



Patient Generated Data Public Hearing

Health Information Technology Policy Committee

Meaningful Use Workgroup

June 8th 2012

Thank you for the opportunity to contribute to the Patient Generated Data Public Hearing.

As physicians, we know that patient-provided information has always been central to diagnosis of medical conditions- otherwise known as taking a history. We assert that patients in a modern health care system should not only provide data but also have access to specific educational resources, decision-support tools and collaboratively negotiated goals that can most efficiently come from systems based on patient-generated data and can result in improved adherence and health behavior change which are key to most improved outcomes in modern medical care.

Regulations and standards for EHRs to accept patient-generated data in a structured format are crucial to achieve efficiencies of care, quality improvement processes and the patient engagement needed for health behavior change and optimal health outcomes.

Pre-visit data collection: Patients and their caregivers have the most important information needed for making a correct diagnosis but the time needed to elicit and record this data during the visit presents challenges to workflow. Although paper methods can be used to collect such information before the visit and may include validated tools, this involves organization and cost for mailing and, even if received and legible, the data is not in a form that can be readily entered into the EHR much less used in standard form for other purposes such as Quality Improvement (QI) processes, Clinical Decision Support (CDS), research or later patient engagement. Paper pre-visit patient-generated data is also usually limited to one respondent leaving out other people who could contribute to the care process such as other parents or teachers. Paper also poses privacy issues.

Use of web technology allows for pre-visit patient-generated data entry either as free text or in standardized tools by multiple respondents in multiple locations at a time when the patient or caregiver can be thoughtful and confidential in answering. In pediatrics, recommendations for comprehensive care known as Bright Futures, called for in the Affordable Care Act (ACA), involve review of a great many risks to the child's health and development. When we tested how long it would take to elicit even the routine suggested information through direct questions during the visit we found that it took 90 minutes, far too long for the average 12-minute pediatric visit.



Using Patient-Generated Data During the Visit: When clinicians have detailed information before beginning the visit, the visit is more likely to be able to both address the patient's agenda and recognize the most serious that the patient may not have been aware of, such as a positive screen for autism, and best prioritize other things the patient/caregiver want to discuss if time does not allow for all of them. This is most respectful of the patient, can make the biggest health difference and also makes the best use of valuable professional time.

Technology can also allow for negotiated goal setting e.g. for weight loss that can be carried over to visits with other professionals such as dieticians and further into the patient's own CarePortal for reminders or review later. Pre-visit patient interaction with the computer can result in not only identifying health or safety risks but also begin to suggest specific barriers to adherence that the patient may perceive. Clinicians equipped with data regarding both risks and barriers has a head start in processes such as problem solving counseling and motivational interviewing which have been proven to improve outcomes but take time and training but can be overcome with decision supports such as suggesting known approaches to perceived barriers. These clinical processes can be continued when the appropriate next steps are triggered by decisions made jointly by clinician and patient including, at times inviting other supports to join a post visit dialogue. We call this collaborative motivational interviewing, where the computer is a collaborator as well as the patient.

Another way patient-generated data can assist the Clinician in providing the best care is when the data itself triggers access to specific CDS useful for that issue such as a validated follow Up Interview that reduces over referral of children with positive screens for autism. Patient-generated data can also trigger templates of evidence-based guidance where Clinicians can record actions taken during the visit saving documentation time and producing a searchable record for QI processes.

Post-visit engagement: When patients have contributed actively to the content of their visit they are more likely to follow through with needed referrals or health behavior changes. In addition, patient-generated data have the potential to trigger patient specific educational materials, risk algorithms, and local and national resources from a trusted source without advertising even without any actions from the Clinician other than making the system available and checking to be sure the computer selected defaults are appropriate. Clinicians could also more easily select, and print or direct this kind of helpful information to the patient using links from structured patient-generated data.

Quality Improvement: While there are many ways to improve quality in healthcare and expanding requirements to do so, the ability of an EHR to facilitate QI is limited by the forms of data they contain. As a result, practices often select the easiest measures to document QI such as Blood Pressure that are not often the most important ones to



address to transform health care, especially for child health. When the system allows the patients to generate data, richer and more relevant measures such as psychosocial risks can be readily assessed in standard format allowing them to become the subject of QI efforts.

We assert that the ideal regulations regarding to patient-generated data should include requirements that data be:

- *Accepted* into the EHR not only from patient interview but also from other technologies or from a care portal.
- *Standardized*, at least in part, to allow for: comparison with other patients, decision support individualized to the patient, quality improvement documentation, needs assessment/planning for the community and comparative efficacy studies.
- *Interoperable* within the HIT landscape
- *Designed to include multiple respondents* so that a collaborative care plan includes all participants in care, across settings, and including the patient and his or her designee.
- *Apply to both EHRs and other patient-facing systems* like CHADIS.
- *Use vocabularies across EHR and patient-facing systems* like CHADIS.
- *Involve shared decision-making tools*: Expand the use of Clinical Decision Support to identify patient-centered/sensitive care, treatment, or tests, provide e-tools for shared decision making between the patient and the provider(s) and record the patient decision/preference within the EHR.
- *Involve clinical content experts*, not often part of commercial EHR teams, as these product developers may not be motivated to make revisions as new evidence becomes available.
- *Facilitate integration of content specific apps or electronic modules* within commercial EHR products.
- *Involve quality improvement leaders* who have interest in using patient data and related CDS in conjunction with medical specialty boards requiring QI data for recertification. Commercial EHR vendors are unlikely to take on such a role and specialty boards are unlikely to certify specific commercial products for this



- purpose. Therefore electronic modules that provide both patient data and CDS, such as CHADIS, should be allowed easy integration into commercial EHRs
- *Not be limited by Legacy Technology:* Patient-facing HIT is still in the early phases of adoption. They should not be limited by the transactional and proprietary nature of older legacy systems. Interoperability, web services, and mobile technologies all prevalent in consumer technology are absent in integrated HIT or in core EHRs. While interoperability is needed to engage patients in HIT, the restrictive nature of these EHR systems should not restrict innovation. In fact, patient engagement in HIT could drive both interoperability and innovation in the EHR legacy systems. Although MU incentives are for the meaningful use of HIT by eligible providers and eligible hospitals, the patient is an important care team member. Developing policy and standards that drive interoperability and interconnectivity of EHR can create market and technology innovation for patient-facing systems. By identifying what, when, where, and how a legacy EHR can operate with patient-facing systems, and leaving the market to create the patient-facing systems, we can drive the use and innovation of both.

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What are the emerging best practices in integrating patient-generated data into EHRs for optimal health management?

Standards for packaging and transmitting health-related data have existed for a quarter-century and continue to undergo expansion, revision, and evolution. A legacy HL7v2 standard is being rapidly replaced by a more modern and flexible HL7v3 standard, which can more easily be integrated into products and services. These emerging standards should be reinforced through Meaningful Use guidelines to encourage vendors to aggressively support them.

- HL7 messaging is an entrenched industry and ANSI standard that has been used in countless data exchange environments. Developing the technical capabilities to send and receive such messages is non-trivial: the costs of building, supporting, and paying for these necessary components create a barrier to entry for smaller organizations.
- CDA (Clinical Document Architecture) documents, while allowing for a robust architecture to exchange and use patient-generated data, continue providing a large barrier for implementation. CDA documentation and creation is very complicated and few industry leaders have the expertise and resources to implement this technology. In addition, the industry itself has yet to advocate the switch to this architecture. Therefore, there is no business driver to apply the significant resources required to harness CDA documentation.
- No existing document templates (in either HL7v2 or HL7v3/CDA) appeared to match exactly the content requirements of CHADIS and other patient-generated HIT. Consequently, new document templates need to be developed to specify the implementation guidelines for this new type of information. Developing a new document template and getting it implemented by all the EHR vendors' presents a huge barrier for small- and medium-sized companies and will limit innovation.
- Due to these barriers, custom and proprietary APIs (Application Programming Interface) for both packaging and transferring data are being developed to fill the gap. Web-based services that can securely exchange EHR data between the patient and the provider's systems are becoming increasingly popular between both vendors and care team partners.

We see the future of healthcare data exchange realized by CDA and related technologies if the high costs and barriers to implementation can be reduced in some way.



Encouraging or even mandating the use of CDA for Meaningful Use would be a major step forward for healthcare IT, and would give all vendors solid ground on which to build future solutions. A second major step would be to develop and promote a standard for data *delivery* so that disparate systems can more easily implement the physical exchange of clinical documents. Finally, development of smaller, more targeted templates – or even less-strict document standards such as green CDA will reduce the barriers for smaller organizations with limited focus and limited means. The S&I Framework CDA Consolidation Project represents major improvement in clarity and consistency for the body of established CDA templates. Where possible, guidance will be taken from this recent work.

Without taking the steps above to achieve a standards-based healthcare IT ecosystem, the industry will likely become fragmented to allow the exchange of these other forms of data. Smaller, more targeted APIs, which allow greater flexibility in the exchange of patient-generated data, are available *now* and are a preferred strategy for vendors and care team partners to capture this data.

Similar to the travel and banking industries, applications should be able to share information without requiring unnecessary duplication of functionality and data. Deliberate promotion and encouragement of existing standards bodies and vendors to handle patient-generated data is essential to the viability of ubiquitous consumption of this essential data.

Once the data has been consumed by a vendor's system, their needs to be a place for the data to reside besides the CDA (or other) document used to transmit it. This last step will allow providers to access and manipulate data aggregated from arbitrary sources for a number of purposes including coordinated care, research, and quality improvement.

What is the role of mobile devices in integrating patient-generated/reported data into EHRs?

Technology should be implemented in a way that will provide access to everyone and not act to increase health disparities. While EHR technology is so costly as to be a barrier even to some physician groups, mobile technology can be a key to closing the technology disparity gap for patients. The majority of low income US adults own or have access to mobile phones even if they do not have access to Internet-connected computers. CHADIS has been designed and tested with various kinds of mobile technology to provide a high level of accessibility to families of low income and low



literacy. CHADIS facilitates collection of patient-generated data from the patient and caregiver even when the respondent does not read well as follows:

- CHADIS can use Interactive Voice Response technology to allow patients and caregivers to enter data by being asked questions over any touch-tone telephone, gathering responses by the press of keypad buttons. Once collected, the data is available to clinician in the same form as if it had been entered through a website.
- Tablet technology (iPads) and smartphones allow for a more robust mechanism for engaging patients and collecting information. We conducted a study to research patients' preferred mechanisms for reporting their own data comparing paper, laptop, IVR and touch screen iPad after hands on experience with these alternative modalities presented in random order. Subjects were parents of either Medicaid eligible or privately insured and both suburban and inner city practices were recruited. We found that the touch tablet technology was preferred across demographics. To our surprise, the parents of the Medicaid insured children differed from others only in asserting that paper was their least preferred modality. While disadvantaged families are often considered to be on the other side of a digital divide, and may be relegated to last in line for technology, it became clear that use of our touch tablets had special advantages for that population. First we presented a simpler one item at a time kiosk view than when presented on the computer and there was an ear icon inviting them to have items read out loud in English, Spanish or Chinese – reducing barriers not only for computer literacy but also for the literacy limitations inherent with paper versions. We have explored and implemented ways to facilitate both registration and data entry by patients via iPads in the waiting room of the office. This information is instantly summarized and presented to the doctor looking the same whatever modality or language was used to collect the data.

What is the clinical workflow for management of these data?

How do clinicians use these data?

The CHADIS program was devised to be easy to utilize in day-to-day operations of a practice while achieving the ultimate goal of helping Clinicians provide better care and support to patients and families. The patient collaborates with pre-visit data entry, within visit shared decision-making and post-visit engagement in a MemoryBook/Care Portal. Current technology allows for such user-friendly workflows. Below is the step-by-step workflow:

1. The office chooses sets of questionnaires to be automatically delivered at the office's choice of visit types and age of the child.
2. The office requests that patient register and enter data in the form of questionnaires with a simple instruction over the phone at the time of making



- appointments to “Go to CHADIS.com and use our office phone number as your invitation code”. Alternatively, all patients of a practice are pre-registered in CHADIS via data dump. If email addresses are part of existing data, reminder emails can be sent securely via email.
3. Respondents (parents, teens or teachers – when specifically invited) log in at their convenience *outside of visit time* either from home, work or in the waiting room. Once logged in, they complete the questionnaires that are automatically presented based on child age, prematurity and type of upcoming visit.
 4. CHADIS instantly scores and summarizes patient-generated data results for the Clinician. The Clinician logs into CHADIS to access the results. Alternatively, CHADIS results can be sent over to the EHR using the mechanisms discussed above. This step requires custom interface development by the EHR or EHR user.
 5. If the above step is not utilized due to the lack of technical resources, the Clinician or office staff cut-and-paste a CHADIS generated report into their respective EHR. This is not the best workflow, but until patient reported data fields are required of EHR vendors, one-off development will be required.
 6. CHADIS suggests CDS based on questionnaire results accessed from links next to results from which the Clinician can select to review, print or send to the patient’s personal CarePortal. CDS not only includes the patient-generated data itself but also eChapters with links to the National Library of Medicine, specialty guidelines as PDFs, patient handouts in English and Spanish, other resources such as websites, support groups, equipment, etc. and local agency listings sorted and searchable by zip code. The clinician education information differs a great deal from a standard textbook. It is organized to support “point of care” prompting which can be glanced at even when the patient is in the room but also in layers of bulleted information that can be efficiently accessed close in time to the visit with layers of more detailed information such as the National Library of Medicine links when the clinician feels they have the time and interest to pursue. A new form of CDS now functional in our sandbox is called a Patient Specific Template (PST). This template, for use during the visit, combines patient-generated data with standard care guidelines and CDS. The patient-generated data answers some of the potential questions that the Clinician might ask the patient that cover all the evidence-based guidelines for a specific topic e.g. maternal depression and the PST may suggest further clarifications that the clinician might pursue based on the initial patient inputs, such as if suicidal ideation was raised by the parent. This produces a Quality Improvement process of prompts and simultaneous documentation. The PST includes a “teleprompter” suggesting words to use to interview the patient on the topic. Video interview examples of “how to” deal with challenging situations are being prepared that can be accessed by the clinicians before or after the visit. Clicking answers results in editable autotext for the Clinician’s report and different text to go to the patient’s CarePortal as well as generating items for the Problem List. CHADIS suggests related resources that the Clinician can select to print and also send to



the CarePortal.

7. Patient's use the patient-generated data as described below.

How do patients/families access these data and use it in coordination with their clinicians?

Products can be, and are being, designed with both the practice and families in mind. There are a few simple rules CHADIS follows when engaging patients and encouraging participation.

- Free-Text: Respondents (parents, teens or teachers) are given the opportunity to identify their chief concerns and goals for change in free text initially and as well as through the structured data within questionnaires. Their chief concerns are listed prominently above the summary of results to attract the Clinician's attention.
- Inviting multiple respondents: Parents can securely invite others (other parent, step-parents, deployed parents, teachers/daycare providers) to provide data promoting a comprehensive view of the patient to achieve the best care.
- Evidence-based screening: Patients are guided in providing data by evidence-based validated questionnaires whenever available so that the resulting data is not only structured but scored against cut scores that allow comparison to national samples and facilitate Quality Improvement projects.
- Patient specific CDS: Patient-generated data trigger CDS for the Clinician as well as specific resource suggestions for the patient that the clinician has the option to modify or add to.
- MemoryBook: Selected patient-generated data such as developmental milestones of the young child pre-populate an attractive MemoryBook keepsake to reward questionnaire completion. These milestones are accompanied by suggestions for developmentally stimulating activities appropriate to the child's current skills as determined by the patient-generated data. This MemoryBook is visible to people the parent invites where those guests can also add comments, upload photos and view selected alerts about health risks. The goal is for the guest to provide support for the parent to address the risks.
- CarePortal: Patient-generated data in questionnaires are set to trigger alerts in the CarePortal about health risks and engage the parent in submitting an action plan to address it.
- Resources in the CarePortal: Resources are sent to Notices in the CarePortal automatically based on patient-generated data, by Clinicians and can also be searched by patients.