Presentation at HIT Policy Meaningful Use and Certification / Adoption Workgroups Clinical Documentation Hearing
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1. Introduction

Good morning. My name is Gil Kuperman. I am Director for Interoperability Informatics at NY Presbyterian Hospital, Adjunct Associate Professor of Biomedical Informatics at Columbia University and Board Chair of AMIA, a 4000-member organization of informatics professionals. My colleague from Vanderbilt University, Trent Rosenbloom, and I are here this morning to provide a brief summary of a Policy Conference that AMIA held in late 2011 to understand the current state of computer-based clinical documentation and how best to advance it.

We want to thank to the Certification / Adoption and Meaningful Use WGs of the Health IT Policy Committee for inviting us to speak and for holding this day of hearings to explore this important topic.

a. Computer-based clinical documentation – definition and context

Clinical documentation is the process of recording historical data, observations, assessments, interventions, and care plans in an individual's health record. The purpose of documentation is to facilitate clinical reasoning and decision making by clinicians and to promote communication and coordination among members of the care team.

Computer-based clinical documentation creates opportunities to improve patient care and collaboration and communication, and capture data more effectively and efficiently for research, clinical decision support, the needs of the legal medical record and certain regulatory and compliance requirements.

Leading informatics organizations have had computer-based clinical documentation for decades. As the prevalence of this capability increases, there is opportunity to realize benefit on a widespread scale, however, as we will discuss, important challenges must be acknowledged and addressed.

b. MU3

AMIA recognizes that the Request for Comments on Stage 3 reflects a perspective that the EHR needs to support a collaborative model of care rather than care based in a single setting and AMIA agrees with this perspective. The Request for Comments also notes the need to capture and report clinical quality measures while minimizing the data collection burden on providers. Clinical documentation has a critical role to play both in transitions as well as in quality measurement.

c. 2011 conference

In 2011, AMIA held its 6th Annual Invitational Policy Meeting, called “Enabling the Future State of Clinical Data Capture and Documentation”.

The goals of the conference were to:

(i) Outline the current state of computer-based clinical documentation,
(ii) Identify a set of principles that could serve as requirements for a future state of computer-based documentation,
(iii) Identify knowledge gaps and create a research agenda to help close those gaps, and
(iv) Formulate policy recommendations to help drive towards a future state.

There were approximately 100 attendees at the conference. Attendees included (i) clinicians who had extensive “hands-on” experience with clinical documentation systems, (ii) vendors and other developers of clinical documentation systems, (iii) human factors researchers, (iv) researchers with experience measure the quality of documentation, (v) policy makers seeking to understand how clinical documentation can best advance health and health care processes and want to assure that innovation continues in this critically important aspect of electronic health records, and (vi) representatives from specialty societies and consumer organizations.

Trent will present the review of the current state and the findings and recommendations and I will present the proposed research agenda and some closing comments.

2. Summary of evidence and knowledge gaps

Good morning. My name is Trent Rosenbloom. I honored to have the opportunity to speak with you alongside Dr. Kuperman. I am the Vice Chair for Faculty Affairs, the Director of Patient Engagement and an Associate Professor of Biomedical Informatics, Internal Medicine, Pediatrics and Nursing at Vanderbilt University. I am a member of AMIA and the American Academy of Pediatrics. I have been fortunate to have had the opportunity to have had federal support do detailed research in clinical documentation, and to participate in the AMIA 6th Annual Invitational Policy Meeting in 2011.

In your meeting materials, you have a copy of the recent JAMIA publication, “The future state of clinical data capture and documentation”, describing the 6th Annual Policy Meeting.

The manuscript includes a review of the biomedical literature, which you will note is brief. A key reason for the literature review’s brevity is that there has been inadequate research evaluating computer-based documentation in particular, and clinical documentation in general. Research has been hamstrung by the ever-changing natures of factors influencing clinical documentation , including: technology evolution, third-party administrative and legal requirements, healthcare provider and team expectations, and the presence of a large number of clinical workflows. A lot of what is known in the

field is based on reasonable anecdote rather than empiric data, and much of the empiric data we have reflects single sites that does not inform clinical documentation in general. As a result, there remain numerous gaps in our knowledge about clinical documentation.

The manuscript does recount what is known about the history and evolution of clinical documentation. It then reviews research on the influence of clinical workflow on clinical documentation, various approaches to measuring the quality of documentation, and how documentation informs care-team collaboration, such as how multiple care-team members contribute to clinical notes —e.g., nurses enter the vital signs, the doctor records a physical exam.

Due to a lack of adequate research in the area, the literature review found no evidence for a single best method for clinical documentation. For example, there is no evidence to support that structured or narrative documentation can meet all needs. By contrast, there is evidence and anecdote that allowing healthcare providers to access multiple methods of clinical documentation may enhance EHR system adoption and use. Examples include dictating a note to a transcriptionist and differing types of unstructured or structured computer-based documentation. In addition, the literature review was unable to uncover evidence for a single standard for determining what constitutes quality clinical documentation, although there is ample anecdote describing what is poor quality. For example, terms like “note bloat” and “cloned notes” riddle the literature as case reports and anecdote.

In summary, there remain important knowledge gaps around what we SHOULD be doing in the field of clinical documentation, but there are lots of reports about what we SHOULD NOT be doing.

3. Findings / recommendations

Meeting participants concluded that high value documentation is important to—and represents—high quality patient care. However, participants recognized that with growing complexity of care delivery and advances in heath IT, there is a need to transform the way we capture and document clinical care. The manuscript’s findings represent observations participants had about the current state of computer-based documentation. Among the findings, the following four points emerged as common themes to participants’ discussions:

- The fundamental purpose of computer-based documentation must be the direct support of health and health care. Other purposes such as performance measures, quality reporting, payment and legal requirements have encroached upon this central purpose. As a result, computer-based documentation does not always primarily serve healthcare delivery.

- New documentation requirements frequently require changes to organizational infrastructures and processes. The evidence base and benefits for such requirements are not always apparent.

- Healthcare providers in different subspecialties and venues have different workflows during which documentation is carried out. Current usability and functionality do not align with diverse workflows across multiple venues and providers, and as a result there is often a mismatch between their documentation needs and system capabilities.

- Current computer-based documentation paradigms do not facilitate multidisciplinary, team-based care, coordination and delivery that includes the patient as a key member of the team.

Meeting participants articulated seven major recommendations to serve as guiding principals for computer-based documentation. Guiding principals serve as a set of requirements for clinical documentation. These requirements stated that clinical documents and documentation systems should:

- Be clinically pertinent, patient-centric foremost

- Work within EHR systems that store and represent an individual's lifetime health and healthcare.

- Be efficient and usable, and should support capture of high quality information that is accurate, relevant, confidential, reliable, valid, complete, and secure

- Enhance the healthcare organization's and the care team's overall efficiency, effectiveness and productivity.

- Support downstream uses without additional effort on the part of the author, including quality measurement, performance improvement, population health care delivery, policymaking, research, education, and reimbursement.

- Enable joint patient-provider decision-making, team collaboration, care process management, and advanced clinical decision support.

- Leverage multiple sources of data and interpretation when assembling notes, including data automatically captured in other systems and devices, and direct input of expressive medical discourse as appropriate.

Meeting participants articulated a number of recommendations. Key among these were:

- Foremost, the field still needs more research around clinical documentation. Dr. Kuperman will discuss this need in greater depth in just a moment.

- When considering how best to support other needs—such as quality measurement, billing, support for transitions of care, research, etc—clinical documentation should be only one among

many sources of data that are considered. Other sources may be acceptable and would not add to healthcare providers' work burden. Developers and policy makers should consider performing an environmental impact scan for changes to user interfaces and new requirements for clinical documentation.

- Regulations about any particular goal, e.g., quality measurement, billing, etc., should allow flexibility in the ways that clinical documentation can be used to meet that need. This would promote innovation in the use of clinical documentation to meet various needs.

- Increasing patient access to the clinical documentation process and to clinical notes should be considered as a way to make documentation more efficient and to motivate healthcare providers to make their notes more concise and correct.

- There should be pilot programs that examine the influence of relaxed or modified billing requirements on patterns of clinical documentation.

In summary, upon reviewing the fairly scant research based around computer-based clinical documentation, participants at the 2011 AMIA Health Policy Meeting identified a number of observations and guiding principles, and then made recommendations for the future state of clinical data capture and computer-based documentation. Computer-based documentation should be patient-centered, leverage input from automated devices and all relevant team members and should be conducted in a policy setting where external regulatory requirements on the clinical note itself are minimized. In addition, research in the area of computer-based documentation is lacking.

4. Research agenda

As mentioned, there are high expectations for clinical documentation being able to contribute to such multiple worthy goals as (i) patient care, (ii) collaboration communication, both within and across care teams, (iii) billing justification, (iv) creation of a medical record for legal purpose, (v) support of research, (vi) use of data for clinical decision support and (vii) performance measurement, both for operational as well as clinical quality measurement purposes, and that all this should be done without imposing unreasonable burdens on the physician or other clinician.

New knowledge on a variety of fronts is needed if these goals are to be realized.

1) First, there is a category of research that is needed to better understand approaches that could be used to capture data from clinicians in ways that minimize the burden and yet allow the data to be used for as many of the envisioned purposes as possible. Specific areas in this category include:

a. Identify the combination of structured data entry and unstructured data entry that provides the flexibility that clinicians need to capture the nuances of the clinical encounter as well as the data that are needed for other purposes.

b. Understand whether there are alternatives to keyboard or mouse-driven entry for clinical documentation, for example, voice recognition.

c. To understand how a clinician can "point to" other electronic data in the record, for example, laboratory data or other clinicians' notes, rather than having to per se copy the data into the note.

d. To understand how clinical documentation entered as narrative text can be transformed into coded concepts, for example, through natural language processing.

e. To understand how each additional documentation requirement, whether for regulatory or other purposes, adds to the burden on the clinician and at what point levels of satisfaction decrease or there is decreased accuracy or decreased quality of documentation.

2) Second, there is a set of research questions related to how clinical documentation can best be used to support collaborative care, for example:

   a. In the context of a particular workflow task, such as discharging of the patient, what are the documentation-related roles and responsibilities for each member of the team? And what features would allow the patient to participate in this process?

   b. What are the data display paradigms that make clear each team member's role in the care of the patient and what are next steps?

3) Third, there are opportunities to understand to what extent data from other electronic sources, for example, physiologic data from devices, reports from diagnostic studies, records of procedures, and other clinical data can be combined with electronic clinical documentation to support the desired goals and minimizing the documentation burden on clinicians.

4) Fourth, there are opportunities to define and better measure the quality of clinical documentation and to understand to what extent high quality documentation is correlated with high quality care.

5) Fifth, there are opportunities to understand to what extent physicians change their documentation behavior as patients increasingly have access to data in their medical record.

6) Sixth, as Trent mentioned, it would be intriguing to evaluate in a pilot setting how documentation patterns would change if billing compliance rules were relaxed.

7) And seventh and lastly, some foundational informatics research is needed to advance standards for the representation of data obtained from clinical documentation so that the data can support the myriad envisioned uses.

Agencies that may have an interest in addressing some of these questions include: ONC, AHRQ, NSF, NIH, NLM, etc. Some of the research questions outlined here may lend themselves to comparative effectiveness research.

5. Summary

In summary, we believe that increasing the prevalence of computer-based clinical documentation provides opportunities to improve the quality of care. Important factors to keep in mind as we move down this road in Stage 3 and beyond include keeping the highest priority for documentation on support of the patient's health, assuring that opportunities for innovation are preserved, being mindful not to place excessive burdens on the provider and seeking creative ways to leverage other data in the record to achieve certain goals, recognizing the need for research to address important questions and seeking ways to involve the patient in documentation related activities and as an engaged member of the care team.

We hope this information is helpful. We'd be happy to take any questions.