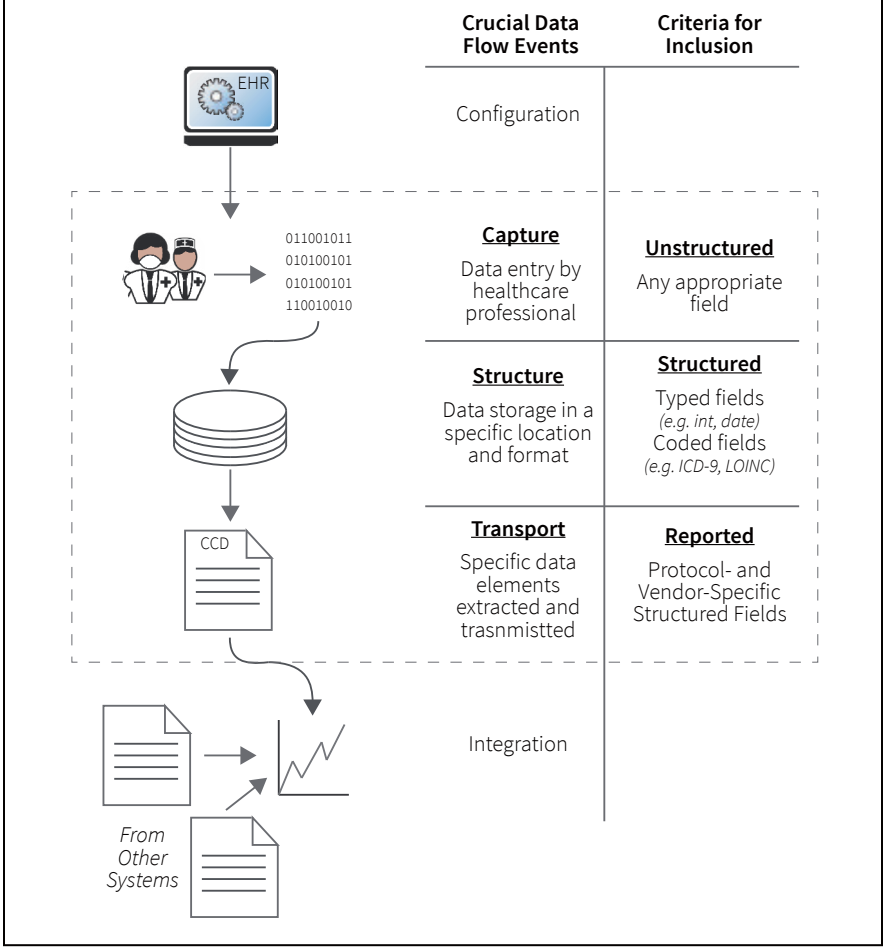
Based on this analysis, consultants identified several points critical for safeguarding data quality in the data flow (**Figure 1**):

Capture represents the stage at which clinical professionals (e.g. MD, RN, MA) and/or automated systems (e.g. lab results) enter data into the EHR. Valid data capture requires that a clinical event happen – e.g. a patient encounter or a returned lab result – and that the results be accurately entered into the system.

Structure represents the process by which captured data are stored in an appropriate format and location. Valid structure depends both on the way in which the data are entered, as well as on the configuration of the EHR platform. If an integer is entered into a text field, its accessibility for reporting and analysis is reduced. Even if it is entered in a structured field, however, if the template is not mapped configured properly, the value may still be stored to an inappropriate location.

Transport represents the process by which data are extracted from storage and made available to external systems for reporting or analysis. In the absence of a direct ("back-end") database connection, not all pertinent data would be included in an extract. Which fields are extracted, and how records are selected for inclusion, are characteristics of the Transport mechanism that impact the quality of outgoing data.

FIGURE 2: Tiered Inclusion Criteria for Patient Counts



How are the data quality gaps affecting results? Data quality issues were identified based on changes in population counts between the Reported, Structured and Unstructured criteria for inclusion.

For example, two of the metrics needed to calculate Measure 22 (Diabetes: Hemoglobin A1c Control (<8%)) were whether the patient was diagnosed with diabetes mellitus (denominator) and the results of the most recent circulating hemoglobin A1c (HbA1c) lab test in the measurement year (numerator), labeled "DM" and "A1c", respectively, in **Figure 2**.

For the A1c metric, lab tests that were marked as reviewed by a provider and that included a standard LOINC number were captured in the CCD and sent to the reports (Reported Cut). If the lab order was present, assigned a vendor-specific code and returned with a value, the order and result would still be stored unambiguously, even if not captured by the CCD (Structured Cut). A lab report could also be scanned in by the provider's office and stored as an image, thus making the information available in the medical history but not in a structured format accessible to external analytic tools (Unstructured Cut).

Similarly, for the DM metric, diabetes

TABLE 2: Data Source Types

Category	Category Description	Source Data Elements (Ideal location bolded)	Quality Gap Root Causes	Affected Measures
Diagnoses	Any indication of a diagnosis (e.g. ICD-9 code, encounter note)	ICD-9 code in Problem List, Assessments, Encounter Dx, Encounter Notes, Medical History	Listing in assessment/encounter Use of Encounter Notes or Medical History	22, 23, 24, 25, 26, 28, 29, 30, 31
Vitals	Measurements taken by care staff during an encounter (e.g. heart rate, blood pressure)	Structured number in vitals table, with a specific field identifier, Encounter Notes, Medical History	Clinically correct fields not captured by reporting feed Use of Encounter Notes or Medical History	21, 24, 28
Lab/Orders	Laboratory Orders and Results (e.g. LDL, HbA1c)	Coded, reviewed lab with LOINC code in labs table, Encounter Notes, Medical History, Scanned Document	Lab result unreviewed by provider LOINC code absent Lab result entered with units (e.g. "8%") Use of Encounter Notes or Medical History Lab result image scanned	22, 23
Medications	Medication history and current status	Entry in medications table with NDC code, Encounter Notes, Medical History	NDC code absent from entry Use of Encounter Notes or Medical History	22, 23, 24, 25, 26, 29, 30, 31
Procedures	Procedures conducted separately from the encounter (except labs)	Entry in diagnostic imaging table with lab or procedure code, Encounter Notes, Medical History, Surgical History	Result not captured by reporting feed Use of Encounter Notes, Medical History, or Surgical History	19, 20, 21
Contraindications	Allergies, alerts, and any other non-demographic patient condition meriting an exception	Entry in Problem List with NDC code, allergy table, medication table, Encounter Notes, Medical History	Use of allergy or medications table Use of Encounter Notes or Medical History	14, 15, 18, 19, 20, 21, 26, 29, 31

mellitus diagnoses listed explicitly in the problem list would be captured in the CCD Feed (Reported Cut). If the diagnosis was not in the problem list, but an assessment had been conducted and the diagnosis coded properly, the data could still be extracted as structured data (Structured Cut). If the provider only mentioned the diagnosis in an encounter note or medical history (free-text) a pattern search of the patient's medical history could reveal the presence of the diabetes diagnosis and identify this individual as a diabetic patient, but such an outcome would not be easily accessible to traditional analytic tools (Unstructured Cut).

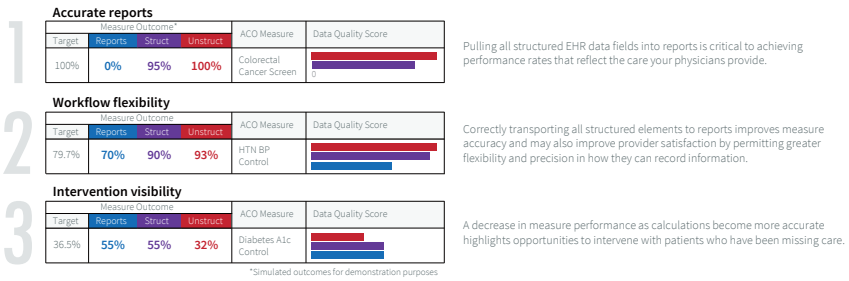
Measure 22 is only one example of how a measure may depend on numerous metrics – in this study, 8 separate metrics were necessary to calculate Measure 22 – each of which may change depending on the measure. A summary of the vulnerable data sources identified can be found in **Table 2**, described next.

What are the root causes of the data quality gaps? Identifying the root causes of the data quality gaps was initially a daunting task due to the sheer number of data elements fed into each measure. Each of the 15 measures used in this study were composed of between 4 and 23 metrics, like an asthma diagnosis or cholesterol test results. 72 distinct metrics were identified as relevant to this study, each of which might make use of multiple data elements. The number of different data sources involved in measure calculation is one of the factors that makes tracking data quality gaps so challenging – another is the complexity of the measure definitions[18] – so identifying patterns in the quality gaps was essential to establishing the root causes of the gaps and developing actions to address those issues.

We approached this challenge by associating each metric with one or more data element types. For example, the numerator of Measure 23 (Diabetes: High Blood Pressure Control) calls for the most recent blood pressure reading. Therefore, that metric was assigned to the "Vitals" data element type. The denominator fell into the "Diagnosis" category, because only diabetic patients were included, and certain diagnoses excluded those patients, as well.

After characterizing all metrics, removing gap-free categories, and combining overlapping categories, we arrived at six categories of data element sources: Diagnoses, Vitals, Labs/Orders, Medications, Procedures, and Contraindications. Each source was associated with the most sig-

FIGURE 3: Examples of Quality Impacts Based on Model Results



nificant root causes of data quality gaps identified during the analysis and measures most substantially impacted by those data quality gaps. The source categories, "ideal" data elements, root causes for quality gaps and associated measures can be found in Table 2.

DISCUSSION

The data quality assessment performed in this case study had the effect of identifying the sources of the quality gaps, both in terms of what agents were contributing to the issues and at what points in the work flow they were occurring. However, it also provided insights into the root causes of these issues, based on a set of relatively straightforward categories.

This classification scheme offered two advantages: First, it simplified the process of describing measure dependencies. Compared with thinking about 15 disparate clinical measures with hundreds of metrics, binning each of those measures into one or more of six sources made describing outcomes more straightforward. Second, by dividing the sources into six categories, we were able to prioritize actions not only by workflow (Capture, Structure, Transport) but also by data types. Such an arrangement more clearly delineates the options available to decision makers, as well as the specific impacts of those improvements (Figure 3). As one individual in the client's leadership team put it, "If you can make me understand all these data, you can make anyone understand it."

TRANSLATION INTO ACTION

The specific identification of data source issues was a key requirement for this study, but by combining the breakdown of the primary gap sources along with the workflow pinch-points (Table 2), a set of specific recommendations could be advanced.

The most immediately obvious points of failure arose during Transport. A substantial improvement in data quality could be yielded simply by adding diagnostic imaging procedures such as mammograms and colonoscopies to the CCD. Additionally, lost blood pressure measurements could be recovered by adjusting the reporting mechanism to search for and accept any of the ten structured and potentially clinically relevant vital fields representing blood pressure – permutations of sitting, standing or supine, for example, rather than only the Primary blood pressure field.

Recovery of coded information lost due to Structure failures also represented a rich source of quality improvement. By reconciling medications captured without NDC codes, data gaps in 8 of the 15 measures could be closed dramatically. Similarly, accuracy of lab-related measures, like Measures 22 and 23, suffered from gaps related to missing LOINC codes or results. For some cases, like those with scanned-in or entirely missing results, re-capturing/structuring the information will require manual intervention, but for many other cases, such as recovering missing codes, an automated repair process may be a much more effective option.

Ultimately, improvement priorities are a function of the impact on outcomes and the availability and priorities of resources. By mapping out the steps ahead, we found this model to be an effective tool for informing the quality improvement process.

IMPLICATIONS FOR EHR CHOICE

The impacts just discussed relate to clinical workflows and EHR configuration, both key to effective data quality. However, in the process of identifying sources of data quality loss, we came across EHR-specific characteristics that directly or indirectly impact data quality, as well.

The Structure stage of data flow is clearly impacted by where and how data are stored. EHRs fall generally into two camps in this regard: Some EHRs maintain a strict and consistent data model, which enforces internal Reporting consistency; it may also result in a mismapping of local concepts and practices to the system data model and failure to Capture to the intended location. Other EHRs allow administrators to create flowsheets or templates that map to local concepts and workflows; however, if these newly-created tables are not also mapped to existing reporting systems, the change may result in a failure to Report complete patient records.

Quality is also impacted by the platform philosophy toward workflow. EHRs that allow administrators to customize workflows are more accommodating to local practices, processes, and preferences. However, the additional configurability is bought at the price of increased likelihood for the data quality errors identified in this study: incomplete capture, incorrect structure, misplaced transport. EHRs that require users to follow a consistent path, "clicking" through a set of required screens for each defined activity, are less likely to suffer these issues. However, such "locked-down" workflows are more likely to be subject to frustration, workarounds, and inaction. In extreme cases, the set workflow may go against clinical best-practices, forcing providers to choose between system compliance and their clinical knowledge. This characteristic most closely matches the target of the intense (and public) ire of

SUCCESSFUL POPULATION health management, while dependent on dedicated and effective clinical care, will also ultimately rely on accurate and comprehensive healthcare data.

providers who find they must spend more of their patient-facing time instead facing the computer and their hands-on time instead clicking a mouse.

Clearly, balance is needed. We are not aware of a perfect solution at this time. Using the analysis described here, however, we suspect that a better understanding of the scale of data quality issues, as well as the roots of those issues, whether based in EHR configuration or provider practices, will help individuals make more effective and evidence-based EHR procurement and configuration decisions for their organizations.

LIMITATIONS

A limited sample set was used for this pilot study – 4 of BIDCO's 80 practices, representing only one EHR platform – and so the specific outcomes of the model are not necessarily applicable to all organizations. Ongoing research will establish both the scalability of the technique and the results. More importantly, however, the model employed here is specifically agnostic to the EHR platform employed. This methodology offers a rapid means to identify data quality issues related to workflow and EHR configuration. It also clarifies pathways to improved operation by specifically enumerating the sources of data quality gaps. Off-the-shelf technology can be used to conduct this analysis, making this model highly accessible for organizations interested in identifying gaps.

As previously discussed, this model did not assess the validity of entered data – Weiskopf and Weng's Completeness and Correctness criteria[7] – instead focusing on quality gaps caused by EHR configuration and provider workflow. Assessing the accuracy of captured data for high-throughput analysis would have required a criterion standard against which EHR data elements could be compared; no such criterion standard was available. Nonetheless, it is possible to infer a likelihood of error based on existing data. For example, the presence of a diabetes mellitus (DM) diagnosis in a Problem List for a patient with no DM-related encounters in recent history indicates a potential gap in reporting, but it also calls into question the reliability of the Problem List and indicates a potentially important area of attention for that patient's physician. If the patient is not diabetic, the Problem List should be updated. If he is diabetic, it is now particularly important that a member of our patient's care team check on his status.

Although this model has been tested on a set of recognized national standards, its ability to fulfill other data quality assessment needs requires further testing. Efforts toward achieving population health management on a broader scale will depend not only on clinical data but also on demographic and socioeconomic factors. Identifying capture, storage and reporting gaps for such data elements will be crucial; the additional source categories and data error types that emerge from such an analysis will be important additions to the model proposed here. And, as the value of care teams in conducting Patient-Centered-Medical-Home-style care-coordination rises, traditional EHR workflow and reporting will not be adequate for patient-focused activities like pre-clinic "huddles."[19] Generating patient-focused and scenario-relevant reports will only increase the importance of data quality gap analysis that is both flexible and actionable.

CONCLUSIONS

Successful population health management, while dependent on dedicated and effective clinical care, will also ultimately rely on accurate and comprehensive healthcare data. The advent of powerful data mining tools to fuel the Big Data revolution provide a fortuitous and enabling infrastructure for healthcare, but that revolution will not be possible without a means to identify and correct quality gaps in healthcare data. Here, we present a model for identifying data quality gaps in electronic health records. By specifically categorizing points

of failure and identifying the most prevalent data element types for those failures, this model not only elaborates when, where and to what degree data gaps are incurred. It also clarifies what can be done to resolve the issues. In that way, this model gets closer to the goal of advanced health information technology in clinical transformation: By tying into knowledge of the underlying populations, improved quality of data enables improved quality of care. **JHIM**

Michael A. Simon, PhD, is Principal Data Scientist at Arcadia Healthcare Solutions focusing on developing analytic tools and platforms to increase the value and utility of healthcare data.

Zachary Baum, MSc, is a Senior Consultant at Arcadia Healthcare Solutions and champion of EHR data quality, illustrating through EHR analysis and care team interviews how data quality gaps can be identified and resolved.

Lindsay Lebel, BS, is a Practice Consultant at Arcadia Healthcare Solutions working on data-driven improvements in healthcare quality across a range of systems, including a community-based insurance program in Cambodia and a Pioneer ACO in New England.

Leanne Harvey, MBA, is the Director for Electronic Health Records at the Beth Israel Deaconess Care Organization responsible for EHR Optimization and improving data quality and completeness for community-based providers.

Bill Gillis, MS, Chief Information Officer for Beth Israel Deaconess Care Organization. Gillis has 17 years of healthcare experience specializing in EHR, HIE & interoperability strategies, technologies and deployments.

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FEATURE Direct Pay

The Impact of Direct Pay Medicine on Health IT Use

A Pilot Study

By Divya Srinivasan Sridhar, PhD

ABSTRACT

This pilot study analyzes the attitudes, usage and implementation of health information technologies (health IT) and meaningful use (MU) policies by *direct pay* medical practices (also called concierge medicine, direct primary care and other terms). Direct pay practices vary by subscription/payment model (either fee-for-care (FFC) or fee-for-service (FFS)) and participation in health insurance (pure vs. hybrid practices), which accounts for differences in health IT utility and MU participation.

The researcher emailed an electronic survey to over 300 direct pay practices, of which 180 direct pay practices responded between October 2013 and January 2014. Survey results were analyzed utilizing multinomial and binary logistic regressions.

Ninety percent of the practices use EHR systems. The pure and FFC practices also differed significantly from hybrid and FFS models on utility of health IT and participation in MU objectives. Pure and FFC practices have 1) lower functionality for EHRs for electronic claims, decision making and public health reporting, and 2) reduced interest and participation in MU of health IT (RRR=0.02, $p<0.05$), due to a lack of financial incentives to participate (RRR=23.98, $p<0.05$). FFC practices are more likely than FFS practices to use telemedicine, personal health records (PHRs), and mobile health applications (RRR=0.04, $p<0.05$).

The health IT use of direct pay practices impacts the broader community, because they are not participating in data sharing and exchange, public health reporting and quality measurement. The government should encourage encrypted data capture and sharing through incentive payments specific to direct pay EHR functionality.

KEYWORDS

Direct pay, retainer medicine, electronic health record (EHR), mobile health, meaningful use (MU), health policy, health IT, adoption rate.

While the rate of EHR adoption has increased rapidly, averaging 70 percent for small practices (1-5 physicians), a recent poll found that 70 percent of organizations do not feel that they are making the most of government "Meaningful Use (MU)" objectives.[1,2] Adoption of EHRs, participation in MU and a number of other regulatory reforms that require heavy commitments of resources and social and financial capital were part of the HITECH Act of 2009 and Affordable Care Act (ACA) of 2010. These reforms increase the costs, work flow problems and medical errors that private practice physicians face and produce discomfort and anxiety for providers and patients in the short term. A growing trend for private physicians has been to close down and join a hospital system,[3] or to join a unique subset of the private practice physician population that opts out of accepting traditional health insurance and engages in direct pay. Because loss of private practices to hospital settings has been linked to lower productivity and reduced continuity of care, my study focuses on participation in direct pay and analyzes the impact of HITECH policies on direct pay physicians.[4]

This study accomplishes the following steps: 1) analyzes the rate of health IT

adoption for a sample of direct pay practices, 2) tests the hypothesis that many of the direct pay practices do not participate in traditional EHR functions, 3) analyzes the usage of *other health IT* (including telemedicine, mobile health applications and patient-controlled health records) by direct pay physicians and 4) tests the participation rate and reasons for participation (or lack thereof) in MU incentive policies. The model of direct pay may pose a solution to the disinterest, burnout and exodus of physicians from medical care, especially in the aftermath of changing health reform and health IT regulations. At the same time, the business model may appear problematic in producing uniform data sharing standards across provider networks, and may require policy recommendations to mitigate this problem.

Retainer medicine, known by other terms, including concierge medicine, boutique medicine, direct pay and direct primary care, has become the new payment model of choice for a subset of the physician workforce, many of whom are in private practice.[5] Direct pay practices vary by their ability to take insurance. *Pure* direct pay practices do not participate in any form of health insurance, while *hybrid* practices accept insurance from one patient panel, while also participating in direct pay medicine for a separate patient panel. Many hybrid practices are in transition to a direct pay model and allow their patients to participate in insurance-reimbursed services until the practice has transitioned to the pure retainer model.[6]

The practices are also categorized by their subscription services/ payment structure. Two categories are fee-for-care (FFC) subscription models and fee-for-service (FFS) models. FFC models are defined in the study as models in which patients are charged an all-inclusive fee on a monthly or annual basis for a set of non-insurance covered/reimbursed services.

On the other hand, FFS models typically offer the following options: 1) a flat fee charged per service, 2) an FFC subscription fee for the annual exam alone, and then additional fees charged for additional, non-insurance covered services or 3) an FFC model for some patients and an FFS model offered to other patients. The major differences between these overarching categories is based on whether there is only subscription-based services (FFC) or a combination of subscription and non-subscription services at the practice (FFS). Some FFS practices accept insurance, including capital rich organizations, such as Proctor and Gamble's subsidiary, MDVIP, or organizations affiliated with hospitals (e.g. Inova 360) or franchises (e.g. MedLion).

Direct pay practices advertise patient-centered, individualized care in return for membership, though little is known about their health information technology (health IT) use. Studying health IT use in direct pay practices is informative for two reasons: 1) most direct pay practices include unique, 24-7 access to patients, such as through a variety of information communication technology (ICT) services including their cell phone number, email address and other confidential information, yet no research has been conducted regarding the use of mobile health (mhealth), PHRs and telemedicine/telehealth services, under a subscription fee provided to patients,[6] and 2) the form (pure, hybrid, FFC, FFS) of direct pay medicine may impact financial incentives to effectively meet MU guidelines, based on the presence (if any) of Medicare and Medicaid patients in the patient panel at a practice. The care delivery and type of services provided through FFC subscription practices is atypical of traditional forms of FFS care.[6,7,8] Many pure and FFC physicians participate in house calls, video chat with patients and may even deliver lab tests and wellness services under one roof, at discounted prices. Because the physicians strive for patient-centered, personalized care, the physicians typically operate on a patient panel that is half the size of a traditional private practice, averaging only between 400–700 patients.[7]

Understanding the ability of direct pay practices to use EHRs to capture and share data, potentially across the health information exchange (HIE) and to operate other forms of electronic and mobile health technologies, will suggest how technologically savvy, connected and interoperable these practices are. The differences between FFC and FFS practices in EHR participation and other health IT will suggest whether there is a relationship between subscription models and the model's impact on health IT use.

The subject of retainer medicine has been briefly reviewed in past academic and non-academic literature. Currently, there are an estimated 4,400 direct pay practices in the U.S.[7] Most past studies document concierge medicine, which is traditionally known as a high-end form of direct pay, ranging between $150 and $1,500 per month. New forms of direct pay include direct primary care and cash only practices, which are seemingly economical, ranging between $50 and $150 per month.[9]

The subject of retainer medicine has been researched by Alexander et al (2011) who completed a survey on retainer practices.[6] They compared the state of retainer practices, including demographic characteristics and patient panel sizes to traditional private practices. They also analyzed characteristics of retainer physicians, including time spent on charity care and the types of patients served. The study found that these practices were less likely to serve Medicare patients, yet more likely to perform charity care. A follow-up study by MedPAC performed interviews and assessed differences across FFC and FFS models, which were used to categorize the two groups of subscription services in this study.[7]

Chase (2013) interviewed a number of direct primary care practices as part of a case study to learn about their EHR systems and found that a number of the large leaders of direct pay models of care, including Qliance, MedLion, OneMedical Group and Aurora Health systems are participating in EHR MU objectives.[9] The case study does not systematically analyze a sample of direct pay practices, nor does the study suggest differences in health IT function and policy preferences between groups of pure and hybrid practices. Thus far, no study has suggested the impact that forms and subscription models of direct pay have on health IT use and attitudes, which is how this study contributes a new body of research to the field.

If the direct pay business model continues to spread successfully, and the trend becomes widespread across the nation,

more private practices may be saved from closing. Direct pay business models may help physicians meet the growing demand for access to primary care that has been created by the ACA.

METHODS

The study received institutional review board (IRB) exemption #8578 through George Mason University. Collecting primary research through a survey was the most applicable method for the study, given the nature of the hidden population and the lack of the secondary data available. The researcher collaborated with Healthcare Information and Management Systems Society (HIMSS) on the subject and received an independent consulting grant to provide incentives to physicians who participated in the primary research. The participants recruited were all private practices that operated at least partially on a direct pay medicine model of care. Physicians and office managers of such practices were allowed to participate, with the requirement of one survey respondent per practice. Each survey respondent who completed the survey in entirety received an Amazon gift card for participation.

To garner a generalizable sample size, the researcher actively engaged in Google searches using keywords such as "boutique", "concierge" and "retainer" medicine, "direct pay," "direct primary care," and "cash only." The researcher also hoped to improve data collection efforts by submitting a news article on the study through *HIMSS Insider News*, *Concierge Medicine News* and in various forums and conferences. The study utilizes a convenience sampling technique.

A total of 300 physicians received survey links, many whom were part of a direct pay coalition or who had an online listing. After data collection, the sample size was 180 (response rate of 60 percent). Following the survey, findings were bolstered by hosting interviews with a total of 45 direct pay physicians that were pure, hybrid, FFC and FFS in nature.

The survey included four sections: demographics, health reform, health IT attitudes and use and organizational behavior. The demographics section provides characteristics of the practices, including number of physicians, number and type of patients (insurance type, if accepted), types of services, years of practice, degree type of physician and other data that could affect the analysis. The health IT section asked questions about the presence of an EMR or EHR system, questions to classify the components of the EMR as "any" or "basic" EMR (modified from the Physicians Foundation survey on health IT use), questions regarding meaningful use (MU) standards fulfillment, questions regarding the presence of direct pay on the health information exchange (HIE), use of "other" health IT with patients, greatest barriers to using the EMR, greatest strengths of the EMR and HIPAA compliance in the practice. Two other survey question sections, which tested health reform and organizational behavior, were not used in the results of this article.

The specific research question being tested was: how do forms of direct pay (pure/hybrid and FFC/FFS) differ in their perceived impact from, and utility of, HIT changes since the HITECH Act of 2009? The study tests the hypothesis that there is a higher presence of health IT among pure practices, compared with hybrid practices. The second hypothesis is that pure and FFC models will be less likely to participate in MU policies. The study hypothesized that pure and FFC payment model practices would be less likely to utilize the EMR for many of the major functions, including decision making, electronic prescribing, electronic claims and public health reporting. Pure and FFC payment model practices would be more likely to use other types of electronic health, including telehealth, mobile health applications and patient portals. The study was able to suggest these relationships through the data analysis process. The results are discussed next.

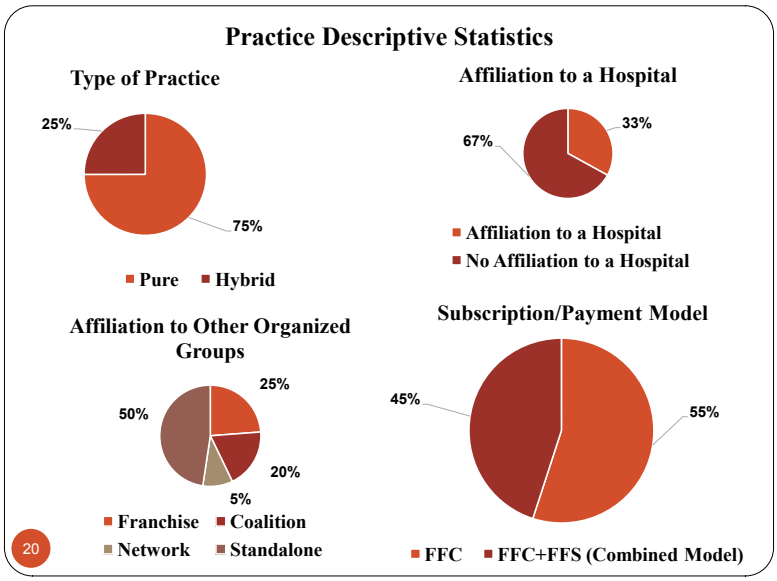
RESULTS

Descriptive and Inferential Statistics. The descriptive analyses include information regarding demographic characteristics of the respondents and their practices. The average survey respondent's age was 47 years, and nearly three quarters were physicians with MD or DO degrees. Only about one quarter of respondents were office managers. The average respondent had about 5 years of experience in direct pay, but had about 17 years of experience in any form of medicine. All respondents had owned at least one practice in the past. About three quarters of all respondents were practicing primary care, and the other one quarter was practicing specialty care. Most physicians either owned or partially owned the practice.

Figure 1 depicts practice characteristics. On average, direct pay practices had 2 physicians working in the office and 641 patients. Nearly 80 percent of all responding practices had between 1 and 7 total staff members in the practice. On average, Medicaid was accepted at 10 percent of the practices, Medicare was accepted at 17 percent, private insurance was accepted at 23 percent and charity care was accepted at 8 percent of the practices. The average membership fees were in the range of $500 and $1,000 on an annual basis. When asked about general trends in the practice, the average response was an increasing trend in patients since opening the practice. About one quarter of the practices were affiliated with a franchise, about one fifth were affiliated with a coalition and half stated being a standalone practice. About 10 percent of practices considered themselves on a network model, where the practice would own and operate a number of other practices based on a business model created internally. About one third of all practices were associated with a hospital or hospital association. The average household income in zip codes where the practices participated in direct pay was $60,000. Practices that participated were 75 percent pure direct pay and 25 percent hybrid. From the sample, 56% of the practices were on a FFC payment model, and 44 percent were on a fee for extra service or a combination FFC/FFS payment model.

Multivariate regression. The next section provides a summary of the multivariate statistics and findings of the study and states the significant impact of pure/hybrid status and payment models on health IT use (EMR/EHR use and use of "other" health IT). EMRs or EHRs were present across most pure, hybrid, FFC, and FFS practices,

FIGURE 1: Descriptive Statistics of Practice Characteristics



at a cumulative of 90 percent of the practices, compared with 78 percent of traditional small practices.[11] About 57 percent of direct pay practices had an intent to participate in or were already participating in meaningful use (MU) policies, which is lower than the 69 percent of all traditional, office-based physicians who had applied or were planning to apply for MU policies in 2013.[11]

Utility of the EMR/EHR. The utility of the EMR/EHR was reported as four measures, selected from a longer set of menu and core measures. These measures are modified from the Physicians Foundation Survey, which requires specific core and menu measures to meet the definition of having a "basic," certified EHR, rather than having "any" uncertified, EMR/EHR system in the practice.[12] E-prescribing, electronic public health reporting, decision making through electronic means and using electronic claims and billing systems are part of the core, menu and clinical quality measures in MU Stage 1.

After conducting a number of logistic regressions, we determined the following results, summarized in Table 1. Being an FFC practice reduced the likelihood of using EHRs for decision making and decision support by nearly 92 percent (odds ratio, OR=0.08; p<0.05). A higher number of patients in the practice also increased the odds of using the EMR for decision making by a factor of 1 (OR=1.00; p<0.10). The results suggest that FFC practices do not find the traditional EMR/EHR system useful for communication with patients; if anything, perusing and completing all the criteria in the interface of the EMR/EHR strained communication with patients and reduced the "personalized" quality of the direct pay services.

Pure practice used fewer MU EMR and EHR functions for specific reasons. For example, pure practices were 96 percent less likely to use the EMR/EHR for reporting and participating in electronic claims (OR=0.04; p<0.05), compared with hybrid practices. Many interviewees and respondents stated having no reason to monitor claims on a cash only basis. Without health insurance documentation, electronic claims only proved to be an additional administrative hassle. Being a primary care practice also reduced the likelihood of using the EMR/EHR for e-claims by 88 percent (OR=0.12; p<0.10).

FFC payment models were about 92 percent less likely to use EMRs/EHRs for government public health reporting, as FFC models were less likely to participate in public health reporting (OR=0.08; p<0.05). This could be because subscription FFC services were less likely to participate in large-scale data exchange with other hospitals, public health departments or federally qualified health centers.

Participation in Meaningful Use. FFC payment model practices were less likely to engage in MU policies than the FFS practices (RRR=0.02; p<0.05). Only a few practices stated that they were not sure what MU is or that they had completed the requirements for MU and were fully electronic (i.e. had reached stage 7 of the HIMSS adoption model), but these responses were negligible and were dropped from the analysis. Practices that included both FFC and FFS models were more likely than FFC practices to participate in MU, because these practices were more likely to qualify for the incentive payments. Many of the qualifying FFS practices also suggested difficulty in meeting MU standards because of difficulty in coping with the administrative requirements in MU Stage 1. Some suggested willingness to accept a penalty rather than participating in MU objectives.

Reasons for not meaningfully using the technology included being opposed to exchanging and sharing patient data, as well as not benefiting financially from MU. FFC practices were more likely to suggest that they did not utilize MU because they were not likely to benefit from government financial incentives (RRR=23.98; p<0.05). Most subscription model practices did not accept health insurance, especially Medicare and Medicaid, which are required to qualify for Meaningful Use. The FFS practices suggested that participating in Meaningful Use was a "hindrance," another set of "administrative red tape," and was a reason that their practices preferred the subscription payment model, in which they could easily bill and code one amount for a wider gamut of services. Most practices are making their choices understanding the consequences, as only a negligible percent stated that they did not know what MU is. Pure practices were more likely to answer that they did not want to share their data with the government or participate in the HIE, though this was not

TABLE 1: EMR or EHR Function and Meaningful Use by Direct Pay Practices

EMR or EHR Function	Percent More or Less Likely	Odds Ratio (OR)	Statistical Significance
Pure Practices Use of EMR for e-claims	96% Less Likely	OR=0.04	p<0.05
Pure Practice Use of EMR for public health reporting	90% Less Likely	OR=0.10	p<0.05
Being a primary care practice and impact on use of EMR for e-claims	88% Less Likely	OR=0.12	p<0.10
FFC practice Use of EMR for public health reporting and decision making	92% Less likely	OR=0.08	p<0.05
FFC Practice Use of MU policies	Less Likely	RRR=0.02	p<0.05
Pure/Hybrid Reason for non-participation in MU policies: Lack of Financial incentives to participate	Less Likely	RRR=23.98	p<0.05
FFC Practice Use of telemedicine when affiliated with a hospital	10 times More Likely	RRR=0.12	p<0.10
FFC Practice Use of PHRs, telemedicine, mobile health applications	More Likely	RRR=0.04	p<0.10

statistically significant (RRR=4.36).

Next, the use of telemedicine, patient controlled health records and mobile health apps is analyzed to suggest differences across pure, hybrid, FFC and FFS practices.

Use of Other Forms of Health IT. Compared with hybrid practices, pure practices were more likely to utilize to use all three types of technologies (telemedicine, PHRs, mobile health applications) in the practice (RRR=0.04; p<0.10). Many of the pure practices stated that having fewer data capture, reporting, and public health guidelines increased their likelihood to use new and innovative technologies. On the other hand, hybrid practices had to follow government reporting standards and guidelines, which increased the time it took to get used to the technologies (due to inertia and routine rigidity) and lowered interest in using the technologies. The pure practices' motivation to use these technologies also stemmed from an interest in individualized care. Pure practices were able to investigate new technologies because of greater autonomy in the practice and because they were not required to follow instructions or an interface linked to MU objectives. On the other hand, hybrid practices were more likely to utilize PHRs, compared with a variety of other technologies. Practices that were associated with hospitals or hospital associations were 10 times more likely to use telemedicine (OR=10.2; p<0.10), as portrayed in Table 1.

The same results were magnified when interviewing practices that were connected to hospitals, including Inova 360 of Inova Hospital System. Some practices suggested using laptops for telemedicine, whereas others use more advanced health information systems and recording devices. A few practices suggested the usefulness of telemedicine when providing care for populations in disparate parts of the country. For examples, one physician suggested its ability to care for a unique population of Indian tribes in Oklahoma who were uninsured.

CONCLUSION

Direct pay practices are gaining ground across the U.S. This study suggests the impact of health IT policy changes on direct pay and important ramifications, provided next. I propose a number of policy recommendations from the study. FFC, FFS, pure and hybrid practices directly and indirectly impact the supply and demand of primary care and specialty care, service delivery and costs. Their use of uncertified EHRs and lack of participation in government EHR incentive programs reduces data capture, data sharing and exchange and the ability to benchmark, compare and evaluate patients' health outcomes.

Pure and FFC direct pay practices were less likely to participate in many traditional functions of the EMR or EHR, compared with hybrid and FFS practices. This could have important implications going forward for vendors in the direct pay market and for patients of the pure and FFC direct pay practices. Vendors focused on direct pay will need to better serve the goal of customization of the EMR and its functionality for direct pay physicians, which may not be linked to MU standards. Many pure and FFC direct pay physicians suggested the importance of a "well designed" EMR or EHR, especially a system that provides customizability of patient lists, medications, medical histories and billing. A subscription-based FFC practice is more likely to evaluate patients regularly, know patients' histories and behaviors and perceive the traditional certified EMR/EHR as a hindrance because of the routine reminders and exercises (including notifications and compulsory MU tasks) that need to be completed to move from one screen to the next. FFC physicians also noted that computer decision support systems of EMRs/EHRs are a hassle to use and did not improve their ability to individually treat patients. In general, pure and FFC physicians required greater free text area in their EMR/EHR, rather than the point-and-click box format. Some capital rich, pure and FFC organizations and practices are developing their own EMR/EHR platforms or mobile health applications that

are user friendly and meet the needs of direct pay physicians and their practices. Examples include Atlas MD, Twin Peaks EHR, Qliance EHR and more.

The following EMR/EHR preferences were cited among pure and FFC practice physicians: 1) access on any internet capable device with a modern browser for real-time sync between devices; 2) a streamlined billing system; 3) capability to self-sufficiently operate an in-house pharmacy; 4) 24-7 access to a vendor/support and 5) access to more "free text" space for clinical notes.

Pure and FFC practices also were less likely to participate in the HIE, or other forms of collaboration or connectivity, that affect their patients and the community in which the providers are practicing. The choice of uncertified and customized EHRs by physicians reduces the likelihood that patient records can be easily transferred from the practice to another practice, or to specialists, other healthcare organizations or hospitals, because direct pay are not located in a provider networks. The type of health technologies that direct pay practices use may not be conducive to public health reporting standards, which reduces participation in public health awareness, syndromic surveillance and ability to benchmark short- and long-term outcomes and impact on the community.

Pure and FFC direct pay practices were more likely to use health IT that involves patient participation, such as patient controlled health records, telemedicine and mobile health applications. These innovative practices may interest patients who need connectivity to their personal physician, especially patients with chronic conditions. Patients may view the accessibility to a personal physician and their records as an important benefit to the care delivery process. At the same time, such practices need to be more closely monitored to ensure that health information passed through the physician to the patient from other types of health IT are encrypted and meet HIPAA standards to ensure that confidential and private data are not breached.

The study found that pure and FFC direct pay practices are not as likely to use MU policies as hybrid and FFS practices, which impacts the ACA objectives of increased health reporting and measurement of quality and cost metrics. Accountability of direct pay practices will remain a concern for the government. If more practices are "off the grid" and participate in "out of provider" networks, it becomes difficult to measure the impact of direct pay on larger providers, patients and society. For this reason, the government needs to incentivize direct pay providers to use EHRs that will meet MU standards or that can be measured similar to MU, with added benefits of customizability and efficiency to the practices. This may be more likely to occur if direct pay practices collaborate with health insurance companies on the HIE.

The government should also try to incentivize data sharing between direct pay practices and government health centers, clinics and hospitals to ensure representation of these practices in the market economy, especially as the number of direct pay practices grows. These practices present a new approach to traditional private practice as new policies and legislation reinforce the legality and inclusion of these practices in the health services market. There is a need for greater efforts by the government to 1) encourage participation of direct pay practices in purchasing certified EHRs; 2) produce compatibility standards between MU and non-MU technologies (which may be part of the 2015 and 2017 EHR certification rules), so that data exchange may still occur; and 3) promote wrap-around direct pay plans on the HIE, which will market direct pay primary care services in conjunction with health insurance. Meeting and measuring HIPAA compliance remains an important concern during a highly digitized age of health communication and HIE for direct pay practices. Purchase, upgrade and compatibility to basic and certified EHRs that meet MU Stage 1 and Stage 2 will become important to measure the impact of direct pay practices in larger data sharing networks, state and national health information exchanges and on the community at large. **JHIM**

Divya Srinivasan Sridhar, PhD, is a researcher in health informatics and health reform. She authored ***Impact of Healthcare Informatics on Quality of Patient Care and Health Services*** (CRC Press, 2013) and Health IT as a Tool for Prevention in Public Health Policies (CRC Press, 2014), as well other academic publications.

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FEATURE Clinical Data Registries

Addressing Sustainability and Informatics Challenges for Clinical Data Registries

A Qualitative Study

By Christopher P. Boone, PhD, MSHA, FACHE

ABSTRACT

Clinical data registries (CDR) are one of the primary means to generate comparative effectiveness research (CER) evidence using electronic clinical data. Each has been used to aggregate data and produce reports on the appropriateness and effectiveness of care delivered to patients across the U.S. Consequently, there has been immense interest from various stakeholders (e.g. providers, payers policy makers) to leverage data from CDRs for research and policy analysis purposes. However, these organizations are faced with ongoing challenges such as unsustainable business models and technical challenges associated with the collection, linkage and secure transmission of patient data from a variety of clinical data sources managed by many healthcare organizations across the country.

This study utilizes a qualitative multi-case study research method to identify the major barriers and lessons learned from establishing CDRs. It highlights four U.S.-based CDR programs and discusses how each has built a sustainable business model and technologic infrastructure while managing the challenges unique to CDRs. More than twenty semi-structured interviews were conducted via telephone following the interview guide with a variety of interviewees, including program representatives, physicians, policy makers, technology experts and industry personnel. The findings were generated using exploratory semi-structured interviews conducted under naturalistic inquiry over the course of four months. Themes, challenges and innovations were identified using both primary and secondary data collection methodologies.

All the studied cases share a vision of improving the overall healthcare system, but each differs in its therapeutic focus, organizational design and funding sources. Success will be simply defined as continuous enrollment of new participants, generating new medical knowledge and creating new revenue streams for the program.

KEYWORDS

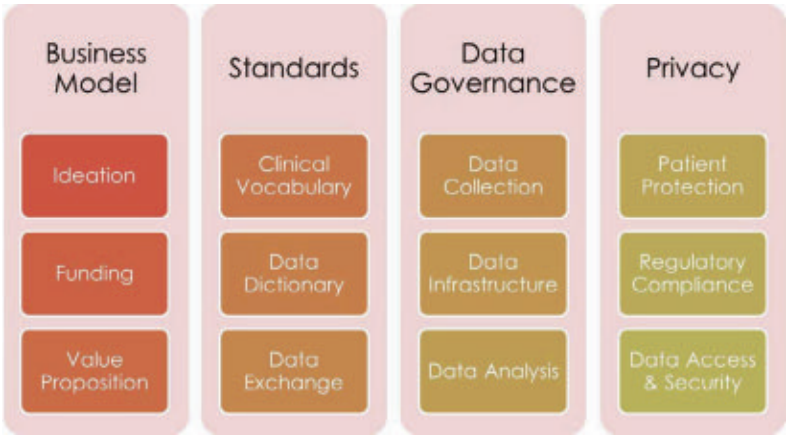
Clinical data registries, health informatics, electronic health records, clinical data registry challenges framework, national registry agenda

WITH THE DATA democratization movement that is occurring in the U.S., the overarching question by many care providers and policy makers is: how can clinical research knowledge be realized to improve healthcare decision making? CDRs are one of the primary means to generate clinical research knowledge using electronic health data. Each has been increasingly utilized as a means to aggregate data and produce reports on the appropriateness and effectiveness of care delivered to patients across the U.S.

CDRs can be extremely powerful tools for collecting, storing and analyzing electronic clinical data. The Agency for Healthcare Research and Quality (AHRQ) defines CDRs as: "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease [or] condition."[1-3]. These capabilities are instrumental in conducting CER, understanding effective disease management practices, improving quality of care and providing public health surveillance.

President Obama and his administration have been the most influential administration to date in the publically-funded efforts to increase the adoption of systems that generate electronic health data and its secondary use for generating scientific evidence and improving clinical- and cost-related decisions. The American Recovery and Reinvestment Act of 2009 ("Stimulus Bill") was the first piece of legislation to introduce the use of CDRs and electronic clinical data as a source for clinical evidence.[4] Then, the Patient Protection and Affordable Care Act of 2010 ("Health Reform Bill") expounded on these initiatives, calling for the development of registries to collect and analyze data for clinical outcomes measurement and comparative effectiveness studies using electronic clinical data. The Health Reform Bill was the first bill to allocate public funding directly to supporting the expansion of CRD programs (PPACA 2010).

FIGURE 1: Clinical Data Registry Challenges Framework



Lastly, in December 2012, Section 601(b) of the American Taxpayer Relief Act of 2012 ("Fiscal Cliff Bill") took it a step further and outlined a new process for qualifying for the CMS's Physician Quality Reporting System (PQRS), which is a pay-for-reporting program launched to increase the level of quality care provided.[5,6] As the concept EMR-based observational research continues to expand in practice, CDRs are expected to see colossal demands on its supporting business and informatics infrastructures.[7] Despite the potential of CDRs, there are still some clear challenges to using EMR-based clinical data registries for CER.

CONCEPTUAL FRAMEWORK

The framework below highlights and categorizes key challenges associated with the development and management of clinical data registries.

The primary domains of the framework include: Business Model (sustainable business practices that support rapid expansion of the program from a marketing, financial and legal perspective); Standards (clinical and technical standards necessary to facilitate care coordination, electronic data sharing and data aggregation); Data Governance (management processes that facilitate the data collection, analysis and knowledge dissemination); and Privacy Regulations (complying to regulations that are designed to protect the health information of every American citizen).[8-12]

BUSINESS MODEL

In a broad sense, the business model for a CDR is no different than any other business operation. It requires a good idea (to capture interest) that is supported by an effective marketing plan (to reach the right audience at the right time) and adequate financial resources (to support the efforts to associate it with building the business). There is an abundance of preexisting literature on the technical challenges associated with utilizing EMR-based data for research purposes; however, there is very little with regard to building a sustainable business model for these organizations. There are three primary dimensions of the business model domain: (1) Ideation, or the need to frame a research question as the first step; (2) Funding, which is the need to establish secure funding sources; and (3) Value Proposition, which is the need to identify clear value for stakeholders.

STANDARDS

The lack of generally-accepted standards continues to be one of the biggest barriers to moving the industry forward. In the healthcare industry, the term *standards* encapsulates many definitions when dis-

DATA GOVERNANCE IS defined as: "an accountability framework to encourage desirable behavior in the valuation, creation, storage, use, archival and deletion of information.

cussing the use of electronic health data for patient-centered outcomes research. For the purposes of this study, it refers to the standardized clinical terminology, data sharing languages (or code sets) and data collection practices that promote universal participation from each individual and/or organization in the system.[13]

DATA GOVERNANCE

Data governance is defined as: "an accountability framework to encourage desirable behavior in the valuation, creation, storage, use, archival and deletion of information."[14] For the purposes of CDRs, the focus is on the collection, storage and analysis of electronic clinical data. Firstly, Data Collection involves addressing the challenges, such as the heterogeneity that exists with electronic health record systems utilized by providers and the lack of system interoperability that exists between the disparate systems. Data Storage, on the other hand, represents the challenges associated with building an informatics infrastructure that emphasizes *economies of scale*, which would allow multiple studies to occur simultaneously on the same set of data.[15] Lastly, Data Analysis is the ability to generate new knowledge about the health of certain patient populations.

PRIVACY & INFORMATION SECURITY

Patient privacy and confidentiality have been documented as one of the most compelling challenges for CDRs.[16] These organizations are looking to exchange clinical data from one institution to another, and most of the time these data include protected health information (or data that can be used to identify a patient). The Privacy Rule, under HIPAA, is a safeguard put in place to prevent the unauthorized access of patient data; however, it does allow the exchange of patient data across organizations for research purposes. In this instance, it is required that each participating organization in the data sharing arrangement sign a business associates agreement (BAA), which is a legal document that outlines the permitted and restricted uses of the shared data.[16,17] In addition to the signed data sharing agreements, the Institutional Review Board (IRB) requires that all EMR data be de-identified or anonymized.[15]

Other methods used to protect patient data involve: building secure systems that require user authentication (i.e. passwords); encrypting all EMR data files that are transmitted across organizations and constructing protective safeguards of all computer systems that store these data (i.e. network firewalls).[9,18]

RESEARCH QUESTIONS AND OBJECTIVES

The purpose of this study was to explore the clinical research informatics barriers involved with CDRs using electronic clinical data to conduct CER studies. The overarching research question for this study is:

- RQ: What are the primary facilitators and barriers for constructing a CDR?
- RQ: How can program administrators address these sustainability and informatics barriers?

This research project had four primary objectives: (1) to understand the similarities and differences in the strategies, operations and technologic innovations in clinical data registries; (2) to examine what interventions have been put in place to address the various challenges; (3) to build a model that can assist those parties interested in developing and/or currently operating a clinical data registry; and (4) to identify innovative approaches to leveraging clinical data registries for health policy decision.

STUDY DATA AND METHODS

This study utilized a comparative case study method that allowed for an in-depth examination of the unique phenomena of each selected CDR in this study. It was carried out by a single academic investigator

(Christopher Boone) with assistance from leaders of the four U.S. non-profit organizations selected for this study.

STUDY SAMPLE

The selected organizations were selected as a convenience sample; however, each was required to meet the specific inclusion criteria including: (1) an ability to accept electronic clinical data from electronic health record systems; (2) to be owned and operated by a professional association that focused on generating new clinical knowledge related to a particular chronic disease (diabetes, cardiovascular disease), clinical procedure (anesthesia), or condition (pregnancy); and (3) had to have been operational for at least 24 months. To participate in the study, the researcher screened each CDR against the inclusion criteria via email and/or telephone solicitation. The approved cohort included:

- Anesthesia Quality Institute™ (AQI)
- National Cardiovascular Disease Registry® (NCDR)
- Northern New England Perinatal Quality Improvement Network (NNEPQIN)
- Wisconsin Collaborative for Healthcare Quality (WCHQ)

DATA COLLECTION

The author sought qualitative data and selective quantitative data elements (i.e. total participants, operational budget figures and costs of investments). Other aspects investigated include the following data elements: program scope and strategy; key factors driving program design; key business model activities (e.g. marketing and financing); data governance practices; and electronic clinical data infrastructure. To create the interview guide, the researcher utilized Clinical Data Registry Challenges Framework (described under Conceptual Framework) to develop a set of specific questions that could be answered by registry administrators.

The findings were generated using exploratory semi-structured interviews (lasting approximately 90 minutes) conducted under naturalistic inquiry over the course of four months (March-June 2013) via telephone. The conceptual framework provides the basis for the questionnaire used in the semi-structured interviews. Themes, challenges and innovations were identified using both primary and secondary data collection methodologies.

DATA ANALYSIS

Data collected from the interviews was triangulated with observations and electronic documents to build a case profile for each clinical data registry program. The researcher used a qualitative software tool called QSR*NVIVO to assist in the collection, aggregation and thematic analysis of the data collected. These themes were grouped in parent and child relationships to identify the prominent applicability across participants. The themes highlighted similarities and differences in the business models, information governance practices, key challenges and the future plans for each program.

LIMITATIONS

An important potential limitation exists. This research project was dependent largely on the cooperation and uniformity of information sharing from key individuals associated with each CDR. The author did receive full cooperation from the study participants; however, there were certain key pieces of information that the programs felt was confidential and/or proprietary (e.g. specific program financials, detailed future plans).

Aside from the author's dependence on the key individuals from each of the clinical data registries, there are some potential limitations in the research approach. First, this is a new area of research with limited available literature and expertise, as many experts are still attempting to determine best practices for CDRs. Secondly, the sample size is relatively small and the focus is on one particular type of CDRs, those which are owned and operated by professional associations. The author is only aware of a small number of professional associations that operate existing CDRs with a technical infrastructure that supports the collection and analysis of electronic clinical data, thus this study may not provide a representative overview of the different types of registries or even those registries that are not operated by professional associations.

However, this research project is not intended to project its findings about registry specifics to the broader population of CDRs, but, rather, hopes to provide a detailed and informed overview of the types of CDRs that are actively utilizing electronic clinical data to support CER efforts and to present key lessons learned at these sites for those interested in implementing a CDR. Another potential limitation is that the findings relate to characteristics of registries during a defined period of time. These characteristics can change as each registry is expected to remain adaptive to increasing demands from stakeholders.

FINDINGS: LESSONS LEARNED

Ideation: Quality improvement is the primary driver for establishing the clinical data registry.

In establishing a registry and evidence-based knowledge, it is imperative to establish a scientific question for why the CDR exists. Oftentimes, the vision and mission articulate what that particular purpose is for a registry. All studied cases have identified "quality improvement" within their segment of the healthcare industry as the primary purpose for the existence of each program. Each registry is looking to establish clinical benchmarks and to develop clinical guidelines for their profession, so that providers can clearly understand their performance relative to their peer group and ultimately improve the health of their patient population. Similarly, each registry has defined secondary purposes for its existence, which includes activities such as comparative effectiveness research, post-marketing surveillance studies and regulatory-related advocacy efforts.

Funding: Establishing a viable funding model to support the clinical data registry is a challenge.

The development of a sustainable business model for each CDR requires a different skill set. Oftentimes, the thought leaders behind establishing a CDR are not considering the economic aspect of it and its direct implications to the viability of

the registry. The average start-up costs for a CDR range from $2.0 to 3.5 million, and the annual operating costs range from $1.0 to 2.0 million.

Each participant identified funding as its primary barrier to sustainability and expressed their frustration with the inability to adequately generate revenue within the first two years of existence. Thus, the funding models for each case study vary, but most have multiple revenue streams. However, the bulk of its revenue comes directly from its parent organization and/or member fees. Most registries are actively exploring ways to use its collected data for secondary purposes with public agencies and/or life sciences companies.

Value Proposition: All clinical data registries target specific professional constituencies.

It is expected that the marketing strategies for each registry will vary because each has different medical reasons for its existence. Even so, all CDRs in this study are focused on recruiting providers from certain professional communities, such as by focusing on a medical specialty (e.g. diabetes or cardiovascular disease) and/or geographic region (e.g. the state of Wisconsin). In either scenario, registries are encouraged to take an approach that makes its community aware of its existence and its purpose(s). Each interviewee noted that it takes an average of 2 to 3 years for most registries to grow its membership to a sufficient size.

Clinical Vocabulary: All registries have developed therapeutic-specific standard clinical terminology.

In the absence of universal standards, it is necessary for each CDR to develop its own clinical nomenclature for provider participants to adhere. Each studied case has developed its own clinical data standards to circumvent this challenge. These clinical data standards and definitions are conveyed to participants in the Data Specifications document. All the studied CDRs require that each participant adhere to these clinical standards as a shared responsibility to increase the effectiveness of data collection and accuracy of performance reporting.

Data Dictionary: Most registries have adopted a technical standard as a means to appropriately map data to data fields on importation.

Each organization has taken a unique approach to addressing these challenges. For instance, AQI has decided to partner directly with their primary data sources, which are the anesthesia billing companies. On the other hand, WCHQ has decided to forge a relationship with Epic (health information technology vendor), which 70 percent of its target constituency uses for its electronic health record system. These vendors have lessened the burdens for providers when submitting data and CDRs when collecting it, as each vendor has constructed a technical utility that converts patient data into a standardized format for the CDR.

Data Exchange: Each clinical data registry is actively negotiating or sharing data with another clinical data registry or data sharing networks.

Contrary to an independent CDR, multi-registry data sharing networks necessitate effective system interoperability capabilities to transmit large data quantities from one registry to another. In addition to establishing clinical terminology and data standards, these relationships require each participating registry to adopt homogenous technology infrastructures to enable system interoperability. Most of the studied cases are exploring ways to share data with other CDRs. This effort will require developing clinical terminology standards, data exchange standards, homogenous technology infrastructures and understanding the patient privacy laws in the other countries.

Data Collection: Each registry has an automated process for collecting data and managing data quality challenges (e.g. missing data elements in the submitted data extract).

Generally, the two data collection processes are primary and secondary data collection. Primary data collection is the active process of collecting data real-time from a clinical system (e.g. NNEPQIN and the web-based perinatal system "OBNet"). On the other hand, secondary data collection is a more passive approach, which means data are captured through data extraction mechanisms. Most of the studied cases (i.e. AQI, NCDR, and WCHQ) utilize the secondary data collection method.

In addition, each studied registry has developed an automated process for managing data quality challenges; however, the approach depends on the type of data collection (i.e. primary versus secondary). As the sole primary data collector in the study, NNEQPIN enforces data quality by having rule-based error detection when users are entering data into the OBNet system. If a data entry is erroneous, then an alert message is displayed to notify the user and the data entry is not accepted into the system. On the other hand, registries that utilize the secondary data collection method have established a secure electronic data file transfer systems that conducts rule-based error detections (checking for completeness and accuracy in the data) once the file is uploaded to the system. If an error is detected, then the user is alerted instantaneously and granted the opportunity to correct the issues and resubmit the data file.

Data Infrastructure: Most registries require a flexible and scalable technology platform to take advantage of economies of scale.

CDRs have a unique challenge of building a robust technologic infrastructure that is scalable and has the ability to collect, store and aggregate clinical data from multiple electronic data sources that are not designed to transmit data to alternate systems seamlessly. In addition, the technologies supporting the registry are required to expeditiously and accurately compute sophisticated statistical analyses of complex clinical data. With limited off-the-shelf technology platforms to support these efforts, CDRs are faced with the decision of building the technology or completely outsourcing it to a vendor that can build it. Several interviewees described the process of building an in-house infrastructure as highly expensive (from a technical expertise perspective) while acknowledging the heightened level of autonomy and innovation allowed when building it in-house.

Data Analysis: Each registry provides performance feedback reports to par-

PATIENT PRIVACY AND CONFIDENTIALITY have been documented as one of the most compelling challenges for CDRs. One of the key questions posed by many stakeholders focuses on the ownership of data upon collection.

ticipating providers, but only one has robust public reporting.

The provider participants are interested in better understanding their clinical performance in general and their performance relative to their peer group. These performance reports provide feedback on each provider's adherence to evidence-based clinical guidelines. These reports are designed to examine and measure clinical performance over time for each provider. All cases studied provide regular performance feedback reports (via online or paper means) to its members. Public reporting is not a prevalent practice among the cases studied. WCHQ is the only group that willingly publishes this performance information for public consumption, which requires trust and cooperation from its provider groups.

Patient Protection: All registries believe they own or have exclusive rights to use the de-identified clinical data for its own purposes (e.g. research, publications, and advocacy).

Patient privacy and confidentiality have been documented as one of the most compelling challenges for CDRs. One of the key questions posed by many stakeholders focuses on the ownership of data upon collection. Each registry believes that it owns the "de-identified" data once it is collected and stored in the registry's data warehouse. De-identified data refers to the data that has been stripped of any patient and/or provider identifiable data elements (e.g. patient SSN or provider identification number). In all cases, the rights to the data are explained in the participation agreement for the registry. Thus, each registry has the right to utilize the data for its desired purposes.

Regulatory Compliance: All registries studied require a signed participant agreement and a data use agreement.

To comply with the Privacy Rule of HIPAA (of 1996), every registry studied requires every participant to sign a Participation Agreement (contract with the registry) and a Business Associates & Data Use Agreement (allows the sharing of patient data). In addition, each registry identifies a staff member to address any questions and/or concerns from participants regarding the legalities of the agreements. All registry participants are granted the opportunity to accept, decline or modify certain parts of each agreement; however, these contract changes could prohibit their participation in the registry. For these reasons, each registry attempts to limit the required data elements to only those are necessary.

Data Access & Security: Each registry has implemented HIPAA-compliant technology to secure patient data collected from the providers.

Each registry has implemented robust data security measures to ensure the data are treated confidentially. Both NCDR and AQI decided to build the technology infrastructure for its CDRs internally, but the computer servers are physically located in a secured data center location that requires special authorization to gain access. All WCHQ data are stored in a secure data warehouse that is managed by a third-party vendor, which is audited regularly by an independent party. Moreover, the NNEPQIN technology is fully HIPAA-compliant and has the necessary security protocols prebuilt into the system to restrict provider access to patient data from its own institution.

FINDINGS: STRATEGIES FACILITATING PROGRAMS' SUCCESS

Success Strategy #1: Successful clinical data registries clearly define the mission, vision and primary/secondary purpose(s) during the Ideation phase of development.

In establishing a registry, it is imperative to "begin with the end in mind" and design the question and registry accordingly. Every decision should begin with the end in mind and the end is the vision. In some cases, CDRs are looking to improve population health within a specific region of the U.S. (e.g. WCHQ, NNEPQIN) or within a specific thera-

IF THE BUSINESS OPERATIONS are similar to the operations of any private business, then it needs to be treated as a legitimate business venture, which means both participant growth and the expansion of services are essential to its existence.

peutic area (e.g. NCDR). Irrespective of the question, each CDR requires strong leadership to see the vision come to fruition. Every interviewee emphasized the importance of having committed and visionary leadership at the helm to drive the registry to a successful outcome.

Success Strategy #2: Successful clinical data registries develop thoughtful strategic plans that focus on expansion to remain innovative, increase revenue opportunities and attract more participants.

If the business operations are similar to the operations of any private business, then it needs to be treated as a legitimate business venture, which means both participant growth and the expansion of services are essential to its existence. Typically, the development of business strategies is conducted during a formalized strategic planning process. Across each case studied, each registry has developed and implemented a formal strategic planning process, and it is led by the highest governing body within the organization, or referred to as the Board of Directors (Steering Committee) in most cases.

Success Strategy #3: Successful clinical data registries develop innovative funding models that create multiple revenue streams and immediate value for the stakeholders.

Each registry has looked to innovate and identify conventional and non-conventional methods of generating revenue. The conventional means include funding sources such as member fees and public/private grants. In some cases, each has received in-kind donations from various sources; however, these funds are not recurring. With threats to their funding, as many non-profit organizations are cash-strapped, CDRs are looking at the secondary use of their data as a revenue stream.

Success Strategy #4: Successful registries are very prescriptive with clinical vocabularies and data field definitions to address informatics challenges.

Each registry convenes stakeholder groups comprising provider and payer participants to discuss the clinical terminology and the latest science for that particular therapeutic area. The goal is to get consensus from the participants on clinical definitions. Moreover, each studied case has developed clinical data definitions and data element specifications documents to guide each provider through the configuration stage of its registry participation. The documents describe the necessary data requirements and technologies for sending data to the registry.

Success Strategy #5: Successful registries have adopted XML as the technical standard for exchanging data via the secondary data collection approach.

There are multiple approaches for effective data collection among CDRs. If the clinical data registry and/or participating providers choose to have data submitted to the registry via an electronic data extract file from the electronic health record system, then it is highly recommended that the XML [extensible markup language] technical standard be considered for this process. All of the studied cases using secondary data collection approaches used XML as the technical standard and found the standard to immensely effective.

Success Strategy #6: Each clinical data registry has established a Data Use Committee as part of its overall gover-

nance structure to manage necessary clinical and data exchange standards.

Each studied case has established a Data Committee (or some derivative of it) as a committee with its organization. Typically, this group is responsible for the approach to collecting data (e.g. primary or secondary), the use of collected data (e.g. research and publications), and being active in the development of clinical terminology and data exchange standards. This group is a multidisciplinary team (i.e. clinical and technical expertise) that can be highly influential in key standards and information governance decisions for the clinical data registry.

Success Strategy #7: Successful clinical data registries leverage advanced technologies to improve the data governance processes.

The healthcare industry has seen a rapid progression innovation due to advanced computer and information technologies. Technology companies, such as Amazon and Google, have demonstrated the value of using advanced technologies to create an improved and customized user experience. CDRs are now adopting many of the same data mining and analytics technologies to improve the data collection, storage, analysis and research experiences of its users. Registries have been faced with the complexities associated with building a flexible and scalable technology infrastructure that secures patient data, while allowing researchers to conduct highly sophisticated data analyses. Each studied registry has embraced the value of modern information technologies from other industries to resolve technical challenges.

CONCLUSIONS

The data collected from each case supported the literature and its description of the technology challenges. Study participants described their methods to managing various informatics challenges, including: data collection; data quality and validation; data storage; multi-site data aggregation; lack of system interoperability and the absence of clinical and data exchange standards. The informatics challenges, however, are not considered the barrier to success for registry administrators. Each felt that these challenges were a nuisance but building a sustainable business model was the most significant. They felt the technology would improve with continued advancements in data extraction, auditing, storage and analytics tools. However, they felt a weak business model could bring demise to the registry.

In summary, there was tremendous value in studying the multiple clinical data registries across the country. Each organization was different but the cross-case analysis captured the broader lessons and strategies from each registry. It is important for practitioners to recognize that each registry was established with a specific purpose and its evolution was directly influenced by the internal and external variables that exist for any organization, including: culture, politics, governance structure, funding, therapeutic focus and technologic capabilities. **JHIM**

Christopher Boone is a Vice President at Avalere Health LLC in Washington, D.C, where he advises healthcare clients on the use of clinical research informatics and health IT policy. Boone has a BS in Management Information Systems, MS in Healthcare Administration and a PhD in Public Affairs.

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FEATURE Data Collection

Listening to the Patient

Leveraging Direct-to-Patient Data Collection to Shape Clinical Study Design

By John Reites, Jared Downing, and Adam Calderon

ABSTRACT

Empowering patients to influence clinical study development is at the forefront of innovative research study design. Patient data capture is enabled by leveraging digital technologies, engaging patient communities and employing targeted social outreach.

The end result is rapid collection of patient perspectives via cost-efficient technologies and processes to improve study design. This engagement enables patients to be key stakeholders in the study development process and influence the design of the research in which they, or others with their condition, will participate.

Quintiles routinely reaches out to its 3.1 million global patient community members and the "digital universe" across multiple platforms to conduct assessments of patient perspectives. Over the past 4 years, Quintiles has conducted more than 250 insight assessments directly with patients concerning a wide variety of conditions.

Using innovative technology platforms and engaging with patient communities such as MediGuard.org and ClinicalResearch.com, these assessments have yielded important findings that have supported development of study protocols, feasibility calculations, recruitment and retention plans, etc. We present two case studies to demonstrate how direct-to-patient outreach can support study development. In one case, surveying patients with the particular disorder of interest resulted in an adjustment of the patient reported outcome (PRO) survey instrument cutoff score used for study inclusion. In the second case, patients with a neurodegenerative disease and their caregivers provided perspectives that encouraged investigators to approach them regarding postmortem research.

Digital initiatives that include patients in the clinical trial design process have the potential to maximize the likelihood for study success that may, in turn, yield improved treatment options for their conditions.

KEYWORDS

Patient survey, direct-to-patient, recruitment, protocol design, digital, clinical trial development

THE LENGTHY PROCESS of clinical development of a pharmaceutical product culminates in the clinical trials that are required for market approval. However, at least 80 percent of pharmaceutical trials experience enrollment delays.[1] In addition to delaying the approval of a product that might provide effective intervention for patients, consequences of poor recruitment include increased workload and cost, potential for closure of a trial and the possibility that the trial will not be properly powered to provide significant results.[2-4]

It is important to design trials with a study population that is representative of the population with the disease and that is appropriate for the research question(s) being asked. Inclusion and exclusion criteria should be carefully considered, as inadequate exclusion criteria might introduce confounding factors, while overly stringent criteria will make recruitment more difficult. It is also important to identify optimal recruiting strategies, based on the nature of the disease, level of treatment needed, patient population and the requirements of the trial. While it is common practice to conduct feasibility assessments with investigators to seek input on protocols and enrollment estimates, little attention has been focused on the information that can be gained from patients themselves.

This article describes two case studies in which digital patient communities were engaged through online surveys to provide input into study protocol development. The information obtained from patients was used to optimize study design and, consequently, increase the chances for successful trial recruitment.

CASE 1: ADJUSTING PROTOCOL INCLUSION CRITERIA

During clinical trial recruitment, many potential participants diagnosed with the disorder being studied were considered "screen failures" because they did not meet the study inclusion criteria. In particular, patients were required to have a certain cut-off score on the patient-reported outcome (PRO) survey instrument used in the study that assesses the frequency and severity of symptoms. To develop a better understanding of the potential effect on enrollment if the entry criteria were adjusted, members of the MediGuard.org community who indicated that they were taking certain medications and met other protocol criteria, were invited to participate in a voluntary survey. A total of 100 patients took the survey, which included the PRO survey instrument. Survey results indicated that a minor, statistically acceptable adjustment to the lower range of the inclusion criteria associated with the PRO survey tool could lead to a much larger pool of patients to draw from. Specifically, adjusting the range downward slightly resulted in a ten-fold increase in the number of patients who could be eligible for the study. On review of the survey feedback, the protocol developer revised the PRO survey tool range requirement to facilitate enrollment.

CASE 2: CHANGING SITE STAFF PERCEPTIONS

Investigators at several clinical trial sites had expressed concern about approaching patients with a neurodegenerative disease and their caregivers to participate in a study protocol that involved postmortem brain research. Specifically, site staff was apprehensive about raising what might be a sensitive issue. Using the MediGuard.org patient community, 50 caregivers/patients with a neurodegenerative disease (75%/25% split) were surveyed to determine their receptivity to the patient's participation in a postmortem brain study. Survey results indicated that more than one half of respondents had already discussed end-of-life issues with their physician; no respondent indicated that they did not want to discuss such matters.

- Most survey takers expressed a positive opinion about allowing their brain to be studied after their death, as the research might be able to help others.
- Questioned as to the best way for site staff to broach the issue with patients, many respondents replied that site staff should just ask in a straightforward manner.

Survey results indicated that patients and caregivers were comfortable with being approached about the issue and strongly suggested that the investigators' concerns about the sensitivity of the discussion were unwarranted. Based on this feedback, the overall study strategy was revised, and this discussion step was incorporated into the protocol.

DISCUSSION

While patients are the ultimate beneficiaries from advances in therapy, they are also a critical factor in ensuring the success of the research needed to bring these therapies to market. There is a lot of discussion in the literature about strategies to recruit and retain patients to clinical trials once the protocols are written.[3] As demonstrated by these two cases, involving the patient very early in the clinical development process, when clinical trials are being designed, can yield valuable information that may ultimately impact the success of a trial.

These cases also demonstrate the value of engaging directly with patients in the "digital universe." Findings from a national survey conducted by the Pew Research Center indicated that as of September 2012, 81 percent of U.S. adults use the internet, and 72 percent of those have looked for health information in the last year. Additionally, one in three U.S. adults has gone online to figure out what medical condition he or she or another person may have.[5] While patients use internet references as resources to gain information about their own health needs, many also actively engage in online social exchange through support groups and become active members of patient communities.

In both of the cases, patients who had enrolled in MediGuard.org, a free online service that monitors the safety of prescription medicines, over-the-counter medicines and healthcare supplements, were also able to actively contribute to the study design.

The MediGuard.org platform currently has more than 3.1 million global patient community members who have enrolled to gain information about their medications. When patients enroll, they have the option to indicate whether they would like to be contacted regarding surveys and other activities. Over the past 4 years, Quintiles has conducted more than 250 assessments

WHILE IT IS CLEAR THAT patients can provide information that can impact study approach or design, there is no definitive way to directly measure the impact of patient input on the success of a study.

directly with these patients regarding a wide variety of conditions. Patients have provided valuable information on topics such as burden of illness, medication side effects, patient preferences, treatment dynamics and, as previously illustrated, study design.

While it is clear that patients can provide information that can impact study approach or design, there is no definitive way to directly measure the impact of patient input on the success of a study. Rather, empirical evidence based on practical aspects, the perception of a smoother recruitment process or actual study enrollment and retention can serve as indicators of the value provided by eliciting patients' perspectives.

Overall, engaging with patients via digital technologies including web and mobile devices provides a means to rapidly collect patient perspectives in a cost-efficient manner. This engagement enables patients to be key stakeholders in the study development process and influence the design of the research in which they or others with their condition will participate, and from which they can ultimately benefit. **JHIM**

John Reites As the head of Offer and Product Development for this organization, John Reites is responsible for developing service offers that meet our clients' objectives, future product development and providing subject matter expertise for direct-to-patient and digital health research. Reites is passionate about leading innovation that empowers patients as a key stakeholder in the research process through novel execution methods. Reites has over 11 years experience on 150+ research projects spanning all product development phases for pharmaceutical clients. His experience includes research projects conducted in 52 countries reaching over 4k investigator sites and 33k patients. Prior to his current role, Reites held various leadership positions at Quintiles within Clinical Operations, Project Management and Late Phase.
Connect with John Reites on LinkedIn to learn more.

Jared Downing has worked in pharmaceutical and healthcare marketing research for the past 20 years, the last 4 of which have been with Quintiles. His specialty is using aggregated data collected in market research to provide Quintiles with the "voice of the patient" across a wide spectrum of disease areas. Downing has conducted successful marketing research on six continents, personally interviewing hundreds of physicians/healthcare providers and patients. Downing is fluent in Italian and has a BA in History from Brigham Young University.

Adam Calderon is a respected technology executive with 19 years of demonstrated career success developing and executing technology strategies, building and managing highly focused and well-respected development teams and designing and delivering software solutions that successfully meet and exceed client objectives. He has extensive experience leading operations for technology, business development and application development within a diverse range of industries including insurance, healthcare, pharmaceutical, automotive, telecommunications, oil and gas.

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FEATURE Communications

Healthcare Communications

Connecting the Dots with Existing Technology

By Robert J. Schwartz, MD

ABSTRACT

Healthcare organizations struggle with getting the right information to the right person in the right way at the right time and place. Making these connections is the mortar of the healthcare industry. Getting everyone in sync is even more important now as we begin to move from a fragmented fee-for-service model to outcomes-based accountable care. To tighten connections, healthcare organizations should recognize communications as an asset, re-use existing technology in innovative ways and encourage physicians and other clinicians to take the lead.

This article is based on a decade of results at a major teaching hospital in the Northeast. It explains why keeping caregivers in sync is tough and why it matters so much. The article presents original quantitative and qualitative research that shows what healthcare organizations can do to keep caregivers in the loop, improve patient care quality and safety and, ultimately, save money.

KEYWORDS

Hospital communications and technology, clinical messaging, physician-patient engagement, electronic health records

AFTER RECENTLY getting hurt in a traffic accident, a young man wound up in the emergency department. His injuries were minor enough that he went home after a couple of days. Yet he left before a CT (computed tomography) scan revealed possible lymphoma. The 20 year-old had no primary care physician, only a pediatrician who was not the right physician to follow up with him.

Because he had no primary care physician, the electronic health record (EHR) generated a message, kicking off a predesigned chain of events. The hospital called the man, told him an x-ray needed follow-up, arranged an appointment with a family doctor and made sure he kept his appointment. At some healthcare organizations, this patient may have fallen through the cracks. Coordinating patient care among clinicians can be difficult. Indeed, few healthcare organizations can respond well (or quickly) when communication breaks down.

The implications of this problem are huge. Nearly two-thirds of all sentinel events or patient safety issues stem from miscommunication and patient details getting lost among caregivers, hospitals and offices, according to a study at a major teaching hospital in the Northeast. Healthcare organizations struggle with getting the

right information to the right person in the right way at the right time and place. Making these connections is the mortar of the healthcare industry and involves everyone – floor nurses, office physicians, lab technicians, patients and so on. Getting everyone in sync is even more important now as we begin to move from a fragmented fee-for-service model to outcomes-based accountable care.

To solve this problem, healthcare organizations need to recognize communications as an asset, not a cost. Fortunately, they already have most of the infrastructure in place. Healthcare organizations need to redeploy existing technology to support caregivers and their patients. The following discussion is based on a decade of results at a major teaching hospital in the Northeast. It explains why keeping caregivers in sync is tough and why it matters so much. It also shows what healthcare organizations can do to keep caregivers in the loop, improve patient care quality and safety and, ultimately, save money.

THE CORNERSTONE OF HEALTHCARE

Effective communication must permeate every corner of healthcare organizations—from the housekeeping, transport, dietary and administrative departments to lab technicians, floor nurses, physicians and patients. In theory, healthcare organizations understand the importance of keeping every healthcare team member in the loop. In reality, however, many organizations fail to see communications as an asset that can connect the dots. Too many healthcare leaders view communications as a cost, leaving its various components—voice, data, software, etc.—in separate departments. They overlook the details and believe:

- Healthcare workers communicate "well enough."
- EHRs can magically "auto fax" information between applications.
- Healthcare workers accept their current role of searching for contact information.

Admittedly, some aspects of keeping healthcare workers in sync are fairly simple. But keeping dynamic relationships straight among staff, clinicians and patients is complex, more so than in any other industry.

TABLE 1: The Cost of Miscommunication Between Nurses and Physicians

Unit	Annual labor costs associated with clinical communication failures.
Medical-surgical	$929,071
ICU	$683,280
Total	$1,612,351

Of course, failure to communicate also has costs. A study we conducted at the same teaching hospital showed that hospital nurses often waste time trying to contact physicians. For example, nurses on a medical-surgical unit tried to contact physicians an average of eight times per shift and failed to reach the right physician once per shift, thereby spending nearly seven times longer on failed attempts than on successful ones. (The study found similar results on an ICU unit.)[1]

Indeed, lost nursing time on the medical-surgical and ICU units amounted to $1.6 million per year (see **Table 1**). To fix this problem, one option might be for healthcare organizations to assign call center operators to contact physicians when the information to be conveyed does not require subsequent physician-to-nurse orders, allowing nurses to remain focused on patient care.

UNDERSTANDING THE PHYSICIAN-PATIENT RELATIONSHIP

Why is it so difficult to communicate effectively in healthcare? First, clinical information systems usually focus on the patient, which works well for individual transactions to predefined entities such as sending patients bills and test results. But the most critical communications are the messages sent to physicians. The current patient-focused approach breaks down when the goal is to send a patient's test results to a primary-care physician or a provider who has not seen the patient in a year or more. By connecting these dots, healthcare organizations can enhance continuity of care and avoid patient hand-off errors.

To do this, healthcare organizations need to first understand the relationships among patients and their physicians. That means following the trail from patient to physician and defining, typically through a rule-based process, whom messages are to be addressed. Unfortunately, defining the rules and filling in all variables can be a very challenging process. For example, most patients, and especially patients in the hospital, have multiple physicians. Questions that arise at this point include:

- Is the message going to one physician or a group?
- Who is on call? Who is/was the attending physician? Is he or she available and accessible?
- Are details of each contact route accurate (phone, fax, cell phone, e-mail, text, etc.)?
- How does each physician prefer to be contacted?

Delivering messages to the right physicians is critical. If the wrong physicians get messages about a patient, they will initially assume the sender is correct and then waste time looking for that patient in their records only to discover he/she is not their patient after all. As a result, physicians have wasted time and the right physicians still have not been found.

Finding the right physician requires a few more steps. For example, at the same hospital, we programmed the hospital's EHR to create a message if a patient has both diarrhea and a white blood cell count of more than 25,000. With both condi-

HEALTHCARE ORGANIZATIONS OFTEN assume deploying the latest technology alone will allow clinicians and staff to communicate and coordinate patient care more effectively. In fact, the journey begins with understanding communications theory.

tions, a patient risks a serious, potentially fatal infection (*Clostridium difficile*), which requires quick attention from the right physician.

To whom do you send that message? Many healthcare organizations send it to multiple physicians—the hospitalist who ordered the test and the patient's primary care physician. This may take hours to resolve; those who receive the message must communicate further to decide who needs to act. The hospitalist who ordered the test may defer to the primary care physician (if the patient has been discharged). Meanwhile, the primary care physician may balk because he/she did not order the test, which occurred while the patient was admitted to the hospital.

To solve this dilemma, healthcare organizations need to know where the patient is—are they in, say, the cardiology or oncology area? Have they left the hospital? If the patient has been discharged, then healthcare organizations should send a note to the patient's primary care physician, saying "We believe you are the right person to follow up with the patient. If, however, you disagree, please contact the hospitalist (listed below)." Healthcare organizations should also send the message to the attending physician, saying, "We believe this is the primary care physician's responsibility. If he/she disagrees, he/she might contact you about it." With this approach, both physicians who are tied to the message understand the situation and who is responsible for it.

KEEPING PACE IN THE ACO RACE

Few healthcare organizations coordinate care with their physicians in this way. Yet they should strongly consider automating such tools to keep pace as the healthcare industry shifts from paying for individual services to paying for improved patient outcomes, lower costs and enhanced population health. Although organizations will rely significantly on the availability of data, they can achieve these goals only if physicians and other clinicians communicate more efficiently and effectively.

Suppose a primary care physician in an ACO wants to refer a patient to an outpatient cardiology department after detecting an arrhythmia. Currently, the physician's office staff must call the cardiology department and make an appointment. The patient is responsible for showing up. If the patient ignores the appointment, he or she misses treatment and the care process breaks down.

Technology can help. If the physician ordering the referral uses EHR tools to schedule the appointment, the tools can send a message to the ordering physician if the patient fails to show up, at which point further action could be taken. The tools within the EHR now allow the physician to coordinate care, shifting part of the burden away from office staff. (Healthcare organizations that improve care coordination also lower malpractice risk by reducing the potential for delayed diagnoses and harm from non-treatment.)

BASICS OF COMMUNICATIONS THEORY

Technology is only a tool, however. Healthcare organizations often assume deploying the latest technology alone will allow clinicians and staff to communicate and coordinate patient care more effectively. In fact, the journey begins with understanding communications theory, the basics of which are explained next.

Everyone communicates every day in many ways – written notes, voice mail, e-mail, conversation, text messaging, social media, telephone and fax. There are three components: the one who sends the information, the channel by which it is sent, and who receives it.

As just mentioned, examples include:

1. Paging: A nurse sends a page to a

physician to discuss a patient's vital signs. A telephone is the channel, linked to the paging transmitter and to the pager. The physician with the pager receives the page.

2. Request for release of records: A patient sends information after signing a release form. A fax, sent directly to the Health Information Management (HIM) system, is the channel. The receiver is a department member, not necessarily a specific individual.

3. Decision support rule: The decision support engine within the EHR sends an alert. There are many ways to do this, but the decision support engine is the channel via a note to an inbox. The caregiver receives the message.

Different channels have different characteristics – some more complex than others. For example, one characteristic – reliability – is fairly simple to estimate. However, another characteristic – addressing – is more complex because sending messages to the right person (or group) is difficult when variables such as on-call schedules change constantly. (For a more detailed explanation, see "Communications 101.")

This complexity requires healthcare organizations to handle clinical messaging internally. Building infrastructure that better connects healthcare workers is too important to outsource to third-party vendors. These new connections must be supported by technology, but relying on technology alone will miss the mark.

STARTING POINT: CONNECT EXISTING DATA, INVOLVE PHYSICIANS

Fortunately, many healthcare organizations can rearrange their existing staff and technology to strengthen communications and tighten patient care coordination. These changes require investment and redesigning workflows, but cost less than replacing all existing infrastructure. Indeed, 70 percent of the staff and technology is already available at most hospitals. Their roles and functions just need to shift. Many types of employees manage contacts within hospitals—operators, schedulers, secretaries, healthcare coaches, care managers, care coordinators, etc. The goal is to encourage these employees to become knowledge workers who make decisions and help clinicians make decisions (as opposed to focusing on individual transactions). This increases efficiency and productivity.

Another strategy is to integrate the phone system—which every hospital has—with the computer systems. Healthcare organizations that arrange for effective data exchange between their phone and computer systems (and vice versa) have a competitive advantage by connecting the rich, available and combined data from these two sources with a decision-support engine from an EHR that can create and follow rules.

One example, mentioned earlier, is the rule for alerting physicians of hospital patients who may have a fatal infection. Another example involves hospitals' current efforts to reduce or prevent readmissions. One condition with a high readmission rate is congestive heart failure. An EHR rules engine can identify when a congestive heart failure patient leaves the hospital and then notify a healthcare coach to follow that patient closely. In addition, the phone system can make

Communications 101

TO COMMUNICATE EFFICIENTLY, healthcare organizations must first grasp the benefits and drawbacks of all available communications channels and then craft a plan to maximize these channels. Successful healthcare organizations typically start with the following concepts:

Reliability. Knowing a message will arrive at the desired destination. Sometimes the post office loses envelopes and e-mails end up in the ether; reliability varies for each channel.

Scalability. Can the message channel handle increasingly larger volumes of messages? Many hospitals do not need to scale their messaging over a long period of time, but most need "blast-style" communication to support their disaster plans.

Addressing. Identifies the unique data of where a message needs to go. Relies on a message's channel (i.e., postal mail uses postal addresses for addressing, cell phones use 10-digit numbers, text is variable, and aliases are possible). Messages can be addressed to individuals as well as locations, groups, roles (i.e., department chair, supervisor of 3N), and changing identities (i.e., on-call schedules). Navigating these possibilities makes it tough to provide reliable addresses.

Synchronized vs. asynchronous. Communicating in real-time (telephone conversation) versus back-and-forth (e-mail). When two people speak, they can confirm and acknowledge information directly. This is valuable when messages must get through. The drawback: Both people must be available, and it can interrupt the workday. Sending messages back and forth saves time, but the exchange may remain incomplete – a major drawback.

Delivery confirmation and acknowledgement. Did the message arrive? (confirmation) Did the right person receive and respond (acknowledgement)? Clinically, these concepts are extremely important and relate directly to patient care and risk management.

Escalation. How should healthcare organizations deal with confirmed, yet unacknowledged, messages? They escalate from intern to attending to physician on-call to department chair. This process is extremely valuable and supports productive healthcare operations, but only if an organization has a thoughtful escalation plan. Without one, this process can consume vast amounts of time and resources.

Dynamic status. Data changes every minute —on-call schedules, group relationships, phone numbers, workers by shift. This multiplies the complexity and chance of error and requires a real-world operational plan.

NEARLY TWO-THIRDS OF ALL sentinel events or patient safety issues stem from miscommunication and patient details getting lost among caregivers, hospitals and offices.

automated calls to remind such patients to weigh themselves daily and take their medications.

Although these projects require new technology and resources, they must be led by an interdisciplinary team of physicians, nurses and other clinicians. A physician champion can help manage the organizational change these projects require and encourage healthcare leaders to establish governance structures that engage their peers and other clinicians. Clinicians need to have a voice and be involved in redesigning workflows and processes.

Several years ago, the teaching hospital previously mentioned began sending electronic discharge summaries to patients' primary care physicians. At first, the hospital succeeded in having the discharges reach their target only 55 to 60 percent of the time. Today, however, through rigorous management of the summaries' transmission error queue, the success rate has risen to 95 percent.

BUILDING TIES THAT BIND

As we enter a new era of accountable care, many hope to achieve the triple aim of healthcare reform: improving the patient care experience, while lowering per capita costs and advancing population health. Conventional wisdom says these goals can be accomplished by (among other things):

- Investing in technology to track patient outcomes and analyze patterns.
- Then better deploying nurses, social workers and other physician extenders to help physicians coordinate outcomes-based care.

Both strategies are needed to reform healthcare. But simply hiring more healthcare workers and supplying technology to support them is not enough. Also needed is a broad, practical approach to connecting all healthcare workers in real time. To tighten connections, healthcare organizations should recognize communications as an asset, re-use existing technology in innovative ways and encourage physicians and other clinicians to take the lead. Improving communication among healthcare workers is challenging, but, with the right approach, healthcare organizations can succeed. **JHIM**

Robert J. Schwartz, MD, is a Physician Executive at Dearborn Advisors, LLC, has over 28 years of clinical experience and remains active in clinical medicine. He is board certified in Emergency Medicine and Preventive Medicine. Prior to joining Dearborn Advisors in 2009, Dr. Schwartz served as Vice President and Medical Director of Referring Physician Relations at a major teaching hospital in the Northeast.

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FEATURE Malpractice

Can EMRs Affect the Outcome of Medical Malpractice Cases?

A Review of Illinois Medical Malpractice Trials

By James Meyer

ABSTRACT

Four years of medical malpractice trials in Illinois were reviewed to determine what types of medical records issues arose in medical malpractice cases, how often the issues occurred, their effect on trial verdicts and the effect that electronic medical records are likely to produce in future malpractice cases.

KEYWORDS

Electronic medical records, medical malpractice, metadata, data-mining

When medical professionals consider the relationship between electronic medical records (EMR) and medical malpractice claims, their conclusions seem divergent. Some see EMRs as a positive development because studies show the adoption of EMRs to be associated with fewer malpractice claims being made.[1]

Others see a negative impact because they expect metadata in EMRs will make it easier for attorneys to prove their malpractice claims.[2] Both views could be accurate. EMRs and their associated metadata could both promote better clinical practice, and thus be responsible for fewer claims in the first instance, while simultaneously, making meritorious claims easier to prove.

There is another perspective, more typical of lawyers, from which to view the likely effect of EMRs on malpractice claims—a review of the known outcomes in past malpractice cases. In other words, a lawyer would first try to determine how significant medical records issues were in recent medical malpractice trials to estimate the effect the new technology may have in future cases. In one state, Illinois, there is such a record of past medical malpractice trials that can be used to estimate how often and how important medical records are in medical malpractice trials.

CONTENTIOUS MEDICAL RECORD ISSUES IN ILLINOIS MALPRACTICE CASES

The *Jury Verdict Reporter* is a paid subscription publication that is commonly accepted by the legal community as an accurate, and valuable, record of the number and type of cases tried to verdict in Illinois.[3]

Unlike the more familiar Appellate Court and Supreme Court Reporters, the *Jury Verdict Reporter* covers the evidence and issues as they occurred during the trial of cases. Although the *Reporter* does not contend to report every injury trial or settlement in the state, it is generally considered by practicing lawyers to be an accurate record of the vast majority of trials and settlements that occur in Illinois. And, it is particularly helpful in an investigation of medical records issues because, unlike a trial transcript, it contains a synopsis of each case supplied by the trial lawyers involved in the case, including the issues and evidence the

lawyers thought were important in producing the verdict in their case.

To estimate how often medical records issues arise in medical malpractice cases in Illinois, the author reviewed the case synopses of all medical malpractice cases in the four most recent years of the Cook County and Illinois reporters, identifying cases in which the lawyers reported a contentious medical records issue. By "contentious medical records issue" is meant a dispute about some aspect of patient care described in the trial synopsis that may have been obviated or resolved if EMRs had been in use in the case. The types of issues described included:

- Instructions or disclosures to patients "not documented" or "not recalled."
- Staff communications to attending physicians not documented.
- Test results not sent to attending physicians.
- "Missing" monitor "alarm strips," "nursing progress notes," "code blue sheets" and test results.
- Monitor records "inadvertently erased."
- Significant unexplained delays between the order and performance of diagnostic tests.
- Significant delays in the production of paper copies of diagnostic test results.
- Commingled patient test results.
- Notes, observations of staff, and x-ray reports "not written" or "not filed" in the record.
- Inability to explain how and when "revised" test results were entered into the record or transmitted to physicians.
- Inability to identify who read CT scans and reported results.
- Undocumented patient "refusal" of treatment.
- Undocumented prescription dates.

My review found 87 medical malpractice jury trials occurred in Illinois in 2012; and 25 of those trials resulted in verdicts for the plaintiffs totaling $73 million. In five of the 25 plaintiffs' verdicts (20 percent), one or more parties described a contentious medical records issue during trial.[4]

In 2011, 98 malpractice trials were reported with 22 plaintiffs' verdicts with a total of $40 million awarded; three cases (13 percent) describe contentious medical records issues.[5] In 2010, there were 110 medical malpractice trials reported with 33 plaintiffs' verdicts totaling over $111 million; contentious medical records issues were reported in eight cases (24 percent).[6] And in 2009, there were 50 verdicts for plaintiffs with $162 million awarded; 10 cases (20 percent) reported contentious medical records issues.[7]

FIGURE 1: Cases with and without contentious medical records issues in 130 verdicts awarded to plaintiffs 2009-2012

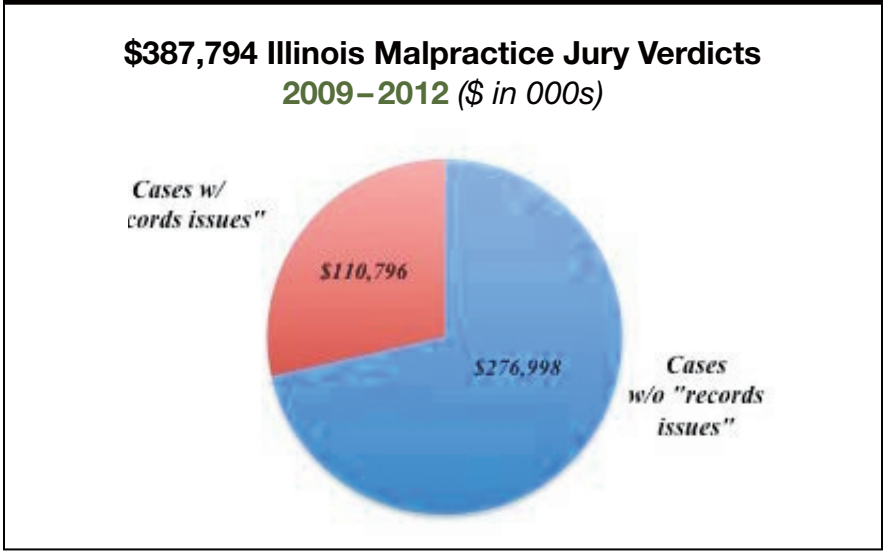

FIGURE 2: Distribution of total verdicts between cases with and without contentious medical records issues 2009-2012

THE EFFECT OF MEDICAL RECORD ISSUES ON ILLINOIS JURY VERDICTS

The fact that contentious records issues appeared in a significant number of medical malpractice trials is not to suggest that those issues were the cause of the verdicts. Even though the attorneys involved in those cases felt the record issues was significant enough to include in their synopsis of the trials, they were not the only issues reported in those cases, and there is no

RELEVANT METADATA WILL BE admissible evidence in medical malpractice cases as a part of patient's medical record. The importance of all record evidence is that it changes the character of events from subjective, first-person experience—what a witness remembers—into objective, third-person existence—what is recorded.

way to determine exactly how important any issue was in driving the outcome in any particular case. Certainly, a plaintiff in a malpractice case must prove more than corrupt or missing records to be successful.

However, cases with "contentious medical records issues" do appear to affect total jury verdicts out of proportion to their number. **Figure 1** shows the total number of cases with and without "records issues" for the four years reviewed, and **Figure 2** shows the total amount of the verdicts in each category.

Records issues are also associated with larger average verdicts. **Figure 3** compares the average verdict in cases with and without records issues. In three of the four years reviewed, larger average verdicts occurred in the cases with records issues, in some years substantially larger.

In addition to verdicts, the Jury Verdict Settlement by Categories also reports Illinois medical malpractice cases that were settled without trial. In 2012, there were 138 cases reported as settled with a total of over $288 million paid.[8] In 2011, 105 cases were reported settled with a total paid over $345 million.[9] In 2010, 113 medical malpractice cases were reported settled with a total paid of $286 million.[10] And, in 2009 163 cases were reported settled with a total paid of $398 million.[11] The descriptions of the settled cases do not contain enough detail to determine whether medical records issues played any part in the settlements, but if the same percentages of contentious medical record issues found in the cases with verdicts occurred in the settled cases, the number of settled cases with medical records issues is significant.

Obviously, the number of medical malpractice cases and the amounts of verdicts and settlements varies from state to state. But, there is no reason to believe that the percentage of cases with medical records issues, and their correlation to verdicts, found in Illinois should be different in other states; there is nothing unique about "records issue" cases or medical malpractice litigation in Illinois that would produce atypical results.

Assuming the Illinois numbers are typical of other jurisdictions, they suggest that contentious medical records issues arise in a significant number of medical malpractice cases. They also suggest that when unexplained, medical records issues work against the interests of the medical record-keeper, i.e., the defendant(s) in malpractice cases. This is consistent with a universally accepted legal presumption—the adverse inference drawn from a party's failure to produce records that they control.[12] In Illinois, as in most states, a standard jury instruction tells jurors that the failure of a party to produce records within his control, or explain their absence, creates a presumption that the evidence if produced would have been adverse to him.

HOW EMRS ARE LIKELY TO CHANGE FUTURE CASES WITH RECORD ISSUES

What reasonable predictions can be made about how EMRs will affect records issues in future malpractice cases?

First, EMRs should prevent some issues—those particular to paper records—from occurring at all. If a record of a patient encounter, the results of a diagnostic test, or a communication between staff is entered in an EMRs system, it is unlikely to go "missing," be "erased" or misfiled. Second, metadata in EMRs will be used to supply detail that may resolve other issues. Relevant metadata will be admissible evidence in medical malpractice cases as a part of patient's medical record. The importance of all record evidence is that it changes the character of events from subjective, first-person experience—what a witness remembers—into objective, third-person existence—what is recorded; and the actors in the case become, for better or worse, characters in that recorded narrative. Because EMR metadata will produce a more finely detailed narrative of events

FIGURE 3: Average verdicts in cases with and without contentious medical records issues 2009-2012

than can be reconstructed from paper records, EMR metadata can supply the details to resolve issues that involve questions of who saw what, when. And, because this kind of evidence could be *the* dispositive factor in proving the case for a plaintiff or, conversely, exculpate a defendant, electronic medical record-keepers can expect there will be more data-mining in medical malpractice cases. More data will surely result in more data-mining.

It is important to realize that increased data-mining will not pose a new danger for healthcare professionals. Because the adverse inference imposed on record-keepers for their failure to produce records under their control will apply to EMR metadata just as it does to paper medical records, healthcare professionals will not be exposed to a danger they have not previously faced. If metadata assists a plaintiff in proving a case, the defendant will be in no worse position than if the metadata were not produced and assumed to be adverse to his position. As long as metadata is required to be collected, it will have the same positive or negative effect in a malpractice case as any other record. In a case where the standard medical record is incomplete or in cases in which the details of "whom, when and where" are critical, metadata is just as likely to reduce the chance of an adverse result for a doctor or hospital. Even those who warn of the potential drawbacks of EMRs recognize that "[E]lectronic documentation is likely to bolster the accuracy of courts in determining liability by enhancing the evidence available to evaluate claims."[13]

Finally, it is likely that EMRs will be data-mined in cases without records issues. Plaintiffs, looking to support their claims, and defendants, conducting proactive defensive investigations, will likely be data-mining. Although a patient's personal health information is normally strictly private, once a claim is made or a malpractice case filed, and proper HIPAA requirements have been met, defendants will have access to all the EMR data available to his adversary. Even without a records issue, both sides will be interested in early identification of advantages or problems to be further investigated, thereby promoting early resolution or remediation of a claim.

Issues involving patient medical records arise in a significant number of medical malpractice cases. EMRs will likely easily resolve some of the issues that occurred in paper record cases. And, because of the detail they contain from which to reconstruct clinical events, they will likely have an important role in future cases, whether or not those cases present records issues. **JHIM**

James Meyer is an attorney in private practice in the law firm of Ialongo & Meyer in Chicago. He is the co-author of an article on electronic medical records as legal evidence recently published in the *Illinois Bar Journal*, a publication of the Illinois Bar Association.

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Journal of Healthcare Information Management

Writer's Guidelines

ABOUT JHIM

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Abstract proposals must include a single-spaced abstract (no more than 250 words) and a complete list of authors and contact information. Send abstracts to Matt Schlossberg, Manager (matthew.schlossberg@himssmedia.com).

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JHIM seeks articles in the following formats:

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- **Technology overview:** Articles surveying and defining the key enabling technologies and/or business methodologies for the industry or its components, formulas for budgeting and/or needs assessment.
- **Case studies:** Articles explaining who, what, when, how and why of a problem or challenge, and how it was solved or solution proposal. These include consumer-focused case studies. "Marketing" articles are unacceptable. Products names area allotted a single mention. We strongly suggest that articles be co-authored by the provider and vendor.
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Send articles to Matt Schlossberg, Manager (matthew.schlossberg@himssmedia.com).

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Length:

- *Articles:* 3,000-5,000 words
- *Columns:* 1,000-1,500 words

Format:
Single-spaced, single-column format, with ragged right body text.

Layout:

- Opening page will include title and bylines. Articles MUST include the abstract and six to 10 keywords.
- DO NOT include headers or footers in article. Do not include page breaks or numbering.
- Footnotes and references should NOT be formatted. To indicate a footnote within the body of text use a standard unformatted number inside brackets. (Exp. [1]). Use AMA style for references.
- Major headings should be in CAPITAL LETTERS, flush left within the column.
- DO NOT include any graphics, illustrations, figures or tables in the body of the article. All graphics must be submitted in separate documents.
- Author biographies are limited to 30 words and should appear at the end of text.
- Caption text for each figure and graph MUST appear at the end of the article.

Figures/Graphs/Charts:

- Articles are limited to three figures, graphs and charts.
- Do not create graphics (tables, figures, charts, graphs, illustrations) in a word processing program.
- Graphics MAY NOT be included within the text of an article. They must be submitted in native file formats.
- Graphic files must be a minimum resolution of 300 dpi and submitted in native file formats. Vector-EPS extensions are strongly preferred. Tables should be as Microsoft Excel documents. PowerPoint presentations, PDF and Web-based (.gif) extensions are UNACCEPTABLE.
- Assign a title and/or figure number to each graphic in the extension. DO NOT include title within body of graphic.
- Label x and y axis of every graph.
- Distinguish bars or pie chart sections by pattern, not color.

Style and Presentation:

- Use standard spelling, style, reference, and grammar guides such as *Webster's New Collegiate Dictionary*, the *American Medical Association Manual of Style* and *The Elements of Style*.
- Use active sentences and be specific. Back up generalities with examples. Avoid jargon.
- All articles will be copy edited and, where necessary, rewritten. The process by which authors may review and approve changes is defined in the letter of agreement.

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FALL 2014
Topic: Innovation in Health IT: Bringing Creativity to the Industry's Most Pressing Challenges
Abstracts Due: July 3, 2014
Manuscripts Due: August 21, 2014
Publication Date: October 19, 2014

WINTER 2015
Topic: IT Infrastructure & Implications: Cloud Computing, Security, Data Analytics & Other Technologies
Abstracts Due: August 11, 2014
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