Perspectives and Updates on
Health Care Information Technology

HIT Perspectives

About the newsletter

HIT Perspectives is published by Point-of-Care Partners. Individuals at the leading management consulting firm assist healthcare organizations in the evaluation, development and implementation of winning health information management strategies in a rapidly evolving electronic world. The team of accomplished healthcare consultants, core services and methodologies are focused on positioning organizations for success in the integrated, data-driven world of value-based care.

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1 Part 1: Interoperability: The Glass Is More than Half Full

By Tony Schueth, Editor in Chief, and Michael Burger, Senior Consultant

Interoperability — or the perceived lack thereof — is one of the hottest topics in healthcare and the health information technology (healthIT) industry. Improved interoperability is at the top of the agenda for the Office of the National Coordinator for HealthIT (ONC), which just issued a road map for the next decade. Meanwhile, fingers are pointing everywhere in very public ways at the perceived lack of interoperability. Everyone, it seems, is to blame.

In our view, while there is definitely room for improvement, coordination and innovation across the healthIT landscape, much has been accomplished already. In our view, the interoperability glass is more than half full. Here's why.

Jason Report. The "guidebook" for interoperability bashing is the JASON Report, which was issued a year ago with funding from the Agency for Healthcare Research and Quality (AHRQ). Highly critical of the status and trajectory of interoperability, it concluded that meaningful use (MU) stages 1 and 2 have not achieved meaningful interoperability "in any practical sense" for clinical care, research or patient access due to the lack of a comprehensive, nationwide architecture for health information exchange (HIE). The report pointed to the lack of an architecture supporting standardized application programming interfaces (APIs), as well as electronic health records (EHR) vendor technology and business practices, as structural impediments to achieving interoperability. JASON recommended that health care interoperability be reoriented away from "siloed legacy systems" toward a centrally orchestrated interoperability architecture based on open APIs and advanced intermediary applications and services.

ONC sponsored a task force to conduct an analysis of the JASON Report, which rebuts many of its assertions. According to this analysis, "…JASON does not accurately characterize the very real progress that has been made in interoperability, especially in the last 2 years. Second, JASON's description of current generation clinical and financial systems does not accurately portray the broad range of functionality of these systems, or the innovation occurring on those platforms. Third, the report addresses software engineering and architecture aspects of interoperability but explicitly does not examine policy, legal, governance, and business barriers to health information exchange. Yet, the report recommends aggressive timelines for change that would be difficult to achieve when taking into account policy, legal, governance, and business barriers. Fourth, the software architecture recommended by JASON assumes a high degree of centralized orchestration; however, the report does not describe the source, structure, and process for achieving such orchestration…" We couldn't have said it better ourselves.

We would also add that while useful, APIs are not the end all and be all. They are one way to allow third-party programmers (and, hence, users) to bridge from existing systems to other software. However, APIs can impede interoperability — particularly how they are supported. Companies can discontinue or limit the services and APIs that are necessary to make certain applications work. Terms and conditions of use can change dramatically at any time. Prices can escalate. Worse yet, companies offering APIs can simply go out of business, leaving users high and dry. Also, as previously noted, the healthIT landscape is rapidly changing. Consequently, an API that is necessary in today's world may not be needed tomorrow.

Vendors. Vendors are feeling the brunt of the blame game for this perceived lack of interoperability. Some of this is fueled by the overwhelming number of vendors. There are more than 600 EHR vendors alone, by last count. Do they all do the same things in the same way? No. Should they? According to many users and government agencies, they should do everything the same way so they can "talk to each other." In reality, not all systems will do all things the same way because the functionality, cost and innovativeness of individual products speak directly to branding, competitive advantage and market

share. Nonetheless, the sheer number of vendors and their functional differences (good, bad or indifferent) make it easy for government agencies and users to perceive a lack of vendor interoperability.

Some of the blame game is being fueled by the very public infighting among vendors themselves —specifically those belonging to the Commonwell Alliance and those who are not members (one major player, in particular). Will pushing all vendors into one camp or another crack the interoperability code or lessen the perceived lack of interoperability? We don't think so. However, there is considerable interoperability gravitas in both camps, which have done much work and have real foundational elements on which to build.

All that being said, we believe vendors are getting a bad rap. The bottom line is that there is a core level of interoperability for EHRs which have met certification standards for MU. And yes, the certification processes and requirements must be met by everyone as they have been mandated by the government and grudgingly adopted by the industry. While the one-size-fits-all MU requirements and processes have tended to stifle innovation, they have left a core of basic interoperability across all EHR vendors. The glass is definitely more than half full.

Providers. Some blamers point to providers, who often appear conflicted about what they want. Providers are concerned about receiving volumes of clinical information from other caregivers and then being tasked with the responsibility for reconciling them to try to find pertinent information. Overarching this concern is potential liability. What happens if an important piece of information was inadvertently overlooked and then harm comes to a patient? Identifying the pertinent information that providers want is a significant challenge because needs vary widely by circumstance and preference. The problem is not so much lack of interoperability as it is legitimate differences in the practice of medicine from provider to provider, as well as their business needs and priorities.

The business case: the missing piece of the puzzle. We at Point-of-Care Partners believe the missing piece of the interoperability puzzle is the lack of a business case.

No one can argue the public health benefits of an interoperable EHR. Study after study have shown that providers can take better care of patients by having access to the full breadth of a patient's care records. Other studies have pointed to the cost effectiveness of an interoperable health record that reduces the possibility of duplicate testing and administrative overhead.

From a competitive perspective, sharing patient records may not make sense. In markets having multiple integrated delivery networks (IDNs), participants are vying for the same patients. A significant advantage promoted by IDNs is their ability to offer all of the services a patient needs — primary, specialty, and emergency care; surgery; etc. One way to ensure that patients stay "in network" is by enabling complete and seamless access to patient records within the network, and to make records available in a less convenient (on paper) and slower manner (i.e., faxed) outside the network. Why? Because there's no business case for a network to make it easier for a patient to choose a competitor.

No IDN would ever publicly admit to such a notion, but the lack of success among HIEs points to this conclusion. IDNs give lip service to a desire to share data but are slow to act, and the HIEs created as hubs to share the data close in bankruptcy while waiting.

Competition also contributes to the bad rap EHR vendors are receiving. While one could argue that it is the design of EHRs to create silos of data, could it not also be that for competitive reasons, IDNs silo their data?

In short, we have done a poor job creating a viable business case for interoperable healthIT. The answer isn't to create new standards and mandate via regulation that records be shared. Creating incentives and removing competitive barriers to data sharing will enable the market to self-adjust based upon supply and demand. Existing healthIT technologies already "talk to each other." Addressing competitive barriers will enable us to confidently build on the base that has already been created.

2 Part 2: Biosimilars: Opportunity Knocks – Building a Better Technology Mousetrap

By Brian Bamberger, Life Sciences Practice Lead

Biosimilars are officially approved subsequent versions of off-patent biopharmaceutical products, sometimes also called "follow-ons." Like the biologics they're following, these "large molecule" drugs are made from living organisms and used to treat complex diseases, including Alzheimer's and cancer. Examples of biologics include gene therapies, blood or blood components, vaccines, allergenics or recombinant therapeutic proteins.

Already in use in Europe, biosimilars are poised to enter the US market in 2015, with two such drugs already in the Food and Drug Administration's (FDA) approval pipeline.

Paving the way for their introduction was the Biologics Price Competition and Innovation Act passed in 2009. Market entry has been slow for many reasons, not the least of which is the challenge of integrating biosimilars into the current US drug supply, order, distribution and administration system.

Perhaps one of the biggest challenges is that biosimilars are not generics, which are FDA-defined bioequivalents of small molecule (traditional) drugs synthesized using chemical processes. Unlike generics, biosimilars are not integrated with pharmacy inventory and dispensing, ePrescribing, claims switching – all core infrastructure components built for pharmaceuticals marketed by chemical name and bioequivalent to a brand/reference drug product.

Biosimilars, on the other hand, are manufactured in or from biological sources and not always interchangeable, identical or bioequivalent. In fact, the FDA will give them four ratings: 1) not similar, 2) similar, 3) highly similar, and 4) highly similar with a fingerprint-like similarity. Clarity will be provided in the Purple Book, which is meant to be the equivalent for biologics profiled in the Orange Book, a statutorily required, FDA publication that links small-molecule drugs to approved therapeutic equivalents.

Regardless of the rating, biosimilars may perform very differently from the original branded version, thus posing a safety concern.

Whereas the chemical process used to synthesize small molecule generics is relatively straight-forward, that's not necessarily the case with large molecule biologics. One of the challenges with biosimilars is that their manufacturers do not have access to the innovator product's original molecular clone or cell bank, nor to the exact manufacturing processes or active drug substances. Furthermore, there are concerns that even within the same manufacturer, there may be variations by lot. All of this leads to the importance of tracking by manufacturer and lot number.

Like small molecule medications, prescriptions for biologics and biosimilars are written by physicians.

Unlike traditional medications, biologics and biosimilars are dispensed via channels that are more limited and controlled, which makes them theoretically easier to track. However, they may be administered in a variety of clinical settings, or self-administered by the patient him or herself. Today the drug, manufacturer and lot numbers rarely reach the point of administration, making it a challenge to record specifically what was administered, particularly for cases of patient self-administration.

Further confounding the situation is that information about the administered biologic does not get communicated back to the prescribing physician. The reason is that there is no consensus on the rationale for doing so, and the supporting transactions either do not exist, are not being used or have yet to be standardized.

This is important because adverse events are most commonly reported by the patient to their physician. Without the knowledge of what biologic or biosimilar was dispensed, linking the adverse event to the manufacturer, drug and lot number is a real challenge and a missed opportunity.

It is suboptimal because, ideally, an adverse drug event would be traced back to the manufacturer, drug and lot number of the administered biologic or biosimilar, ensuring that impacted patients are alerted and situation addressed more efficiently. In addition, it would provide data to help justify non-impacted patients remaining on therapy, and provide critical information to the manufacturer and Federal government that will help address potential future challenges and decrease risks.

This is where electronic health records and health information technology can help. We will address these benefits and the potential high value of biosimilars in a future article.

3 Part 3: How EHR Vendors Are Making Productive Use of Regulatory Downtime

By Tony Schueth, Editor in Chief, and Michael Burger, Senior Consultant

The hard work of thrashing through requirements and building new features for meaningful use (MU) stage 2 has come to an end for most electronic health record (EHR) vendors. Analysis of what must be done for stage 3 has begun, but those features won't be needed until 2017. In addition, there have been numerous stops and starts for the use of the International Classification of Diseases, 10th edition (ICD-10), the new compliance date for which has been put off until October 1, 2015. That's a long hiatus from what are essentially regulatory requirements, and savvy EHR vendors have an opportunity to use that time wisely.

We wondered what EHR vendors plan to work on in the interlude between MU stages and ICD-10. At the recent annual meeting of the Medical Group Management Association (MGMA) in Las Vegas, we learned that many EHR vendors are using their time productively to:

- **Address customer-requested enhancements.** Those we spoke with for this article lament the good old days when the majority of product enhancements came from users. That hasn't been the case since HITECH. You see, despite its benefits, MU has taken up the vast majority of development bandwidth, first in a rush to incorporate functionalities and later to optimize them. It's not clear who struggles more with this pace of change – the EHR vendors or their clients. One thing is certain – the delays have presented an opportunity to focus anew on customer-requested enhancements.

- **Tackle usability.** It's no secret that many physicians are dissatisfied with their EHRs. This has been confirmed by many studies, most recently one by the RAND Corporation. It found that EHRs worsen physicians' satisfaction in areas such as increased time performing data entry, interference with face-to-face care, interfaces that don't match work flow, poor health information exchange and a mismatch between MU and clinical practice—all of which may adversely affect patient care. Smart vendors are using this hiatus to make work flows more efficient and optimize their products for usability.

- **Revisit outsourced functionalities.** Many vendors have outsourced functionalities for ePrescribing as a shortcut to achieve MU stage 1 or 2 certification. While these bolt-on applications have served their purpose, vendors are now revisiting the need to outsource them and developing native functionalities that are more cohesive with the overall product offering.

- **Avoid sharing revenue with other vendors.** Two considerations of outsourcing EHR functionalities are cost of goods and sharing revenue with third parties. Some vendors are evaluating what they can do or change to cut out the middle man. When pass-through costs for partner products are reduced or eliminated, revenue opportunities increase. For example, one EHR vendor is replacing a consolidator for prescription co-pay coupons and working directly with sponsors' direct physician messaging.

- **Improve patient engagement capabilities.** MU stage 1 introduced a need for physicians to provide patients electronic access to their medical information. Stage 2 added the need for physicians to conduct secure messaging with patients. Now that the baseline functionalities have been built and the rush toward MU certification has passed, vendors are doubling down on their offerings for patient engagement. Some are beefing up web portals. Some are adding or improving

functions to make them more patient friendly, such as the ability to schedule appointments electronically, refill prescriptions, access and update their information and pay bills. Others are exploring innovative ways to provide educational materials and adherence programs, which are important toward improving outcomes and managing costs for patients with such chronic conditions as diabetes.

EHRs are, after all, a product offered by a business. It's clear in our discussions with vendors that their focus during this cycle is on improving the usability of features that already exist rather than adding new functionalities. During this hiatus of MU-related development, they have an opportunity to listen to what that their clients want, which is to be able to more easily use features that they already have, and not add new ones. This strikes us as a very productive way for EHR vendors to differentiate themselves, create demand for products and increase market share.