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Clinical Decision Support and Primary Care Acceptance of Genomic Medicine

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Abstract

Clinical decision support systems (CDS) have an important role in the implementation of precision medicine, particularly for pharmacogenomics. This study examines potential factors for their acceptance by primary care clinicians.

For this qualitative study we purposively selected five U.S. primary care sites with a variety of sizes, electronic health record vendors, and patients. We interviewed an average of seven clinicians per site.

Clinicians placed a low priority on incorporating pharmacogenomics into practice. Other themes included the potential of precision medicine, clinician unfamiliarity with genomics, minimal evidence for primary care uses, additional costs and time burdens, workload, and a need to first successfully complete other electronic health record interventions.

This study outlines issues in implementing primary care precision medicine and the role for genomic CDS. Currently there are signficiant barriers. With more evidence and the development of effective CDS, however, there is potential for turning each of the barriers into facilitators.

Keywords:

Decision Support Systems; Clinical, Precision Medicine; Genomics

Introduction

Genomics-guided precision medicine – the ability to individualize therapies and guidance based on an individual's genetic makeup – has been a research target for over fifty years [1]. While there have been significant breakthroughs in oncology, primary care applications of genomics precision medicine have been limited [2]. But the potential is there. Just two of the CYP450 enzymes are involved in the metabolism of ninety percent of all drugs [3]. The expression of these enzymes can be predicted using genomic data, and patients divided into fast, normal, slow and non-metabolizers for a given drug. How an individual metabolizes a drug can determine whether a "safe" dose represents an ineffective treatment, an effective treatment, or an overdose.

Clinical trials are underway to demonstrate the value of using genomics guided precision medicine in primary care settings – ClinicalTrials.gov lists several hundred trials with potential applications in primary care [4]. Once demonstrated however, the deployment of this genomics based precision medicine in primary care will still face challenges. Effective CDS can increase the usage of genomic testing for primary care. Peterson et. al. [5], found that two-thirds of clinicians who had a genomics CDS available planned to order a genomics-based test, compared to only 13% in an earlier survey of those without a robust CDS [6].

This qualitative study, based on interviews with clinicians at five very different sites, examines some of the barriers to clinical decision support systems for precision medicine.

Methods

This study was conducted within the context of a larger study on the use of clinical decision support for workers' health issues [7]. Five U.S. sites were selected based on maximum differences in geography, experience with using an EHR, and type of parent health care organization. All of the sites were implementing the patient-centered medical home delivery model. Subjects were selected with the assistance of an inside contact person based on their roles as clinicians (MDs, DOs, PAs, and NPs).

The data were collected using a Rapid Assessment Process (RAP) [8-9]. A multi-disciplinary team visited each of the sites and conducted both semi-structured interviews and observed clinicians using the EHR. The process utilized a set of structured tools (interview guides, observation templates, and overall clinic data); results and progress were reviewed by the team every evening, and presented to the clinic at the end of our visits.

The data presented here are largely based on semi-structured interviews, as we did not observe any use of genomics data in the clinics we visited. To start the conversation clinicians were asked "How would you prioritize the implementation of meaningful use, work related data, and genomic medicine CDS?" For those who asked for clarification we provided the example of pharmacogenetic dosing for coumadin. After they replied, we would ask them to elaborate. Probes included questions about their knowledge of genomic based precision medicine and what barriers they perceieved to its implementation. Their responses were recorded and transcribed.

We followed guidelines for assuring rigor by triangulating (multidisciplinary researchers, multiple sites, different types of data), member checking (feedback to sites about results), auditing (tracking data gathering), reflexivity (researchers' awareness of their own bias), and data saturation (gathering data until little more is being learned) [10]. Data were analyzed with the assistance of qualitative data analysis software in three ways. First, a template method was used to identify answers to our interview questions. Second, a grounded hermeneutic approach was taken to discover patterns and themes across sites. Finally, comments about the factors influencing precision medicine implementation and their connection to CDS were extrated, coded, grouped by themes, and interpreted.

Approval was obtained from the OHSU and NIOSH Institutional Review Boards as well as the IRB's at the sites we visited.

Results

Participating clinics

Five sites participated. An average of seven primary care clinicians were interviewed at each site for this portion of the study.

The number of providers (Doctors of Medicine and Osteopathy, Nurse Practitioners, and Physician Assistants) at the sites selected varied from 5 to over 2,000; the geographic locations spanned both East and West Coasts and from the Gulf of Mexico to the Great Lakes; the type varied from community clinics to large academic medical centers, and the experience with EHRs varied from three to fifteen years. The EHR vendors included NextGen, AllScripts, and EPIC.

Themes

1. Priority for genomic CDS

Although the potential of genomic medicine was a motivating factor for the inclusion of genomic-related CDS for the most of the clinicians, none of those interviewed viewed genomic CDS as a higher priority than including other data, including work-related CDS, in the EHR. Factors that influenced these lower priorities were the interviewee's personal unfamiliarity with genomic medicine, a lack of compelling evidence for better outcomes, the increased cost of testing, potential work flow interruptions, and the need for other, higher priority, EHR related interventions. Clinicians across all sites were intrigued by the concept, but did not believe genomic-based precision medicine was ready for wide application.

2. Perceived potential

The concept of individualized medicine was appealing to the interviewees. As one said: *"I'm a little wary of it but I'm also excited because I think it will help us get closer to having an individualized plan for people that really is about who they are."* This knowledge could then translate into more effective treatments*: "if there's a way to pinpoint what medication would really be the best for the patient based … genetic makeup or, you know, whatever is going on, then I think that would be great… I have seen a lot of patients where we try one, two or three different types of IV treatments and it just doesn't work and you have to wait so many months for it to kick in and if it doesn't, then switch over. ..if there's a way to narrow it down to … find … that best drug.."* And they also thought it might help with risk assessment *"I think it's important to try to identify future risks for people, not just--which you can get at with cancer risks but-- so what are the future risks of you developing diabetes?"* This positive attitude was consistent across clinics.

3. Clinician lack of knowledge

There was a wide range of familiarity with genomic medicine, from those who have worked in the field to those who profess ignorance: *"we did some work when we were using Naltrexone for … so I'd be interested." "Well, genomic information. Okay. So there's -- and maybe I don't know enough about it. … I don't think there's a specific place that I would find it except I refer a lot of people to medical geneticists." "I mean I manage a lot of patients, you know, each month and I don't know anything about, you know, whether their genes tell me to a do a certain thing."* Although our samples were not selected to allow quantitative analysis, it did appear that the larger clinics were more likely to have practitioners who were at least aware of current work in genomics.

4. Need for evidence

Some thought that they were getting enough "genetic data" by just reviewing the family history, while others cited a lack of trials showing significant benefits for primary care providers: *"We do that already. Like, if the patient when they come in for physicals, we ask them family history." "nobody has actually linked any of those genetic markers to anything that we do."* This pattern appeared to be consistent across clinics.

5. Cost concerns

Not only were the additional tests viewed as adding additional cost for limited value, there was also the questions of who would pay for them: *"It's the cost containment. I probably would not [use genomic testing] if there wasn't a huge difference in patient outcomes." "I don't even know if MediCal [state insurance] covers things [DNA testing for breast cancers] like this."* Cost concerns appeared to be more frequently measured by the community clinics.

6. Work flow issues

Without a significant perceived benefit, providers were unwilling to have interruptions on their workflow: *"So that would involve additional blood work … I'm not sure how that would be incorporated into my work flow." "It is not part of the flow."* This was a concern for all clinics, and appeared to be more prevalent for clinicians with prior EHR implementation experience.

7. Current EHR implementation and priorities

Even if the providers wanted to incorporate genomic information into their CDS, there are many priorities that were viewed as more important, including work-related data: "*We can't do everything…right now the priority is to make the system work for us I think we are working too hard for it." "I think [incorporating occupational health and social determinants of health] can help more right now than personalized medicine and at lower cost."* But there is a possibility that this could change in the future: "*I probably don't think about genomics, … but in the future, if we have that kind of information, that would be awesome*." Once again, this was a uniform concern across all clinics.

Discussion

This is the first multi-site qualitative study of this topic that spans community, regional, and academic health care sites. In addition to the barriers identified in prior studies on genomic-based CDS, we found that the status of the current EHR system also affected the prognosis for genomics based CDS. Our results also differed from more generalized CDS implementation studies – the lack of evidence and provider knowledge created barriers that are more significant than for other types of CDS.

As discussed above, we identified six factors involved in the acceptance of genomic-based CDS: the potential for improving care, clinician knowledge about precision medicine, evidence that genomic based CDS improves outcomes, costs, workflow integration, and other priorities due to system status.

These factors are similar to those found in two earlier studies (by Unertl *et al* [11] and Haga *et al* [12]), both of which were conducted at one site and had a lower number of primary care

clinicians participating. The study by Unertl was conducted as semi-structured interviews at a large academic medical center following the implementation of CDS for genomic based dosing of clopidogrel and coumadin. The Haga findings were based on three focus groups at another academic medical center that had not implemented a genomic CDS. The Unertl study included six primary care physicians and nine cardiologists, the Haga study twelve primary care providers and six geneticists. Table 1 compares results of the three studies.

Table 1 – Comparison of factors for success

Theme	This study	Unertl et al [11]	Haga et al [12]
Potential of Genomic Based Precision Medicine	x	x	x
Clinician Knowledge	x	x	x
Need for Strong Evidence	x	x	
Costs	x	x	
Workflow	x	x	x
Current EHR Implementation	x		

Some of these barriers have been identified in prior work on general CDS implementation. Both Bates' Ten commandments for successful CDS [13] and Kawamoto's review of factors for successful CDS [14] implementation cite workflow as an important element in CDS success. Only seven percent of all CDS implementations, however, had the evidence included as one of its components [14], despite the strong association with implementation success. Further, only 31% of all CDS efforts had an associated educational component; the inclusion of which was not associated with increased success [14]. We believe that genomics implementations are more likely to require an educational element based on this studies providers' knowledge issues.

A limitation of our work is that it was conducted in parallel with a study of the inclusion of worker-based health CDS in the EHR and this could have biased our results. But, as shown in Table 1, our results are similar to those of two prior studies. The other two studies also had two themes ours did not – the need for help in communicating results to patients and issues with data storage and usage after the initial test. This may be due to a difference in the degree of implementation of genomics testing. Our study included sites that had not implemented a robust primary care genomic CDS, the other two studies either involved medical geneticists or already had a robust implementation.

Another limitation of our work is that it was a qualitative study; our work was designed to discover the range of possible responses. As a result, any of the differences between clinics is not statistically valid and only a starting point for future work.

Of the six factors shown in Table 1, one is a facilitator – clinicians can see a potential benefit. The other five are currently barriers. But these barriers can be changed to facilitators. Clinical trials can, and hopefully will, produce clear evidence of better outcomes. Once these trials are completed effective CDS can help with the other barriers, especially those involving clinician readiness. Our results lead to the following recommendations:

Clinician knowledge: Effective clinical decision support can provide "just in time" knowledge to clinicians through best practice alerts before the patient encounter, alerts at the time orders are placed, pop-ups with additional information regarding labs, and linkages to more information. Continuing education of clinicians about genomic medicine is needed for increasing their awareness of the evidence as well.

Costs: With effective data transfer from other institutions a genomic test can be done once and shared across multiple organizations, thus minimizing costs. There are already CDS implementations that have significantly reduced duplicate lab test, similar strategies can be used for genomic testing [15].

Workflow: Gathering the genomic data can be implemented by adding the typical tests required to the normal order sets for new patients and incorporating them into the templates. It is encouraging to note that workflow considerations are part of several current pharmacogenomics CDS projects [5,16].

Communication: Customized patient handouts can assist clinicians by providing simple illustrations of probabilistic concepts. These handouts can help implement shared decision making using graphical tools (see http://shareddecisions.mayoclinic.org).

Current EHR Implementation: And as the EHR implementations mature and organizations become more proficient at implementing CDS, the development and deployment of genomic CDS will become easier.

Conclusion

Except for the potential of genomic-based precision medicine, the factors identified in our interviews are currently barriers to its acceptance. With more evidence, and education, CDS will be a critical tool in bringing the promise of genomic guided precision medicine to fruition. The barriers – clinician knowledge, need for evidence, costs, workflow, and other EHR issues can be addressed with CDS.

The primary care clinicians we interviewed, from a wide range of clinics, want to improve the care they provide for patients. They only need to see a clear path to do so. What is needed is an easy to use, relatively low cost CDS intervention with clear evidence of improved patient outcomes for primary care. There are many clinical trials currently underway that are attempting to provide the evidence to support the CDS, but successful implementation will require both the evidence and the tools to implement. Clinical decision support is needed to make these interventions less expensive, easier for both clinicians and patients to understand, and able to fit into the clinical workflows.

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