

Blackford Middleton

on

Cloud Based Clinical Decision Support Systems

A Conversation with David Harlow at *HealthBlawg*

February 2016

David Harlow: This is David Harlow at HealthBlawg, and I am speaking today with Blackford Middleton who is a clinical informatics expert and has a long history and career in this field. He is currently on the faculty at the Harvard School of Public Health. He is on the board of the American Medical Informatics Association, AMIA. He is a past Chair of HIMSS and he has been on the faculty at Vanderbilt and Harvard and worked at related affiliated institutions as well. Welcome Blackford, thank you for joining us on HealthBlawg.

Blackford Middleton: My pleasure David, thank you.

David Harlow: I would like to talk with you today about clinical decision support systems and I know you've been speaking and writing recently about cloud-based clinical decision support systems. So I wonder if for starters you could explain to us: When you say "cloud-based clinical decision support system," what do you mean?

Blackford Middleton: I would be happy to, David. Thank you. Let me describe first what I see as the essential motivation, because I think that helps to put into context. In our country certainly we've seen, with the HITECH Act and the Meaningful Use investment, significant adoption of EMR with a goal of attaining meaningful use and the ultimate goal of improving quality and lowering cost of care. One of the fundamental problems I've seen, though, with this policy is that while health systems and clinicians have adopted EMR across the land, fundamentally we're not achieving the value proposition that I and others have estimated should result from the effective use of healthcare IT.

For example, at the CITL, the Center for Information Technology Leadership, Boston; we have estimated that advanced clinical decision support in ambulatory EMR, computerized provider order entry should result in savings of approximately \$44 billion in this country from reduced tests and procedures, duplicative interventions, less adverse drug interactions, etc. So we believe there is significant value potential with health IT of course, as many do, but I'm afraid the country is not fully achieving this value proposition. So why is that?

Fundamentally, every time we install an EMR we have to implement not only the software and technology and train the user, but implement the knowledge artifacts that go into decision support and the systems are highly variable -- the capabilities in clinical decision support and in the facility with which they support the end user in translating his or her knowledge or the best evidence or guidelines into clinical decision support. So in essence when I have a beautiful decision support rule at the Brigham it's hard to share that with a user in California or elsewhere.

So, when I talk about cloud-based CDS what I'm really referring to is moving the management of knowledge for clinical decision support from the local implementation of an EMR to the cloud. In making that decision support then available to the cloud in standards-based web services to remote EMRs. In a large project based at the Brigham and Women's Hospital funded by the AHRQ we demonstrated this successfully by running rules and alerts at Partners Healthcare and delivering decision support to Epic, NextGen, GE, the Riegenstrief Institute, and our own Partners EMR via the cloud. So that in a nutshell is what I mean by cloud-based CDS and why it's important.

David Harlow: Great, so you're talking about developing rules, if you will, or guidelines based on local experience and then generalizing it, making those guidelines available more broadly?

Blackford Middleton: Absolutely, and the trick is to get not only local experience performing the best practice, but then to arrive at a consensus statement or consensus rule that reflects the best practice that everyone can abide by. We oftentimes think that my practice is different and my patients are special and different --

David Harlow: I've never heard that before ...

Blackford Middleton: -- and certainly they may be, but in the CDS consortium work we found, for example, that very small and essentially meaningless differences in clinical decision support rule statements could be worked out, and a consensus decision could be arrived at -- across very different health systems like Kaiser and Partners Healthcare.

David Harlow: Okay and was there -- in this work -- was there general agreement among frontline clinicians that these guidelines made sense? Were they adopted? Were they used?

Blackford Middleton: Absolutely, you know the thing about decision support currently is it's impeded or challenged in several ways that are well-known. Usability issues, fitting it into the workflow, making it relate to the clinicians' mindflow if you will; so we have challenges to address still with clinician decision support. But what is clear is that physicians -- when the decision support is useful and improves the care of their patients -- will use it and abide by it and it can improve quality and cost of care. Bottom line, I think what we need to be sure we don't try to do in this country is reinvent or rediscover best practices for care at each and every EMR implementation. We should be sharing the best evidence and best practices instead.

David Harlow: Right, so there has been a lot of talk over the past year about information blocking, about lack of interoperability among or across EHRs or EHR implementations. Has this stood in the way -- well from what you've said this has not stood in the way of the work that you have done, you've been able to garner buy-in and support; but does this stand in the way of broader implementation of these ideas?

Blackford Middleton: It has been a significant impedance or detractor, if you will, in the sense that the EMRs historically have not been very open. The walled garden ideas you're very familiar with, but I see dramatic progress in that space. For example, when we were doing our

EMR, the services insertion in remote commercial EMRs from Partners we had to figure out a workaround essentially to get the data and then to present the decision support to the end user. But now with the advent of things like the SMART on FHIR technologies -- the Boston Children's Group Substitutable Medical Applications & Reusable Technologies on the FHIR protocol, the Fast Health Information Resources, you know, there is now much more openness coming in EMRs that I think will promote exactly this kind of activities and many more; so that we can innovate around the edges of EMRs.

David Harlow: So there has been a lot of talk about FHIR and I'm wondering if you could speak to a couple of questions about FHIR. One, I guess, specifically is that these are early days. As I understand it we're at an 0.9 level of implementation of FHIR and another kind of question or criticism that's been raised by some is that even if we get beyond the 0.9 state, FHIR addresses a limited set of issues and that there is much in a record that would not be rendered interoperable through the use of FHIR. Your thoughts on these questions?

Blackford Middleton: I think that is accurate. It is an evolving standard, 0.9 is a good way to put it. What we did for example in the CDS consortium, we took the CDC immunization rules and implemented them in a SMART container and used sort of early FHIR technologies to make that decision support available to remote EMRs, now it's very successful, it's very interesting. What the FHIR protocol has to do, of course, is to try to standardize these interface specifications or the profiles such that we don't have a proliferation once again in a new standard that, you know, gets out of control. So, I'm very hopeful, I think the demonstrations to date have been extraordinary and I think will lead to even more secure and safe methods for interoperability via these open APIs to EMRs.

David Harlow: Sure, I would agree that the open API approach is seemingly the way to go, but what about the question of unstructured data that resides in EHRs, which in many cases, which in many kinds of situations, may even be the bulk of the information present. How or can an API deal with such information and how does that effect the viability of the project, the decision support project?

Blackford Middleton: Certainly the tension between structured and unstructured data is not addressed completely by an interface protocol including FHIR or even SMART containers like the SMART architecture. So that remains a challenge. You know, to the extent that an API can deliver lots of text versus structured data certainly technically that's feasible. However, what one needs for input into a decision support algorithm or an expert system of any kind typically is more structured data as you say of course. Now at the same time NLP methods are becoming much more robust and really incredible. So, I think it will be a combination and hybrid, you know, combinations of these technologies that will get us down the road.

David Harlow: Would you have any predictions in terms of what is the next step for adoption or proliferation of this approach to cloud-based clinical decision support?

Blackford Middleton: Well it's an excellent question and I think there are probably regulatory dimensions to the answer that is what's going to happen with CMS and MU3 and where Andy Slavitt will take us with the ONC, Karen DeSalvo, in terms of what finally becomes the rule in

this very space, you know, the open API idea. I think they're well aware of the potential as well as the issues. I look forward to seeing them at HIMSS and I think that will be an interesting conversation.

Beyond the regulatory dimensions obviously there needs to be ongoing technical work and standardization and standardization processes to arrive at an industry benchmark -- the 1.0 if you will -- that makes sense and provides value to the end user or the customers of EMRs. And I see dramatic movement in that space actually. We have the Argonaut Project and demonstration projects underway using both SMART or FHIR or both together.

David Harlow: I'm familiar with the Argonaut Project. Could you say few words about what that is and where you see that going?

Blackford Middleton: Sure, I've not been intimately involved myself, but I know a group of thought leaders and technology companies came together in almost a skunkworks, a non-standards-organization based effort at first, but now it's been sponsored by HL7 to flesh out the conceptual framework and the standards specification, so they can go to a final ballot and be approved at a 1.0.

David Harlow: So how do you see this working? You mentioned the ONC regulatory framework, Meaningful Use regulatory framework; do you see this sort of evolution of the EHR and related systems as getting closer to the line in terms of medical device regulation?

Blackford Middleton: Excellent question and way above my pay grade. Certainly the FDA is worried about not only how to regulate smart phone apps that become simulations of medical devices historically considered, you know, but also they're worried about how to address clinical decision support and underlying technologies and knowledge bases. So that's a work in progress and I don't know how that will land exactly yet. I think though on the regulatory framework side, where things are moving already of course is in the value-based payment reform, new value-based payment models and where HHS and Secretary Burwell are taking us in terms of moving towards those kinds of payment models. So, that then establishes a business case in a way that allows the end user, the clinician, to bear risk -- two-sided, ideally, both upside and potentially downside -- so that they will receive or pursue optimal care to produce high value care and clinical decision support will play an integral role in that process. So, in many ways the business case for decision support is becoming much stronger.

David Harlow: Do you see an opportunity for the regulators to identify a standard that's going to be specific to clinical decision support in the next evolution of not necessarily meaningful use, but certification standards that will continue post meaningful use for certified EHR systems, certification of which is required to participate or take advantage of various payment models for CMS?

Blackford Middleton: David it's a great question. I wouldn't suggest or I couldn't foresee CMS specifying actual knowledge artifacts or care pathways per se. Rather I think on the EHR certification side I expect that they will perhaps certify EMRs for API functionality in

conformance with an expectation on that API, but I can't imagine CMS entering a prescriptive regulatory framework, which says, you know, a CHF patient has to be cared for on this protocol.

David Harlow: Yeah, I wasn't suggesting that level of specificity; but rather a standard that a certified EHR system that would enable a provider organization to take advantage of future CMS payment initiatives must accommodate some sort of clinical decision support integration. Is that a way that you would see that happening?

Blackford Middleton: Not in a specific sense, but in a generalized framework sense -- absolutely.

David Harlow: Yeah.

Blackford Middleton: So if the API were conforming to a 1.0 emerged FHIR standard or other protocols then the capability exists, which could be a certifiable capability.

David Harlow: Five years from now, ten years from now, what do you see as the state of affairs of the use of tools like the ones we've been discussing today?

Blackford Middleton: It's a great question. Five or ten years from now we'll have nearly complete adoption of health IT infrastructure across the land. I think we'll have most healthcare transactions and information exchange automated. Hopefully we'll have the seamless interoperability of those data requisite for collaborative care and team-based care for patients across the healthcare delivery system. And I think what this implies then is that we'll see the emergence of a rich ecosystem of value-added services in the form of web services and modules and perhaps apps that fit into this ecosystem to provide extra value to the care delivery process and fundamentally to patients themselves.

David Harlow: Thank you very much. I've been talking with Blackford Middleton about clinical decision support and value-based payment -- and the future of healthcare. This is David Harlow at HealthBlawg. Thanks for listening.