Digital Learning Collaborative

of the

IOM Roundtable on Value & Science-Driven Health Care

May 30, 2014

National Academy of Sciences Building
Room 120
2101 Constitution Avenue, NW
Washington, DC
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SECTION 1
Day of Materials
IOM Roundtable on Value & Science-Driven Health Care

Digital Learning Collaborative

May 30, 2014
National Academy of Sciences Building
Room 120
2101 Constitution Ave NW
Washington DC

Meeting goals

1. Learning from EHRs. Together with the Learning Healthcare Community’s Essential Standards to Enable Learning (ESTEL) working group, convene essential stakeholders, including standards groups, federal agencies, academic health systems (AHSs), and electronic health record (EHR) and research technology vendors around the issue of the implementing standards-based EHR-enabled research.

2. Facilitative standards. Describe approaches to EHR-enabled research, including those based on the ONC Structured Data Capture (SDC) Initiative, CDISC Healthcare Link, IHE Quality, Research and Public Health, and FDA eSource Guidance and identify how to realize available opportunities.

3. Vendor opportunities. Identify opportunities for vendors, interested AHSs, and research sponsors to accelerate progress towards more widely implemented EHR-enable research.

8:00 am  Coffee and light breakfast available

8:30 am  Welcome, introductions, and meeting overview

Welcome from the IOM
Michael McGinnis, Institute of Medicine

Opening remarks and meeting overview by Collaborative Chairs
Jonathan Perlin, HCA Inc.
Reed Tuckson, Tuckson Health Connections, LLC

8:45 am  EHR-enabled research as part of a learning health system

The learning health system context
Doug Fridsma, Office of the National Coordinator for Health IT
### Essential Standards to Enable Learning (ESTEL)

*Rebecca Kash, Clinical Data Interchange Standards Consortium*

**Q&A and Open Discussion**

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<thead>
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<th>Time</th>
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<tr>
<td>9:15 am</td>
<td>Standards available to facilitate EHR-enabled research</td>
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**ONC’s Structured Data Capture initiative**  
*Evelyn Gallego-Haag and Farrab Darbouze, Office of the National Coordinator for Health IT*

**Enabling interoperability across the continuum of health and health care**  
*Charles Jaffe, HL7*

**eSource: FDA Guidance on using electronic source data for clinical investigations**  
*Ron Fitzmartin, Food and Drug Administration*

**Role of CDISC and IHE in EHR-enabled research**  
*Landen Bain, Clinical Data Interchange Standards Consortium*

**Q&A and Open Discussion**

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<th>Time</th>
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<td>10:30 am</td>
<td>EHR-enabled research activities</td>
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**The I-SPY Trial**  
*Sarah Davis, I-SPY*

**Duke University experience**  
*Iain Sanderson, Duke University*

**NYU experience**  
*John Speakman, New York University*

**Virginia Commonwealth University experience**  
*David Fenstermacher, Virginia Commonwealth University*

**Q&A and Open Discussion**

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<td>12:30 pm</td>
<td><strong>Opportunities for vendors to lead the way</strong></td>
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<td><em>Scott Moss</em>, Epic</td>
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<td><em>Ryan Moog</em>, Cerner</td>
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<td><em>George Cole</em>, Allscripts</td>
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<td><em>Trent Rosenbloom</em>, Vanderbilt University</td>
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<td><em>Joseph Dustin</em>, Medidata Solutions</td>
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<td><em>Ken Pool</em>, OZ Systems</td>
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<td><em>Vijay Pillai</em>, Oracle</td>
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<td><em>Q&amp;A and Open Discussion</em></td>
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<th><strong>Accelerating progress</strong></th>
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<tr>
<td></td>
<td><strong>Session description:</strong></td>
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<td></td>
<td>A moderated roundtable discussion about what different stakeholder groups can do in order to accelerate progress including stimulating sharing and measuring success.</td>
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<td><em>Q&amp;A and Open Discussion</em></td>
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<th><strong>Summary and next steps</strong></th>
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<td><em>Jonathan Perlin</em>, HCA Inc.</td>
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<td><em>Reed Tuckson</em>, Tuckson Health Connections, LLC</td>
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<td><strong>Comments and thanks from the IOM</strong></td>
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<td><em>Michael McGinnis</em>, Institute of Medicine</td>
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| 3:30 pm | **Adjourn** |
Digital Learning Collaborative  
May 30, 2014

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SECTION 2
Background Materials
Panel I

EHR-enabled research as part of a learning health system
Transforming Medical Research with Electronic Health Records
Rebecca Daniels Kush, PhD

Rebecca Daniels Kush, PhD, is Founder, President and CEO of the Clinical Data Interchange Standards Consortium (CDISC), a non-profit standards developing organization (SDO) with a mission to develop and support global, platform-independent standards that enable information system interoperability to improve medical research and related areas of healthcare and a vision of informing patient care and safety through higher quality medical research. Dr Kush has over 25 years of experience in the area of clinical research, including positions with the US National Institutes of Health, academia, a global CRO and biopharmaceutical companies in the US and Japan. She earned her doctorate in Physiology and Pharmacology from the University of California San Diego School of Medicine. She is lead author on the book: eClinical Trials: Planning and Implementation and has authored numerous publications for journals including The New England Journal of Medicine and Science Translational Medicine. She has developed a Prescription Education Program for elementary and middle schools and was named in PharmaVoice in 2008 as one of the 100 most inspiring individuals in the life-sciences industry.

Disclosure: The author has no conflicts of interest to declare.
Correspondence: rkush@cdisc.org  Citation: iHealth Connections, 2011;1(1):16–20
Acknowledgment: The author would like to acknowledge the expertise and contributions of Landen Bain, CDISC. This progress would never have been made without his diligent efforts.

In the global world of clinical research, it is the Clinical Data Interchange Standards Consortium’s (CDISC) vision to inform patient care by improving data quality and patient safety. This article reflects on the impact electronic health records could potentially have on transforming medical research in the clinic. Specifically addressed are misperceptions or barriers that must be hurdled to achieve a common goal—to accelerate the cycle through which research informs healthcare and thus the opportunity to bring new therapies to patients sooner.

Despite the explosion in new technology and re-engineering in other industries, the clinical research process has not changed substantially in the past two decades. The dated ‘traditional’ way that clinical studies are conducted today has imposed such a burden on many clinicians and potential investigators that they are unwilling to participate. The capacity for research is not keeping up with the demand for new knowledge. Woodcock and Griffin argue that the clinical trial system is currently at capacity and will not be able to support additional research, such as that for comparative effectiveness, unless resources are diverted. It has been estimated that the length of time to translate research findings into informed medical decisions is around 17 years, and it will only become a more cumbersome process with the voluminous clinical genomics information that is emerging—unless dramatic changes are made.

There is now an unprecedented opportunity to truly transform (not just ‘tweak’) the overall research process. One launch point is to leverage current trends to encourage the adoption of electronic health records (EHRs) in the US and many other countries, while another lies in the increase in the number of patients willing to voluntarily provide their health information for research purposes. Standards to improve information exchange and profiles to integrate research workflow into healthcare practices are already available to support such measures.

What is holding us back? Unfortunately, misperceptions around the use of EHRs and personal health records (PHRs) for research abound, and there is either a lack of awareness of the new opportunities available or a resistance to adopt transformative measures over the status quo; these misperceptions (perceived barriers) continue to impede a ripe opportunity to transform research, and therefore, to hasten new therapies to patients.

Before delving into the details, it should be clarified that using EHRs to conduct clinical research studies should not be confused with harvesting claims data to seek safety signals or harvesting EHR data for insight into the current use of prescription medications. In other words, it is not ‘all about the data’. Instead, accelerating research will require process changes (integration profiles), standards (data sharing enablers), and the trust and willingness to support a true transformation in the current clinical research process. Fortunately, the first two of these requirements have been developed over the past decade (based upon global standards, regulations, and good clinical practices [GCPs]) and are now readily available; progress around the third requirement is gaining momentum in certain circles.

The Benefits of Transforming Medical Research through Electronic Health Records
We are witnessing a sea change in technology, especially with the volume of participation of individuals around the world in social media
and mobile phone applications, EHR adoption is being encouraged by governments around the globe. In the US, ‘meaningful use’ of EHRs, which requires adoption of certified EHRs, health information mobility, and reporting of measures of quality, is being rewarded with monetary incentives. The genomics explosion is producing vast quantities of information that need to be interpreted. Fortunately, computing power is increasing dramatically and computers are being programmed to support clinical decisions, thus ushering in a ‘new generation of medicine’. It is time to think about the EHR not as a static record but rather as an integral part of the healthcare system—part of the process. Harvesting research information during this process can allow any willing patient and clinician to participate readily in accelerating the path to informing clinical decisions.

The Health and Human Services (HHS) Office of the National Coordinator (ONC) has outlined the “fundamental properties of a highly participatory rapid learning system” that can be developed in part from meaningful use of EHRs to enhance the availability of increasing amounts of clinical information in an electronic form. Use of such data in a secure and trusted manner can “speed the progression of knowledge from the laboratory bench to the patient’s bedside”. If researchers (biopharmaceutical and academic) are actively engaged in influencing and taking advantage of these activities in the healthcare arena to support research appropriately, potential benefits include:

- substantially increasing the number of clinicians and patients willing to participate in research; thus increasing the overall research capacity;
- making it significantly easier for clinicians to participate in research by integrating research into their primary care workflow;
- bringing more research opportunities and potential therapies to more patients; and
- accelerating the feedback loop for research information to inform clinical care decisions.

The Available Opportunity

Many clinicians do one research study and no more; they find the work cumbersome and an interference with their primary objective of delivering patient care. The importance of increasing the capacity for research in the US has been explored in depth. A potential ‘glide path’ to increasing this capacity will be provided through EHR adoption. Integrating the workflow of research into the patient care setting has the potential to vastly increase the capacity for research within countries beginning to adopt EHRs for clinical care. This process modification is based upon years of work studying the global requirements for using eSource (e.g. EHRs) for clinical research. The solution that has emerged is a suite of standards-based ‘profiles’, the backbone of which is a very simple, but powerful, integration profile called Retrieve Form for Data Capture (RFD). RFD was developed by the Clinical Data Interchange Standards Consortium (CDISC) and Integrating the Healthcare Enterprise (IHE). A key feature of RFD is that it allows a clinician to continue to work in the EHR environment while accessing a form (e.g. a case report form) from a remote manager such that the form can be readily populated by the EHR and completed by the clinician with minimal interruption of the workflow. A second key feature is that the independent form allows for validation of the process around the research study without requiring validation of the entire EHR system for regulatory clinical research purposes. Another key feature is that an EHR vendor can provide patient data for studies from a variety of sponsors, by supporting one integration profile, and, conversely, a given research study can be done at a number of sites using different EHRs. For these reasons, EHR vendors endorse this standards-based methodology (see Figure 1).

To complete the integration profile suite for research, with the RFD backbone, the EHR can use a common healthcare standard electronic document (continuity-of-care document [CCD/HL7 CDA]), adhering to ‘meaningful use’ criteria, constrained to produce a core research dataset (i.e. the clinical research document or CRD). The core research dataset can then be exported in a case report form (CRF) standard—CDISC CDASH (Clinical Data Acquisition Standards Harmonization); this paves the way for eSubmissions to be in a format encouraged by the Food and Drug Administration (CDISC Study Data Tabulation Model), if that is the ultimate objective or, for other purposes, the data are readily aggregated into an operational database ready for analyses. The electronic data capture (EDC) tool or ‘back-end’ Clinical Data Management System (CDMS) can still cover the task of performing edit checks on the data and sending queries back to investigative sites.

The opportunity is available now to leverage this standards-based suite of integration profiles to accelerate the clinical research process by integrating it with clinical workflow. In fact, initial implementations are in progress in Europe and Japan, and also in Phase IV studies in the US.

Figure 1: Integrating Workflow for Patient Care and Research at Research Sites

This figure shows the potential to perform a ‘translational’ multicenter study with one site entering data into a paper case report form (CRF) (top), one site using electronic health record (EHR) A and another using an electronic data capture system. Because the data are all collected/exported in a standard CRF—Clinical Data Acquisition Standards Harmonization (CDASH) format, they readily integrate into the operational database and pave the way for regulatory eSubmissions. This is the ultimate goal, and to develop true clinical study reports or analyses for publications. ARO = academic research organization, CRO = clinical research organization, CCD = continuity-of-care document; CDASH = clinical data acquisition standards harmonization, CRF = case report form; EHR = electronic health record; PHR = personal health record; EDC = electronic data capture; CDM = operational data model, RFD = retrieve form for data capture.
Table 1: Misperceptions (Perceived Barriers) Around the Use of Electronic Health Records for Clinical Research and the Analogous Available Solutions

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<th>Common Misperception (Perceived Barrier)</th>
<th>Available Solution</th>
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<tr>
<td>Patients fear having their EHR data used for research purposes</td>
<td>Patients can enter their own data and/or data used for research can be appropriately pseudonymized, redacted or de-identified using integration profiles such as the redaction profile and/or applications such as Private Access.</td>
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<td>It is &quot;all about the data&quot; and EHR data will not support clinical research because not all data are available in the EHR</td>
<td>EHR data for research can be pre-populated in an eCRF accessed using the IHE RFD integration profile. Additional data needed for the study can then be entered anew and captured in the eCRF and the EHR. Research data can then be archived electronically at or under the control of the site.</td>
</tr>
<tr>
<td>EHR data are not available in the right format</td>
<td>EHR data for research can be mapped from the CCD (constrained as a clinical research document) to CDASH in an eCRF shown in the EHR window.</td>
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<tr>
<td>Data in an EHR are not of sufficiently high quality</td>
<td>By pre-populating eCRF fields with available EHR data in CDASH format and then entering any missing data anew, quality is maintained and/or enhanced.</td>
</tr>
<tr>
<td>The entire EHR must be validated per regulations if it is used for a regulated research study</td>
<td>It would be impossible to validate an EHR that is in a typical hospital setting, with links to the financial systems etc. Instead, the process of collecting research data through an EHR window into an eCRF and archiving the ESource data at or under control of the site.</td>
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<tr>
<td>EHRs have privacy and security risks</td>
<td>Such risks are mitigated as for any EDC system or even the paper CRFs. With RFD, data can be redacted or pseudonymized to ensure that the site holds the re-identification information.</td>
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<tr>
<td>All sites in a multicenter research study need to be using the same data collection system</td>
<td>See Figure 1. The use of data interchange standards and standard integration profiles allows for sites to use disparate data collection systems while still enabling ready aggregation of the data from these sites into an operational database.</td>
</tr>
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<td>Data standards are rigid and inhibit creativity and innovation</td>
<td>Other industries have shown that the adoption of standards actually stimulates innovation. Standards do not interfere with creative study designs or other innovations.</td>
</tr>
<tr>
<td>Mining claims data or other EHR data for safety signals or patient eligibility criteria implies that EHRs are being used for clinical research</td>
<td>It is true that these are research purposes, but the entire research process, from recruiting patients to enrollment and study conduct to safety reporting, stands to gain from use of EHRs across the clinical research spectrum.</td>
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CDISC study design/protocol representation model. Automation of the protocol design or process, using a business process execution language, can enable the EHR to identify eligible patients, automate the visit scheduling and perhaps even generate eCRFs.

The ASTER study was a demonstration of the impact of workflow integration on process improvement and adoption.12 Clinicians who did not report adverse events because it took 35 minutes, during which they could see another patient or two, began reporting such events when the form was integrated into their patient care routine. The time to report an event dropped from 35 minutes to less than a minute.13 This work was made possible through the implementation of RFD along with a drug safety profile.

Perceived Barriers and Misperceptions around Using Electronic Health Records for Research

Despite the current availability of well-developed process improvements (integration profiles) and standards (data sharing enablers), misperceptions and/or lack of understanding of important nuances around the use of EHRs for clinical research continue to impose perceived barriers to transforming the research process. An exploration of these misperceptions/perceived barriers and available solutions may help address lingering trust and willingness issues so that we can find ways to grasp the present opportunity and increase the conduct of 'prototypical' transformative research studies (see Table 1).

One perceived barrier seems to be the misperception that patients fear having their health information used for research purposes. In a February 2011 meeting of the National Cancer Institute (NCI) Director's Consumer Liaison Group, it was declared after much discussion that the patient is NOT the problem; patient privacy is not the inhibitor to progress in data sharing for research purposes. "One has to simply examine the phenomenon taking place in the various 'PatientsLikeMe' web-based communities to gain a glimpse of what a world of shared patient data looks like. Daily entries by tens of thousands of individuals indicate the drive some people possess for sharing data with others."14 Yet, a core barrier to conducting clinical trials continues to be slow and/or an inadequate enrolment of patients. Facilitating the participation of investigators and patients in research during the course of clinical care (in other words, integrating research into the patient care workflow) provides an untapped opportunity. In addition, standardization and new technology such as PHRs can empower patients to have more control over their own care.15

Another perceived barrier is the misperception that it is "all about the data" and that EHR data will not support clinical research either because the data are either not all available, not available in the right format within the EHR itself, or not of sufficiently high quality.16,17 The aforementioned integration profile (RFD) has been developed to enable an EHR to pre-populate certain CRF fields while leaving others for the clinician (or patient) to readily populate during the course of a patient encounter or research event. In addition, many EHR vendors support the CCD and the RFD in a manner that enables the population of core standard research elements (CDASH) in an eCRF automatically, thus collecting the data in a standard format to facilitate aggregation downstream. And, collecting the data in a
standard format upfront increases data quality. As long as the EHR can generate a dataset in a standard format, the EHR does not have to store data in that same format. This allows EHR vendor flexibility while providing researchers with data in a format that can be readily aggregated and compared or analyzed.

Yet another perceived barrier is the misperception that the entire EHR must be validated per regulations if it is used for a regulated research study. The RFID process coupled with a back-end EDC tool or CTMS provides the means to:

- automatically archive the electronic source data for clinical trials at the investigative site or in a secure accepted environment in a separate file to satisfy regulatory audit requirements;
- document electronic signatures of the site personnel on CRF data; and
- supply an electronic audit trail for all data collection and query resolution to meet regulatory requirements.

The perceived barrier around privacy and security can be addressed through profiles that support redaction of the data that should not be supplied to a research sponsor and ‘pseudonymization’ of the research data such that it does not carry identifiers that would allow sponsors to identify study participants. Only the site personnel should be able to re-identify the patient if this becomes necessary. This is consistent with procedures in place today. If tools are employed to enable patients to control the access to their data, this could replace the need for ‘redaction’.

Finally, there still seems to be a misperception that all sites in a multicenter research study need to be using the same data collection system. The beauty of implementing data interchange standards and standards-based integration profiles is that the site can use an EHR of their selection or an EDC tool (or even paper CRFs) and, as long as the data are sent to the sponsor (academic, biotech, pharma, or other research sponsor) in a standard format, these data can be readily aggregated into a common database. Such a process will not put EDC vendors out of business, but rather increase their value in the research arena. And, using the CDISC CDASH format (which many EDC vendors support, along with CDISC transport standard operational data model [ODM]) will pave the way for data sharing across other sponsored studies (e.g. for cross-study comparisons) and/or submitting data in the CDISC study data tabulation model format that has been encouraged by the FDA for facilitating regulatory reviews. An additional benefit is that the ODM carries an electronic audit trail in a standard format, and it is compliant with the relevant regulations (21CFR11) for electronic record retention.

Collecting the data in a standard format also reduces costly and time-intensive ‘back-end’ mapping to aggregate data and it allows study sponsors to be able to find and use that data. Unfortunately, some still have a misperception that standards are rigid and inhibit innovation. Nothing could be further from the truth since the standards under consideration here only affect the data formatting and not the design of the study, nor the selection of variables to be studied. Standards in other industries have recognizably spawned innovations.

From a Patient Perspective
For patients to agree to participate in a controlled clinical trial, they sign an informed consent form, or in some manner grant their permission to use their healthcare data in a research study. This ‘contract’ is generally perceived to be a commitment on behalf of the patient to participate. However, it is equally a commitment on behalf of the study sponsor to use the patient’s health information to develop a new therapy and/or improve public health. If the sponsor cannot find the data after the study or cannot use it in a meaningful way, they have broken their contract with the patient. This also goes for collecting excessive data, more than will be used. The CDASH standard reflects a minimum/core dataset, and it was developed for several purposes:

- to make it easier for investigators and patients to participate in studies (and vendors to support the technology) by requesting the same information in the same format across study sponsors (e.g. collecting ‘sex’ as M and F or one and two and one... or is it ‘gender’ instead of ‘sex?”);
- to identify a core minimum research dataset (supporting all research studies and related regulations around the world) to which additional variables/elements can then be added per the specific protocol (since most protocols are unique);
- to streamline the clinical research process (including data collection, validation, edit checks, audit trails, and aggregation) allowing for new technologies and innovations to be developed and applied across various sites; and
- to collect data once for multiple purposes to improve data quality and patient safety.

If research sponsors begin to use EHRs to support data collection to streamline clinical studies, the next step is to automate the EHR to identify a potential research candidate, schedule that patient for the study visits and automate the CRF generation. This point is not as far away as it sounds. As previously mentioned, research on such opportunities is being conducted now through IHE and an HHS/ONC Strategic health IT advanced research project (SHARP) in which CDISC is participating with the Mayo Clinic, Intermountain Healthcare, IBM Watson Research Labs (Watson computers and natural language processing), and others in the collaborative.

In the US, the President’s Council of Advisors on Science and Technology have issued their ‘Report to the President realizing the full potential of health Information Technology to improve healthcare for Americans: the path forward’. The executive summary begins: “Information technology (IT) has the potential to transform healthcare as it has transformed many parts of our economy and society in recent decades. Properly implemented, health IT can:

- Integrate technology into the flow of clinical practice as an asset, while minimizing unproductive data entry work.
- Give clinicians real-time access to complete patient data, and provide them with information support to make the best decisions.
- Help patients become more involved in their own care.
- Enable a range of population-level public health monitoring and real-time research.
Expert Opinion

• Improve clinical trials, leading to more rapid advances in personalized medicine.
• Streamline processes, increase transparency, and reduce administrative overhead, as it has in other industries.
• Lead to the creation of new high-technology markets and jobs.
• Help support a range of economic reforms in the healthcare system that will be needed to address our Nation’s long-term fiscal challenges.

Clinical research is clearly global, and the enablers that CDISC and other organizations have developed collaboratively over the past decade are global, open and freely available thanks to thousands of volunteers and contributors around the world. It is the CDISC vision to inform patient care by improving data quality and patient safety. The goal is to accelerate the cycle through which research informs healthcare and thus the opportunity to bring new therapies to patients sooner—and we are all patients.

13. PatientsLikeMe. Available at: www.patientslike.me (accessed April 21, 2011).
20. President’s Council of Advisors on Science and Technology. Report to the President Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward. Available at: www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf (accessed April 21, 2011).
Panel II

Standards available to facilitate EHR-enabled research
Structured Data Capture (SDC) Initiative

With electronic health record (EHR) adoption rising across the U.S., the volume and detail of information captured by healthcare organizations and providers will grow exponentially. Although healthcare providers and others use various sources and methods to capture and synthesize patient-level data, EHRs have been recognized as the data source with the highest potential to provide timely and relevant data in a form that is quickly usable for quality and safety improvement, population health, and research (sometimes labeled “secondary” use or “reuse”). EHR data obtained during episodes of care will become increasingly valuable to healthcare organizations striving to leverage electronic information to drive efficiency and quality. Of particular interest are efforts to leverage clinical data captured during episodes of care and link the clinical data to supplemental data collected for other purposes including: 1) research, 2) patient-safety and adverse event reporting, 3) public health reporting, and 4) determination of coverage. Once captured, aggregated and analyzed, these combined data can be used to identify trends, predict outcomes and influence patient care, drug development and therapy choices.

The S&I Structured Data Capture (SDC) Initiative aims to define the necessary requirements (including metadata) that will drive the identification and harmonization of standards to facilitate the collection of supplemental EHR-derived data. The SDC Initiative recently published Implementation Guidance that defines how structured data can be accessed from EHRs and be stored for merger with comparable data for other relevant purposes to include:

- The electronic Case Report Form (eCRF) used for clinical research including Patient Centered Outcomes Research (PCOR)
- The Incident Report used for patient safety reporting and adverse event reporting for drugs and medical devices leveraging AHRQ ‘Common Formats’ and FDA form 3500/3500a
- The Surveillance Case Report Form used for public health reporting
- The collection of patient information used for determination of coverage

Value Statement for Participating Entities

The implementation of consensus driven standards for structured data capture from EHRs is expected to improve efficiencies and promote collaboration by:

- Advancing the Stage 3 Meaningful Use of EHRs Learning Health System where patient information can flow securely from EHRs to other systems like research consortia, registries, bio repositories and public health systems
- Reducing the data collection burden on health care providers by enabling secure, single-point data entry that populates to multiple systems

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• Improving the comparability of data to better inform research, quality reporting and ultimately, influence patient care
• Reducing the need for site-specific EHR enhancements so that disparate EHR systems can participate in important reporting and research activities
• Limiting barriers to volunteer adverse event reporting on medical products to public health agencies leading to improvements in population health

SDC Accomplishments
Through broad participation—by providers, HIT vendors, federal and public agencies, research communities, patient safety organizations (PSOs), pharmaceutical firms, Public and Private Health Insurance Payers, Standard Development Organizations (SDOs) and other interested parties—the SDC Initiative has achieved consensus-driven deliverables to include:

• Project Charter. Defines the SDC Initiative goal and scope of work, deliverables and timeline.
• Use Case. Outlines the functional and technical specifications to enable an EHR system to retrieve, display, and fill a structured form or template, and store/submit the completed form to an external repository.
• Standards Solutions Plan. Identifies all SDC applicable standards and maps each to the interoperability transactions identified in the Use Case.
• SDC SOAP/SAML Implementation Guide. Provides guidance to support implementation objectives of SDC Use Case with a focus on the structure of the in-scope transactions and how those transactions can incorporate semantics through use of standard terminologies, value sets and taxonomies.
• IHE SDC Content Profile (Volume I). Builds on the SOAP/SAML Implementation Guide with clear alignment to existing IHE Profiles (Retrieve Form for Data Capture and Data Element Exchange).

SDC Next Steps
The SDC Initiative is currently working towards publication of the IHE SDC Profile that will be available for industry testing in August 2014. The Initiative is also directly engaged with HL7 in the development of a FHIR based resource for the common data element definition that utilizes ISO/IEC 11179-3 syntax with core attributes to facilitate the definition of CDEs; and in the development of a mechanism for clinical systems to expose CDEs for research leveraging the existing FHIR Questionnaire Resource. The SDC HL7 FHIR CDE profile will be published as a draft for comment in September 2014 and will balloted as a draft standard for trial use (DSTU) in January 2015.

Other key activities the Initiative is engaged in include:

• Identifying Meaningful Use Stage 2 Data Sets and their associated CDEs that can be defined using the emerging FHIR CommonDataElement Resource
• Mapping AHRQ and FDA identified CDEs and forms to SOAP/SAML IG specifications so they can be used for Patient Safety Event and/or Adverse Event Reporting Pilot Projects
• Finalizing workflows that may guide future pilot projects on reporting patient safety event and adverse event data from EHR system
• Convening organizations to test and validate the SDC SOAP/SAML IG and/or IHE SDC Profile
Panel III

EHR-enabled research activities
I-SPY 2 Innovations

I-SPY 2 represents an unprecedented reengineering of the clinical trial design process. Incorporating a number of highly innovative and unique features, the I-SPY 2 TRIAL rapidly tests emerging and promising new agents. The goal is to significantly reduce the cost, time and number of patients required for efficiently bringing new drug therapies to breast cancer patients who need them urgently.

The I-SPY 2 TRIAL represents a significant departure from conventional clinical trial models. Five critical components contribute to the I-SPY 2 groundbreaking approach:

1. I-SPY 2 uses tissue and imaging markers (biomarkers) from individual cancer patients’ tumors to determine eligibility, guide/screen promising new treatments and identify which treatments are most effective in specific tumor subtypes.

2. The trial’s adaptive design allows the I-SPY 2 Team to “learn as we go,” enabling researchers to use data from patients early in the trial to guide decisions about which treatments might be more useful for patients who enter the trial later. I-SPY 2 provides a scientific basis for researchers to eliminate ineffective treatments and graduate effective treatments more quickly.

3. The I-SPY 2 neoadjuvant treatment approach—in which chemotherapy is given to patients prior to surgery—allows the team to evaluate tumor response with MRI before removing the “evidence.” This approach is as safe as treating after surgery, allowing tumors to shrink, and most importantly, it enables critical learning early on about how well treatments work.

4. Key to the trial’s distinctive design, the team will screen multiple drug candidates developed by multiple companies—up to 12 different investigational drugs over the course of the trial. New agents will be selected and added as those used initially either graduate to Phase III or are dropped, based on their efficacy in targeted patients. Not only does this enable an enormous improvement in efficiency but, by using only one standard arm for comparison throughout the trial, it also immediately saves 35% of the costs of standard Phase III trials.

5. The trial incorporates a robust informatics system that allows data to be collected, verified and shared real-time and to be accessed early and in an integrated fashion—enhancing and encouraging pre-competitive collaboration.
Industry Collaboration

As with its predecessor, I-SPY 2 is focused on collaboration across institutions. Collaboration in I-SPY 2 includes the Food and Drug Administration (FDA), the National Cancer Institute (NCI), the Foundation for the National Institutes of Health (FNIH), Biomarker’s Consortium, at least 11 leading academic centers (researchers and physicians), major pharmaceutical companies and breast cancer patient advocates. It involves investigators sharing data, tissue and tools as well as common information management platforms and repositories. A sophisticated informatics portal has been built to integrate and interpret the complex and disparate data (genomics, proteomics, pathology and imaging) from many investigators, providing real-time access to study data for effective adaptation in the trial.

I-SPY 2 Technical Highlights

Biomarkers to be used in I-SPY 2 are of three classes:

- **Standard biomarkers**, in clinical use or FDA-approved, will be used to determine patient eligibility and randomization.
- **Qualifying biomarkers** (hypothesis-testing), showing promise for predicting which patients will respond to which agents, but not yet FDA approved, will be evaluated under Clinical Laboratory Improvement Amendment (CLIA) quality standards.
- **Exploratory biomarkers** (hypothesis-generating) of predictive or prognostic value for breast cancer treatment will also be investigated. Importantly, emerging platforms of the future can also be tested to prevent technology obsolescence even many years from now.
We know from whole-genome molecular analysis of solid tumors that cancer is a disease at the level of dysregulation of cellular pathways. These pathways provide the targets for “targeted” therapies. In I-SPY 2, this vital pathway information forms the basis for rationalized therapeutic guidance for patient selection, stratification and further exploration to find response-predictive biomarkers.

I-SPY 2 investigators use new state-of-the-art technologies to provide a comprehensive overview of gene mutation, gene copy number, gene expression (at mRNA and protein level) and protein phosphorylation of both tumor and normal background tissue and blood. The net impact should be more targeted therapies, developed, tested and approved for the appropriate patient or tumor subgroup. The process and collaborative framework of the trial will allow testing in greatly accelerated time frames and at significantly lower cost, benefiting an ever-growing number of patients across an ever-increasing diversity of cancer types and subtypes.

I-SPY 2 Benefits

I-SPY 2 provides significant benefits for the breast cancer patient, for the FDA and for industry, and it responds to critical problems in clinical research. The goal is to create a new paradigm to:

I-SPY 2 provides significant benefits for the breast cancer patient, for the FDA and for industry, and it responds to critical problems in clinical research. The goal is to create a new paradigm to:

• Dramatically reduce the cost of bringing a drug from discovery to market (or from compound to approval);

• Dramatically reduce the time to conclusive results;
• Dramatically reduce the number of patients needed to enroll in trials—a tenfold reduction for Phase III trials;

• Significantly improve the pace of innovation;

• Significantly improve the success rate of Phase III trials—as high as 85% vs 25-30% historically

• Significantly improve pre-competitive collaboration for applying molecular and protein pathway profiling and imaging in clinical trials;

• Significantly improve the efficiency of drug evaluation and approval in concert with the FDA, and provide support for innovation in regulatory decision-making.

**Looking Ahead**

I-SPY 2 is a great beginning, and with additional funding the approach can be further expanded. The I-SPY 2 model holds tremendous promise for many cancers and diseases in addition to breast cancer. It also poses the possibility of moving the adaptive trial concept even further, to the point of adapting within patients once we have identified successful new agent/biomarker pairs.

Given the highly motivated and expert I-SPY 2 Team, existing infrastructure from the original I-SPY 1 TRIAL, adaptive trial design, existing and developing biomarkers, promising investigational cancer drugs and the use of early endpoints to learn what works within months rather than years, this initiative promises to be transformational for women with breast cancer.

- See more at: [http://www.ispy2trial.org/](http://www.ispy2trial.org/)
Automated determination of metastases in unstructured radiology reports for eligibility screening in oncology clinical trials

Valentina I Petkov, Lynne T Penberthy, Bassam A Dahman, Andrew Poklepovic, Chris W Gillam and James H McDermott

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What is This?
Automated determination of metastases in unstructured radiology reports for eligibility screening in oncology clinical trials

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Abstract

Enrolling adequate numbers of patients that meet protocol eligibility criteria in a timely manner is critical, yet clinical trial accrual continues to be problematic. One approach to meet these accrual challenges is to utilize technology to automatically screen patients for clinical trial eligibility. This manuscript reports on the evaluation of different automated approaches to determine the metastatic status from unstructured radiology reports using the Clinical Trials Eligibility Database Integrated System (CTED). The study sample included all patients (N = 5,523) with radiologic diagnostic studies (N = 10,492) completed in a two-week period. Eight search algorithms (queries) within CTED were developed and applied to radiology reports. The performance of each algorithm was compared to a reference standard which consisted of a physician’s review of the radiology reports. Sensitivity, specificity, positive, and negative predicted values were calculated for each algorithm. The number of patients identified by each algorithm varied from 187 to 330 and the number of true positive cases confirmed by physician review ranged from 171 to 199 across the algorithms. The best performing algorithm had sensitivity 94%, specificity 100%, positive predictive value 90%, negative predictive value 100%, and accuracy of 99%. Our evaluation process identified the optimal method for rapid identification of patients with metastatic disease through automated screening of unstructured radiology reports. The methods developed using the CTED system could be readily implemented at other institutions to enhance the efficiency of research staff in the clinical trials eligibility screening process.

Keywords: Clinical trials, eligibility screening, metastases, radiology reports, information extraction, automation

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Introduction

Clinical trials are essential in evaluating new therapies before they become a standard of care. Enrolling adequate numbers of patients that meet protocol eligibility criteria in a timely manner is critical to this process, yet clinical trial accrual continues to be problematic, particularly for cancer studies.¹⁻⁵ Despite the significant body of literature focusing on barriers to clinical trial accrual,¹⁻⁵ few advances have been made to improve patient recruitment and enrollment.

One approach to meet these accrual challenges is to utilize technology to automatically screen patients for clinical trial eligibility. Successful pre-screening will improve research staff efficiency by reducing the number of ineligible patients requiring manual review, while simultaneously increasing the total number of patients evaluated. The researchers consistently reported doubling the enrollment rates by using electronic screening,¹²⁻¹⁴ increasing the number of prescreened patients while decreasing the total screening time,¹² and significantly increasing the physician referrals.¹³ Much larger proportions of electronically screened patients were eligible and enrolled in studies compared to conventionally screened patients.¹⁵

Automated pre-screening is now feasible because the widespread of implementation of electronic health records (EHR). A variety of automated clinical trial screening tools and software that use EHR data have been piloted,¹⁶⁻²⁰ though few are commercially available.²¹,²² A common limitation of such tools is the inability to utilize unstructured clinical text documents which represent the bulk of clinical information that must be reviewed to determine eligibility. While screening tools based only on discrete data are valuable,¹²⁻¹⁵ accuracy can be improved if information locked in narrative reports is utilized. Although the field for information extraction (IE) based on Natural Language Processing
(NLP) is growing rapidly, IE use to support research is limited.23

Cancer metastatic status is frequently a key inclusion or exclusion criterion for oncology clinical trials. The current practice is to determine new metastatic disease through manual review of medical records of cancer patients. This approach is highly inefficient due to time required, limited number of patients assessed, and difficulty identifying these patients prior to treatment. Automatic screening can be performed using billing records (International Classification of Diseases, Ninth Revision [ICD-9] diagnosis codes for secondary malignancies). While this is valuable in cancer surveillance and cohort discovery, it is of limited use in clinical trial eligibility screening mainly due to the lag time in billing and the need to identify patients at the time of diagnosis and prior to initiation of treatment. Information to quickly and accurately identify patients with metastatic disease is typically available only in clinical text documents (particularly radiology reports) and has the challenges inherent in extraction through Natural Language Processing due to the complexity of language expression and inconclusive text to express uncertain or negative conditions. Because of these challenges, we evaluated different approaches to determine the metastatic status from unstructured text in radiology reports in near real time. This manuscript reports the results of this evaluation. Our objectives were to formally assess the performance of several automated algorithms to identify metastatic status from radiology reports, select the algorithm with the optimal measures of accuracy, and to identify methods to improve this automated process.

Methods

Study overview

The Clinical Trial Eligibility Database Integrated System (CTED) was utilized for identifying patients with metastases in radiology reports.24–26 Search algorithms (queries) within CTED were developed and applied to radiology reports completed at our Institution. The performance of each algorithm was compared to a reference standard which consisted of a physician’s review and validation of the metastatic status from radiology reports.

Brief overview of the CTED system

The CTED Integrated system is an investigator-developed set of software tools to aid in the clinical trial recruitment process at the Massey Cancer Center, Virginia Commonwealth University (VCU). It consists of three components: the CTED Tracking System, the CTED Automated Matching Tool (CTED-AMT), and the Provider/Clinical Research Staff (CRS) Alert Notification System (CTED MD Alert). Detailed information on the CTED system has been reported in prior publications.24–26 The CTED-AMT is the component used in this study to automate patient identification. This tool searches the VCU patients’ data collected from multiple electronic sources and maintained longitudinally in a data warehouse. It allows for automatic selection of potentially eligible study patients based on protocol inclusion/exclusion criteria. The electronic sources include data from the scheduling system, billing data, and all clinical notes including surgical pathology reports, radiology reports, and clinic visits or hospital admissions. The system searches discrete data including demographics, billing diagnoses (cancer and other diagnoses related to comorbidity), prior treatment for cancer (including specific and generic categories of treatment), and laboratory test results indicating current and prior measures of disease status (e.g. metastatic disease, recurrence, disease progression, tumor markers). It also searches unstructured text documents based on the National Cancer Institute Enterprise Vocabulary Services (NCI EVS) meta-thesaurus27 or user-defined search terms and text strings. A list of patients who meet a set of protocol-specific eligibility criteria is created each time a query is executed. This list is matched with the patient scheduling system for automated notification of physicians and research staff regarding visits for potentially eligible patients.

Study sample

The study sample consists of all patients who had one or more radiology reports completed during two consecutive weeks (10/31/11 to 11/14/11) at VCU Health System. A total of 5523 patients with 10,492 radiology reports were included in the analysis. We chose not to limit the algorithms only to patients with cancer diagnosis because some categories of patients with metastases may not be included (for example, patients who present with advanced metastatic disease at the first encounter or patients who were not receiving cancer care at our institution but had only radiology tests/consults). In order to automatically subset patients based on cancer diagnosis, the billing ICD-9 diagnosis code or EHR problem list must be used. However, the billing data usually lag in time and the problem list is not routinely updated. Thus, we chose to include all patients because for oncology clinical trials patients must be identified at the time metastases are initially detected. All diagnostic radiology reports were included in the evaluation (plain radiographs, fluoroscopic studies, ultrasound exams, computed tomography (CT) scans, magnetic resonance imaging (MRI), positron emission tomography (PET), scintigraphic tests, and angiographic studies). Although some of the radiologic diagnostic tests such as fluoroscopic exams have limited sensitivity to detect metastases, we included all types of reports to assure that we are capturing any evidence of metastasis and to test how our algorithms perform against the entire range of radiographic diagnostic tests.

Algorithms for identifying metastatic disease in unstructured radiology reports using CTED

We used eight different search algorithms (queries) to identify patients with metastatic disease from radiology reports. These queries represented two types of approach, term/ string matching and document indexing. Each approach was then combined with ICD-9 cancer diagnosis and/or the “Ignore phrase” feature in CTED-ATM (see below), Table 2.
The details for each query are provided below.

1. Term search only: This method used the “Term search” feature in CTED-AMT. The Term Search feature allows for an unlimited number of terms or text strings to be entered and to establish relational operators (AND, OR, NOT) between each of the terms or strings specified. In addition to user-defined terms, some or all of NCI EVS metathesaurus 27-related terms may be included with or in lieu of the specified term. Further, the system allows selection of the report type to search as well as date ranges. For the “term search only” algorithm, we performed the search in the radiology reports within the study period using the terms: “metastatic,” “metastasis,” “metastases,” and “carcinomatosis.” These four terms were found to capture the majority of the radiology reports with metastatic disease findings during the pre-testing and development of the CTED metastatic algorithm (approach #5).

2. Term search and a cancer diagnosis based on ICD-9 diagnosis codes in billing: Limiting the search to those patients that had prior diagnosis for cancer may decrease the number of false positive cases. Thus, we added searching for any ICD-9 cancer diagnosis codes (ICD codes 140-239) in the billing claims data to algorithm 1.

3. Term search and use of the “Ignore Phrases” feature in CTED-AMT: This feature allows the user to enter an unlimited number of phrases or sentences in conjunction with the primary term or text string. Any terms, phrases or sentences specified as “Ignore Phrases” are ignored by the system in searching and selecting cases with the specified term or phrase in the narrative reports. The “Ignore Phrases” were identified during the manual review of radiology reports. An example of an “ignore phrase” is “evaluate for metastases.” In this context, the patient may or may not have metastatic disease. Without further positive corroborating evidence in the same report, it will not be categorized as positive for metastases (i.e. it will be ignored). The ignore phrases were added to algorithm 1.

4. Term search and any billing ICD-9 cancer diagnosis, and CTED-ATM “Ignore Phrases” feature (Algorithm 1, 2, and 3 combined).

5. Metastatic algorithm programmed in CTED: This is a hard-coded option algorithm that is a component of the CTED system. It automatically screens incoming radiology reports and indexes each report as positive or negative based on a sequence of positive and negative relations using metastatic terms.

6. CTED metastatic algorithm and a billing ICD-9 cancer diagnosis code: As for strategy 2 above, a billing code for cancer was added to the algorithm to reduce false positives.

7. CTED metastatic algorithm and “Ignore phrases” feature in CTED: The same ignore phrases used in approach 3 were included here to reduce false positives.

8. CTED metastatic algorithm and any billing ICD-9 cancer diagnosis, and CTED-ATM “Ignore Phrases” feature (Algorithm 5, 6, and 7 combined).

Review of electronic medical records (validation)

Figure 1 outlines the selection of patients for review. The consensus opinion of three physicians, one of whom is an oncologist, served as a gold standard for final determination of a radiology report as being positive or negative for metastatic disease. One physician reviewed all radiology reports of patients identified by any of the queries as positive in order to verify metastatic disease and classify cases as True Positive (TP) or False Positive (FP). These 750 reports represented 7.1% of all radiology reports received during the two-week study period, and they are for 330 unique patients. Twenty percent of all patients reviewed by the first reviewer were reviewed by a second physician to determine inter-rater agreement. Disagreements between the two physicians were adjudicated by a medical oncologist and a final decision was reached. Any radiology report that was suggestive but not conclusive as to the presence of metastatic disease (e.g. consistent with, cannot be ruled out) was considered a positive report because in practice all potentially eligible patients identified by CTED will be followed up by the research nurse or the Principal Investigator.

Estimating the number of FN cases

The false negative (FN) cases are those cases that were not identified by any of the algorithms although their radiology reports indicated that they had metastatic conditions. We estimated the number of FN cases among patients that were not selected by any of the algorithms \( N_{\text{patients}} = 5193 \) as follows: A simple random sample of 500 patients (approximately 10% out of 5193) was selected and all of their radiology reports completed in the two-week study period were reviewed \( N_{\text{reports}} = 923 \). The rate of FN cases was estimated as number of FN found in the random sample divided by 500. The total number of false negatives in the complete sample (FN) was estimated by multiplying this rate by the 5193 sample size. Further, for each query, the number of estimated FNs was adjusted to reflect positive cases that were identified by other queries but not the query in question. The patients and TP identified by the second through eighth queries were subsets of query 1.

Analyses

We categorized patients into four categories using the following definitions for each query: True positive (T\text{P}_{\text{query}}) – patients identified by a query as positive for metastases that were confirmed by the manual review to have metastases; False positive (F\text{P}_{\text{query}}) – patients identified by a query as positive for metastases but not confirmed by the manual review; False Negative (F\text{N}_{\text{query}}) – estimated number of patients with a radiology report positive for metastatic
disease that were not identified by a query; True Negative (TNquery) — estimated as the number of patients not selected by a search algorithm minus the estimated number of FN for that algorithm. The exact numbers of TP and FP were determined by the manual review of all patients selected by the different approaches. The FNs and TNs were estimated for each query separately using the methods shown in Table 1.

The performance of each algorithm was assessed by calculating sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) along with 95% confidence interval using physician expert classification as a reference standard. Since PPV is affected by the prevalence of the condition of interest, specifically when the prevalence is low, we calculated the likelihood ratio positive (LR+ = sensitivity/false positive error rate) and likelihood ratio negative (LR− = false negative error rate/specificity) for each metastatic finding algorithm. The likelihood ratio provides a more accurate estimate of the usefulness of a test in low prevalent conditions such as in this study where the prevalence of metastatic disease in radiology reports was <3%.28,29 The overall accuracy of each approach was calculated as (TP + TN)/(sample size).

Inter-rater reliability was estimated with Cohen’s kappa statistics.

IBM SPSS Statistics version 20 and R version 2.15.0 (R Foundation of Statistical Computing) were used in the analysis.

Ethical considerations

The CTED system is maintained under IRB Protocol HM 11089. This project was performed as a component of our continuous quality assessment and improvement of the CTED integrated system in supporting the cancer center research enterprise.

Results

During the two-week evaluation period, 5523 patients had a total of 10,492 radiology reports. The number of patients identified as having metastatic disease according to each approach ranged from 187 to 330 (Table 2). Patients selected by the second through eighth queries represented a subset of patients identified by the first query (terms search). The total number of patients validated as having metastatic
Table 2 Characteristics of different approaches to detect presence of metastasis in free text radiology reports.\(^a\)

<table>
<thead>
<tr>
<th></th>
<th>N patients identified</th>
<th>N true positive</th>
<th>Sensitivity, 95% CI</th>
<th>Specificity, 95% CI</th>
<th>Positive predictive value, 95% CI</th>
<th>Negative predictive value, 95% CI</th>
<th>Likelihood ratio positive, 95% CI</th>
<th>Likelihood ratio negative, 95% CI</th>
<th>Accuracy, 95% CI</th>
</tr>
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<tbody>
<tr>
<td>1. Term search of radiology reports (RR)(^b)</td>
<td>330</td>
<td>199</td>
<td>94.8 [90.8, 97.4]</td>
<td>97.5 [97.1, 97.9]</td>
<td>60.3 [54.8, 65.6]</td>
<td>99.8 [99.6, 99.9]</td>
<td>38.4 [32.4, 45.6]</td>
<td>0.05 [0.03, 0.1]</td>
<td>97.4 [97.0, 97.8]</td>
</tr>
<tr>
<td>2. Term search of RR AND billing ICD-9(^d) diagnosis for any cancer</td>
<td>284</td>
<td>179</td>
<td>85.2 [79.7, 89.7]</td>
<td>98.0 [97.6, 98.4]</td>
<td>63.0 [57.1, 68.7]</td>
<td>99.4 [99.2, 99.6]</td>
<td>43.1 [35.4, 52.6]</td>
<td>0.15 [0.11, 0.21]</td>
<td>97.5 [97.1, 97.9]</td>
</tr>
<tr>
<td>3. Term search AND use of “Ignore phrases” feature in CTED(^d)</td>
<td>268</td>
<td>198</td>
<td>94.2 [90.2, 97.0]</td>
<td>98.7 [98.3, 99.0]</td>
<td>73.9 [68.2, 79.0]</td>
<td>99.7 [99.6, 99.9]</td>
<td>71.6 [56.6, 90.5]</td>
<td>0.06 [0.03, 0.10]</td>
<td>98.5 [98.2, 98.8]</td>
</tr>
<tr>
<td>4. Term search AND use of “Ignore phrases” feature in CTED AND billing ICD-9 code for any malignancy</td>
<td>239</td>
<td>179</td>
<td>94.8 [90.8, 97.4]</td>
<td>97.5 [97.1, 97.9]</td>
<td>60.3 [54.8, 65.6]</td>
<td>99.8 [99.6, 99.9]</td>
<td>38.4 [32.4, 45.6]</td>
<td>0.05 [0.03, 0.1]</td>
<td>97.4 [97.0, 97.8]</td>
</tr>
<tr>
<td>5. Metastatic algorithm (programmed in CTED)</td>
<td>267</td>
<td>198</td>
<td>94.3 [90.2, 97.0]</td>
<td>98.7 [98.4, 99.0]</td>
<td>74.2 [68.5, 79.3]</td>
<td>99.8 [99.6, 99.9]</td>
<td>72.6 [57.3, 92.0]</td>
<td>0.06 [0.03, 0.1]</td>
<td>98.5 [98.2, 98.8]</td>
</tr>
<tr>
<td>6. Metastatic algorithm AND billing ICD-9 diagnosis for any cancer</td>
<td>232</td>
<td>178</td>
<td>84.8 [79.2, 89.3]</td>
<td>99.0 [98.7, 99.2]</td>
<td>76.7 [70.7, 82.0]</td>
<td>99.4 [99.1, 99.6]</td>
<td>83.4 [83.6, 109.4]</td>
<td>0.15 [0.11, 0.21]</td>
<td>98.4 [98.1, 98.8]</td>
</tr>
<tr>
<td>7. Metastatic algorithm AND “Ignore phrases” feature in CTED</td>
<td>220</td>
<td>197</td>
<td>93.8 [89.6, 96.7]</td>
<td>99.6 [99.4, 99.7]</td>
<td>89.5 [84.7, 93.3]</td>
<td>99.8 [99.6, 99.9]</td>
<td>216.7 [143.9, 326.3]</td>
<td>0.06 [0.04, 0.11]</td>
<td>99.3 [99.1, 99.5]</td>
</tr>
<tr>
<td>8. Metastatic algorithm AND “Ignore phrases” feature AND billing ICD-9 diagnosis for any cancer</td>
<td>187</td>
<td>171</td>
<td>81.4 [75.5, 86.4]</td>
<td>99.7 [99.5, 99.8]</td>
<td>91.4 [86.5, 95.0]</td>
<td>99.3 [99.0, 99.5]</td>
<td>270.4 [165.1, 442.9]</td>
<td>0.19 [0.14, 0.25]</td>
<td>99.0 [98.7, 99.2]</td>
</tr>
</tbody>
</table>

\(^a\)Presence of metastases was determined based on manual review of radiology reports by physicians;\(^b\)Terms used: metastatic, metastasis, metastases, carcinomatosis;\(^d\)ICD-9: International Classification of Diseases, Ninth Revision; \(^d\)CTED: Clinical Trials Eligibility Database Integrated System.
disease among these patients was 199, but the number of TP cases identified varied by query. The review of the 500 randomly selected patients not identified by any of the algorithms found only one case positive for metastases. The rate of FN cases was 0.002, 95% CI [0, 0.012]. Based on this FN rate, the estimated numbers for FN cases ranged from 11 (Query 1) to 39 (Query 8). The inter-rater agreement between the two reviewers was excellent with a kappa value of 0.90, 95% CI [0.80, 0.98].

Sensitivity, specificity, PPV, NPV, LR+ and LR−, and accuracy are also shown in Table 2. While specificity and NPV were very high for each of the search strategies, query # 7 (based on the CTED programmed metastatic algorithm and “Ignore phrases” feature) had the most favorable combination of sensitivity (93.8%), PPV (89.5%), and LR+ (216.7). Adding any billing ICD-9 diagnosis for cancer improved PPVs by 2–3% but decreased the sensitivity by almost 10%.

Because a focus of this project was to improve the system, we performed a detailed review of all 69 FP cases identified by the CTED programmed metastatic algorithm (query #5) to identify methods to improve the accuracy of the system. The results are provided in Table 3. The majority of the FP cases were eliminated when the “ignore phrase” feature is used and were due to negation expressions or diagnostic test indicators in the report such as “evaluate for,” “assess,” or “rule out metastases.” Applying the “Ignore phrases” feature decreased the number of FP cases by 46, resulting in an increase of 15% in the PPV. A slight drop in sensitivity by 0.5% was due to one TP case eliminated by the “Ignore phrases” function.

Discussion

As a screening tool to identify cancer patients with metastatic disease, the automated system using the CTED programmed metastatic algorithm and “ignore phrases” (approach 7) was shown to have excellent results with sensitivity of 94%, specificity of 99%, PPV– 90%, NPV– 100%, and an LR+ of 216. The CTED programmed metastatic algorithm had excellent sensitivity and specificity (94% and 99%, respectively), but the PPV was somewhat lower (74.2%). Because the goal is to quickly and accurately identify patients with metastatic disease, the approach using the algorithm programmed in CTED in conjunction with the “ignore phrases” was optimal as it identified the most patients with the lowest FP rate.

The concepts utilized herein are not entirely new, but the combined processes and potential for generalizability represent a novel use of existing methods. Previous studies have tested information extraction of various conditions of interest in different types of unstructured medical records such as identification of “medical problems” from clinical notes for the purpose of enriching the EHR problem list, determining cancer stage from pathology reports and clinical notes to improve cancer registries, or smoking status in medical free text documents. Few studies have focused on radiology reports and cancer. For those studies, our results are comparable. Hripcsak et al. reported sensitivity of 81% (CI, 73% to 87%) and specificity...
of 98% (CI, 97% to 99%) for a natural language processor in determining six conditions (one of which was neoplasm) in 200 admission chest radiographs. Sensitivity of 80.6%, specificity 91.6%, PPV 82.4%, and NPV 92.0% were found by Cheng et al.\textsuperscript{36} in a study testing the ability of NLP to detect brain tumor progression from pre-selected unstructured brain MRI reports. Carrell et al.\textsuperscript{37} used unmodified caTIES (a software developed to extract findings from pathology reports) to identify cancer in radiology reports with sensitivity of 82% and specificity of 95%.\textsuperscript{37} Our CTED built-in metastatic algorithm alone or in combination with the “Ignore phrase” feature performed somewhat better and across a broader range of cancers, clinical trials and was used to effectively screen all types of radiologic diagnostic tests.

Our estimated performance characteristics reported in Table 2 reflected the system performance on a limited cross-sectional basis. In the clinical trials recruitment practice, automated screening would occur on an ongoing basis. Thus, some FNs occurring during the two-week period would likely be identified either before or after the study interval, as cancer patients have multiple radiology tests throughout the disease course. In order to evaluate the longitudinal performance of the system as it would be used in production, we attempted to broaden our search to identify actual patients with metastatic disease (FNs) that would be identified from data sources other than radiology reports. This included searching clinical notes for metastatic terms and screening patients with ICD-9 billing diagnoses for secondary malignancy during the two-week study interval. Using these alternate methods, 18 FN cases were identified. These FNs were then run against the metastatic algorithm (Query #5) with no date limits (i.e. before and after the two week study window) to mimic ongoing longitudinal use of the system. The algorithm (using only the radiology reports) correctly identified 78%, 95% CI [52, 93] of these 18 FN cases from radiology studies completed either before or after the two-week study interval. Of the remaining four FN cases, three had limited information in the EHR with only one radiology report. The fourth case was a widespread follicular lymphoma with organ involvement. From a practical perspective, it is unlikely that three of these patients would be eligible for a trial as they did not receive their care within our health care system. The resulting system performance measures based on this adjusted FN rate are as follows: sensitivity 98%, specificity 100%, PPV 90%, NPV 100%, LHR + 225, and LHR− 0.02.

The major challenge in identifying patients with metastatic disease is that the earliest indicator is typically information only available through unstructured text. Thus, the ability to screen these text documents to accurately identify patients in a timely manner is critical. Identification of negation phrases in unstructured clinical reports represents the most significant challenge to this process.\textsuperscript{38} The presence or absence of metastatic disease is a component of the inclusion or exclusion criteria for the majority of cancer clinical trials, thus is a key factor that if known can quickly eliminate patients and reduce the number of patients research staff must screen to identify eligible patients. Minimizing the FP rate is important when excluding patients with possible metastatic disease, whereas maximizing the TP rate is important when using metastasis as an inclusion criterion. In oncology trials that include patients with metastases, the FP rate is less crucial but still important as it will result in unnecessary review of records and increase the time spent by the research staff reviewing erroneously included patients. For clinical trials that exclude metastases the issue of negation becomes more important. In these trials, the search algorithms can be used to exclude patients during the automated pre-screening. The inclusion of the “ignore phrases” with the CTED programmed algorithm (approach 7) was a very important outcome of our evaluation as it resulted in a 15% improvement in the PPV (from 74.2 to 89.5) while maintaining a good sensitivity and increased specificity.

The decreased sensitivity that occurred when cancer diagnosis was added may be due to several reasons. Patients may not have been treated at the VCU Health System and the radiology report was performed for an outside health care provider who is treating the patient. These patients may therefore not have a cancer diagnosis in the billing records. Further, some patients were diagnosed with metastatic disease during their first encounter at our health care system. Billing data typically lag by several weeks the real time radiology dictations thus may not have been incorporated into the system until well after the radiology report was available.

There were several key benefits in the methods from this study compared with systems reported in the published literature. First, we included all radiologic diagnostic tests to maximize the ability to capture information on metastases as close to the diagnosis as possible. Other studies focused on a limited set of diagnostic radiologic procedures such as chest radiographs\textsuperscript{35,39} or brain MRI.\textsuperscript{36} Our approach based on near real time capture and screening of all reports provides information to clinical research staff at the earliest point at which metastatic disease is identified whether it is by chest X-ray, CT, or MRI. Typically, radiology reports are available the day of or day after the diagnostic study is completed. Thus, the tool is optimal for rapidly including or excluding potential study eligible patients for clinical trials. The ability to accurately detect metastatic disease through radiology reports is a key step in identifying patients with a progressive metastatic disease burden. Rapid identification in real time of patients with known cancer and newly metastatic disease is critical to clinical trial enrollment, as these patients are the ones most likely to need access to a clinical trial. The near real time identification is also critical as these patients are often in need of immediate treatment. Although our evaluation did not focus on newly diagnosed metastases, the CTED system provides features that can be used to successfully identify new metastases particularly in patients that received the majority of their cancer care at the VCU Health System (VCUHS). These features include restricting the search to recent time and excluding patients who had evidence of metastases in clinical documents or billing records prior to the specified time point. This approach has been used to identify not only new metastases but other newly diagnosed medical conditions.
An additional differentiating factor of this analysis is the inclusion of cancers of any site. Previous studies have focused on one organ.35,36 While these studies have provided valuable contributions, the ability to identify metastases across all cancer sites is critical for a cancer center that typically conducts clinical trials in a broad range of cancers. Further, some studies enrolling patients with metastases may enroll patients with very different types of cancer (for example bone metastases in lung, breast and prostate cancer). The CTED system was developed to support all oncology trials, thus it was important to evaluate the system’s performance in determining metastatic status irrespective of cancer site.

Although optimized currently for cancer trials, the system is being used to identify patients with a variety of other clinical characteristics for assessing eligibility in clinical trials not only in oncology but in other clinical arenas. Examples of medical terms/text strings searches in unstructured text documents that we used in various clinical trials included specific medications use, type of sickle cell disease (Hemoglobin SS, SC, SB), eosinophilic pharyngitis, and large volume paracentesis. The latter two concepts are examples where discrete data would not be helpful since there are no specific ICD-9 or Current Procedural Terminology (CPT) codes for these conditions.

**Limitations**

The results from this evaluation are for a single institution. Thus, the findings may not be entirely generalizable. However, the 10,492 reports that were assessed represented dictations by 69 radiologists, who trained at a variety of institutions, thus reducing the concern that the results may be skewed by dictation patterns associated with only a limited set of radiologists.

A second limitation is the length of the study period. Although two weeks is a relatively short period, there were more than 10,000 radiology reports generated during that period, representing every radiologic diagnostic test performed at our institution. During this interval a total of 1673 (16%) of all radiology reports in the study sample were reviewed.

Another potential limitation of the proposed approaches for identifying metastases in text documents could be misspelled words. We did not observe this to be the case in our study. This may be because the “metastatic” terms are used typically more than once in a report and frequently multiple imaging studies are performed in relatively short periods of time, thus decreasing the probability of not identifying a patient due to a typing error.

**Conclusion**

In summary, our evaluation process identified the optimal method for automatically screening radiology reports for rapid identification of patients with metastatic disease and identified additional methods to optimize PPV while simultaneously minimizing the FN and FP rates. The results demonstrate that these screening tools can be implemented successfully to provide critical information for identification of patients for consideration in cancer clinical trials.

While we used the CTED system, similar approaches based on these results could be implemented at other institutions to enhance the efficiency of research staff in the clinical trials eligibility screening process.

**Authors’ contributions:** VP, LP, BD, and AP contributed to the concept and study design; LP, CG, and JM were responsible for the design, development, and implementation of CTED-Integrated system; VP, LP, and AP reviewed radiology reports; VP and BD conducted statistical analysis; VP, LP, BD, and AP interpreted the results and drafted the article; all authors approved the final manuscript.

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**REFERENCES**


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Panel IV

Opportunities for vendors to lead the way
Implementing Standards-based EHR-enabled Research

IOM Roundtable on Value & Science-Driven Health Care

30 May 2014
Agenda

• History of efforts
• Ready, Willing and Able
• Where is the demand?
• How can we advance?
History

• CDISC and IHE (Integrating the Healthcare Enterprise)
  – Retrieve Form for Data Capture (RFD)
  – Clinical Research Document (CRD)
  – Authentication and Security workgroup
  – IHE revisions and updates

• Presentation to FDA Office of Scientific Investigation

• ONC S&I Structured Data Capture (SDC)
I’ve got Mrs. Jones here for her research visit and I need to **retrieve** her **form** so that I can do the **data capture**. And here’s some data on her to start off.

Sure, here’s the form we need for Mrs. Jones. I’ve inserted the data you sent me, and you do the rest.
Ready, Willing and Able

• IHE North America Connectathon
• HIMSS Interoperability Showcase
• Drug Investigators Association
• PHIN
• Discussions leading to *ASTER Project
Where is the demand?

- Shhhhh… We have a well kept secret
- We have technical capability to Reduce the Burden of Reporting
- However, consider the Allscripts Clients
  - 180,000 physicians in 50,000 practices
  - 1,500 hospitals
- No Current Projects using our Standards-based Approach
What does Success look like?

• 4,993 hospitals eligible for Medicare and Medicaid incentives
  – more than 94% have registered for EHR incentives
  – nearly 91% have been paid incentives

• 537,600 professionals eligible for Medicare or Medicaid incentives
  – nearly 87% have registered for an Incentive Program
  – 68% have received payments
How can we advance?

• Socialize / Evangelize
  – get coverage in HIT, Healthcare Executive Summary, ... publications, blogs
  – Publicize this meeting

• Getting inside provider workflow
  – Enrollment - automate
  – Study / Subjects – some sort of federated data support ?
  – Protocol support – automate

• Certification/ Meaningful Use – a very powerful driving force

• Additional gaps – identify and close
  – See one, do one {, teach one} – why is the latter often missing?
Relationship between documentation method and quality of chronic disease visit notes

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Keywords
Clinical documentation, documentation quality, EHR, electronic documentation

Summary
Objective: To assess the relationship between methods of documenting visit notes and note quality for primary care providers (PCPs) and specialists, and to determine the factors that contribute to higher quality notes for two chronic diseases.

Methods: Retrospective chart review of visit notes at two academic medical centers. Two physicians rated the subjective quality of content areas of the note (vital signs, medications, lifestyle, labs, symptoms, assessment & plan), overall quality, and completed the 9 item Physician Documentation Quality Instrument (PDQI-9). We evaluated quality ratings in relation to the primary method of documentation (templates, free-form or dictation) for both PCPs and specialists. A one factor analysis of variance test was used to examine differences in mean quality scores among the methods.

Results: A total of 112 physicians, 71 primary care physicians (PCPs) and 41 specialists, wrote 240 notes. For specialists, templated notes had the highest overall quality scores (p ≤0.001) while for PCPs, there was a statistically significant difference in overall quality score. For PCPs, free form received higher quality ratings on vital signs (p = 0.01), labs (p = 0.002), and lifestyle (p = 0.002) than other methods; templated notes had a higher rating on medications (p≤0.001). For specialists, templated notes received higher ratings on vital signs, labs, lifestyle and medications (p = 0.001). Discussion: There was no significant difference in subjective quality of visit notes written using free-form documentation, dictation or templates for PCPs. The subjective quality rating of templated notes was higher than that of dictated notes for specialists.

Conclusion: As there is wide variation in physician documentation methods, and no significant difference in note quality between methods, recommending one approach for all physicians may not deliver optimal results.
Introduction

The rate of adoption of electronic health records (EHRs) has been rapidly increasing under the new meaningful use and accountable care requirements [1]. Many have argued that EHR adoption and use can lead to significant improvements in the cost and quality of care [2, 3]; and, 82% and 85% of physicians currently using EHRs report that the system has had a positive effect on delivery of (1) preventive care and (2) chronic illness care, respectively [4]. However, there have been concerns raised about the quality of visit note documentation in EHRs as well as the time expended to perform electronic clinical documentation [5–8].

Since physicians spend a significant part of their day on clinical documentation [9], it is crucial to ensure that the transition from paper documentation to electronic documentation optimizes the quality and efficiency benefits of implementing EHRs. At present, there is no single best method of visit note documentation, and physicians are likely to continue to use a range of documentation methods in the future [4]. Although 85% of physicians use one particular method for more than three-quarters of all documented notes, their method of choice varies based on clinical and non-clinical factors [10]. 49% of providers use structured templates for at least three-quarters of all visit notes authored, while about 22% still use dictation for the majority of their notes and 13% use free form [10].

Thus, while physicians seem to have a preference for the particular documentation method they use most often, it is important that their chosen methods create clinical notes that provide accurate, complete, and useful documentation of the visit. Effective clinical documentation may be important to support quality of care not only at the time of the visit, but throughout the duration of a patient’s healthcare experience, and especially for those with a chronic disease. Visit notes can be especially important for coordinating care across the healthcare spectrum for patients with a chronic disease.

Although structured documentation has been linked to more thorough and complete notes, disadvantages include a loss of expressivity and thoughtfulness [11]. In addition, templates and the ability to import text have been shown to lead to additional errors [12]. One study investigated documentation method and quality of care for diabetes and CAD, showing that physicians that use structured EHR documentation in comparison to dictation seem to have a higher quality of care [13]. While we know that structured data can support downstream uses such as automated alerts, decision support and quality assessments, additional factors may be involved in choice of documentation method such as documentation time efficiency, expressivity, and note quality [11, 14]. Additionally, physicians reported that some automated features of electronic notes, such as template generation, created issues such as increase in length, redundancy, or poor formatting [8].

2. Objectives

Because care for patients with chronic disease is responsible for more than 75% of our nation’s health expenditures, it is particularly important to evaluate the quality of notes for chronic care of patients written using different documentation methods [3]. Our goal was to determine the relationship between methods of documenting visit notes and the quality of notes of primary care providers (PCPs) and specialists, as well as the variables that contribute to higher quality notes for patients with two chronic diseases, diabetes and coronary artery disease (CAD).

3. Methods

3.1 Setting

Massachusetts General Hospital and Brigham and Women’s Hospital are affiliated with Partners HealthCare, a large integrated healthcare delivery system in Massachusetts. The primary ambulatory electronic health record in use at these medical centers is the Longitudinal Medical Record (LMR), an internally developed, Certification Commission for Healthcare Information Technology (CCHIT) certified system that includes problem lists, medication lists, primary care and specialty
notes, allergies, immunizations, and family history. The LMR supports electronic note documentation, medication ordering, and results review.

3.2 Sample
We identified Brigham and Women’s Hospital (BWH) and Massachusetts General Hospital (MGH) PCPs, endocrinologists and cardiologists who used the outpatient electronic health record in 2010. These physicians were categorized based on the documentation method (free form, dictate, template) they used most often to document their visit notes based on the total number of notes authored in 2010. The method of entry was determined by metadata within the note. In contrast to free-form text entry or dictation, templates can contain a varying number of pre-defined structured fields, such as medications, allergies, physical exam and past medical history, and may include custom text previously created [10]. Templates can be created by practice staff or individual providers and maintain some flexibility so that fields can be modified by the provider. In order to compare between documentation methods, we identified notes that would have a similar purpose and complexity. We retrieved visit note encounter data from the Research Patient Data Registry for all BWH and MGH patients with an outpatient visit characterized as moderately complex (CPT code 99214) and with an ICD-9-CM diagnosis code of diabetes (250), CAD (414), or both. We excluded notes that were identified as patient letters or preceptor notes in order to standardize the type of note as much as possible. We then matched the encounter data to our sample of physicians and filtered out encounters with providers not in our sample population. The final sample of notes from the encounters identified was selected for chart review based on whether the method of documentation used for that note matched the predominant method of the provider. We selected at least 30 notes of each documentation method for both PCPs and specialists. In cases where the number of unique providers in the category was low and we expected the within-physician correlation to have a larger impact, we selected up to 50 notes in that category in order to improve our power. We excluded multiple visit notes per provider/patient pair. We calculated that with 80% power at a significance level (alpha) of 0.05, we could detect a .66 point difference in note quality between the documentation methods for PCPs and specialists (assuming a standard deviation of 0.89).

For PCPs and specialists, we selected a subset of 10 notes from each of the physician documentation method categories (free form, dictate, template) to pilot the chart review.

3.3 Instrument Development
We reviewed the literature related to quality documentation tools, methodology for assessing quality of documentation and quality indicators for diabetes and CAD. From this review, we generated a list of note content items and potential variables related to note quality to create an electronic abstraction form for the chart review. The abstraction form was developed through research team consensus meetings with the assistance of clinician experts (DB, GS, HR) with significant combined experience in quality and patient safety research. The form included six sections that our experts identified as major content areas of a note (vital signs, medications, lifestyle, labs, symptoms, assessment & plan) with specific questions related to note content and subjective quality. This paper reports on only the subjective ratings for quality that were included as part of the form. Each section required the reviewer to indicate an overall quality rating for that section by responding to the question “Please rate the overall quality of documentation of (vitals) in this note only” on a scale from one (very poor) to five (excellent). The reviewer was also asked to respond to “Please rate the overall quality of this note” on a scale from one (very poor) to five (excellent). Two additional subjective statements were included that asked the reviewers to rate their agreement with: “The note reflects the writer’s understanding of the patient’s overall status and synthesizes the main problems and goals into a clear assessment and plan” and “The note is formatted and laid out in a way that makes it easy to read and find relevant and critical information.” The final section of the form was the 9 item Physician Documentation Quality Instrument (PDQI-9) [15] that we included as an additional subjective measure of note quality. The 9 PDQI attributes were Up-to-date, Accurate, Thorough, Useful, Organized, Comprehensible, Succinct, Synthesized and Consistent.
We also collected any patient data (medications, allergies, problem list etc.) in the electronic health record that would have been available to the physician in the EHR on the date of the review note. We presented these data to the chart reviewers within the abstraction tool.

Two internal medicine residents conducted the chart review. These residents both had previous experience with the electronic health record but were not currently practicing at a Partner's affiliated practice. We developed a set of written instructions for the reviewers to use during the chart review which included clarification and definitions for some of the elements, in addition to general information on using the form. The reviewers had not created any of the notes themselves. They were not blinded to the provider writing the note but were told to inform us if they felt they had any conflicts of interest so that we could remove that note and replace it with another.

We piloted the form with the two reviewers. The reviewers used the form to review a subset of 10 records. The reviewers were told to 'overuse' the comment fields in the form to identify any issues with the form, the patient data, or the questions. We debriefed the reviewers following the pilot to discuss issues with the form and suggestions for improvement to further revise the chart review instrument, written instructions and process before they began reviewing the final sample. We also checked in with the reviewers periodically during their review of the final sample and reviewed any issues or questions they had, making sure to provide consistent instruction to both reviewers.

3.4 Data Analysis

Each reviewer assessed all notes in the final sample so that two sets of scores were obtained. The nine PDQI attributes that were rated on a scale from one (not at all) to five (extremely) were totaled for an overall PDQI-9 score ranging from 9–45. Subjective ratings given for overall quality and PDQI-9 scores (overall and for each attribute) were averaged for both reviewers to determine a single rating for each note. The correlation between the two reviewer's overall quality score was good (Pearson's r 0.5). Physician assessment of overall quality score varied by 1 point or less in over 88% of the responses. The quality ratings by section, overall quality score and PDQI-9 scores were then averaged across physicians within each of the documentation methods. We also pulled data on note word count, and physician characteristics such as specialty, age, gender, and busyness, which was defined by estimated patients per hour over a one year period.

3.5 Statistical Analysis

A one factor analysis of variance (ANOVA) test was performed for PCPs and specialists separately to determine whether differences in mean quality scores and PDQI-9 scores among the groups (free form, template, dictate) were significant.

We ran a linear regression analysis on both the overall quality average and the total PDQI-9 score to determine predictors of perceived note quality, which included provider characteristics such as specialty (PCP or specialist), age, gender, and busyness, patient chronic condition (CAD, Diabetes or both), documentation method and note word count. We incorporated Generalized Estimating Equations (GEE) in the regression analysis to account for clustering by physician.

4. Results

The final sample meeting our criteria included a total of 240 notes written by 112 physicians (71 PCPs and 41 specialists) in 2010. Of the 71 PCPs, 30 predominantly used templates when documenting notes, 29 documented free-form notes, and 12 dictated their notes. Of the 41 specialists, 6 predominantly used templates when documenting, 26 type free-form notes, and 9 dictated their notes. The physicians who dictated were significantly older than those that used templates (mean age 55 and 49 respectively; p = 0.006). There were also significantly more males in the dictation group (84%) than in the template (51%) or free form groups (53%), (p<0.0001).

Average quality score and total average PDQI-9 score results are in the tables below for primary care and specialist physicians (Table 1). For PCPs, overall quality score for free form notes was 0.25 and 0.26 points higher than templated notes and dictated notes, respectively. For specialists,
templated notes had significantly higher overall quality (p<0.001) and PDQI-9 scores (p = 0.03), with a difference in overall quality score of .48 and a difference in PDQI-9 total of 1.54 when compared to dictated notes.

Quality ratings for each of the content areas and ratings on the individual PDQI-9 attributes are shown for both primary care providers (▶ Table 2) and specialists (▶ Table 3). For primary care physicians, the quality ratings of vitals, labs and lifestyle sections favored a higher documentation quality score for free form notes (0.35 points compared to templated notes, p = 0.01 for vitals; 0.35 points, p = 0.002 for labs; 0.06 points, p = 0.002 for lifestyle). Medications were the exception with significantly better quality ratings for templated notes versus the other note types (0.63 points compared to free form notes, p<0.0001). For specialists, the quality ratings of vitals, labs, lifestyle and medications sections were all significantly higher for templated notes compared to free form (0.30 points, p<0.001; 0.72 points, p<0.0001; 0.78 points, p<0.001; 0.75 points, p<0.001, respectively). Symptoms was the exception with significantly better quality ratings for free form notes compared to the other note types (0.23 points for template and 0.37 points for dictated notes, p = 0.20).

The PDQI-9 ratings also differed between PCPs and specialists. For PCPs, Up-to-date and Thorough attributes of notes were found to be significantly higher for free form than for templated or dictated notes. For specialists, templated notes had significantly higher Up-to-date, Accurate and Thorough scores (p<0.001, p = 0.01, p<0.001 respectively), free form notes had significantly higher Useful (p = 0.03) and Consistent scores (p = 0.05). Dictated notes had the highest Succinct score (p<0.001).

Two additional subjective statements were rated by the reviewers (▶ Table 4). For specialists, templated notes ranked significantly higher (p = 0.02) than the other methods on "the note is formatted and laid out in a way that makes it easy to read and find relevant and critical information," although the actual difference was small.

After adjusting for clustering by physician, the results of the linear regression indicate that clinicians were consistent in the quality of their documentation; quality scores and PDQI-9 ratings were highly correlated within a physician, 0.65 and 0.64, respectively. Overall quality of documentation and overall PDQI-9 score were significantly higher when the clinician was documenting for a patient with both CAD and diabetes than with just diabetes alone (p = 0.02 for PDQI-9 and overall quality). Also, notes for patients with both CAD and diabetes were associated with higher PDQI-9 ratings (p = 0.005) than if the patient had CAD only. There was no significant association between quality ratings and provider specialty, age, gender, busyness, note word count or documentation method.

5. Discussion

We evaluated key elements to assess the quality of the documentation, comparing three types of electronic note entry from both specialty and primary care physicians’ notes for patients with two chronic diseases. Overall quality and PDQI-9 values for the sample for both PCPs and specialists were above 3.7 on a 5 point scale and 37.5 on a 40 point scale, respectively. There were no statistically significant differences in overall quality and PDQI-9 scores of notes written by PCPs using the three methods. Notes documented using templates were rated as having significantly higher overall quality and total PDQI-9 score among specialists than other documentation methods. The regression found no significant associations between quality ratings and physician specialty, age, gender or busyness, note word count or documentation method.

Differences in the quality and content of templates available for specialist visits compared to primary care visits may partly explain the significant results for the specialists. All but one section (assessment and plan) had quality ratings that were significantly better for templated specialists’ notes. Templates received highest ratings on the subjective statement “The note is formatted and laid out in a way that makes it easy to read and find relevant and critical information.” Templates may be a better option for specialists who tend to focus on a more narrow set of problems to be documented. Thus, designing a template for a specialist visit with a predefined set of questions and responses may be easier than designing one or multiple templates for a PCP, who often must address myriad issues.
and types of patients. Future research should include a variety of note complexity and additional diseases.

Free form notes may offer more flexibility and readability when constructing clinical narratives for other clinicians reading PCP notes. Templates were rated highest on many measures for specialists; however, free form notes were rated higher than templates on the Useful attribute. Some attributes of the notes received higher scores than others, supporting the idea that certain methods may have strengths in some areas whereas others do not. Thus the best choice of note documentation type may vary depending on the note's purpose.

For both PCPs and specialists, notes documented using dictation were given the lowest scores for overall quality and total PDQI-9 score. Dictated notes scored slightly higher on some note attributes such as succinctness, but lower on most other quality measures that were related to note completeness. Dictated notes may be easier for a reader to understand the overall picture; however, it may be more difficult to locate details regarding lab results or medications which may be better entered and viewed within a more structured format [14, 16, 17], though the extent to which these data should routinely be included in electronic visit notes is debatable since they are readily accessible elsewhere in the EHR.

One challenge in determining the quality of a note is that a patient's data may be available in other parts of the medical record (e.g. the patient's problem and medication lists etc.). A key question is to understand when data should be included in the note (to both document clinician awareness as well as include in for other readers of the note) vs. when does this become redundant “clutter” that distracts from key narratives in clinical notes? For example, does the list of medications need to be documented in the actual note, or is an updated structured medication list a better “source of truth” for documenting the medications a patient is taking? And, how will these decisions affect the medication reconciliation process? Future analysis to assess how the documentation of such patient data stored elsewhere in the EHR affects the note quality would be useful to better understand and design efficient workflow and more useful notes.

EHR use is growing rapidly, and at the same time, the EHRs themselves are being improved, with more effort being put into system design and development. The availability of clinical decision support, structured data, and ability to pull in data from other parts of the EHR are additional features of electronic documentation that may impact note quality, depending on their design, implementation and utilization. Recent research in this area has focused on the relationship between structured documentation and patient quality outcomes [13], but our study sought to take a step in understanding the quality of the note itself. Note quality may have implications for patient safety, provider satisfaction and efficiency, and provider communication. Continued research in the ways in which physicians interact with these systems and their expectations for the system is necessary in order to better design these tools as technology, and practice and physician workflow evolve.

While there are some differences in the quality of notes based on the type of documentation method, these results suggest that no single current approach is clearly superior across the board. Getting providers to adopt EHRs is a major challenge, so that building systems to support a variety of methods and optimize the potential of electronic documentation thus may be important for ensuring physician buy-in as well as their ability to produce the highest quality notes for the specific situation using their preferred method. Many organizations are struggling with finding the balance between free-text and structured documentation or choosing a vendor product that meets their needs. Alternatively, there may be better solutions that incorporate many of the positive aspects of several of these methods, such as combining voice recognition entered free text into structured templated notes. Schiff and Bates describe the ways in which the EHR and electronic documentation could reduce diagnostic errors by such re-engineered documentation [18]. It may be important to take a step back and understand the ways in which documentation can support the clinician’s thinking and revise the system as a whole rather than prescribe a method currently in place. In addition, many decisions about what to include about notes have been driven by billing, which is probably not in alignment with better care delivery—the billing rules regarding notes badly need reform.
5.1 Limitations

We evaluated providers from only one healthcare system with a locally developed EHR and in only two chronic diseases, so the results may not be generalizable to other organizations or to patients with other conditions. The instrument we used included both objective items and subjective rating scales. Note quality is inherently subjective and difficult to measure. We used a well validated scale and analyzed subjective items by averaging the ratings of the two reviewers to obtain an overall score for those items.

6. Conclusions

While some differences in note quality were present among the methods of documentation, there was no clear method that was superior in all aspects. Each method has relative advantages and disadvantages and proposing one method for all physician specialties in all settings may not be the best option. Designing a documentation system to accommodate the majority of physicians may require a complete shift in the way in which documentation systems are designed and used today to ensure the best combination of note quality, physician satisfaction, system usability, and patient care outcomes. Future policies – both locally and at the national level – which attempt to address these issues should consider these factors. More research on documentation approaches is needed, as documentation takes substantial time, but the best approaches are not yet clear.

Clinical Relevance

Our finding that no clear note documentation method excelled, suggests that efforts to improve and reengineer documentation efficiency and quality overall may be more fruitful than imposing one particular note documentation method or workflow. Our finding also suggests that various specialties adopt differing note documentation methods that may best match their practice needs and resources, something that additional research is warranted to better understand.

Conflict of Interest

The authors report no conflict of interest.

Human Subjects Protection

This research was approved by the Partners Human Research Committee.

Acknowledgements

This project was funded by the Partners Siemens Research Council. We would like to thank Amy Fitzpatrick for assistance with the chart review and E. John Orav for his statistical consultation.
### Table 1  Overall Note Quality Score and PDQI Total Score

<table>
<thead>
<tr>
<th>Documentation Method</th>
<th>Overall Quality</th>
<th>PDQI Total</th>
<th>Overall Quality</th>
<th>PDQI Total</th>
<th>Overall Quality</th>
<th>PDQI Total</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Template (N = 30 notes)</td>
<td>Free Form (N = 30 notes)</td>
<td>Dictated (N = 50 notes)</td>
<td></td>
<td>Template (N = 50 notes)</td>
<td>Free Form (N = 30 notes)</td>
<td>Dictated (N = 50 notes)</td>
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<td>Primary Care Provider</td>
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<td>4.12</td>
<td>4.00</td>
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<td>Specialists</td>
<td>38.27</td>
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<td>37.94</td>
<td>0.52</td>
<td>39.08</td>
<td>39.03</td>
<td>37.54</td>
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### Table 2  Primary Care Physicians Average Quality Ratings by Documentation Method

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<th>Documentation Method</th>
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<td>Free Form 4.65</td>
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<td></td>
<td>Dictated 3.92</td>
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<tr>
<td>Labs</td>
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<td></td>
<td>Free Form 3.80</td>
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</tr>
<tr>
<td></td>
<td>Dictated 3.09</td>
<td></td>
</tr>
<tr>
<td>Lifestyle</td>
<td>Template 3.62</td>
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<tr>
<td></td>
<td>Free Form 3.68</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dictated 3.01</td>
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</tr>
<tr>
<td>Medications</td>
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<td></td>
<td>Free Form 3.87</td>
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<tr>
<td></td>
<td>Dictated 3.15</td>
<td></td>
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<tr>
<td>Symptoms</td>
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<td>0.49</td>
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<tr>
<td></td>
<td>Free Form 3.80</td>
<td></td>
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<tr>
<td></td>
<td>Dictated 3.60</td>
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<tr>
<td>Assessment &amp; Plan</td>
<td>Template 3.73</td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>Free Form 4.05</td>
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<tr>
<td></td>
<td>Dictated 3.99</td>
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<table>
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<th>PDQI Attributes</th>
<th>Documentation Method</th>
<th>P-value</th>
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<td>Dictated 3.30</td>
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<td>Accurate</td>
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<td></td>
<td>Free Form 4.75</td>
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<td></td>
<td>Dictated 4.62</td>
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<tr>
<td>Thorough</td>
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<td>0.04</td>
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<td></td>
<td>Free Form 3.78</td>
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<td></td>
<td>Dictated 3.29</td>
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<td>Useful</td>
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<td></td>
<td>Dictated 4.22</td>
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<td>Organized</td>
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<td></td>
<td>Free Form 4.20</td>
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<td></td>
<td>Dictated 4.15</td>
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<tr>
<td>Comprehensible</td>
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<tr>
<td></td>
<td>Dictated 4.51</td>
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</tr>
<tr>
<td>Succinct</td>
<td>Template 4.35</td>
<td>0.14</td>
</tr>
<tr>
<td></td>
<td>Free Form 4.28</td>
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<tr>
<td></td>
<td>Dictated 4.52</td>
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<tr>
<td>Synthesized</td>
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<td>Dictated 4.42</td>
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<td>Consistent</td>
<td>Template 4.87</td>
<td>0.10</td>
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<td></td>
<td>Free Form 4.78</td>
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</tr>
<tr>
<td></td>
<td>Dictated 4.92</td>
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</tr>
</tbody>
</table>
Table 3  Specialists Average Quality Ratings by Documentation Method

| Collection Form Sections | Documentation Method | | | |
|--------------------------|----------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                          | Template             | Free Form       | Dictated        | P-value         | Template         | Free Form       | Dictated        | P-value         | Template         | Free Form       | Dictated        | P-value         |
| Vitals                   | 4.67                 | 4.37            | 3.88            | <0.001          | 4.14             | 3.68            | 3.19            | <0.001          | 4.24             | 4.18            | 4.03            | 0.20            |
| Labs                     | 3.99                 | 3.27            | 3.01            | <0.001          | 4.78             | 4.77            | 4.60            | 0.01            | 4.36             | 4.45            | 4.47            | 0.51            |
| Lifestyle                | 3.65                 | 2.87            | 2.72            | <0.001          | 4.37             | 4.47            | 4.15            | 0.03            | 4.38             | 4.25            | 4.16            | 0.14            |
| Medications              | 4.52                 | 3.77            | 3.13            | <0.001          | 4.36             | 4.45            | 4.47            | 0.51            | 4.09             | 4.22            | 4.56            | <0.001          |
| Symptoms                 | 3.64                 | 3.87            | 3.50            | 0.02            | 4.36             | 4.58            | 4.43            | 0.15            | 4.75             | 4.93            | 4.86            | 0.05            |
| Assessment & Plan        | 4.12                 | 4.17            | 3.94            | 0.21            |                  |                 |                 |                 |                  |                 |                 |                 |

Table 4  Subjective Statements and Ratings

**Statement 1:** The note reflects the writer’s understanding of the patient’s overall status and synthesizes the main problems and goals into a clear assessment and plan.

| Documentation Method | | | | |
|----------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                      | Template         | Free Form       | Dictated        | P-value         | Template         | Free Form       | Dictated        | P-value         | Template         | Free Form       | Dictated        | P-value         |
| PCPs                 | 3.90             | 4.18            | 4.03            | 0.20            | 4.24             | 4.30            | 4.12            | 0.27            |                  |                 |                 |                 |
| Specialists          | 4.20             | 4.08            | 3.90            | 0.18            | 4.22             | 4.03            | 3.88            | 0.02            |                  |                 |                 |                 |

**Statement 2:** The note is formatted and laid out in a way that makes it easy to read and find relevant and critical information.
References

The future state of clinical data capture and documentation: a report from AMIA’s 2011 Policy Meeting

Caitlin M Cusack,1 George Hripcsak,2 Meryl Bloomrosen,3 S Trent Rosenbloom,4 Charlotte A Weaver,5 Adam Wright,6 David K Vawdrey,2 Jim Walker,7 Lena Mamykina2

ABSTRACT
Much of what is currently documented in the electronic health record is in response to increasingly complex and prescriptive medicolegal, reimbursement, and regulatory requirements. These requirements often result in redundant data capture and cumbersome documentation processes. AMIA’s 2011 Health Policy Meeting examined key issues in this arena and envisioned changes to help move toward an ideal future state of clinical data capture and documentation. The consensus of the meeting was that, in the move to a technology-enabled healthcare environment, the main purpose of documentation should be to support patient care and improved outcomes for individuals and populations and that documentation for other purposes should be generated as a byproduct of care delivery. This paper summarizes meeting deliberations, and highlights policy recommendations and research priorities. The authors recommend development of a national strategy to review and amend public policies to better support technology-enabled data capture and documentation practices.

INTRODUCTION
Since 2006, AMIA has convened an annual invitational Health Policy Meeting to examine emerging issues linking healthcare and health information technology (health IT) policy. The overarching objective of each meeting has been to further a national understanding of important topics in this domain and inform subsequent public policy deliberations and decisions. Previous meetings have focused on innovation challenges in health IT and informatics; unintended consequences of health IT and policy; informatics-enabled evidence-based care; and development and advancement of a national framework for health data use. Each meeting has identified policy recommendations and highlighted areas for further study and research. Post-meeting outputs have included reports, published in JAMIA synthesizing conference outcomes.1–5 As described in this paper, AMIA’s 2011 Health Policy Meeting focused on the current state of technology-enabled clinical data capture and documentation in the hope of shaping these key healthcare processes in the future.

Background and significance
Discussions about the future of clinical data capture and documentation should be viewed within the overall context of trends in the healthcare arena. Key aspects of this context include a vision for the transformation of the US healthcare system into a ‘learning healthcare system’; the ramp-up of electronic health records (EHRs) into an essential technology for healthcare improvement; and a growing system-wide emphasis on securing better health outcomes for both individuals and populations. A ‘learning healthcare system’, as defined in a 2007 Institute of Medicine (IOM) report, is ‘… designed to generate and apply the best evidence for the collaborative healthcare choices of each patient and provider, to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in healthcare’.6

Among the key prerequisites for the learning system is the ‘… comprehensive deployment and effective application of the full capabilities available in EHRs …’.7 A 2010 IOM workshop focused on clinical data as the knowledge generation engine that could provide the foundation for national efforts to transform health and healthcare.8 Shifts toward the next generation of health records that will yield the rich data to power this engine are currently underway. From the 1997 IOM report that found a long list of uses for EHRs9 to the 2010 report by the National Center for Health Statistics citing increased uptake10 to the 2012 announcement by the US Department of Health and Human Services (DHHS) that the EHR Incentive Program has spurred more than 100 000 healthcare professionals to use EHRs,11 evidence is growing that adaption and use of EHRs is gathering speed throughout the healthcare system.

Concurrent with these trends is the nationwide focus on improving healthcare quality, reducing costs and, ultimately, achieving better patient outcomes.12 EHRs play a key role in these efforts by providing access to data that can improve individual care as well as support clinical research, quality improvement efforts and the achievement of public health objectives—all of which work towards system-wide improvement of outcomes.13

Evolution of health record documentation
Very early medical and health records can be found in ancient Egyptian papyri14 15; today’s health records are in transition from paper to an electronic format. This transition is enabling the inclusion of multimedia elements in addition to clinical chart information, allowing mining of EHR data using sophisticated semantic and statistical techniques, and fostering experimentation with new approaches such as the integration of streaming media into EHRs.16 17
Historically, patients’ health records ideally contained comprehensive health information including medical and family history, list of recent symptoms, list of past and current medications, physical examination findings, results from diagnostic tests, clinicians’ assessments, and therapeutic procedures. Clinical data capture and documentation refer to the processes of eliciting and recording clinical histories, findings, observations, assessments, care interventions, and care plans in an individual’s health record. The main purposes of these functions are to support and enhance health and healthcare by facilitating clinical reasoning and decision making by individual clinicians and allied health practitioners, and by promoting communication and coordination within and across clinical teams, ideally with patients as part of the care team.

There are concerns that documentation processes, practices, and requirements are heavily and inappropriately focused on payment and regulatory requirements rather than on care delivery, health promotion, and prevention. Much of what is currently documented and contained in the health record responds not to clinical needs but, instead, to diverse and increasingly complex and prescriptive medicolegal, reimbursement, accreditation, and regulatory requirements. Data capture and documentation processes are influenced strongly by multiple layers of federal and state regulations and private sector requirements and mandates such as health services utilization review, quality reporting, accreditation, payment justification, and licensure. This often results in redundant data capture and cumbersome documentation processes. A recent addition to the documentation burden is the requirement engendered by the Centers for Medicare & Medicaid Services’ (CMS) incentive payments for the Meaningful Use (MU) of EHRs to report specific data elements for MU objectives and clinical quality measures. The transition from paper to electronic documentation has introduced fundamental changes as existing paper-based practices are being adapted to an electronic environment. Increasing adoption and use of EHRs has raised concerns that the paradigm for electronic data capture and documentation is overly determined by the historical model of paper-based documentation, and that suboptimal documentation practices in the paper world will be propagated to the electronic world.

To realize the full potential envisioned by the IOM of the shift from paper to EHRs will require addressing fundamental issues: sorting out the different roles of documentation within a technology-enabled environment; determining what data are key to creating a vibrant learning healthcare system that is not supportive of billing or utilization review or clinical quality measures. One method of understanding clinical note writing workflow is to study what is not being documented within formal clinical notes. Instead of progress notes that are an official part of the patient record, clinicians often rely on unofficial parallel forms of daily documentation such as ‘sign out’ notes in their day-to-day care of their patients. It is likely that a substantial amount of important clinical activity that never becomes part of the formal health record is captured in these informal paper documents. For example, clinical ‘to-do’ lists are commonly used to keep track of important care plan items and to facilitate the hand-off of clinical responsibilities.

**Value and quality of documentation**

Stetson et al noted that documents are created for many different purposes and their value and quality may be assessed using different metrics that may not be compatible. For example, a note might be written to inform a colleague about the clinical status of a patient without concern that it generates a ‘comprehensive bill’. Thus, it might be deemed of high value with respect to clinical communication but poorly compliant and not supportive of billing or utilization review or clinical quality measures. Others have discussed the challenges to quality associated with excessive clutter and wrong information stored in electronic notes.

Several investigators have analyzed detailed EHR system usage logs to determine how clinical documentation and data are used after they have been stored in the EHR. An analysis by Hripcsak et al showed that about 16% of attending physicians’ notes, 8% of resident physicians’ notes, and 38% of nurses’ notes were never read by anyone at all; however, it also revealed that clinical notes are sometimes viewed in the EHR months or even years after they are authored, buttressing the argument for persistent storage of, and access to, historical health information. The study did not shed light on which notes should be read by other members of the care team or what proportion of documentation was captured primarily for medicolegal, administrative, or research purposes.

One of the benefits of electronic data capture and documentation is the potential to provide clinical decision support. However, East et al and Nelson et al have described problems
with data accuracy and timeliness as major challenges for computerized decision support applications. Vawdrey et al. assessed the quality of EHR documentation in the intensive care setting by measuring the percentage of time that manually-recorded and automatically-acquired data sources matched, as well as the charting delay (the interval between an individual collecting a measurement, such as a patient’s blood pressure, and entering it in the EHR). Automated collection of physiological measurements and other parameters from devices such as bedside monitors, infusion pumps, and mechanical ventilators can reduce the documentation burden on clinicians and also improve the quality of data stored in EHRs.

Collaboration
Among the benefits of EHRs is the ability to foster clinical collaboration. However, a 2009 National Research Council report noted that EHRs provide little cognitive support for collaboration. O’Malley et al. discussed ways in which EHRs have been shown to facilitate care coordination in physician practices as well as obstacles that inhibit realization of this goal; one example of the latter is the fact that existing reimbursement policies encourage documentation of billable events in EHRs and not of care coordination activities which are not billable. MacPhail et al. reported on a qualitative multiple case study of coordination of diabetes care using EHRs in four Kaiser Permanente Medical Centers which showed that, while coordination was attained across providers, coordination challenges persisted. Chan et al. described the development of five EHR-based care coordination measures for use in primary care and specialist settings, and assessed the relevance and acceptability of the measures by primary care providers.

AMIA’s 2011 HEALTH POLICY MEETING
Because of the importance of high quality documentation and data in supporting patient care, and given current initiatives encouraging EHR adoption and use, it is crucial to understand how documentation and data capture processes and related policies may be impacted by ‘going electronic’. The goals of the 2011 Health Policy Meeting were the following:

- Articulate a vision of the future ideal state of clinical data capture and documentation in a technology-enabled environment.
- Consider the strengths and weaknesses of current approaches to electronic clinical data capture and documentation from multiple stakeholder perspectives and identify knowledge gaps and research priorities.
- Formulate policy recommendations to stakeholders to foster the realization of an ideal future state of clinical data capture and documentation that fully supports achievement of improved patient outcomes.

The meeting convened on December 6–7, 2011 in the metropolitan Washington, DC area. In the months leading up to the meeting, a Steering Committee comprised of AMIA members who are experts in the field set the meeting goals, prepared the agenda, and made suggestions about discussants, presenters, and attendees. The nearly 100 attendees included representatives from various segments of the health IT and informatics fields including providers, academicians, technology vendors, specialty societies, pharmaceutical companies, consulting firms, researchers, government agencies, and consumer advocates.

Plenary sessions provided context for the discussions and helped participants to focus on key issues in the dynamic area of technology-enabled data capture and documentation. Speakers included Jon White, Director, Health Information Technology (Health IT) Portfolio, Agency for Healthcare Research and Quality (AHRQ) and Farzad Mostashari, National Coordinator, Office of the National Coordinator for Health Information Technology (ONC). A panel discussion on research and innovation in this field featured presentations by Jim Cimino, Chief, Laboratory for Informatics Development, NIH Clinical Center; Bethany Daily, Administrative Director, Peri- Operative Strategic/Business Initiatives, Massachusetts General Hospital; and Hal Wolf, Senior Vice President and Chief Operating Officer, Kaiser Permanente.

Plenary sessions were followed by facilitated breakout discussions designed to help participants focus ideas, summarize comments and formulate recommendations, and action items. During the breakouts, participants explored the ways in which recording data for multiple purposes competes with the fundamental purpose of documentation of supporting sound clinical care. They highlighted the shortcomings of current approaches that impede efficient data capture and presentation, fall short of accurately representing clinicians’ thinking, and fail to accommodate clinical workflow. Breakout sessions also focused on ways in which advancing technologies are affecting documentation and data capture, and the role of policy in driving innovative change in the health record that will yield improvements in terms of data input and output. The sessions helped formulate potential recommendations to government, industry, academia, and other stakeholders that could enable the realization of the ideal state of electronic clinical data capture and documentation.

Meeting products
The major products of the meeting (see below) were policy-oriented recommendations and a suggested research agenda to strengthen the evidence base related to clinical data capture and documentation. Additionally, participants reviewed and refined a set of proposed principles (box 1), developed by the Steering Committee before the meeting, to guide the future evolution of high value data capture and documentation. Participants also discussed strategies to promote widespread dissemination and application of the principles.

Meeting participants also reviewed a proposed set of descriptors for high quality information that had been developed by the Steering Committee in advance of the meeting. These attributes include high sensitivity (all of the information needed by the patient’s care team is created and recorded) and high specificity (information that is not needed by the care team is not displayed); cogency (information is created and recorded in ways that make it easy to read, process, and act on by humans and computers); and actionability (information helps guide the patient’s team in executing effective, safe, efficient, and satisfying interventions. Being actionable includes being computable, for example, in clinical prediction rules when appropriate to the patient’s needs). While high sensitivity and high specificity are attributes of high quality information, it should also be noted that they are context-dependent. For example, an item of information might be highly useful and should be displayed to a decision maker when a diagnosis is being established, but of lower usefulness and should be hidden when management or disposition is the task at hand. Further refinement of these descriptors is needed to reflect these nuances.

"Sensitivity is used here in a statistical or epidemiological sense rather than referring to ‘sensitive’ patient information that is subject to privacy concerns."
Clinical data capture and documentation should:

1. Be clinically pertinent, patient-centric, and represent an individual’s lifetime health and healthcare.
2. Support capture of high quality information that is accurate, relevant, confident, reliable, valid, complete, and secure.
3. Be efficient and usable while enhancing the healthcare organization’s and the care team’s overall efficiency, effectiveness and productivity.
4. Support multiple downstream uses as a byproduct of the recording of care delivery including quality measurement, performance improvement, population health care delivery, policymaking, research, education, and reimbursement.
5. Enable joint patient-provider decision making, team collaboration, care process management, and advanced clinical decision support.
6. Enable collection of data and interpretation of information from multiple sources as appropriate and necessary, including nuanced medical discourse, structured items, and data captured in other systems and devices.
7. Automation of data capture and documentation should be optimized whenever appropriate, allowing human beings to focus on gathering and entering data that cannot be effectively collected by automated tools (eg, automated acquisition of data from biomedical devices).

Meeting findings and recommendations: policy and research

Meeting participants concluded that high value documentation is important to—and representative of—high quality patient care. The consensus among participants was that, in the move to a technology-enabled healthcare environment, the main purposes of documentation should continue to be to support and enhance patient care by facilitating clinical reasoning and decision making of individual clinicians and by supporting team communication and coordination, with the inclusion of the patient. However, participants recognized that, given the growing complexity of care delivery and advances in health IT and informatics, there is a need to transform the way we capture and document clinical care. To some extent, the industry has failed to exploit technology in ways that would help to capture and present healthcare data. With some reimbursement methods at least partially based on the amount of documentation, there is an incentive to document extensively. This leads to duplicate information, ‘captured’ repetitively, without any resultant improvement in the provision of care. Because more efficient patient assessment and information capture may have the potential to reduce payment, there is little incentive to explore alternative data capture or documentation practices.

Key findings and public policy recommendations discussed by meeting participants and refined by the authors are outlined below. The authors propose that public and private sector organizations work together to implement these recommendations.

1. Finding. The fundamental purpose of clinical data capture and documentation in a technology-enabled environment must be the direct support of health and healthcare. Other purposes such as performance measures, quality reporting, payment, and legal requirements have encroached upon this central purpose.

- Recommendation. The Federal government should lead a public-private sector initiative to propel a transformational shift away from the longstanding emphasis on ‘payment-focused’ data capture and documentation towards an approach that focuses on quality, safety, and good outcomes of care. This shift must consider future approaches to payment and care delivery such as those associated with Accountable Care Organizations (ACOs), patient-centered medical homes, and bundled payments.

2. Finding. The Proposed Guiding Principles for Clinical Data Capture and Documentation, a product of the meeting (box 1), is a first step towards establishing benchmarks for the future evolution of these critical healthcare functions.

- Recommendation. The DHHS should lead an effort to promote widespread public and private sector vetting of the proposed principles followed by healthcare system-wide adoption of an agreed-upon version of them. Agencies such as AHRQ, Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), ONC, and the Department of Veterans Affairs should be involved in vetting and dissemination activities.

3. Finding. The expectation that the EHR should serve as a repository for a wide variety of data elements, many of which are unrelated to direct patient care, is outpacing the ability of data providers to efficiently and effectively collect and enter such data. New data reporting and/or documentation requirements frequently require changes to organizational and health IT infrastructures and processes. The evidence base for such requirements is not always apparent, nor it always clear what the benefits of the new requirements are, and to whom benefits accrue. Data capture and documentation should align with and not impede the care team’s workflow and care delivery; indeed, it should support improvement in work processes. To the extent possible, documentation needed to support purposes other than direct patient care should be generated automatically as a byproduct of healthcare delivery.

- Recommendation. Clinical data capture and documentation requirements should be reviewed on a regular basis, with outdated ones revised or removed as needed. The agencies and organizations responsible for current governmental and organizational requirements should align and harmonize them to reduce data capture and documentation burdens. Examples of these requirements include MU, EHR certification, Medicare Conditions of Participation, National Quality Forum quality reporting measures, Food and Drug Administration (FDA) regulations, CDC public health reporting, AHRQ quality reporting, The Joint Commission, and state rules and regulations. Existing requirements under HIPAA that promote more uniform data capture and documentation should be enforced.

4. Finding. Clinicians in different subspecialties and venues have different workflows during which documentation is carried out. EHR usability and functionality must improve to align with these diverse workflows across multiple venues and providers.

- Recommendation. Developers of electronic documentation tools and EHRs must consider where and how clinical data are captured and documentation is recorded, such as during teaching rounds, on a cell phone, in a private office, at a shared computer at the nurse’s station, via a telehealth or medical device, or in the patient’s home. EHR design...
elements should accommodate these differences. MU and EHR certification criteria should recognize such differences.

5. **Finding.** Clinical data capture and documentation paradigms must facilitate multidisciplinary team-based care, coordination, and delivery. The transition from paper to electronic documentation can reveal and sometimes exacerbate barriers to team communication. At the same time, increased adoption and use of health IT may spark increased attention to administrative, clinical, and workflow process improvements that can help overcome some of these barriers.

   ► **Recommendation.** The multidisciplinary ‘team’ encompasses everyone who provides care to the patient in whatever venue the care is provided, (e.g., clinic, hospital, home, long-term care facility, school, and hospice). Where possible and permitted by external and institutional regulations, clinical documents should accommodate data entered by the most appropriate team member; where not currently permitted by existing regulations, policymakers should consider modifications to existing regulations and potential alternative approaches to allow this. Developers of EHRs and electronic data capture and documentation systems should incorporate role-specific user interfaces in these tools to help each member of the care team create and record the data needed to support high quality, high efficiency, satisfying care processes—regardless of time and user location.

6. **Finding.** The patient must be a key member of the care team. As the emphasis shifts to increased involvement of patients in their care and in creating their own health records, there will be a growing need to help these non-clinical members of the care team gain health literacy so that their contributions will be meaningful.

   ► **Recommendation.** The individual-centered health record, facilitating an individual’s engagement in health promotion and disease management, should be embraced by stakeholders in all sectors of the healthcare system. Individuals and their designees should be able to view, recommend changes to, and contribute directly to the health record, with the provenance of the data clearly noted. Patient-entered data could start with high value data that patients can often enter as well or better than providers, such as their family history; patient goals should be entered and translated into clinical goals and actions.

   ► **Recommendation.** Efforts to raise the health literacy of individuals, their caregivers, and their families must be a higher public policy priority than it currently is so that they can participate effectively as members of their healthcare team. DHHS should create and deploy a national educational program/resource to engage and educate patients and their families, including information on how patients can contribute to and use their health data and documentation. Agencies such as AHRQ, ONC, and the National Library of Medicine should be involved in these education activities. Current programs such as the CMS Partnership for Patients could be leveraged for such an effort.

7. **Finding.** Clinicians often have different goals and motivations for authoring notes, including documenting clinical care, communicating with the clinical care team, fulfilling training requirements, justifying billing, meeting regulatory requirements, and creating a record that they believe will help protect them from a medicolegal perspective. Amid a continually shifting political and technology landscape, it appears that providers may be misinterpreting regulatory, payment and legal requirements. Such misunderstandings may result in unnecessary data capture and documentation practices. In particular, clinicians’ concerns about perceived legal liabilities and malpractice may be overly influencing the quality, content, and amount of data capture and documentation.

   ► **Recommendation.** Educators should develop new approaches to teaching students in clinical and allied health professions about clinical data capture and documentation. There is a need to harmonize how and when students learn about and practice these key tasks. The ethos of training should be changed from ‘what if I miss something?’ to ‘how do I learn precision in information collection and documentation?’ In addition, research should be undertaken to determine the extent to which clinicians and allied health professionals are overly influenced by perceived legal liabilities and malpractice concerns.

**Research agenda recommendations**

Meeting participants highlighted several important questions and gaps in the evidence base pertaining to data capture and documentation that need to be addressed by additional research:

► In-depth understanding of clinician workflow patterns and cognitive needs as related to documentation.

► Measurement of burden on clinicians of specific (and cumulative) data reporting and documentation requirements.

► Potential risks to patient safety from documentation practices.

► Dynamics involved in team-based care and the role of electronic information systems in supporting care coordination within and among care teams and venues.

► Impact of new data sources on documentation and data capture processes.

Below are recommendations for research activities to address these and other pressing questions related to data capture and documentation:

1. **Clinicians’ cognitive needs with respect to documentation.** Funding agencies should encourage studies to gain a deeper understanding of the cognitive needs of clinicians with respect to information flow and documentation. Applying knowledge gained about cognition, DHHS should fund the development of innovative automated documentation tools, including data input methods that accommodate entry by various methods such as dictation with or without voice recognition, digital handwriting, and document scanning with or without optical character recognition. Other approaches to help reduce documentation burdens include development of improved usability interfaces and tools (e.g., dashboards that show changes in patient state); new methods for data transformation; use of natural language processing of textual information; automated acquisition of data from biomedical devices; cloud-based approaches; and collaborative documentation paradigms. Comparative effectiveness studies should address nuances of data capture and interpretation (e.g., comparing voice recognition technologies with template-driven documentation).

2. **Documentation burden of data reporting requirements.** DHHS continues to implement requirements for data reporting including public health and performance measures as well as data related to MU of health IT. Federal health agencies such as AHRQ, CDC, FDA, and ONC should explore the feasibility of new data or documentation requirements and assess the potential burden on the documenter/data provider prior to the implementation of new ones. Any related
policy changes should be informed by such research and the implications of the evidence.

3. **Relationship of electronic data capture and documentation processes and practices to patient safety and quality of care issues.** The evolution of clinical data capture and documentation practices in a technology-enabled environment will necessitate a coordinated effort by all stakeholders to increase understanding of and closely monitor associated risks to patient safety. For example, research is needed to compare the quality of data and the quality of clinical documentation between paper charts and EHRs. Furthermore, it is not clear the extent to which electronic data capture and documentation processes will have a measurable beneficial impact on care delivery. Other data are needed to confirm how and under what circumstances electronic data capture and documentation processes can facilitate team-based care initiatives and care coordination innovations.

4. **Re-use of data via computerized systems.** Given the recognized need to maximize re-use of data, DHHS should fund additional research to demonstrate how computer systems (eg, through automated transformation of data) can help maximize the organization and presentation of data for various users and purposes. For example, research could focus on how data can be entered once, with systems providing different outputs and views of the data for different users and purposes.

5. **Dynamics of team-based clinical care and the role of technology-enabled documentation in supporting care coordination.** AHRQ should fund studies to help gain a better understanding of what a ‘team’ means in the healthcare context: for example, clarifying who is a member of the healthcare team and defining their roles and responsibilities with respect to data capture and documentation. The extent to which technology can be leveraged to support team-based care and associated workflows requires further study. The CMS Center for Medicare and Medicaid Innovation should include funding for demonstrations on data capture and documentation within team-based care, including safe havens from conditions of participation.

6. **Impact of integrating emerging data sources into documentation processes and outputs.** Future clinical data capture and documentation methods, systems, and approaches must accommodate and leverage diverse and increasingly large data sets, including genomic and patient-reported data, and data derived from mHealth and telehealth applications. Research is needed to develop new tools for representation, visualization, and summarization of these types of data. Topics for additional study include whether and to what extent automatically acquired data are more timely, accurate, and reliable than manually charted data; the ramifications for data capture and documentation processes as new data sources are connected to/integrated with EHRs; and review of public policy guidelines and requirements for data capture and documentation in light of data generated by new devices and technologies.

**CONCLUSIONS**

AMIA’s 2011 Health Policy Meeting examined current issues related to clinical data capture and documentation and took the long look ahead to envision changes that would help realize an ideal future state of these functions. Thoughtful consideration by diverse stakeholders of the strengths and weaknesses of current approaches led to the identification of knowledge gaps and policy and research priorities, as described in this paper.

Technological advances in the documentation sphere will continue to emerge to enable the inclusion of increasingly sophisticated data—for example, capture and integration of genomic information in the EHR to help propel personalized medicine. While technology will make futuristic data capture opportunities possible, attention must continue to be paid to the core issues discussed during the meeting that are central to a learning healthcare system using a computer-based infrastructure. These include the need for data capture and presentation methods that support clinicians’ cognitive needs and workflow; the inclusion of the high quality data in the electronic record necessary to undergird national strategies to achieve better health outcomes for individuals and populations; and use of EHR documentation to support holistic approaches such as multidisciplinary team-based care and enhanced participation by patients in promoting health and treating illness.

**AMIA Board of Directors’ response and action**

By convening this meeting and disseminating this report, AMIA has identified technology-enabled clinical data capture and documentation as a critical issue in national efforts to achieve high quality health and healthcare. The AMIA Board of Directors reviewed this paper and endorsed the authors’ recommendations. The Board of Directors anticipates committing additional organizational resources to continue to advance the work of the meeting and will encourage other organizations to work collaboratively to pursue the recommendations and to continue this important public discourse.

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The future state of clinical data capture and documentation: a report from AMIA's 2011 Policy Meeting

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Data from clinical notes: a perspective on the tension between structure and flexible documentation

S Trent Rosenbloom, Joshua C Denny, Hua Xu, Nancy Lorenzi, William W Stead, Kevin B Johnson

ABSTRACT
Clinical documentation is central to patient care. The success of electronic health record system adoption may depend on how well such systems support clinical documentation. A major goal of integrating clinical documentation into electronic health record systems is to generate reusable data. As a result, there has been an emphasis on deploying computer-based documentation systems that prioritize direct structured documentation. Research has demonstrated that healthcare providers value different factors when writing clinical notes, such as narrative expressivity, amenability to the existing workflow, and usability. The authors explore the tension between expressivity and structured clinical documentation, review methods for obtaining reusable data from clinical notes, and recommend that healthcare providers be able to choose how to document patient care based on workflow and note content needs. When reusable data are needed from notes, providers can use structured documentation or rely on post-hoc text processing to produce structured data, as appropriate.

INTRODUCTION
The process and products of documenting clinical care occupy a critical intersection among the diverse domains of patient care, clinical informatics, workflow, research, and quality. For the current manuscript, we define clinical documentation as the process of creating a text record that summarizes the interaction between patients and healthcare providers occurring during clinical encounters. Clinical documents produced in this process may include notes from outpatient visits, inpatient admissions and discharges, procedures, protocols, and testing results. Healthcare providers generate clinical documents to achieve numerous goals, including: to create narrative reports of their observations, impressions, and actions related to patient care; to communicate with collaborating healthcare providers; to justify the level of service billed to third-party payers; to create a legal record in case of litigation; and to provide data to support clinical research and quality-assessment programs. Increasingly widespread adoption of electronic health record (EHR) systems has facilitated reuse of clinical documents for research, quality initiatives, and automated decision support, among other uses. A major emphasis for integrating documentation systems with EHR systems is to increase the availability of structured clinical data for automated downstream processes. This has led to a profusion of computer-based documentation (CBD) systems that promote real-time structured clinical documentation.

The myriad requirements imposed on clinical documentation compel healthcare providers to create notes that are simultaneously accurate, detailed, reusable, and readable. As a result, integrating clinical documentation into workflows that contain EHR systems has proven a challenge. The complex interplay among the note characteristics healthcare providers value, the structure and standardization that data reuse requires, and the attributes of various documentation methods each affect the documentation method's adoption into clinical workflows. The flexibility of a CBD method to allow healthcare providers freedom and ensure accuracy can directly conflict with a desire to produce structured data to support reuse of the information in EHR systems. The challenge is compounded when those implementing CBD systems have different priorities from clinician users working in busy settings. In particular, we have previously demonstrated that healthcare providers prefer the ability to balance using a standardized note structure and having the flexibility to use expressive narrative text.

This viewpoint paper explores the tension between requirements that documentation methods support both structure and expressivity, then reviews two general approaches for obtaining structured data through clinical documentation, and provides our perspective of how best to use CBD systems in a clinical environment.

TENSION BETWEEN STRUCTURE AND EXPRESSIVITY
There exists a tension between the needs of busy healthcare providers documenting clinical care and of those reusing data from healthcare information systems. Busy clinicians generally value flexibility and efficiency, while those reusing data often value structure and standardization. In investigations evaluating healthcare providers' impressions of documentation systems, subjects articulated that the documentation methods they use should promote the quality and expressivity of notes they generate and should integrate efficiently into busy workflows. Expressivity has been defined as how well a note conveys the patient’s and provider’s impressions, reasoning, and thought process; level of concern; and uncertainty to those subsequently reviewing the note. Expressivity refers to the linguistic nuance necessary for describing aspects of the patient encounter using any words or phrases that
the healthcare provider deems appropriate, at whatever length is necessary. An expressive documentation method, for example, may allow a healthcare provider to create notes using nuanced words or pictures that capture the flavor of the clinical encounter. Healthcare providers may rely on expressivity to convey: (1) patients’ linguistic and narrative idiosyncrasies, (2) their level of concern or acuity, (3) the appearance of competence, (4) the provider’s degree of uncertainty, and (5) the unique aspects of the clinical case that distinguishes it from other similar cases. Although healthcare providers value documentation methods supporting narrative expressivity, there have been few studies published in the biomedical literature of CBD systems directly evaluating this attribute, and its value may vary based on the type of note being written. Among existing studies, investigators have demonstrated that when compared to highly structured diagnostic or impressions data, clinical notes containing naturalistic prose have been more accurate, more reliable for identifying patients with given diseases, and more understandable to healthcare providers reviewing patient records. In addition, numerous structured documentation systems include components that generate natural prose notes to increase their acceptance, which implies that natural-language text has value to clinical users. While the value of expressiveness is unknown, there is value in having access to reusable structured data from clinical notes. Unfortunately, systems optimized to acquire structured data from healthcare providers often have user interfaces that are idiosyncratic, inflexible, or inefficient, and thus place the burden of entering the data in a structured format on a busy healthcare provider, rather than leveraging specific computer programs to extract the data from the human-input clinical narrative.

Healthcare providers using EHR systems have two major methods for converting their observations and impressions of patient care episodes into machine-computable and reusable data. With the first method, healthcare providers directly create structured clinical notes by using specialized CBD systems that capture structured data in real time. With the second method, healthcare providers document patient care episodes using relatively unstructured approaches, such as using dictation with transcription or a computer-based CBD system, and then apply computer programs designed to extract clinical data from the notes’ text. These approaches are reviewed in greater detail below.

Using structured documentation tools

Clinical structured entry systems are specialized CBD systems that emphasize capturing structured (ie, conforming to a predefined or conventional syntactic organization) and/or standardized (ie, conforming to a predefined semantic standard) clinical data during standard documentation processes. Users document in structured entry systems by retrieving concepts and assigning them a status (eg, locating in a ‘knee pain’ template the concept ‘knee effusion’ and selecting ‘absent’). Selectable concepts may come from sophisticated reference terminologies, from specialized interface terminologies, or from informal and nonstandardized term collections. Structured entry systems may allow users and developers to create highly customized templates to maximize data completeness and structure. However, such templates may not easily use existing interface terminologies or conform to knowledge representation formalisms.

Over the last half-century, investigators, developers, and pioneers in the field of biomedical informatics developed numerous structured entry systems. As we reported elsewhere, structured entry systems described in the biomedical literature include groundbreaking documentation systems by Slack, work by Ledley for documenting radiology reports, and those by Stead and Hammond that allowed patients to enter their own histories and that ultimately evolved into the TMR medical record system. Other early structured entry systems include Barnett’s COSTAR system, Weed’s PROMIS system, Wirtschafter and Shortliffe’s independent works developing chemotherapy documentation, and decision-support systems. Additional structured entry systems have been described, including ARAMIS which served as a user interface for data collection about patients with rheumatoid arthritis, an endoscopy documentation tool called COR, Musen’s T-HELPER system, for HIV-related clinical trial and medical care documentation; Shultz’s Quill system, Johnson’s pediatric documentation system, Clictate, and several structured entry systems in the government and private sectors, including products by Cerner, Eclipsis, EpicCare, and the Department of Veterans Affairs. Many of these structured documentation systems also allow users to enter narrative text in situations where they cannot find appropriate structured concepts.

While numerous structured entry systems were developed, deployed and described in the biomedical literature, there are limited data demonstrating ongoing adoption or widespread dissemination of structured entry outside of niche settings or clinical domains. Research evaluating why structured entry usage is limited remains sparse, but includes qualitative work by McDonald, Ash, and Johnson. These studies suggest that structured entry systems can have complex interfaces that slow the user down. In addition, structured entry tends to be inflexible in situations where a documentation template does not contain a needed item and may not fully integrate with other EHR system components. Johnson’s studies in particular demonstrated that structured entry users believed that the system helped them comply with clinical guidelines. Although it increased documentation time when compared to paper-based forms, it did not decrease clinician or patient satisfaction. Additional studies identified specific attributes of structured entry systems that can attenuate their efficiency, integration, user interface navigation, and overall user satisfaction.

Structured documentation systems using guideline-based templates may help healthcare providers to be thorough.

Using flexible documentation tools with text processing

With flexible documentation, healthcare providers record patient care episodes using relatively unstructured approaches, such as using dictation with transcription, speech-recognition software, or typing using a loosely templated CBD system. Once the clinical documentation is complete, post-hoc text processing algorithms can be used to produce structured data. We use the term ‘text processing’ to describe any of a number of methods designed to identify specific text, data, and concepts from the natural language stored in unstructured, narrative-text computer documents. Computer programs can then deduce concepts contained in the notes’ text in a subsequent step. Investigators have worked for decades to convert natural language into structured representations of those documents. Text-processing technologies have been developed with differing levels of machine ‘understanding,’ from simple systems that search for key words or specific text strings to those systems that attempt to capture clinical concepts with their context. Text-processing tools can also serve as adjuncts to structured documentation.
systems, as recently described by Johnson discussing ‘structured narrative’.101

A basic approach to text processing involves searching documents in EHR systems for key narrative-text strings or string patterns. The narrative-text string search has been successfully employed in some large-scale clinical research studies.82–85 For example, researchers have used plain text searches of dictated or typed medical records to find rare physical exam findings82 and post-operative infections,85 and identify patients with certain types of drug-induced liver injury.84 Others have employed focused ‘regular expression’ pattern matches to extract text strings that can represent possible blood pressures83 and common section header labels (eg, ‘chief complaint’) in clinical notes,86 and remove patient identifiers such as names, phone numbers, and addresses to deidentify medical records.87 These methods are best adapted for solving focused problems. Since string-matching algorithms can be highly tuned for a given task (eg, by including manually derived synonyms, common abbreviations, and even misspellings), they can perform very well. Simple text searching also has an advantage of faster processing speed and easier implementation than complex natural-language processing (NLP) systems, as many off-the-shelf database systems and text-indexing tools support preindexed text queries. However, simple text searching is limited by a lack of generalizability and requires substantial customization for each new task. For example, finding all patients with liver injury from a single medication (such as phenytoin) is easily accomplished with a simple text search, but finding all medications that may be associated with liver injury requires a more complicated system that matches text with a controlled vocabulary that would include all medication brand and generic names. In addition, problems associated with directly entered clinical notes, such as misspellings102 and ambiguous abbreviations (eg, ‘pt’ can stand for ‘patient’ or ‘physical therapy’),103 also limit the use of the simple string-matching methods.

A more complex approach, called concept identification or concept indexing, attempts to normalize the text phrases to standardized terms representing concepts. Successful concept indexing systems include those by Miller and Cooper,89 MetaMap,90 SAPHIRE,90 the KnowledgeMap concept identifier,91 the Multi-threaded Clinical Vocabulary Server92 93 104 and the recently released Clinical Text Analysis and Knowledge Extraction System (cTAKES).105 A goal of concept indexing is to ‘understand’ the information in natural-language documents by mapping text to standardized concepts using terminologies such as those in the Unified Medical Language System (UMLS).106 These systems have proven effective, mapping natural-language texts to concepts with recall and precision often exceeding 80% for general tasks and near perfect for some highly focused tasks.90 95 107 108

Investigators have extended concept identification systems to combine them with additional algorithms that can extract contextual elements (eg, certainty, values, and temporal information) associated with a concept to form more robust NLP systems. Combining concept identification systems with negation detection algorithms (eg, ‘no chest pain’, which indicates the absence of the finding ‘chest pain’), investigators have created systems that automatically generate problem lists,109 discover gene–disease associations,110 hypothesize new drug effects,111 and new drug–drug interactions from the biomedical literature.96 and identify important findings from clinical narratives.97 96 Building on the work of the Linguistic String Project,79 Friedman and colleagues have been developing the MedLEE (Medical Language Extraction and Encoding System) NLP system since the 1990s.78 95 112 It can identify UMLS concepts from clinical documents, and can discern their timing and negation status. Researchers from several institutions have used MedLEE to identify pneumonia and other clinical conditions from chest x-rays,99 detect adverse events,112 and automatically calculate the Charlson comorbidity index.113 Several of these systems have been successfully incorporated into production clinical systems, some at multiple institutions.78 95 109 112 114 115

The uses of NLP in the clinical domain are quite diverse, including encoding clinical notes for billing purposes,95 116 facilitating clinical research by automating the data-extraction processes110 117 118 conducting EHR-based surveillance97 119 and enriching EHR functionalities, such as to support visualization tools120 and clinical decision-support systems.121 122 One of the earliest examples is the MedLEE system,123 which has been used to process chest radiographs to generate coded data for decision-support systems at New York Presbyterian Hospital since 1995. Recently, Day and colleagues121 reported the use of the MPLUS NLP system to classify trauma patients at a Level 1 trauma center on a daily basis. For specific tasks such as those mentioned above, advanced NLP systems such as MedLEE have shown equivalent performance as domain experts. However, the performance of current clinical NLP systems is still not satisfactory for broader uses. In addition, few NLP systems have been implemented in clinical settings and used in routine workflows in hospitals. For example, Kashyap et al, reported a study of using a commercial product to automatically structure admission notes in which the results were not judged to be acceptable for clinical use.124 With further improvements in advanced NLP technologies and new structures for clinical notes (such as the ‘structured narrative’),101 NLP may be able to structure clinical text such as admission notes automatically with a satisfactory performance.

DISCUSSION

The choice of a documentation method can alter the balance between expressivity and structure in the resultant notes, hamper the healthcare provider’s workflow, influence the process and products of recording clinical information, and influence how well the note can be incorporated into an EHR system in such a way that the note’s contents can be automatically reused and analyzed.15 19 26 36 70 101 While structured documentation systems can facilitate data collection and reuse, they can be cumbersome to use during patient encounters and may lack the flexibility and expressivity required for general medical practices. Transcribed notes create documents useful for text processing, but can require a time delay for the transcription process to occur. The attributes associated with each documentation method influence how they are best used and adopted. While structured entry emphasizes data standardization and structure, human adoption of CBD systems requires an emphasis on expressivity, efficiency, flexibility, and being well adapted to a typical workflow.19 22 27

Both structured clinical documentation and text-processing algorithms for flexible documentation continue to evolve. The rates of evolution may not be the same for each, but we are not aware of clear evidence that shows that one approach is improving faster than the other. Furthermore, we do not intend to convey an impression that one is necessarily more advanced or has greater promise than the other. Each approach offers distinct advantages to the user. For example, because structured
Perspective

documentation systems can do more than just create data, it may be relatively appealing to clinicians in certain settings. A template-based structured documentation system may be useful for notes that have a standard and predictable content and format, such as those recording pedestrian health maintenance visits, preoperative evaluations, formalized disability examinations, and reviews of systems. By contrast, in some settings, clinicians may prefer the flexibility of complex and nuanced narrative text to document the history of a present illness or a diagnostic impression.

We collectively have over 10 decades of personal experience in viewing or using a wide variety of computer-based documentation systems around the country in public, private and academic settings. We gained this experience in the settings of actual clinical use, observations during site visits, and direct reviews of vendor products at trade shows and professional conferences. Based on this experience, we have observed that typically, for a given site’s implementation, computer-based documentation systems are usually configured to take clinical input primarily in narrative or structured form, but not both. Most computer-based documentation systems that the authors have seen do not support hybrid documentation in the way that we recommend in the current manuscript. We note that, in the case where structured clinical data are needed, information entered using structured entry would be immediately available, whereas narrative text would require processing via NLP algorithms to become similarly ‘structured.’ Nevertheless, we observe that in our experience, few nonacademic sites have NLP-based text processing systems readily available to harvest EHR system data, with the possible exception of NLP-type systems that help to extract billing codes from clinical records.

Priorities for structured documentation and text processing will likely vary in different settings and with different user groups, and the priorities may be informed by the tasks the documentation supports. Certain tasks may require that the EHR systems understand only structural information from the clinical document (eg, its metadata or header information), while others may require a deeper concept-level understanding. For example, a quality-assessment program evaluating whether inpatient progress notes are being placed in the chart in a timely manner may require only the document title and date. Any document that has the correct title, including scanned and tagged paper-based notes, could support this need. Tasks that depend on a deeper understanding of the document may require healthcare providers to document using structured documentation tools or to apply computer programs to process the natural language in narrative-text documents. For example, to implement an automated colorectal cancer screening advisor, the advisor system will need to know the patient’s family and past medical history, whether a prior screening test had occurred, and the result of any screening tests. Gathering these data requires that healthcare providers document the relevant information using tools that can support data extraction and analysis, including CBD systems, structured entry tools, or narrative-text typing (either directly or via a dictation/transcription model) with a subsequent application of text processing. In addition, different healthcare providers may value structured data in EHR systems differently. Some providers may be willing to sacrifice a degree of CBD usability or efficiency for the sake of having key elements of their notes available immediately as structured data in EHR systems. Others may preferentially value documentation methods that allow them to express their impressions fluidly or create notes more quickly, without regard to how well the methods support other functions of EHR systems.

Recommendation

Given the tension between structure and flexible documentation, those implementing EHR systems should assume that multiple CBD products will be needed to meet the needs of clinician users, rather than attempting to find a single best documentation method. Factors to consider in selecting CBD products include the method’s fitness for a given workflow, the content in the resultant notes, time efficiency to create a note, costs, ease of using the method, flexibility for using the method to document unforeseen clinical findings or in unexpected circumstances, and support for narrative expressivity, machine readability, and document structure.19 25 46 Certain documentation methods feature some attributes at the expense of others, such as promoting narrative expressivity at the expense of formal note structure. Rather than waiting until documentation tools can be created to accommodate all needs and workflows, or force complex clinical workflows to change to accommodate the EHR system rollout, we recommend that healthcare providers be able to access a variety of different documentation methods and select the one that best fits their documentation, data, and workflow needs. EHR system developers and users can weigh different documentation methods in terms of how they impact relevant documentation-related outcomes such as usability, efficiency, quality, and readability against their utility for EHR systems. The value of this approach is that it allows organizations considering EHR systems to prioritize development and implementation efforts around clinical documentation.

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None.

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REFERENCES

Perspective


Data from clinical notes: a perspective on the tension between structure and flexible documentation

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Ross Rothmeier at Covance evaluates electronic data capture as part of an electronic trial management system: what lies ahead for EDC and what is required for its success

In 2009, the European Medicines Agency (EMA) approved 20 new active substances (NAS), the cost of each NAS close to €1 billion (1,2). Drug sponsors are under increasing pressure to reduce drug development costs while managing more streamlined clinical trials. In an effort to promote a more efficient review, and possibly reductions in paper-based and postage costs, some sponsors have used the electronic common technical document (eCTD) and found that it has resulted in faster submissions (3). In addition to the eCTD, some sponsors are also replacing the paper based system with an electronic data capture (EDC) system that is used by investigators to collect study data during a clinical trial.

BENEFITS OF EDC

The primary benefits of EDC can include lower operational costs, more efficient processes and better data quality. The data does not need to be transferred from the paper forms, and with edit-checks incorporated into the EDC software, there are fewer errors and queries for the data management team, more efficient monitoring for clinical research associates, and more detailed trial information for project managers (4,5). Another benefit of EDC is often improved timelines for getting clean patient data, especially when integrating with data from other sources like interactive voice or web response (IVR/IWR) and lab data.

By integrating these three systems when a patient is randomized, a reliable and consistent subject identifier can tie the data together and reduce the need for reconciliation or delays caused by waiting for data from one system before entering it into another.

Figure 1 shows how a sponsor uses EDC and may include the following steps:

- A clinical trial using EDC requires comprehensive planning, including selecting the interfaces needed for connecting data outside the EDC system.
- With some exceptions, data are typically captured in a source document – such as a patient chart – and then transcribed to an electronic case report form (eCRF) in the EDC application. Although EDC has built-in edit checks, these data are reviewed by trained data management specialists and verified against the source by monitors (5).
- Data from other sources are loaded onto a combined database. Whether integrated with the EDC application database or a central database, the integration process must be monitored for accuracy and verified to ensure the correct data have been received and loaded into the central database.
- Data from the clinical trial must be reconciled with other key systems, such as severe adverse event (SAE) and clinical trial management systems (CTMS). While the processes used to achieve this goal differ, it is important to ensure the events and data in the clinical system are consistent with data in the other key systems.
- To aid analysis, some data are given a numerical code (typically found in WHOMED, SNOMED or MedDRA dictionaries) through a coding system. The
coding process can also identify data discrepancies and spelling, drug name, or event interpretation errors.

**CHALLENGES EDC MUST OVERCOME**

In order to reap the benefits of EDC, thoughtful, advanced planning is often required. Companies which have successfully used EDC defined the roles and goals that EDC would present before beginning a clinical trial. Furthermore, they devised solutions to potential challenges ahead of time. Planning considerations include selecting the hardware and software, vendors, data to be measured and assembling a good help desk to handle any challenges that arise during the clinical trial. The front-end planning does require investing significant money upfront and a sponsor may not reap the benefits for some time (6). In addition, a sponsor may have different vendors for different software and hardware, which makes compatibility increasingly difficult. Even with extensive planning, a team leader for an EDC project needs to convince the clinical research staff that the new way of collecting data will produce benefits to the clinical trial.

In addition to planning, a sponsor has to ensure that the EDC system complies with regulatory guidelines, specifically Annex 11 and Directive 95/46/EC which requires the sponsor to demonstrate that the electronic records are valid and have an audit trail to show when and where data were modified, as well as appropriate controls over the privacy of patient data in the system (7). Furthermore, the Good Clinical Practice guidelines recommend that electronic data systems have appropriate safeguards in place, the existence of standard operating procedures that describe how to use these electronic data systems, and that the systems are validated (8).

**INTEGRATING EDC & OTHER SYSTEMS INTO ETMS**

Although careful planning and training is helpful in implementing EDC, the growth and accessibility of the internet has been useful too. Major EDC vendors have taken advantage of this development by designing web-based software, which circumvents the problem of different computer operating systems or hardware across multi-centre sites. With major EDC vendors basing their software on the internet, this growth is a vital contributor to continued and accelerated adoption of EDC.

EDC also appears to be changing how clinical trials are conducted. Although it can be a useful data collection tool, integrating it with other data related to the trial is more desirable. With the globalisation of clinical trials, it is even more essential to manage data and the trials in as close to real-time as possible. As clinical trials become more complex, a sponsor will need to integrate EDC and other systems into a broader, more comprehensive solution, such as an electronic trial management system (ETMS).

A model for this is underway in the US at the National Institute of Health’s Centre for Biomedical Informatics and Information Technology as part of their cancer biomedical informatics grid (caBIG) initiative. They have implemented an ETMS-like program with appropriate controls and standards that shares information between cancer researchers and the clinical community, such as clinical laboratory data, patient registration and scheduling, and adverse event reporting (9).

With increased internet accessibility, sponsors are now able to use other technologies
with EDC, such as IVR/IWR systems, direct data capture (DDC), and electronic health records (EHR). A variety of IVR/IWR solutions are being used in clinical trials to assign patient randomization numbers, order drug supplies and even collect patient data (10). These integrated technologies represent the present and future direction of clinical trials consisting of a centralized system with near real-time sharing of clinical trial information. Of these technologies, EHR has the potential to change how data are collected in clinical trials, particularly for clinical trial sites in healthcare settings. Because EHRs are required to collect demographic data, medical history, laboratory data, narratives and adverse events, it would make sense to re-use them in a clinical trial (11,12). Using EHRs as secondary data in clinical trials can save time by collecting certain data once and circumventing manual data entry. In addition, EHRs can provide information about drug interactions and outcomes, lab results and real-time analysis of adverse events (13). Information can be shared more quickly when using EDC, which can be helpful to trial monitoring (14).

In spite of these benefits, adoption of EHR systems by the healthcare industry has been slow. For example, a random sample of 2,758 US physicians surveyed identified that only four per cent had a comprehensive EHR system whereas 13 per cent had a basic EHR system (15). Although EHRs may be complex to install, the new workflows can be beneficial with fewer transcriptions of data, for example. Other barriers to EHR adoption include how physicians will use EHRs, incompatibility of EHR systems with other systems, the non-existence of standardized information and code sets, and privacy (16).

THE NEED FOR STANDARDS THAT SUPPORT AN ETMS

Bridging the gap between EHR and EDC for clinical trials is a great opportunity, but requires clinical trial systems to exchange data with, or be embedded within EHR systems. Integrating the healthcare enterprise (IHE) initiative is one way of addressing this problem, developing innovative solutions to enhance interoperability among different systems so that healthcare professionals can access reliable patient data. For example, the retrieve form for data capture (RFD) is a system that can extract EHR data for EDC (17). Having the technology for EDC and EHR systems directly linked can reduce the likelihood of transcription errors, save time by decreasing the workload (reducing repeated data collection, data-entry, monitoring and data reconciliation), and allow data to be transformed and shared quickly (13,18).

To encourage greater compatibility across EHRs, standards are required. Health Level Seven (HL7), Comité Européen de Normalisation – Technical Committee (CEN TC) 215, and the American Society for Testing and Materials (ASTM) E31 are working to create such standards (20). Other ongoing key activities that are addressing some of the top barriers to EHR include:

- The Critical Path Initiative of the US FDA is an effort to use evolving technology and scientific discoveries to improve the drug development process.
- The Clinical Trials Transformation Initiative is a collaboration between the FDA and Duke University Medical Centre which is working on modernizing the way clinical trials are conducted.
- The Certification Commission for Healthcare Information Technology (CCHIT) is a recognized certification body for EHRs and their networks.
The Biomedical Research Integrated Domain Group (BRIDG) is a collaboration among the Clinical Data Interchange Standards Consortium (CDISC), the HL7 Regulated Clinical Research Information Management Technical Committee (RCRIM TC), the National Cancer Institute (NCI), and the US FDA aiming to delineate clinical and medical research domains so that there is a common language across researchers and equipment used in such research.

The goals of these activities include the creation and use of data standards, providing a consistent certification standard for applications that use them, and appropriate data controls under the guidance and support of the FDA.

THE ETMS OF THE FUTURE

With technological advances available, innovative market leaders have the potential to develop products that can integrate IVR/IWR, DDC, EDC and EHR into an ETMS for a sponsor. Integrating these technologies into a single toolset will enable a sponsor to collect more data at multiple study sites and transmit it quickly to a central location. If a sponsor can design a quality and efficient clinical trial using ETMS, then demand for ETMS is likely to increase. A simpler ETMS process may result in better data quality, faster access to source data, and a more efficient drug development cycle (see Figures 2 and 3).

As we evolve toward the ETMS of the future, certain factors may affect adoption. Government regulation, evolution of data standards, and the industry's tendency to cautiously adopt new technology will continue to influence the speed at which ETMS is adopted, but the changes are already underway. The industry is overcoming some of the obstacles to ETMS adoption, and the increasing complexities of trial design, changing technology demands, and pressures to reduce costs should help ETMS move forward. Those companies that understand the ETMS landscape and are willing to integrate these technologies, including EDC, will lead the way. References

SECTION 3
Organizational Background
The Roundtable

The Institute of Medicine’s Roundtable on Value & Science-Driven Health Care provides a trusted venue for national leaders in health and health care to work cooperatively toward their common commitment to effective, innovative care that consistently adds value to patients and society. Members share the concern that, despite the world’s best care, in certain circumstances, health in America falls far short on important measures of outcomes, value and equity. Care that is important is often not delivered, and care that is delivered is often not important. Roundtable Members are leaders from core stakeholder communities (clinicians, patients, health care institutions, employers, manufacturers, insurers, health information technology, researchers, and policy makers) brought together by their common commitment to steward the advances in science, value and culture necessary for a health system that continuously learns and improves in fostering healthier people.

What are the Roundtable’s vision and goals?

– A continuously learning health system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation—with best practices seamlessly embedded in the care process, patients and families active participants in all elements, and new knowledge captured as an integral by-product of the care experience.
– Promote collective action and progress so that “By the year 2020, ninety percent of clinical decision will . . . reflect the best available evidence.” (Roundtable Charter, 2006)

How does the Roundtable work?

– Through stakeholder workshops and meetings: to accelerate understanding and progress toward the vision of a continuously improving and learning health system.
– Through joint projects through the work of six affinity group Innovation Collaboratives focused on:
  • Best clinical practices (health professional societies and organizations)
  • Clinical effectiveness research (innovative research scientists and institutions)
  • Communication of medical evidence (marketing experts and decision scientists)
  • Digital technology for health (health IT and care delivery experts)
  • Incentives for value in health care (health care purchasers and payers)
  • Systems engineering for health improvement (medical, engineering, and IT leaders)

How is the Roundtable making a difference?

– Describing the possible through the 13 publications in the Learning Health System series providing the foundation for the landmark IOM report Best Care at Lower Cost.
– Stewarding action projects of the Roundtable’s Innovation Collaborative stakeholders, working cooperatively to advance science and value in health and health care. Examples include:

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<th>Public &amp; patient involvement</th>
<th>Science &amp; evidence improvement</th>
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<td>Documentation of cost and waste</td>
<td>Core metrics for better health at lower cost</td>
<td>Making the case for outcomes research</td>
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<td>Improving the science of transparency</td>
<td>Cost and evidence as patient priorities</td>
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<td>Building patient and family leadership for system improvement</td>
<td>Common Rule update</td>
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<td>Point-of-care evidence access</td>
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<td>Digital infrastructure for a learning system</td>
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<tr>
<td>Systems engineering for high-value care</td>
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<td>Strengthening the science of data-driven medicine</td>
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Care that is important is often not delivered. Care that is delivered is often not important. Improving the return on our healthcare investment is a vital imperative that will require quickening our efforts to position evidence development and application as natural outgrowths of clinical care—to foster health care that learns. (Roundtable Charter)

We seek the development of a continuously learning health system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience. (Roundtable Charter)
# IOM Innovation Collaborative Projects

## Value
*Continuous improvement through transparency on outcomes and cost*

### 2014 in progress
- Pilot analytic project identifying and assessing [cost & price transparency](#)
- Strategy framework for health care [administrative simplification](#)
- An expert vision paper on core expectations for [accountable care organizations](#)
- Additional NGA-IOM Governors’ retreats for value innovation
- Organization of network for [systems engineering field-building](#)
- Strategy paper on [embedding](#) systems engineering in health professions education

### 2013 completed
- Meeting: NGA-IOM Governor’s retreat in Wisconsin (Oct 2013)
- IOM paper: [CEO checklist for high value care](#) (Jan 2013 dissemination)
- New Collaborative: IOM-NAE Systems Approaches for Health (Jan 2013)
- IOM paper: [Bringing a systems approach to health](#) (Jul 2013)
- IOM paper: [Evaluation of health care pilots for scale-up](#) (Apr 2013)

## Science
*Continuous learning through real-time evidence development*

### 2014 in progress
- An expert vision paper on the [future of clinical research](#)
- CEO & executive leaders on convening continuous learning
- A case study of a [test-bed](#) for real-time digitally-facilitated research
- An expert vision paper on [academic health center leadership](#) for continuous learning

### 2013 completed
- Workshop: [Large simple trials for clinical research](#) (Sep 2013)
- Workshop: [Observational studies in CER](#) (Sep 2013)
- IOM paper: [The Common Rule and continuous learning](#) (Aug 2013)
- Workshop: [Data harmonization across networks](#) (Oct 2013)
- IOM paper: [Return on information](#) systems investments (Jan 2014)
- Workshop: [Improving data quality](#) (Feb 2013)
- IOM paper: [Making the case for clinical data use](#) (Apr 2013)

## Culture
*Continuous pursuit of services most meaningful to people and their families*

### 2014 in progress
- Formalize [national network](#) of patient-family advisory leadership
- Vision and strategy piece on practice models for [clinician-patient partnership](#)
- Build the inventory of [case studies](#) on clinical data & care improvement
- An expert vision paper and meeting on [decision-making tool validation](#)

### 2013 completed
- Workshop/Video: [Partnering with Patients](#) (Aug 2013)
- IOM paper: [Team-based care principles and values](#) (Jan 2013)
- Patient Interviews: [Patients’ roles as team members](#) (Nov 2013)
- Survey: [Patients views on clinical data sharing](#) (Jan 2014)
- Meeting: [Patient and family leader partnership](#) (Nov 2013)

## Cross-cutting: Tools advancing science, value and culture

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<td>IOM study initiated: <a href="#">Core Metrics for Better Health</a></td>
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Digital Learning Collaborative
Advancing the digital infrastructure for the learning health system

Issue. With more components—testing, diagnosis, records, and patient-clinician communication—shifting to digital platforms, there exists enormous potential for increasing the efficiency, convenience, and effectiveness of health care. Digitalizing health care processes and information provides the foundation necessary to drive a continuously improving health system in which knowledge from past events is used to guide decisions. A health information technology infrastructure that supports a continuously improving, learning health care system requires consideration of the capabilities, technical and policy approaches, and operating principles needed to allow data from multiple areas of clinical health care, population health, clinical, biomedical, and translational research to be leveraged while protecting patients’ privacy. In 2010, the IOM, with support from the Office of the National Coordinator for Health Information Technology, held a series of workshops to explore the current efforts and opportunities to accelerate progress in improving health and health care with information technology. The resulting report—Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care—highlighted several areas for follow up activities in developing the digital infrastructure such as data stewardship, quality monitoring, research capabilities, and coordinating requirements around leadership, policies, and sustainability.

Collaborative. Formerly the Electronic Health Records Innovation Collaborative (EHRIC), the Digital Learning Collaborative (DLC) is an ad hoc convening activity under the auspices of the IOM Roundtable on Value & Science-Drive Health Care. It was created to provide a venue for joint activities that can accelerate progress towards the digital infrastructure necessary for continuous improvement and innovation in health and health care. This includes fostering a new culture of collaborative action among participants in the learning process—e.g. patients, clinicians, researchers, and product developers.
Participants: Participants include experts from public and private organizations with prominent activities and leadership responsibilities related to development and application of digital technology important to continuous improvement in health and health care. The aim is for an inclusive Collaborative—without walls—and participation in individual projects is structured according to interest, need, and practicality.

Activities: Projects completed, under way, or under consideration by the DLC include:

• **Workshop series and report on the Digital Infrastructure for the Learning Health System.** Cooperative work involving DLC participants with the Office of the National Coordinator and related government agencies to explore strategic considerations in accelerating learning from healthcare delivery.

• **PEDSNet.** A consortium of 15 leading pediatric care institutions, working together to create an organization providing networked clinical data from electronic health records for use in accelerating clinical research in pediatrics.

• **Aligning health reform data needs and priorities.** Engaging leaders from key federal health reform initiatives on strategies and opportunities to leverage health IT for program and monitoring alignment, across initiatives and in the support of population health.

• **Data quality and learning from the digital health utility.** Workshop to explore the data quality issues and strategies central to the increasing capture and use of digital clinical and patient-reported data for knowledge development.

**FEDERAL AGENCIES**
- U.S. Department of Health & Human Services
  - Agency for Healthcare Research and Quality
  - Centers for Disease Control and Prevention
  - Centers for Medicare & Medicaid Services
  - Food and Drug Administration
  - Health Resources and Services Administration
  - National Institutes of Health
  - National Library of Medicine
  - Office of the National Coordinator for HIT
- U.S. Department of Defense (Health Affairs)
- U.S. Department of Veterans Affairs

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- Cincinnati Children’s Hospital Medical Center
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- Vanderbilt University Medical Center

**PRODUCTIVE PARTNERS**
- American Medical Informatics Association
- American Society for Medical Informatics
- Children’s Hospital Los Angeles
- Children’s Hospital of Wisconsin
- Cincinnati Children’s Hospital Medical Center
- Cleveland Clinic
- Duke University Health System
- Geisinger Health System
- Google, Inc.
- Harvard Medical School
- Harvard Pilgrim Health Care
- Hospital Corporation of America, Inc.
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- Johns Hopkins Children’s Center
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- Mayo Clinic
- Microsoft, Inc.
- Nationwide Children’s Hospital
- Nemours Children’s Healthcare System
- New York Presbyterian/Columbia
- NorthShore University Health System
- Partners HealthCare System
- Primary Children’s Medical Center
- Radiological Society of North America
- Seattle Children’s Hospital
- Stanford University
- Texas Children’s Hospital
- The Children’s Hospital-Denver
- UC Davis Health System
- UCLA School of Medicine
- University of Alabama
- University of Chicago
- University of Michigan Medical School
- University of Vermont
- Vanderbilt University Medical Center
SECTION 4
Participant Biographies and Meeting Logistics
Digital Learning Collaborative  
May 30, 2014  

Participant Biographies  

Holt Anderson is the Executive Director of the NCHICA (the North Carolina Healthcare Information & Communications Alliance, Inc.), a 501(c)(3) private, nonprofit consortium of healthcare providers, payers, corporate partners, professional associations and government agencies formed in 1994 with the mission of assisting NCHICA members in accelerating the transformation of the US healthcare system through the effective use of information technology, informatics, and analytics. NCHICA has established a national reputation for its collaboration activities in pursuing consensus based tools and implementation strategies for meeting compliance requirements including: HIPAA Transactions with a current emphasis on ICD-10, Security & Privacy, Informatics & Analytics, Health Information Exchange, and Telehealth. NCHICA has endorsed the core values and vision of a Learning Health System that has the promise of providing evidence-based, decision support tools for care providers utilizing the power of data aggregation and analysis and the capabilities to match a specific patient with a significant population of individuals with similar profiles, diagnosis, treatments and outcomes. NCHICA’s NC Consumer Advisory Council on Health Information currently has projects on Consumer Literacy and Personal Representatives. Holt serves on various national councils, committees and governing bodies including current Vice Chair of the Coordinating Committee for eHealth Exchange and a member of the HIMSS Foundation Governance Council and Advisory Member of the HIMSS Board of Directors. Recently, he served as a member of ONC’s National HIE Governance Forum, the ONC Technical Expert Panel on Patient Generated Health Data, and the Board of Directors of the National eHealth Collaborative (NeHC). Holt is a graduate of Duke University.  

Landen Bain works with CDISC, a global medical research standards development organization, as liaison to the healthcare information community to develop and implement data exchange standards between healthcare and medical research. Mr. Bain focuses his efforts on realizing improved interoperability today, with the immediate demonstration and implementation of existing standards. An example is a cooperative effort Mr. Bain leads between CDISC and Integrating the Healthcare Enterprise (IHE) to enable data capture for clinical research from within Electronic Health Record (EHR) systems, using an IHE integration profile called Retrieve Form for Data-capture (RFD). This work brings together for the first time biopharmaceutical, HER, and research technology companies to develop interoperable solutions. The work has been demonstrated at six HIMSS Interoperability Showcases and continues today with the creation of a number of real world studies in live research sites. Mr. Bain served as co-chair of the HITSP Clinical Research Tiger Team and the CCHIT Strategic Lead for Clinical Research Workgroup. Both of these efforts move the use of EHRs for clinical research into the mainstream of the healthcare and clinical research industries. Mr. Bain is currently working on integration profiles for automating business processes between research and healthcare (Retrieve Process for Execution) and on methods for capturing and respecting the privacy preferences of subjects (Redaction Services). Mr. Bain served for over 20 years as Chief Information Officer of two large academic medical centers: Duke University Health System in
Durham, North Carolina and Ohio State University Hospitals in Columbus, Ohio. Mr. Bain was recognized by the HL7 Board as an ‘HL7 Pioneer’ in 1991 for his work as an early adopter of HL7 while at Ohio State University. He is a charter member of the College of Healthcare Information Executives.

Hunt Blair serves as Principal Advisor on HIT-enabled Care Transformation at the Office of the National Coordinator for Health IT. Hunt is one of ONC’s Health Information Exchange (HIE) subject matter experts working with State HIT and health policy leaders and with the HIE community on systems and architecture to support delivery and payment model innovation. Previously, Hunt spent four years as Deputy Commissioner of Health Reform and State HIT Coordinator in Vermont. Prior to joining state government, Hunt worked extensively on Vermont health reform as Director of Public Policy for the Bi-State Primary Care Association, where he formed a federally-funded rural health network of Vermont’s FQHCs, RHCs, and CAHs to put state health reform policy into practice. He has been an active participant in the national conversation about how to use HIE to advance health reform at the IOM, on ONC’s Policy Committee Information Exchange Work Group, and many other venues since the passage of HITECH. The New England Rural Health Roundtable awarded Hunt its Leadership Award in 2008 for his work on Vermont health reform. He received an AB in Semiotics from Brown University in 1983 and has been conducting post-structural analysis “deconstructing” healthcare systems ever since.

John L. Burch is an individual, private investor. He advises and selectively invests in both early-stage and late-stage companies. He has broad interests, and his educational background includes bachelors degrees in Chemistry and History. After working for several years as a computer programmer, in the 1980s he formed a company that published algorithm-based, multi-disciplinary bibliographic compilations of key literature in scientific fields at the intersection of computer hardware and software design, human factors, and macroergonomics; he personally edited compilations on computer ergonomics and artificial intelligence. He was invited to serve as Chairman of the Ericsson World Conference on Ergonomics in Computer Systems held in New York, City, Dusseldorf, Helsinki, and Stockholm. He has served on the Board of the Biodiversity Institute and Natural History Museum at the University of Kansas. Under his leadership, the Burch family has created an endowment to support the Arctic Studies Center of the American Museum of Natural History at the Smithsonian Institution. Mr. Burch leads the In-Depth Bible Study Group at Plymouth Congregational Church (Lawrence, Kansas), a unique group with a growing following that helps believers look objectively at religious scriptures. Mr. Burch lives on the front lines of this nation’s “culture wars.” In 2005, when the teaching of intelligent design was proposed in Kansas (and in Dover, PA), he organized a half-day conference to support good science education (Science 29 April 2005: Vol. 308 no. 5722 p. 627). Mr. Burch is currently assessing fundamental needs and opportunities for innovation in health care.

Edward W. (Tad) Campion, MD is the Online Editor and Senior Deputy Editor at the New England Journal of Medicine, where he has worked for over 25 years. He oversees the Journal’s presence on the Internet, having worked with a talented team to get the NEJM first onto the Web in 1996, and then into audio, video, and interactive data presentations, as well as onto iPad and smartphone and into the puzzling world of social media. Dr. Campion formerly was the Chief of the Geriatrics Unit at the Massachusetts General Hospital and Spaulding Rehabilitation Hospital and the Educational Director for the Robert Wood Johnson Project in Long Term Care. He graduated with honors from both Dartmouth College and Dartmouth Medical School. Before medical school he studied philosophy at The Queen’s College, Oxford, attended Union Theological Seminary as a
Rockefeller Fellow, and taught mathematics for two years in a public school in upper Manhattan. He completed his internship at Cambridge Hospital and both medical residency and rheumatology training at Massachusetts General Hospital.

Michael N. Cantor, MD, MA is Director of Clinical Research Informatics and Associate Professor (Clinical) of Medicine and Population Health at New York University School of Medicine. As Director of Clinical Research Informatics, his work focuses on optimizing clinical data for use in research and quality improvement. He is also a practicing internist. Prior to rejoining NYU, he was Senior Director, Information Strategy and Analytics at Pfizer, where his work focused on secondary uses of clinical data, personalized medicine, and automated methods of pharmacovigilance. While at Pfizer, he co-lead the formation of two research consortia: MEDIC (Multi-Site Electronic Data Infectious Disease Consortium), which joined four academic medical centers and Pfizer in using EHR data for comparative effectiveness research; and eControls, a collaboration among the pharmaceutical industry, the Critical Path Institute, and Transcelerate Biopharma to share placebo and control-arm data to improve clinical trial design and adverse event evaluation. Before working at Pfizer, Dr. Cantor was the Chief Medical Information Officer for the South Manhattan Healthcare Network of the New York City Health and Hospitals Corporation, based at Bellevue Hospital. Dr. Cantor completed his residency in internal medicine and informatics training at Columbia, has an MD from Emory University, and an AB from Princeton.

Basit Chaudhry, MD, PhD is an internal medicine physician and medical technologist whose expertise focuses on healthcare payment, clinical service redesign, and the use of data analytics to improve clinical and financial performance in healthcare. Tuple Health works with providers, payers and purchasers to transition to new models for value based payment and collaborative, population health. Tuple Health provides services including payment model design and implementation, utilization and financial analysis, and support for value based contracting. Tuple Health products focus on data analytics and technologies focused on clinical re-design and population health. Tuple Health provides services including payment model design and implementation, utilization and financial analysis, and support for value based contracting. Tuple Health products focus on data analytics and technologies focused on clinical re-design and population health. Prior to starting Tuple Health Dr. Chaudhry was a medical scientist at IBM Research where his work focused on using data analytics and information technology to drive innovation in healthcare. His work focused on improving healthcare productivity, ACO & PCMH implementation, optimizing workforce utilization, and improving the quality and efficiency of care. In addition to technology development, Dr. Chaudhry worked on developing IBM's private and public sector business strategies for the healthcare industry. Dr. Chaudhry was lead research clinician for IBM's artificial intelligence computing system Watson—famous for its victories on the quiz show Jeopardy! In this role, Dr. Chaudhry focused on developing the Watson technology for clinical practice. After finishing his medical training in internal medicine, Dr. Chaudhry completed the Robert Wood Johnson Clinical Scholars program at UCLA, earning a PhD focused on biomedical informatics and health services research. Dr. Chaudhry has worked in the Internal Medicine department at UCLA and as a research scientist at the RAND Corporation. He has provided expertise to the U.S. Department of Health and Human Services and the Institute of Medicine and served on a working group of the President’s Council of Advisors on Science and Technology, coauthoring its policy report, “Realizing the Full Potential of Health Information Technology.”

James J. Cimino, MD is a board certified internist who completed a National Library of Medicine informatics fellowship at the Massachusetts General Hospital and Harvard University and then went on to an academic position at Columbia University College of Physicians and Surgeons and the Presbyterian Hospital in New York. He spent 20 years at Columbia, carrying out clinical informatics research, building clinical information systems, teaching medical informatics and medicine, and
caring for patients, rising to the rank of full professor in both Biomedical Informatics and Medicine. His principle research areas there included desiderata for controlled terminologies, mobile and Web-based clinical information systems for clinicians and patients, and a context-aware form of clinical decision support called “infobuttons”. In 2008, he moved to the National Institutes of Health, where he is the Chief of the Laboratory for Informatics Development and a Tenured Investigator at the NIH Clinical Center and the National Library of Medicine. His principle project involves the development of the Biomedical Translational Research Information System (BTRIS), an NIH-wide clinical research data resource. In addition, he conducts clinical research informatics research, directs the NLM's postdoctoral training program in clinical informatics, serves as an internal medicine consultant in the Clinical Center, and teaches at Columbia University and Georgetown University as an Adjunct Professor. He is co-editor (with Edward Shortliffe) of a leading textbook on Biomedical Informatics and is an Associate Editor of the Journal of Biomedical Informatics. He is a Fellow of the American College of Physicians, the New York Academy of Medicine, and the American College of Medical Informatics (currently Past President). His honors include the Priscilla Mayden Award from the University of Utah, the Donald A.B. Lindberg Award for Innovation in Informatics and the President's Award, both from the American Medical Informatics Association, the Medal of Honor from New York Medical College, and the NIH Clinical Center Director’s Award (twice).

**George Cole** manages the clinical standards-based interoperability efforts of the Community Solutions team at Allscripts, focusing on standards-based implementations of both content and transport for the exchange of clinical content. George is a member of the IHE ITI Technical Committee, the Patient Care Coordination Technical Committee, and the EHRA Standards and Interoperability Workgroup. He is co-editor of the IHE Retrieve Form for Data Capture (RFD) Profile. He is a Faculty Board member of The CDA Academy, was an active participant with the Beacon-EHR Affinity workgroup, and a past member of the CCHIT Interoperability Experts Panel. George represented the EHR Association as a member of the CDC IISB Transport Experts Panel. He has participated in ONC S&I Initiatives including the Direct Project, Transitions of Care, and Structured Data Capture (SDC).

**Farrah Darbouze** is a Public Health Analyst with the Office of Science & Technology at the Office of the National Coordinator for Health Information Technology (ONC). She is currently serving as the government lead for the Structured Data Capture Initiative within the Standards & Interoperability Framework. She has spent almost all of her career in cancer-prevention and the public health field. Farrah has been with ONC for three years and previously has served as a Health Communications Research Fellow with the National Cancer Institute. She has also worked in the Government Relations Department of the American College of Obstetricians and Gynecologists. She has been trained in public health at George Washington University. Farrah has also co-authored research on the Current Smoking Policies in LGBT Bars and Restaurants and she earned her bachelor's degree from Wesleyan University in Middletown, CT.

As a Solutions Consultant with Medidata, **Joseph Dustin** has worked with the world’s largest pharmaceutical, biotech, and contract research organizations to improve clinical trial processes and enhance R&D efficiency with innovative, cloud-based technology. He has more than 12 years of consulting, project management, and IT experience in eClinical technologies such as EDC, ePRO, IRT, and CTMS organized in a unified platform for clinical trials in the academic, government, and commercial sectors. Mr. Dustin has spoken at the CDISC Interchange conference, The DIA (Drug Information Association) Annual Meeting, and most recently at the Health 2.0 conference in San Francisco on issues of data standards, patient engagement, and the link between healthcare and
research. Prior to joining Medidata, Mr. Dustin held positions of increasing responsibility at etrials Worldwide, Inc. (later acquired by Merge Healthcare) and CRF Health. He managed teams responsible for the delivery of mobile solutions used for electronic patient-reported outcomes and patient engagement, which collected real-time data from clinical trial participants around the world. Joe holds a BS in computer information systems and political science from the Gabelli School of Business at Roger Williams University. Follow Joe on Twitter @eClinical or at joedustin.com.

**Sarah Davis, MS** is a Translational Bioinformatics Product Manager at the UCSF Breast Care Center, where she has worked over the last eight years with Dr. Laura Esserman, Director of the Breast Care Center. Ms. Davis has helped in developing novel clinical trials like the adaptive phase 2 I-SPY 2 TRIAL along with the integrated bioinformatics platform, TRANSCEND, that runs the trial. Additionally, Ms. Davis has managed the development of several informatics applications aimed at collecting important clinical data at the point of care to integrate into clinical research systems to improve efficiency and accuracy in translational science analyses. Ms. Davis has an MS in Microbiology from the University of Wisconsin.

**Chris Dymek, EdD** is a member of the HHS team in the Office of the Assistant Secretary for Planning and Evaluation (ASPE) that is helping to create an infrastructure to support patient-centered outcomes research. She is a computer scientist and Health IT researcher whose research interests focus on creating transformational change via information technology enablers. Prior to joining ASPE, Dr. Dymek was a Senior Researcher with the Westat Center for Health IT. She was also a Health IT Project Manager for the National Opinion Research Center (NORC) at the University of Chicago. At NORC, Dr. Dymek co-managed the Agency for Healthcare Research and Quality’s National Resource Center for Health IT. Preceding her work at NORC, Dr. Dymek led an electronic medical record implementation for five Adventist Healthcare facilities. She also served as Chief Technology Officer and Product Development Executive at the Commission on Accreditation of Rehabilitation Facilities. In addition to her work in the health and human services sector, Dr. Dymek has directed re-engineering and organization effectiveness efforts for the electric utility industry.

As Vice President, Evidence Generation and Translation, **Margo Edmunds, PhD** leads the AcademyHealth portfolios on information infrastructure, delivery system transformation, population health, and translating research into policy and practice. She has more than twenty years of experience implementing and evaluating health and health care policy initiatives for federal and state government, foundations, associations, and other clients and has directed three national studies on health care coverage, access, and financing for the Institute of Medicine. Dr. Edmunds is a former Adjunct Associate Professor of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health and teaches emergency and risk communication in the graduate communications program at Johns Hopkins Krieger School. She currently chairs the Public Policy Committee for the American Medical Informatics Association (AMIA), for which she received an AMIA leadership award in 2013, and is an Associate Editor for Applied Clinical Informatics. She is an elected member of the National Academy of Social Insurance and a Fellow and former Board member of the Society of Behavioral Medicine. Dr. Edmunds began her health care career as a member of the affiliate staff at Johns Hopkins Hospital and completed a Research and Clinical Fellowship at the Johns Hopkins School of Medicine.

**David A. Fenstermacher, PhD** is currently the Chief Research Information Officer for Virginia Commonwealth University (VCU), Director of Biomedical Informatics for the Center for Clinical
and Translational Research, Director of Informatics for the Massey Cancer Center and Professor in the Department of Biostatistics. Previously he was the Founding Chair and Associate Professor of the Department of Biomedical Informatics at the Moffitt Cancer Center (MCC) and Chief Bioinformatics Officer for M2Gen. He has established and directed multiple informatics research programs for more than sixteen years at the University of North Carolina at Chapel Hill, the Abramson Cancer Center at the University of Pennsylvania, and The Moffitt Cancer Center. During his tenure in biomedical informatics, Dr. Fenstermacher has designed and directed the implementation of several bioinformatics and biomedical informatics distributed computing systems to support basic, translational, and clinical research, including multiple institution research projects. He has also designed data management systems for more specialized projects including integrating patient-level clinical data, genomics (genome-wide association studies, massively parallel sequencing, array-based technologies) and other ‘omics data to support studies focused on cancer and other human diseases. Data management systems designed by Dr. Fenstermacher have included: collection and integration of subject clinical data; data quality methodologies, development of web-based forms for input, storage and retrieval of clinical and research data, customized data representations, data governance and data sharing using data warehouses and Grid technologies. Current work focuses on developing informatics resources that span the informatics continuum of Bioinformatics, Biomedical Informatics, and Clinical/Medical Informatics specifically for precision medicine and health outcomes research. Dr. Fenstermacher received his doctoral degree from the University of North Carolina at Chapel Hill. Prior to joining the fields of bioinformatics and biomedical informatics, Dr. Fenstermacher spent fourteen years as a molecular biologist/geneticist working on several projects, including phage display technologies, FISH for cytogenetic applications, and transcriptional regulation of alternate splicing in mammals. His background as a bench scientist brings a unique perspective to the design of computational tools to support basic, translational, and clinical research studies. Dr. Fenstermacher has held several faculty positions at the University of North Carolina, the University of Pennsylvania, the University of South Florida, MCC, and VCU.

**Ronald Fitzmartin, PhD, MBA** is Senior Advisor, Office of Strategic Programs, CDER, FDA. In this capacity Ron provides strategic planning and policy / guidance advice for the data standards program in support of the regulatory review and evaluation of medical products. Specific areas of focus include: electronic study data standards, electronic source data capture, electronic health records and 21CFR Part 11. Prior to FDA, Ron held scientific and technical leadership positions at Decision Analytics, LLC, Daiichi Sankyo, Inc., Daiichi Medical Research, Inc., and Purdue Pharma L.P. In addition, he served as a statistician at the U.S. Census Bureau and the U.S. Department of the Navy. Ron was elected a member of the Board of Directors and President of the DIA from 2007-2009. Ron has been a frequent presenter at many industry meetings and has authored numerous articles in areas such as informatics, pharmacovigilance, clinical data management, and computer systems validation. Ron received a PhD in statistics from the University of Maryland, a MBA from the University of New Haven, and a MS and BS from Southern Connecticut State University.

**Douglas B. Fridsma, MD, PhD** is the Chief Science Officer and Director of the Office of Science and Technology in the Office of the National Coordinator for Health Information Technology. Prior to arriving at ONC, Dr. Fridsma held academic appointments in biomedical informatics and an active teaching practice in internal medicine at Stanford Hospitals, the VA hospital, and the Mayo Clinic Scottsdale. Dr. Fridsma completed his medical training at the University of Michigan in 1990, his internal medicine residency at Stanford University, and his PhD in Biomedical Informatics from Stanford University in 2003. In his role at ONC, Dr. Fridsma leads the office that is focused on
developing and harmonizing health IT technical specifications and standards, coordinating the Federal Health Architecture (FHA), promoting innovation in health IT and interfacing with the international health IT community. Among Dr. Fridsma’s most significant achievements at ONC is the creation of the Standards & Interoperability (S&I) Framework, a program where members of the health IT community can define interoperability challenges and work collaboratively to develop standards-based solutions. He served on the Clinical Data Interchange Standards Consortium (CDISC) Board of Directors from 2005-2008, as well as the Health IT Standards Committee from 2009-2010. Dr. Fridsma currently serves as a board member of HL7.

Charles P. Friedman, PhD joined the University of Michigan in September of 2011 as Professor of Information and Public Health and Director of the new Michigan health informatics program. This appointment follows 8 years with the U.S. federal government, prior to which Dr. Friedman served for 26 years as a faculty member and administrator in two schools of medicine. Throughout his career, Dr. Friedman's primary academic interests have intertwined biomedical and health informatics with the processes of education and learning. In his academic role at Michigan, Dr. Friedman is leading a novel academic program emphasizing consumer-facing applications and population health. He is also directing several university and national initiatives to achieve a nationwide “Learning Health System.” Most recently, Dr. Friedman held executive positions at the Office of the National Coordinator for Health IT (ONC) in the U.S. Department of Health and Human Services: from 2007 to 2009 as Deputy National Coordinator and from 2009 to 2011 as ONC’s Chief Scientific Officer. While at ONC, Dr. Friedman oversaw a diverse portfolio of nationwide activities that included early steps toward development of a Learning Health System, education of the nation’s health IT workforce, health IT research activities, evaluation of ONC’s programs, and international cooperation for eHealth. He was the lead author of the first national health IT strategic plan, which was released in June of 2008, and led the development of an EU-US Memorandum of Understanding on eHealth. From 2003 to 2006, Dr. Friedman was Senior Scholar at the National Library of Medicine where he oversaw NLM's training and bioinformatics grant portfolios and played a prominent role in developing the National Centers for Biomedical Computing. From 2006 to 2007, he served as an Associate Director and Chief Information Officer of the National Heart, Lung, and Blood Institute. Prior to his work in the government, from 1996 to 2003, Dr. Friedman was Professor of Medicine, Associate Vice Chancellor for Biomedical Informatics, and Founding Director of the Center for Biomedical Informatics at the University of Pittsburgh. He served from 1977 to 1996 in a range of faculty and administrative roles in the School of Medicine at the University of North Carolina at Chapel Hill. He directed the Office of Educational Development and served as Assistant Dean for Medical Education and Medical Informatics. Dr. Friedman is an elected fellow and past president of the American College of Medical Informatics and an Associate Editor of the Journal of the American Medical Informatics Association. He was the 2011 recipient of the Donald Detmer award for policy innovation in biomedical informatics. He is co-author of a textbook on Evaluation Methods for Biomedical Informatics. He was founding chair of the Group on information Resources of the Association of American Medical Colleges and chair of the AAMC's Group on Educational Affairs.

Evelyn Gallego-Haag, MBA is a seasoned professional in leadership, management and consulting across the health, high-tech, and government sectors. She is a trusted advisor in helping organizations bridge the gap between business requirements, technology, and policy. She also has a strong ability to work across diverse stakeholder groups having worked, studied, and lived in Canada, the United States, and Europe. Her career has spanned health transformation and management, information technology, policy analysis, organizational design, strategic planning,
business development, and health standards development. She specializes in Health Information Management (HIM) and Health Policy for both government and commercial healthcare organizations. Ms. Gallego-Haag is currently providing Program Management and Standards Analysis expertise to the Standards & Interoperability (S&I) Framework at the Office of the National Coordinator for Health IT (ONC). In her role she serves as the Initiative Coordinator for two high-profile interoperability initiatives: Longitudinal Coordination of Care (LCC) and Structured Data Capture (SDC). Ms. Gallego-Haag earned her International MBA from the Schulich School of Business in Toronto, Canada and her MPH Certificate in Health Policy from George Washington University. Ms. Gallego-Haag is a recognized speaker and facilitator on various health IT topics including quality reporting, care coordination, and meaningful use.

Charles E. Geyer, Jr., MD is Professor of Medicine and the Harrigan, Haw, Luck Families Chair in Cancer Research at Virginia Commonwealth University Massey Cancer Center, an NCI-designated Cancer Center. He also serves as Associate Director of Clinical Research for the Massey Cancer Center with oversight responsibility for all cancer-related clinical research activities within the Center. Dr. Geyer has devoted most of his academic career on the design and conduct of multi-institutional, phase III clinical trials in breast cancer with a particular focus on the development of HER2 targeted therapies. He has served in several leadership positions for multi-institution research initiatives. These include vice-chair of the National Surgical Adjuvant Breast and Bowel Project (NSABP) Breast Committee from 1999 until 2007, Associate Director of Medical Affairs from 2002 to 2006 and Director of Medical Affairs for NSABP from 2006 to 2011. In 2008, he was appointed as a founding Co-chair for the NCI Cancer Treatment Evaluation Program Breast Cancer Steering Committee and received a Director’s Award at the completion of his tenure in 2011. Dr. Geyer has co-authored over 30 peer-reviewed manuscripts reporting results of numerous phase 3 trials conducted by the NSABP. He has also been active in leadership roles on collaborative global trials in breast cancer, having chaired or co-chaired Scientific Steering Committees on 4 phase III trials. In 2011, Dr. Geyer accepted the position of President and Chief Medical Officer of the Statewide Clinical Trials Network of Texas established to facilitate and coordinate the conduct of multicenter, tissue-based, biomarker-driven phase 2 trials in the academic cancer centers and community practices in Texas. In 2013 he accepted his current positions at the VCU Massey Cancer Center. He earned his bachelor’s and doctoral degrees from Texas Tech University.

Amer Haider is the CEO of Doctella, a company focused on revolutionizing patient safety. Amer co-founded Doctella with Dr. Peter Pronovost and Dr. Adil Haider, medical experts from Johns Hopkins. Prior to Doctella, he was Vice President of Corporate Development at Cavium, a leading publicly traded technology company in Silicon Valley. Amer is an entrepreneur involved in starting, investing, advising, and growing multiple companies that have raised over $100 million in venture capital, have been acquired by technology giants Oracle and Google, and have had a successful public offering creating combined equity value of over $2 billion. Amer has created and managed products in the areas of security, networking, mobility, SAAS, embedded software, and semiconductor processors generating over $1 billion in sales. Amer has masters degrees in engineering and business from University of Illinois at Urbana Champaign and has been awarded 4 U.S. patents in the areas of security and processors. Moved by health challenges in his own family, Amer started two healthcare non-profits to eliminate untreated clubfoot and to improve the quality of medical care for individuals with dwarfism. He serves on the board of Ponseti International Association and manages the Grant for Study of Skeletal Dysplasia. He and his wife Munira live in Saratoga, California with their 3 children.
Marcelline Harris, PhD is associate professor of nursing at the University of Michigan. Prior to joining the Michigan faculty in 2011, she held appointments as a career scientist in the department of biomedical statistics and informatics at Mayo Clinic, as well as an executive informatics administrative role in the department of nursing at Mayo Clinic. Her past research and practice has focused on data integration and semantics, nursing health services research, and the development and implementation of architectural approaches that enable discovery of data from “secondary use” perspectives (e.g., EHRs, departmental systems, warehouses). Currently, she is a faculty member of the Comprehensive Research and Education Enterprise Architecture Team at the University of Michigan Medical School, and leads an effort to architect a Data Set Catalog that is leveraging semantic approaches to discovering and linking federated data sets. She co-leads a University of Michigan group examining research problems associated with knowledge distribution in a Learning Health System. She is also a member of a University-wide taskforce developing principles and guidelines relating to scholarship in the context of digital environments. Her research and operational experiences reflect a unique foundation in “bridging” domain specific knowledge representations, data integration based on current operational/legacy systems, and development of data systems in the context of semantic web technologies.

Erin Holve, PhD, MPH, MPP is a senior director at AcademyHealth where she leads AcademyHealth’s work on analytic methods and research resources for the field of HSR. She directs several projects on patient reported outcomes research (PCOR), including serving as the principal investigator of a multi-year AHRQ-funded grant, the Electronic Data Methods (EDM) Forum and the editor-in-chief of the peer-reviewed open access journal eGEMs (http://repository.academyhealth.org/egems). She is on the executive leadership team for the coordinating center of PCORnet for PCORI and is principal investigator of HSRProj, a database of research in progress supported by the National Library of Medicine. Dr. Holve is AcademyHealth’s primary staff working with AcademyHealth’s Methods Council and the HSR Learning Consortium and manages AcademyHealth’s online learning activities. Previously she was a senior policy analyst with the Henry J. Kaiser Family Foundation. She holds a PhD in public health with an emphasis in health services research from the Bloomberg School of Public Health at Johns Hopkins University and masters’ degrees in public health and public policy from the University of California at Berkeley.

Betsy L. Humphreys, MLS is Deputy Director of the U.S. National Library of Medicine (NLM) at the National Institutes of Health (NIH). As Deputy Director, she shares responsibility with the Director for overall direction and coordination of the Library’s information service, outreach, standards, research, and grant programs and is responsible for day-to-day operations. Ms. Humphreys directed NLM’s Unified Medical Language System (UMLS) project for many years and leads the Library’s extensive activities related to the development and support of standard clinical terminologies used in electronic health records and genetic information sources. Since 2007, she has been the U.S. representative to the general assembly of the International Health Terminology Standards Development Organisation, serving as its founding chair from 2007 to 2010. Ms. Humphreys serves on both the Scientific and Administrative Data Councils at the NIH and contributes to the development of NIH and HHS policy related to health information technology and public access to research results (publications and data), including clinical trial registration and results submission. She has authored numerous articles in professional journals. Ms. Humphreys is a member of the Institute of Medicine of the National Academy of Sciences, a Fellow of the American College of Medical Informatics, and a Fellow of the Medical Library Association. She has received a number of awards, including the Marcia C. Noyes Award, the Medical Library Association’s highest honor; the Morris F. Collen Award of Excellence from the American College
of Medical Informatics; the President’s Meritorious Rank Award in the Senior Executive Service; and the Smith College Medal. Ms. Humphreys received her BA from Smith College, Phi Beta Kappa, and MLS from the University of Maryland, College Park.

**Charles Jaffe, MD, PhD** is the Chief Executive Office of Health Level Seven International (HL7). In the course of more than 30 years, Dr. Jaffe has held various leadership roles in health information management and technology. Prior to joining HL7, he was the Senior Global Strategist for the Intel Digital Health Group. In addition, he led a national research consortium, founded a consultancy for research informatics, served as the Global Vice President of Medical Informatics at AstraZeneca, and was the Vice President of Life Sciences at SAIC. Dr. Jaffe has served on various Boards of Directors of healthcare and healthcare IT organizations. He has collaborated with major charitable foundations, and has led research efforts in basic science and clinical medicine. Dr. Jaffe has held academic positions at the National Institutes of Health and the Lombardi Cancer Center, as well as serving in research roles in the Departments of Medicine and Pathology, and in the School of Engineering. In addition, Dr. Jaffe has been the contributing editor for several journals and has published on a range of subjects, including clinical management, informatics deployment, and healthcare policy. He has been a contributor and contributing editor of several books, including those on basic medical science and medical informatics.

**Kimberly Johnson** is President of ResearchTec, LLC, a research data consultancy. Over 24 years, she served as the IT Director for the Duke Comprehensive Cancer Center and later as IT Director for the Cancer and Leukemia Group B, an NCI Cooperative Group now known as the Alliance for Clinical Trials in Oncology. Ms. Johnson has supported both basic science and clinical research. She co-founded an international conference called the Critical Assessment of Microarray Data Analysis (CAMDA) in 2000 and co-edited three volumes of the conference proceedings (2000-2002). The CAMDA conference has grown substantially and is still active today. Ms. Johnson served on numerous National Cancer Institute Committees to forward the use of technology in cancer research. Ms. Johnson now consults with industry and academic medical centers. She specializes in strategic planning for technology, data warehousing, and the efficient collection and use of scientific data, with a particular interest in the integration of clinical research systems and electronic health records. She has recently begun an entrepreneurial effort to start a preclinical drug discovery company to move promising compounds through the preclinical development stages as quickly as possible. Called Preclinix, the company will assist small biotechs with in silico discovery techniques to model promising drug candidates, provide the necessary capital, and manage the subsequent development process.

**Rebecca D. Kush, PhD** is Founder, President, and CEO of the Clinical Data Interchange Standards Consortium (CDISC), a non-profit standards developing organization (SDO) with a focus on global clinical research standards and a vision of “Informing patient care and safety through higher quality medical research”. Dr. Kush has over 30 years of experience in the area of clinical research, including positions with the U.S. National Institutes of Health, academia, a global CRO, and biopharmaceutical companies in the U.S. and Japan. She earned her doctorate in Physiology and Pharmacology from the University of California, San Diego (UCSD) School of Medicine. Dr. Kush has presented keynotes in the U.S., Japan, South America, and Europe. She has authored numerous publications for journals, including the *New England Journal of Medicine* and *Science Translational Medicine*. She has developed a Prescription Education Program for elementary and middle schools and was named in *PharmaVOICE* in 2008 as one of the 100 most inspiring individuals in the life-sciences industry. Dr. Kush has served on the Board of Directors for the U.S. Health Information
Technology Standards Panel (HITSP) and the Drug Information Association (DIA), Health Level 7 (HL7) and ACRES, and was a member of the advisory committee for the WHO International Clinical Trials Registry Platform. She currently serves as a member of the Informatics Oversight Committee (now the IT Workgroup) of the National Cancer Advisory Board (NCAB) and was appointed in 2011 to represent research on the U.S. Health Information Technology (HIT) Standards Committee (HITSC).

**Peter M. Loupos** has been responsible for providing the vision, strategy, and leadership for innovation and technology initiatives in the pharmaceutical and healthcare industries. Peter began his career in Health Information Technology where he led the development of clinical, financial, and physician services in the U.S., Europe, and Japan. He joined Rorer Pharmaceutical to lead the R&D Information Technology organization, growing in responsibility through successive mergers until the creation of Sanofi-Aventis. During this time he was recognized for his achievements in the design and delivery of industry leading solutions to support the life sciences. He then joined the R&D Strategic Initiatives group focusing on trends shaping the Pharmaceutical industry. He was a co-author of a PhRMA white paper anticipating the impact and opportunities through eHealth and contributed to the launch of numerous national and international breakthrough initiatives. He played a leading role in the development of the corporate digital strategy and led the eHealth working group. Peter is currently a member of **Partners in Patient Health** at Sanofi, where he is responsible for the development of strategies and partnerships with patient groups to accelerate science and innovation, supporting key platforms such as patient-centered research, translational and personalized medicine, improving clinical development, and open innovation collaboration models.

**Amita Malik** is Senior Product Strategist at Oracle’s Health Sciences Global Business Unit. Throughout her career she has focused on Life Sciences industry, specifically working with data capture software used in clinical trials. At Oracle, she works on Oracle’s InForm™ EDC product line and is looking at ways to bring EHR data into EDC. Ms. Malik joined Oracle via the Phase Forward acquisition. At Phase Forward, she worked in Technical Consulting positions and implemented extensive projects with their EDC line of products. She delivered several comprehensive custom solutions and integrations for both Cloud and On-Premise customers. She also led technical efforts rolling out variety of new products internally and at top tier Pharmaceutical, Biotech and Medical Device companies. Prior to joining Phase Forward, Ms. Malik held various software development positions, including at Vips BioMedical Services (a WebMD Company) where she worked on their EDC line of products. Ms. Malik holds a MS degree in Computer Engineering from the University of Florida, Gainesville, FL.

**Ross D. Martin, MD, MHA** is Vice President of Policy and Development at the American Medical Informatics Association (AMIA). Before joining AMIA in December 2012, he was Specialist Leader and co-lead of the healthcare go-to-market team in the Federal Strategy practice at Deloitte Consulting LLP, a global consulting firm, where he focused on the technology standards and policies that support adoption and meaningful use of electronic health records, health information exchange, and the convergence of clinical research and clinical care. Dr. Martin has served in numerous health information technology standards development and advocacy organizations including the American Health Information Community’s Consumer Empowerment Workgroup, the Board of Trustees of the National Council for Prescription Drug Programs (NCPDP), the Board of Directors of the American National Standards Institute’s Health Information Technology Standards Panel (ANSI HITSP), and the Executive Committee of MedBiquitous. He has also been an active participant in HL7, the Health Information and Management Systems Society (HIMSS),
and the American Medical Informatics Association (AMIA). He is a frequent speaker on matters related to healthcare transformation. He was the first recipient of NCPDP’s Rising Star Award in 2004 and taught physician executives about health IT as a Senior Executive Education Fellow at the University of Maryland’s Smith School of Business. Prior to joining Deloitte in 2009, Dr. Martin was Director of Health Information Convergence at BearingPoint, Inc. From 2001 to 2007, he worked in various Business Technology and informatics roles of increasing responsibility at Pfizer, Inc., ultimately serving as Director of Healthcare Informatics at Pfizer where he worked on standards for electronic prescribing, electronic medical records, personal health records, the emerging nationwide health information network, and medical education. He has worked as an obstetric house physician, an urgent care physician, a consultant in managed care, health technology assessment, and medical informatics, and as a professional writer and healthcare publication editor. His peripatetic educational journey included a BA in political science from Wright State University, a medical degree from the University of Cincinnati, OB/Gyn residency at Bethesda Hospitals, a master of health services administration degree from Xavier University, and a National Library of Medicine fellowship in medical informatics at the Harvard/MIT Division of Health Sciences & Technology. An accomplished vocalist, musician, and writer, Dr. Martin has composed musicals, penned screenplays, and produced music videos. He is considered the world’s leading medical informatimusicologist, serving as President, Founder and Fellow of The American College of Medical Informatimusicology (www.ACMImimi.org). He performs on street corners, in coffeehouses, and, increasingly, at medical and technology conferences just often enough to remind himself why it’s good to have a day job. In 2004, he was awarded a U.S. Patent on the one-sided printing and manufacture of Möbius Strips and occasionally develops Words Without End® Möbius creations in support of worthy marketing and promotional efforts. Dr. Martin lives in a suburb of Washington, DC with his wife, Kym, a three-time, 30-year cancer survivor and software sales executive at FedSolutions, and his 12-year-old son, Taylor, who are both constant reminders of the need for accelerating the transformation of our healthcare system through the dynamic flow of health information and continuous process improvement. More than you likely care to know is available at www.rossmartinmd.com.

J. Michael McGinnis, MD, MA, MPP is a physician, epidemiologist, and long-time contributor to national and international health programs and policy. An elected Member of the Institute of Medicine (IOM) of the National Academies, he has since 2005 also served as IOM Senior Scholar and Executive Director of the IOM Roundtable on Value & Science-Driven Health Care. He created and stewards the IOM’s Learning Health System Initiative and its activities to transform the roles of value, science, and culture in health care. In prior appointments, he also served as founding leader for several key programs, including: the Robert Wood Johnson Foundation’s (RWJF) Health Group, the World Bank/European Commission’s Task Force for Health Reconstruction in Bosnia, and, in the U.S. government, the Office of Research Integrity, the Nutrition Policy Board, and the Office of Disease Prevention and Health Promotion. In the latter post, he served as Assistant Surgeon General and held continuous policy responsibilities for disease prevention through four Administrations (Presidents Carter, Reagan, Bush, Clinton), during which he conceived and served as guiding architect for a number of initiatives of ongoing policy importance, including the Healthy People national goals and objectives, the U.S. Preventive Services Task Force, the Dietary Guidelines for Americans, and development of the Ten Essential Services of Public Health. At RWJF, he founded the Health & Society Scholars program, the Young Epidemiology Scholars program, and the Active Living family of programs. Early in his career he served in India as an epidemiologist and State Director for the World Health Organization’s Smallpox Eradication Program, and later, in 1995-6, was Chair of the World Bank/European Commission Task Force for
Donald T. Mon, PhD leads the information management, standards, and interoperability practice in the Center for Advancement of Health Information Technology (CAHIT) at RTI International. He represents RTI in key national and international standards development activities and directs RTI’s business development and project implementations related to information management, as well as data, functional, and interoperability standards. Dr. Mon is immediate past chair of Health Level Seven International (HL7), co-chair of the HL7 EHR Work Group, president of the Public Health Data Standards Consortium, a subject matter expert in the U.S. Technical Advisory Group (the U.S. representative to ISO Technical Committee 215-Health Informatics), and has served on numerous electronic health records, personal health records, quality measurement, secondary data use, and healthcare transformation expert panels. The Mobile Health Work Group and the Usability Work Group were established under his leadership as chair of HL7. Dr. Mon has more than 35 years of experience in health information management/technology and informatics practice, research, and advocacy. Prior to joining RTI, Dr. Mon was vice president at the American Health Information Management Association (AHIMA) where he led the implementation of AHIMA’s top strategic national and international initiatives, including EHR; the legal EHR; personal health record (PHR); health information exchange (HIE), privacy, security, and confidentiality; vocabulary, terminology, classification, and coding systems; quality measurement; and reusing clinical data. He also developed IT strategic and business process reengineering plans and helped design, develop, and maintain large-scale databases and information systems for the Biological Sciences Division/Pritzker School of Medicine at the University of Chicago, Catholic Healthcare West, University of Illinois at Chicago, Premier, Inc., Oracle Corporation, Rush University Medical Center, and Schwab Rehabilitation Hospital. Dr. Mon earned a doctorate degree in education psychology, counseling, and research methods from Loyola University of Chicago and a bachelor’s degree in psychology from San Francisco State University.

Ryan Moog is Strategist for Research at Cerner Corporation in Kansas City, Missouri. Ryan is responsible for Cerner’s business strategy in research solutions, solution integration, research data, and services. Additionally, as part of Cerner’s Population Health business unit, Ryan is responsible for Cerner’s population-level research data strategy. Ryan previously held solution design and strategy positions for Cerner’s Discovere and PowerTrials research platforms, as well as Cerner’s i2b2 service offering. He received his bachelor’s degree from Butler University in Indianapolis, Indiana.

Scott Moss leads the Research Informatics R&D team at Epic. He and his team focus on designing and developing research-enabling functionality within Epic’s software. In addition, Scott has been involved in several industry standards development initiatives specifically addressing integration between Electronic Health Records and Clinical Research Management Systems. This included participating in the development of the IHE Retrieve Process for Execution and Clinical Research
Process Content profiles. He participates in the HL7 Regulated Clinical Research Information Management and IHE Quality, Research and Public Health work groups. Scott studied Applied Computer Technology at Colorado State University where he worked in the Research Services office.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI is President, Clinical Services and Chief Medical Officer of Nashville, Tennessee-based HCA (Hospital Corporation of America). He provides leadership for clinical services and improving performance at HCA’s 162 hospitals and more than 800 outpatient centers and physician practices. Current activities include implementing electronic health records throughout HCA, improving clinical “core measures” to benchmark levels, and leading patient safety programs to eliminate preventable complications and healthcare-associated infections. Before joining HCA in 2006, “the Honorable Jonathan B. Perlin” was Under Secretary for Health in the U.S. Department of Veterans Affairs. Nominated by the President and confirmed by the Senate, as the senior-most physician in the Federal Government and Chief Executive Officer of the Veterans Health Administration (VHA), Dr. Perlin led the nation’s largest integrated health system. At VHA, Dr. Perlin directed care to over 5.4 million patients annually by more than 200,000 healthcare professionals at 1,400 sites, including hospitals, clinics, nursing homes, counseling centers, and other facilities, with an operating and capital budget of over $34 billion. A champion for implementation of electronic health records, Dr. Perlin led VHA quality performance to international recognition as reported in academic literature and lay press and as evaluated by RAND, the Institute of Medicine, and others. Dr. Perlin has served previously on numerous Boards and Commissions including the National Quality Forum and the Joint Commission and currently serves on the Boards of the National Patient Safety Foundation and Meharry Medical College. He chairs the U.S. Department of Health and Human Services Health IT Standards Committee and has been elected chair of the American Hospital Association for 2015. Recognized perennially as one of the most influential physician executives in the United States by Modern Healthcare, Dr. Perlin has received numerous awards including Distinguished Alumnus in Medicine and Health Administration from his alma mater, Chairman’s Medal from the National Patient Safety Foundation, the Founders Medal from the Association of Military Surgeons of the United States, and is one of a dozen honorary members of the Special Forces Association and Green Berets. Broadly published in healthcare quality and transformation, Dr. Perlin is a Fellow of the American College of Physicians and the American College of Medical Informatics. He has a Master's of Science in Health Administration and received his PhD in pharmacology (molecular neurobiology) with his MD as part of the Physician Scientist Training Program at the Medical College of Virginia of Virginia Commonwealth University (VCU). Dr. Perlin has faculty appointments at Vanderbilt University as Adjunct Professor of Medicine and Biomedical Informatics and at VCU as Adjunct Professor of Health Administration. He resides in Nashville, Tennessee, with his wife, Donna, an Emergency Pediatrics Physician, and children, Ben and Sarah.

Vijay Pillai is the Director of Health Sciences Strategy at Oracle Corporation’s Health Sciences Global Business Unit. He was instrumental in developing the company’s strategy and initial push into the health sciences industries. He leads the business and product strategy of Oracle’s Health Sciences Network, a self-service real-time network that helps healthcare institutions connect their patients with the most advanced clinical research available. His vision is to leverage health information to positively impact patient wellness and help industry accelerate the development of better, safer, and more targeted therapies across all populations. Vijay also led the Oracle team at Craig Venter’s Celera Genomics during the human genome initiative where high performance
computation standards for big data were developed. Vijay has an MBA and an undergraduate degree in Mathematics.

Ken Pool, MD, co-founder, Chief Operating Officer, and Chairman of OZ Systems, is recognized as one of the leading healthcare information technology experts - focused on public health, interoperability, and the meaningful exchange of data across health settings to improve care and outcomes. Ken has 20 years of experience in clinical and academic medicine, 15 years of experience in the health information technology sector, 15 years working with national public health programs designing and implementing integrated child health records, and another five years designing and implementing electronic education records serving early childhood education sectors. He is currently co-chair for the HL7 Public Health and Emergency Response Work Group whose mission is to address the requirements of public health agencies, while supporting globally-recognized HL7 standards to support clinical practice and the management, delivery, and evaluation of health services. The workgroup addresses population health, disease and event detection, immunization, vital records, public health registries, emergency preparedness, and reporting to monitoring and regulatory agencies. He also serves on several Office of the National Coordinator (ONC) subcommittees integral to public health and research. He has contributed to projects at the Centers for Disease Control and Prevention (CDC), the National Library of Medicine, and the Secretary’s Advisory Committee on Heritable Disorders in Children and Newborns. He also helped develop the new industry standard of Logical Observation Identifiers Names and Codes (LOINC) as part of his work with the Newborn Blood Screening Programs. A career innovator, Ken has been awarded patents for computer-automated implementation of user-definable decision rules for medical diagnostic or screening interpretations and for hierarchical analysis for professing brain stem signals to define a prominent wave. Before OZ Systems, Ken was a board certified neurologist and clinical electrophysiologist and served as Medical Director for the Neuroscience Center at Methodist Medical Center in Dallas and Medical Director of Neurology at the Dallas Rehabilitation Institute. Ken holds a BS degree from Southern Methodist University and an MD from the University of Texas Health Center at San Antonio, where he interned in internal medicine. He held his residency in clinical neurology and neurophysiology, as well as his fellowship in electrophysiology, at the University of Texas Southwestern Medical School in Dallas. As co-founder, Ken assures the entire OZ Systems team believes in the “behind the curtain magic” that brings innovation in information technology - and is known for his warm (yes, that means southern hospitality) yet no-nonsense approach to collaborations that ultimately improve the health and well-being of others.

Gurvaneet Randhawa, MD, MPH is a medical officer and is also AHRQ’s Senior Adviser on Clinical Genomics and Personalized Medicine. He is a past director of the U.S. Preventive Services Task Force program. He has worked at AHRQ for more than 11 years. Prior to joining AHRQ, he completed his Preventive Medicine residency at Johns Hopkins University and his Internal Medicine internship at University of Pennsylvania. He also trained for 9 years in biomedical research. His research was in cancer molecular genetics and also on genomic applications in tuberculosis control. This training occurred at Johns Hopkins in Baltimore, Maryland, and at M.D. Anderson Cancer Center in Houston, Texas. He was the lead author of four ARRA-funded RFAs that collectively built a national clinical electronic data infrastructure and advanced the methods to collect and analyze prospective, patient-centered outcomes data for Comparative Effectiveness Research (CER) and for Quality Improvement (QI). He was the program officer on all 12 grants that comprised four programs: scalable distributed research networks, enhanced registries for QI and CER, PROSPECT program, and the Electronic Data Methods Forum. He has previously worked with AHRQ’s DEcIDE program, which generated new CER knowledge. He provided scientific direction to two
DARTNet projects, which successfully created a new distributed research network in ambulatory care. He provided direction to a project that developed a new clinical decision support tool for BRCA tests in primary care practice to help implement USPSTF recommendations. This has been adapted for use by the CDC. His past work included being a program officer for three grants in the CERTs program and serving as a task order officer on numerous EPC reports. He has authored numerous publications, served as a peer-reviewer for several scientific journals, and served in several committees including the Secretary’s Advisory Committee on Genetics, Health and Society, and the PCORnet steering committee.

Mitra Rocca joined the Food and Drug Administration (FDA) in 2009 as the Senior Medical Informatician responsible for developing the health information architecture of the Sentinel System. She serves as the FDA CDER HealthIT lead focusing on various re-uses of EHR data for clinical research as well as development and implementation of data standards and controlled terminologies. Prior to joining the FDA, Mitra served as the Associate Director, Healthcare Informatics at Novartis Pharmaceuticals Corporation focusing on the re-use of the Electronic Health Record (EHR) for clinical research, pharmacovigilance and protocol design/feasibility. Mitra serves as the co-chair of HL7 Clinical Interoperability Council (CIC). She holds her advanced degree in Medical Informatics from the University of Heidelberg in Germany.

S. Trent Rosenbloom, MD, MPH is the Vice Chair for Faculty Affairs, the Director of Patient Engagement Technologies, and an Associate Professor of Biomedical Informatics with secondary appointments in Medicine, Pediatrics, and the School of Nursing at Vanderbilt University. He is a board certified Internist and Pediatrician who earned his MD, completed a residency in Internal Medicine and Pediatrics, a fellowship in Biomedical Informatics, and earned an MPH all at Vanderbilt. Since joining the faculty in 2002, Dr. Rosenbloom has become a nationally recognized investigator in the field of health information technology evaluation. His research has focused on studying how healthcare providers interact with health information technologies when engaging patients, documenting patient care, and making clinical decisions. Dr. Rosenbloom has successfully competed for extramural funding from the National Library of Medicine and from the Agency for Healthcare Research and Quality in the role of principal investigator. Funded research grants have included awards under career development (K) award, R01 and R18 funding mechanisms. Dr. Rosenbloom’s work has resulted in lead and collaborating authorship on over 60 peer reviewed manuscripts, which have been published in the *Journal of the American Medical Informatics Association*, *Pediatrics*, *Annals of Internal Medicine*, and *Academic Medicine*, among others. In addition, Dr. Rosenbloom has authored and coauthored five book chapters and numerous posters, white papers, and invited papers. He has been a committed member of the principal professional organization in his field, the American Medical Informatics Association (AMIA). He has served AMIA in leadership roles, including participating in: a Scientific Program Committee, the *Journal of the American Medical Informatics Association* (JAMIA) Editorial Board, a national Health Policy Meeting Committee, the JAMIA Editor in Chief search committee, and a Working Group on Unintended Consequences. As a result of his research success and service to AMIA, Dr. Rosenbloom was the annual recipient of the competitive AMIA New Investigator Award in 2009 and was elected to the American College of Medical Informatics (ACMI) in 2011. In addition, Dr. Rosenbloom has participated in study sections for the National Library of Medicine and the Agency for Healthcare Research and Quality. He has also participated as a member of the HL7 Pediatric Data Special Interest Group and the American Academy of Pediatrics’ Council on Clinical Information Technology. In addition, Dr. Rosenbloom is an active reviewer several journals covering general medicine, pediatrics, and biomedical informatics.
Iain Sanderson, BM, BCh joined Duke Health Technology Solutions and the School of Medicine as Chief Research and Academic Information Officer in August of 2012. In January 2014, he became Vice Dean for Research Informatics. Dr. Sanderson oversees informatics as it relates to research, education, and administration, and serves as the primary IT strategist for the School of Medicine. Dr. Sanderson spent 14 years at Duke as an associate professor in the Department of Anesthesiology and four years as Associate Chief Information Officer for the Duke University Health System. He left in 2007 to become the Chief Medical Information Officer for Health Sciences South Carolina, where he led the effort to bring an integrated clinical and translational research infrastructure to the state’s research universities and health systems. He also rebuilt biomedical informatics into a cohesive and effective program at the Medical University of South Carolina for its successful Clinical and Translational Science Award (CTSA). Vice Dean for Research Informatics, Dr. Sanderson uses his expertise to provide leadership in biomedical informatics, research computing, education, and technology innovation to support the academic and administrative needs of Duke’s research community.

Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN is Vice President of Informatics for HIMSS, a global, cause-based, not-for-profit organization focused on better health through information technology (IT). In her current role she is responsible for the areas of clinical informatics, standards and interoperability programs and initiatives. Sensmeier became Board Certified in Nursing Informatics in 1996, earned the Certified Professional in Healthcare Information and Management Systems in 2002, and achieved HIMSS fellowship status in 2005. Sensmeier has made contributions to enabling health information exchange through standards profiling and harmonization initiatives. She led advancement of Integrating the Healthcare Enterprise (IHE), an international standards organization which, over the past decade, has achieved both regional and international adoption of its public domain technical framework. Sensmeier is president of IHE USA which serves as a voice representing national health IT efforts for fostering the national adoption of a consistent set of information standards to enable interoperability of health IT systems. An internationally recognized speaker and author of multiple book chapters, articles, and white papers, Sensmeier was recognized in 2010 as a fellow with the American Academy of Nursing, the highest honor in the field of nursing. She is also co-founder and ex-officio chair of the Alliance for Nursing Informatics, a global collaboration of 30 distinct nursing informatics groups that represents a unified voice for nursing informatics professionals.

Eve Shalley is the Director, Life Sciences IT Services for Essex Management, an informatics and management consulting firm located in Maryland and Connecticut. Eve has over 25 years working in clinical and research IT. She has managed the global SAE reporting system for the world’s largest pharmaceutical company and led the pharmaceutical and drug development practice for a New York-based management and IT consulting firm. She is currently supporting the National Cancer Informatics Program at the NCI and is working with academic institutions to meet their bioinformatic and integration needs. Eve holds a Bachelor’s from Barnard College, Columbia University and is currently pursuing a Masters in Biotechnology.

Nancy Smider, PhD is the Research Informatics Program Manager at Epic. She focuses on Epic’s electronic health record system as an enabling and accelerating technology in support of the clinical research mission of organizations. Nancy also leads Epic’s annual Research Advisory Council conference which draws over 300 attendees from more than 100 of Epic’s customers, providing a broad perspective on the research-related efforts of leading healthcare organizations across the country. Nancy earned her PhD in 1993 from the University of Wisconsin, Madison. She did her
Post-Doctoral fellowship in health services research, after which she accepted a position as a Research Scientist at the University of Wisconsin, School of Medicine, where she continued her work as part of a multi-disciplinary team examining biopsychosocial models of health and disease. She joined Epic in 2001.

John H. Speakman serves as Senior Director, Research Information Technology at New York University Langone Medical Center (NYULMC). He joined NYULMC in 2012 from the National Cancer Institute (NCI), where he served, first as Associate Director for Clinical Research Programs, and then as Deputy Chief Information Officer for Scientific Programs, within NCI’s Center for Biomedical Informatics and Information Technology. Prior to NCI, he served in multiple research informatics leadership roles at Memorial Sloan-Kettering Cancer Center, where he was appointed in 1991 from the University of London in the United Kingdom. His career has focused on the application of data, especially clinical data, and information technology to biomedicine, with a particular focus on the real-world development and operational adoption of data standards as an enabler of interoperability between the fields of healthcare and life sciences. He serves on the Board of the Clinical Data Interchange Standards Consortium (CDISC), a non-profit organization that has established standards to support the acquisition, exchange, submission, and archive of clinical research data and metadata, on the International Advisory Board of the Farr Institute of Health Informatics Research in London, United Kingdom, and on the editorial boards of multiple journals.

Reed V. Tuckson, MD, FACP, a graduate of Howard University, Georgetown University School of Medicine, and the Hospital of the University of Pennsylvania’s General Internal Medicine Residency and Fellowship Programs, where he was also a Robert Wood Johnson Foundation Clinical Scholar, is currently the managing director of Tuckson Health Connections, a health and medical care consulting business that brings people and ideas together to promote optimal health outcomes. Previously, he enjoyed a long tenure as Executive Vice President and Chief of Medical Affairs for UnitedHealth Group, a Fortune 25 health and wellbeing company, which includes the nation’s largest health insurer and the industry’s most comprehensive health services company. Prior to that, Dr. Tuckson’s career includes leadership positions as Senior Vice President for Professional Standards of the American Medical Association (AMA); President of the Charles R. Drew University of Medicine and Science in Los Angeles; Senior Vice President for Programs of the March of Dimes Birth Defects Foundation; and the Commissioner of Public Health for the District of Columbia. Dr. Tuckson continues to be engaged in leadership positions across the continuum of health promotion and medical care delivery including basic science and its translation into clinical practice; the establishment of biotechnology enterprises; community and individual health enhancement; health information technology and data analysis; telemedicine; clinical care delivery and evaluation; and the integration of clinical medicine and public health systems. Dr. Tuckson is an active member of the Institute of Medicine of the National Academy of Sciences, serving on, or chairing, several boards and committees. He is also active on the Advisory Committee to the Director of the National Institutes of Health and serves on the Boards of Cell Therapeutics, Inc., LifePoint Hospitals, Inform Genomics, Inc., Howard University, and the American Telemedicine Association among others. He has past service on cabinet level advisory committees concerned with health reform, infant mortality, children’s health, violence, and radiation testing. The author of The Doctor in the Mirror, a book and media presentation focused on patient empowerment to overcome everyday health issues for Americans 55 and older, Dr. Tuckson was recently honored to be ranked ninth on the list of the “50 Most Powerful Physician Executives” in healthcare in my Modern Healthcare Magazine.
Thomas A. Verish, MS is Group Director in Global Development Operations at Bristol-Myers Squibb (BMS). He is responsible for the functional groups within Data Operations that provide services and support activities to the drug project teams. In particular, this includes operational ownership of various applications and system-based capabilities including Oracle Clinical, Oracle Siebel CTMS, TMF, MyTrials investigator portal, ePRO, data integration, and analytics. He is a member of the Transcelerate RBM technology team that is working to define technology requirements to support risk-based monitoring. Prior to joining BMS, Tom was responsible for global leadership and management of Data Management, Statistical Programming & Medical Writing for Pfizer Worldwide Research & Development. Tom holds a MS in Systems Management from the Florida Institute of Technology.

Stephen A. Weitzman, JD has four decades of experience as a practicing lawyer and science consultant in the pharmaceutical, medical device, food, and dietary supplement industries. He is a pioneer in the use of computers in legal and science research and litigation support systems from mainframe to personal computers. His current focus is on decision support systems using large medical record databases for healthcare analytics. His areas of expertise in health care include relational database, ontology, standards, full text data coding, and management in compliance with security and privacy laws and regulations. Steve cofounded DataPharm Foundation (now MedDATA) and served as Principal Investigator on the FDA–DataPharm “Drug Labeling” Cooperative Research and Development (CRADA) project. He proposed integration of outcomes databases from patient records to supply newly discovered safety threats so that warnings could be issued in real time through changes in labeling information for professionals and consumers. The project led to the creation of the NLM’s website for drug information called DailyMed. New York University School of Law, JD, 1968, and master’s degree Fellow of the Food and Drug Law Institute, LL.M. (Trade Regulation), 1969; New York University Medical School, Freshman Biochemistry, 1968–69; New York University, University College, AB, 1965.

David Yakimischak (“Yak”) is currently Executive Vice President and General Manager at Surescripts, the national e-prescribing network. He has been working in the fields of information technology and healthcare for over 30 years. After studying Computer Science at the University of Toronto, David started his career in Toronto, working at Merrill Lynch and then Dow Jones Telerate, where he held positions in IT and product management. In 1992 he relocated to the United States where he worked on the team bringing content such as the Wall Street Journal to the Internet. In 1999, he became Chief Technology Officer of Medscape, the leading internet destination for physicians and medical practitioners. In 2000, he launched the consumer health portal CBS HealthWatch, and was part of the senior management team that successfully IPO’d the company and merged with MedicaLogic. After the company was sold to General Electric (to become Centricity) and to WebMD, David joined Surescripts in 2006 as its first Chief Technology Officer. He and his team built the Surescripts network and prepared the company for the exponential growth that was about to come. From 100,000 prescriptions per month, the Surescripts system now handles over 5 million prescriptions per day. David was also responsible for Product Management, Customer Support, Implementation and Certification, Technical Operations, and Information Security. After the merger with RxHub in 2008, David became Chief Quality Officer and took on the responsibility of defining and running its clinical quality program. Starting with a blank sheet of paper, he built an industry leading quality management system, ensuring that electronic prescription quality, accuracy, and safety are measured, managed, and continuously improved. He instituted an innovative recognition program called the Surescripts White Coat of Quality. This annual designation is given to Electronic Medical Records vendors who demonstrate measurable
improvements in the quality of their e-prescribing systems. Over 80 organizations and installations have applied for and received their White Coats since the program’s inception in 2009. David served as a subject matter expert in the 2012 IOM publication Health IT and Patient Safety. He is the inventor on two U.S. patent applications on the topic of quality control of electronic prescriptions. He was also a member of the 2011 HIT Steering Committee (Power Team) on Electronic Prescribing of Discharge Medications. David is currently an MBA candidate at Johns Hopkins University and mentors graduate students at Columbia University in New York.
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Room 120
May 30, 2014

We look forward to your participation in the Digital Learning Collaborative meeting on May 30, 2014. If you have any questions regarding meeting logistics, please contact our office at syang@nas.edu or 202-334-1462.

MEETING LOCATION
The meeting will take place from 8:30am to 3:30pm on Friday, May 30, 2014 in Room 120 of the National Academy of Sciences Building, 2101 Constitution Avenue, NW, in Washington, DC. Breakfast will be available beginning at 8:00am.

HOTEL ACCOMODATIONS
While we are unable to reimburse guests for travel, we are happy to make hotel recommendations. Previous guests have enjoyed their stays at these hotels near the meeting site in Washington, DC (we do not have room blocks). If you would like assistance booking at the government per diem rate ($224), or close to it, please contact Sophie Yang by May 9 at syang@nas.edu. The State Plaza Hotel is generally happy to book at the government per diem rate if you call and say that you are a guest of the National Academies.

- State Plaza Hotel / 2117 E Street, NW / 202-861-8200 (7 minute walk)
- Hotel Lombardy / 2019 Pennsylvania Avenue, NW / 202-828-2600 (12 minute walk)
- One Washington Circle Hotel / 1 Washington Circle, NW / 800-424-9671 (16 minute walk)
- The River Inn / 924 25th Street, NW / 202-337-7600 (16 minute walk)

DIRECTIONS AND TRANSPORTATION

Airports: The meeting site is approximately 5 miles from Washington National Airport (a 20-minute cab ride depending on the time of day) and approximately 25 miles from Dulles International Airport (a 45-minute cab ride).

Metro: The Foggy Bottom metro stop (Orange/Blue Line) is located at 23rd and I Streets, NW. Walking from the metro to the NAS building takes approximately 12 minutes. The C Street Entrance to the NAS building is the closest entrance to the metro. A map is on page 2 of this memo.

Parking: The parking lot for the National Academy of Sciences is located on 21st Street, NW, between Constitution Avenue and C Street. However, space is very limited, so you may want to use an alternate mode of transportation. If the lot is full, there is a Colonial Parking garage near G and 18th Streets, NW (cash only). It is about 15 minutes walking distance from the NAS building.

Detailed driving and Metro directions to the National Academy of Sciences may be found at: http://www.nationalacademies.org/about/contact/nas.html
MAP OF FOGGY BOTTOM METRO TO NAS BUILDING