The Learning Health System Series

Optimizing Strategies for

CLINICAL DECISION SUPPORT

Summary of a Meeting Series

James E. Tcheng; Suzanne Bakken; David W. Bates; Hugh Bonner III; Tejal K. Gandhi; Meredith Josephs; Kensaku Kawamoto; Edwin A. Lomotan; Erin Mackay; Blackford Middleton; Jonathan M. Teich; Scott Weingarten; Marianne Hamilton Lopez, *Editors*

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"Knowing is not enough; we must apply.
Willing is not enough; we must do."

—GOETHE

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NAM Staff

Development of this publication was facilitated by contributions of the following NAM staff, under the guidance of Michael McGinnis, MD, MPP, NAM Leonard D. Schaeffer Executive Officer and Executive Director of the Leadership Consortium for a Value & Science-Driven Health System:

MARIANNE HAMILTON LOPEZ, PhD, MPA, Senior Program Officer and Project Director
MICHELLE JOHNSTON-FLEECE, MPH, Senior Program Officer
VANANH VO, Senior Program Assistant, after November 2016
ROSHEEN BIRDIE, Senior Program Assistant, until September 2016
LAURA DeSTEFANO, Director of Communications
KYRA E. CAPPELUCCI, Communications Specialist
MOLLY DOYLE, Communications Specialist

Consultant

JOE ALPER, rapporteur

REVIEWERS

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ANDREW BAZEMORE, MD, MPH, Robert Graham Center, American Academy of Family Physicians
JONATHAN B. PERLIN, MD, PhD, MSHA, MACP, FACMI, HCA (Hospital Corporation of America)
ADAM WRIGHT, PhD, FACMI, Harvard Medical School and Brigham and Women's Hospital

Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the content of the publication, nor did they see the final draft before it was published. Review of this publication was overseen by **Marianne Hamilton Lopez, PhD, MPA,** Senior Program Officer, NAM; and **Michael McGinnis, MD, MPP,** Leonard D. Schaeffer Executive Officer, NAM. Responsibility for the final content of this publication rests entirely with the editors and the NAM.

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APPENDIXES

ACRONYMS AND ABBREVIATIONS

AFA	Analytic Framework for Action
AHRQ	Agency for Healthcare Research and Quality
AMIA	American Medical Informatics Association
API	application program interface
APMs	alternative payment models
CDS	clinical decision support
CDSC	Clinical Decision Support Consortium
CHIME	College of Healthcare Information Management Executives
CMS	Centers for Medicare and Medicaid Services
CPG	clinical practice guidelines
EHR	electronic health record
FDA	U.S. Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
HFMA	Healthcare Financial Management Association
HHS	Department of Health and Human Services
HIMSS	Healthcare Information and Management Systems Society
HITECH	Health Information Technology for Economic and Clinical Health Act
HL7	Health Level Seven international standards
ICER	Institute for Clinical and Economic Review
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
ISMP	Institute for Safe Medication Practices
IT	information technology

MACRA	Medicare Access and CHIP Reauthorization Act
MRI	magnetic resonance imaging
NAM	National Academy of Medicine
NASEM	The National Academies of Sciences, Engineering, and Medicine
NCQA	The National Committee for Quality Assurance
NQF	National Quality Forum
ONC	Office of the National Coordinator for Health Information Technology
PCOR	patient-centered outcomes research
PCORI	Patient-Centered Outcomes Research Institute
PSOs	patient safety organizations

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CLINICAL DECISION SUPPORT

CHALLENGES TO CLINICAL DECISION MAKING

Facilitative clinical decision support (CDS) is a practical necessity for every clinician in our rapidly evolving health and healthcare landscape. A central promise of health information technology (health IT) within the learning health system is its potential to ameliorate the burden that exponentially expanding clinical knowledge as well as care and choice complexity place on the finite time and attention of clinicians, patients, and every other member of the care team. Realizing this promise demands that health IT deliver the right information, at the right point and format within the decision and care processes to optimize outcomes by consistently applying the best available knowledge in context of every patient's needs and goals. Delivering information this way to all patients and care teams, routinely and at pace with our expanding knowledge, in turn demands shared and sustainable solutions. These solutions must be collaboratively developed across affected stakeholders to address key challenges and exponentially accelerate the availability of reliably curated information resources that are readily, affordably, and seamlessly incorporated with patient-centered, clinician-friendly workflows via interoperable health IT systems and patient data.

A continuously learning health system is driven by the seamless and rapid generation, processing, and practical application of the best available evidence for the circumstance. To achieve such a system, effective and timely approaches for managing the ever-expanding and complex array of clinical knowledge and person-specific data are essential for accelerating routine identification and delivery of the best available evidence to the point of choice by clinicians and patients. Yet our current health care system falls substantially short of both the need and the potential in this respect. As the Charter of the National Academy of Medicine's (NAM) Leadership Consortium for a Value & Science-Driven Health System states: "Care that is important is often not delivered. Care that is

delivered is often not important." In large part, the mismatch results from the failure to update and apply the available evidence.

The rapidly increasing growth in diagnostic and treatment options—accelerated still more by advances in genomics and proteomics and the burgeoning amount of available clinical data—presents a constant and ongoing gap between practice and potential. This gap will expand unless a systematic effort is undertaken to develop and apply tools that can accelerate the capture, assessment, validation, translation, and real-time delivery of best available, appropriately-tailored evidence for point of care decisions by clinicians, patients, and families.

Decision-making guidelines, prompts, and assists, (i.e., CDS tools that deliver the best available information seamlessly and effectively to the point of clinical decisions), are necessary for improved and efficient care. Although it is technically feasible to deliver timely, validated evidence in a useful fashion to clinicians, patients, and families, the actual implementation of such support has generally been the exception rather than the norm. Implementation of CDS tools experienced by clinicians, patients, and other care team members to date, have often been expensive, disruptive, inconsistent, unvalidated, and not presented in timely or fluid points in the decision process.

CLINICAL DECISION SUPPORT CONCEPTS

In the last decade, Electronic Health Record (EHR) adoption rates have soared. As of 2015, 87 percent of office-based physicians had adopted any EHR, 78 percent had adopted a certified EHR, and 54 percent had adopted a Basic EHR, (Jamoom & Yang 2016), paving the way for increased use of CDS tools that leverage EHR data to provide decision support to clinicians and patients. CDS capabilities operating in concert with EHRs hold great potential to help the nation's health care systems provide access to the best current evidence in usable form and at strategic points within care and decision-making processes to help clinicians, patients, and other care team members improve health care outcomes and lower the overall cost of care. As described by the Office of the National Coordinator for Health Information Technology (ONC),[1] "CDS provides clinicians, staff, patients, and other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. CDS encompasses a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and

1 https://www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds (accessed 3/24/2017)

reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools." CDS is a sophisticated health IT functionality that does more than provide alerts, notifications, or explicit care suggestions.

CDS requires computable biomedical information, person-specific data, and a reasoning or inferencing mechanism that combines knowledge and data to generate and present helpful information to clinicians, patients, and care team members as care is being delivered. This information must be filtered, organized, and presented in a way that supports the current workflow, allowing the user to make an informed decision quickly and to take action on that decision. Different types of CDS may be ideal for different processes of care in different settings, and effective CDS must be relevant to those who can act on the information in a way that supports completion of the right action. CDS is not intended to replace clinician judgment, but rather to provide information to assist care team members in managing the complex and expanding volume of biomedical and person-specific data needed to make timely, informed, and higher quality decisions based on current clinical science.

CDS tools can be directed toward reduction of errors and adverse events, promotion of best practices for quality and safety, cost profile improvement, rapid response to public health emergencies, and more—such as supporting shared decision-making or tailoring plans of treatment to patient preferences. Successful CDS designs:

- **provide measurable value** in addressing a recognized problem area or area for improvement;
- **leverage multiple data types** to bring the most current and relevant evidence and evidence-based practice recommendations to bear on clinical decisions;
- **produce actionable insights** from the abundant multiple data sources;
- **deliver information to the user** that allows the user to make final practice decisions, rather than being opaque and acting autonomously;
- **demonstrate good usability principles**, including clear displays and rapid action options;
- **are testable in small settings** with a clear path to larger scalability; and
- **support successful participation in quality and value improvement initiatives.**

In the latter respect, CDS goes well beyond alerts to make use of various CDS activators and approaches aligned with policies, care models, and goals that focus on providing better care at better value. Example approaches include value-based Alternative Payment Models (APMs), the Patient-Centered Medical Home model, and the clinician-consumer *Choosing Wisely* initiative's aims to help patients choose care that is needed and not duplicative, free from harm, and supported by evidence. These initiatives ask and—in a variety of ways ranging from reimbursement incentives to recognition to professional satisfaction—reward health care organizations, individual clinicians, and other members of care teams for delivering optimal care and value. Successful CDS implementations help clinicians continuously achieve and advance care quality and outcomes benchmarks.

STATUS AND BARRIERS

A growing body of literature demonstrates the positive impact CDS can have on care processes, clinical outcomes, and economic outcomes. The Agency for Healthcare Research and Quality (AHRQ) commissioned a literature review in 2012 that found evidence showing that CDS had positive impact on process measures, such as how reliably clinicians ordered necessary and evidence-based preventive and treatment services, and on increasing user knowledge relevant to a medical condition (Lobach et al., 2012). Studies have shown that well-executed CDS can reduce adverse events from drug-drug interactions (Smithburger et al., 2011; Sonnichsen et al., 2016) and medication errors (Fritz et al., 2012); decrease unnecessary laboratory testing (Felcher et al., 2017); reduce cardiovascular risk in patients with type 2 diabetes (Cleveringa et al., 2008); improve practitioner performance (Garg et al., 2005); increase cardiovascular disease risk assessment in routine primary care practice (Wells et al., 2008); improve public health outcomes associated with outbreaks of foodborne illness (Wu et al., 2012); and produce cost savings associated with hospital-based pharmacy interventions (Calloway et al., 2013).

Taken together, the available evidence shows that while there is significant room for improvement, CDS in the right context—implemented properly with the right kind of management—can reduce errors, improve the quality of care, reduce cost, and ease the cognitive burden on health care providers. As a result, achieving widespread adoption of CDS by the nation's health systems and providers will be essential to assuring that the substantial and ongoing investments in biomedical science and innovation are translated as benefits to American taxpayers in terms of improved health and health care in a greatly accelerated timeframe.

Indeed, in a 10-year vision statement for health IT-enabled quality improvement, ONC called for advancing health IT capabilities centered around CDS and clinical quality measurement to enable robust and continuous quality improvement (ONC, 2014). These health IT capabilities will provide all members of the clinical care team real-time access to the best available evidence in a way that is aligned with and does not add burdens to their already heavy workload, but that instead takes advantage of the tremendous advances in computing power and computational analysis to help them efficiently manage, assimilate, and apply the best available evidence to support making better choices that lead to better outcomes for all patients.

Despite its potential, CDS implementation and actualization remain nascent due to the many barriers to realizing the full benefits of CDS-facilitated value improvement. A key barrier is the present need for most health care organizations to independently develop, deploy, and manage CDS content, leading to high costs and redundant work across the system. Factors contributing to these challenges include:

- **lack of reliable, shareable CDS content and capabilities** that can be easily adopted across health care organizations and health IT systems;
- **absence of systematic means to validate content** for provision across delivery venues in a reliable, accessible, and updatable fashion;
- the **technical difficulties** of sharing CDS across institutions and EHR systems; and
- **suboptimal user interfaces, implementation choices, and workflows** that result in many clinicians viewing CDS more as a nuisance than as a helpful tool.

See Chapter 3 for a discussion of the challenges facing widespread adoption of CDS. To address these challenges and realize the full potential of CDS within real-world environments requires the identification of key priorities for action focused on achieving the potential of these tools to improve the quality, safety, and efficiency of health care.

NAM-ONC PROJECT ON CDS STRATEGIES

In an effort to identify necessary key priorities for action, the NAM Leadership Consortium for a Value & Science-Driven Health System, with support from the ONC, convened a collaborative effort with health care leaders to better understand potential opportunities and practical strategies for improving CDS practices and adoption. Over a three-meeting series, expert authorities

met to describe current and emerging CDS practices, identify collaborative opportunities to accelerate progress in the real-time application and use of CDS to inform health and health care decision making, and provide guidance on implementation challenges and strategies at a national scale. In addition to the meeting series, the CDS Steering Committee initiated small subcommittee workgroups to address a number of priority elements of CDS including content development (CDS authoring), platform integration (technical implementation), functionality and measurement (operations), and dissemination (distribution). This project and the associated meeting series were driven by a partnership between the NAM Leadership Consortium and ONC, with the meetings, work groups, and other activities organized by a steering committee.

Steering committee

NAM staff collaborated with ONC staff to gather information and health IT-specific perspectives and then identified a steering committee and other engaged expert authorities who, over the course of nearly a year, worked together and in consultation with others in the field to describe current and emerging CDS practices, identify approaches to their validation, explore collaborative opportunities to accelerate progress in the real-time application and use of CDS of proven efficacy in informing health and health care decision-making, and consider implementation challenges and strategies at a national scale. The steering committee members were Suzanne Bakken, professor of biomedical informatics at Columbia University; Hugh Bonner III, associate program director at Saint Francis Family Medicine Residency Program, Saint Francis Healthcare; Tejal K. Gandhi, president and chief executive officer of the National Patient Safety Foundation; Meredith Josephs, senior medical director and senior director for clinical information technology and training at Privia Health; Edwin A. Lomotan, medical officer and chief of clinical informatics at the Agency for Healthcare Research and Quality (AHRQ); Erin Mackay, associate director for health IT programs at the National Partnership for Women and Families; James E. Tcheng (chair), professor and interventional cardiologist at Duke University School of Medicine; Jonathan M. Teich, emergency medicine physician at Brigham and Women's Hospital; and Scott Weingarten, senior vice president and chief clinical transformation officer at Cedars-Sinai Health System.

Workflow and working groups

The first meeting, held March 16, 2016, had the goal of exploring issues and opportunities to take the real-time application and use of CDS to the next

level in informing health and health care decision-making. The presentations and discussions at the first meeting described current and emerging CDS practices, identified approaches to validating CDS resources, and considered implementation challenges facing frontline providers, governance issues, and strategies to spread and scale effective CDS approaches. The second meeting, convened on October 27, 2016, highlighted opportunities and practical strategies for improving CDS practices and adoption, and featured reports from four working groups focused on CDS content, system integration, operations, and spread. This meeting also included discussions about potential key priorities for next steps for the field and steps that ONC and the NAM could take to accelerate progress. In preparation for the second meeting, the CDS steering committee initiated small workgroups to address four specific topics: content development (CDS authoring), platform integration (technical implementation), functionality and measurement (operations), and dissemination (distribution). Each workgroup met virtually before the meeting to develop brief action plans for their assigned topics.

The CDS **authoring workgroup**, led by Kensaku Kawamoto, associate chief medical information officer, director of knowledge management and mobilization, and assistant professor of biomedical informatics at the University of Utah, addressed standardized approaches and best practices for creating, managing, and curating computable CDS content. This workgroup also considered models for CDS learning, ONC's role in managing standardization and CDS polarization, and opportunities for funding CDS authoring activities.

Steering Committee member Scott Weingarten led the platform integration and technical **implementation workgroup**, which examined preferred and best practice CDS implementation approaches, data interchange and interoperability foundations and prerequisites, and the role the federal government and industry could play in managing CDS technical implementation standards.

The **operations workgroup**, led by Steering Committee member Jonathan Teich, reviewed the available tools for workflow assessment and representation, the challenge of creating consistent and reliable team-based CDS workflow insertion points, and the need for metrics to measure and validate CDS implementation.

The **distribution workgroup**, led by Blackford Middleton, chief informatics and innovation officer at Apervita, Inc., examined the CDS marketplace for content dissemination and discussed business rules that would assure a vibrant and successful marketplace. This workgroup also considered constructs for feedback loops to inform value, and the financial business case for CDS development and adoption, and the possible role of public-private partnerships and incentives in efforts to spread CDS systems.

CDS WORKING GROUPS	
Workgroup	**Workgroup Focus**
Content Development (CDS authoring)	• standardized approaches and best practices for creating, managing, and curating computable CDS content • models for CDS learning • the federal government's role in managing standardization and CDS polarization • opportunities for funding CDS authoring activities
Platform Integration (technical implementation)	• preferred and best practice CDS implementation approaches • data interchange and interoperability foundations and prerequisites • the role the federal government and industry could play in managing CDS technical implementation standards
Functionality and Measurement (operations)	• available tools for workflow assessment and representation • the challenge of creating consistent and reliable team-based CDS workflow insertion points • the need for metrics to measure and validate CDS implementation
Dissemination (distribution)	• the CDS marketplace for content dissemination • business rules that would assure a vibrant and successful marketplace • constructs for feedback loops to inform value • the financial business case for CDS development and adoption • possible role of public-private partnerships and incentives in efforts to spread CDS systems

The partner organizations

ONC, which funded this project, is at the forefront of the federal government's health IT efforts and is a resource to the nation's entire health system to support effective use of health IT and promote nationwide health information exchange to improve health care. ONC is the principal federal entity charged with coordinating nationwide efforts to implement and use the most advanced health IT and develop standards to facilitate electronic exchange of health information. Congress mandated the position and office of the National Coordinator for Health Information Technology in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) in 2009. ONC is located within the Office of the Secretary of the Department of Health and Human Services (HHS).

As the convening body for this initiative, the NAM, through the Leadership Consortium for a Value & Science Driven Health System, was tasked with bringing together experts and stakeholders to consider and reflect upon the key issues for optimizing clinical decision support, and to synthesize the information and insights gathered in this NAM Special Publication. Broadly, the NAM

Leadership Consortium was formed to help transform how the nation generates and uses evidence on clinical effectiveness to improve health and health care, including facilitating continuous improvement in the health care system through enhanced transparency on outcomes and cost. Its vision is a continuously learning health system in which:

- science, informatics, incentives, and culture are aligned for continuous improvement and innovation;
- best practices are seamlessly embedded in the care process;
- patients and families are active participants in all elements; and
- new knowledge is captured as an integral by-product of the care experience.

The NAM Leadership Consortium's approach to address the goal that 90 percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information and reflect the best available evidence is to serve as a forum to facilitate the collaborative assessment and action around issues central to achieving its vision and goal. To address the challenges of improving evidence development, evidence application, and the capacity to advance progress on both dimensions, Leadership Consortium members, all leaders in their fields, work with their colleagues to identify the issues not being adequately addressed, the nature of the barriers and possible solutions, and the priorities for action. They then work to marshal the resources of the sectors represented on the Leadership Consortium to work for sustained public-private cooperation for change. Activities include collaborative exploration of new and expedited approaches to assessing the effectiveness of diagnostic and treatment interventions, better use of the patient care experience to generate evidence on effectiveness and efficiency of care, identification of assessment priorities, and communication strategies to enhance provider and patient understanding and support for interventions proven to work best and deliver value in health care.

A common commitment to certain principles and priorities guides the activities of the Leadership Consortium and its members. These include:

- the commitment to the right health care for each person;
- putting the best evidence into practice;
- establishing the effectiveness, efficiency, and safety of medical care delivered;
- building constant measurement into the nation's health care investments;
- establishing health care data as a public good;
- shared responsibility distributed equitably across stakeholders, both public and private;

- collaborative stakeholder involvement in priority setting;
- transparency in executing activities and reporting results; and
- subjugating individual political or stakeholder perspectives in favor of the common good.

COMMON THEMES AND PRIORITIES

Informed by discussions, presentations, and concurrent work throughout the course of project period, this publication reports and reflects on the following issues: 1) current state-of-the-art and emerging CDS practices; 2) barriers to and strategies for implementing CDS within the context of existing EHR systems; and 3) challenges for developing and validating CDS content. The publication concludes by presenting priorities for action to expand CDS adoption and use by the nation's health care systems and providers.

Common themes

Common themes raised throughout this project include:

- Much like in-person peer learning (e.g., grand rounds with residents), CDS should serve as a **tool to help clinicians at the front-line** think through options at the point of care.
- Current challenges include the **various pathways for implementation of CDS** within different health care organizations**, lack of standards and incentives** to use and improve CDS**, poor data quality**, and **gaps in the evidence**.
- One of the greatest challenges for scaling CDS adoption is its limited financial business case. It remains **difficult to demonstrate the return on investment of CDS**, especially against many competing priorities at the delivery system level.
- Current CDS **lacks measurement practices and standards**. Evaluation of current and future CDS should assess whether it measurably improves quality, health outcomes, safety, cost, and physician productivity.
- The current health ecosystem presents opportunities for:
  - **increased engagement of stakeholders** in the design, implementation, and use of CDS;
  - the **incorporation of new knowledge**, including patient-reported outcomes and contextual information, into CDS;
  - a renewed focus on **clinical decision support for health care teams**;
  - the **creation of new multistakeholder partnerships** to develop practical implementation tools and lead standardization and regulatory efforts;

- the development and deployment of CDS **for public health response**; and
- the strengthening of the **CDS implementation evidence-base**.

Priorities

In addition to these common themes, a number of priorities emerged throughout the meetings' discussions. These were crystalized in a comprehensive list of key actions for optimizing strategies for CDS adoption and use (Box 1–1) developed between meeting two and meeting three of the series, reflecting an approximation of the actionable, collaborative next steps that health systems, researchers, and EHR developers could initiate over the next five years. These priorities for action then served as the focus for the third meeting's presentations and discussions, which in addition to considering these priorities also aimed to identify the organizations that will take the lead in their implementation. These actions will require commitment by multiple stakeholders and are intended to move forward in a way that complements and enhances clinical practice.

BOX 1–1

Priorities for Action

Develop, test, establish, validate, and apply CDS standards

1. Establish CDS technical standards.
2. Engage federal leadership for CDS standards development and maturation.
3. Create a CDS technical information resource.

Encourage CDS adoption, use, and assessment at the delivery system level

4. Disseminate best practices.
5. Create a national CDS repository network.
6. Measure CDS usage.
7. Develop tools to assess CDS efficacy.
8. Publish performance evaluations.
9. Market CDS to stakeholders.
10. Promote financing and measurement to accelerate CDS adoption.

Establish a national CDS infrastructure

11. Create a CDS legal framework.
12. Develop a multistakeholder CDS learning community to inform usability.
13. Establish an investment program in CDS research.

The purpose of this project was not to replicate the many exemplar efforts—described in Chapter 2—to study, regulate, or implement CDS that have occurred (and are occurring) throughout the field. Instead, this partnership of key stakeholders formed to take into account the current political/regulatory/financial environment and incorporate existing best practices, study findings, and expertise to facilitate discussion on actionable next steps for optimizing strategies for CDS within the U.S. health system. This publication summarizes those discussions as they were presented over the course of three meetings and outlines approaches to achieve widespread adoption of CDS.

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2

LAYING THE CDS FOUNDATION STONES

This project draws from and builds upon important initiatives to improve the delivery of care through effective CDS. In essence, CDS is the twenty-first century version of clinical practice guidelines (CPGs)—systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances (Institute of Medicine, 1990)—presented in real time within the context of a patient's EHR. In 2011, a report by the Institute of Medicine (now the National Academy of Medicine), *Clinical Practice Guidelines We Can Trust* stated that clinicians can no longer stay abreast of the rapidly expanding knowledge base related to medicine, that "clinicians increasingly are barraged with a vast volume of evidence of uncertain value," and that increased adoption of EHRs and CDS offers unique opportunities to rapidly move clinical knowledge from the scientific literature to the patient encounter. At the same time, the report noted, CPGs—and by inference CDS since it is often based on CPGs—do not dictate a one-size-fits-all approach to patient care but rather serve to enhance clinician and patient decision-making by clearly describing and appraising the scientific evidence behind clinical recommendations and making them relevant to the individual patient encounter (Institute of Medicine, 2011).

This chapter highlights contributions to developing strategies to develop CDS as an important component of EHR systems. These prior efforts have informed this project and provided important lessons for this current initiative.

A ROADMAP FOR NATIONAL ACTION ON CDS

In 2005, ONC commissioned the American Medical Informatics Association (AMIA) to develop a tactical plan to guide federal and private sector activities to advance the development and adoption of CDS. The resulting roadmap, issued in 2006, included three pillars and six strategic objectives for CDS to "ensure that optimal, usable, and effective clinical decision support is widely available to providers, patients, and individuals where and when they need it to make health

care decisions" (Osheroff et al., 2007). The AMIA roadmap's three pillars and six strategic objectives were:

- Pillar 1: Best knowledge available when needed
  - Strategic Objective A: Represent clinical knowledge and CDS interventions in standardized formats so that a variety of knowledge developers can produce this information in a way that knowledge users can readily understand, assess, and apply it.
  - Strategic Objective B: Collect, organize, and distribute clinical knowledge and CDS interventions in one or more services from which users can readily find the specific material they need and incorporate it into their own information systems and processes.

- Pillar 2: High adoption and effective use
  - Strategic Objective C: Address policy/legal/financial barriers and create additional support and enablers for widespread CDS adoption and deployment.
  - Strategic Objective D: Improve clinical adoption and usage of CDS interventions by helping clinical knowledge and information system producers and implementers design CDS systems that are easy to deploy and use, and by identifying and disseminating best practices for CDS deployment.

- Pillar 3: Continuous improvement of knowledge and CDS methods
  - Strategic Objective E: Assess and refine the national experience with CDS by systematically capturing, organizing, and examining existing deployments. Share lessons learned and use them to continually enhance implementation best practices.
  - Strategic Objective F: Advance care-guiding knowledge by fully leveraging the data available in interoperable EHRs to enhance clinical knowledge and improve health management.

The roadmap included a comprehensive work plan that outlined the full set of tasks needed to create both a robust infrastructure for developing and delivering CDS interventions and an environment that encourages widespread adoption and continual refinement of these interventions. It also included a set of critical path tasks that could be implemented and produce results in the near term, and provide a foundation for further efforts to create a national CDS infrastructure, as well as a straw-man proposal for demonstrating a scalable, outcome-enhancing CDS system.

Lessons from the roadmap exercise included the need to develop standard formats for knowledge and interventions and to conceive approaches for collecting and distributing CDS. The roadmap process also identified legal and financial barriers that needed to be addressed and determined that mechanisms were needed to compile and disseminate best practices for usability and implementation and to improve CDS through actual experience and by mining EHR data systematically to advance knowledge. To foster action on elements of the Roadmap, ONC has also funded related work exploring CDS implementation (Advancing CDS)[2] and CDS standards harmonization (Health eDecisions and the Clinical Quality Information Workgroup).[3,4]

THE CDS CONSORTIUM

In 2008, AHRQ funded a five-year project, the Clinical Decision Support Consortium (CDSC) (Middleton, 2009) to assess, define, demonstrate, and evaluate best practices for knowledge management and CDS in health IT across multiple ambulatory care settings EHR technology platforms. Members of the CDSC included academic and community provider institutions, leading health IT organizations, EHR companies, and knowledge vendors from across the nation. The CDSC solved critical technical challenges for sharing CDS (Boxwala et al., 2011) and developing social and legal frameworks that facilitate such sharing (Wright et al., 2011). The project selected a service-oriented approach to providing clinical decision support (Sittig et al., 2009). Web services were developed at Brigham and Women's Hospital, the lead CDSC site, and made available to consumers across the United States (Wright et al., 2009). In addition, both human and machine-readable artifacts were made available.

STRUCTURING CARE RECOMMENDATIONS FOR CDS

From 2009 to 2011, AHRQ funded a project to develop a process for translating narrative, unstructured, evidence-based clinical recommendations and performance measures into a structured, coded format that can be implemented into health IT systems, applications, and products. The goal for developing such a

2 Available at: https://www.healthit.gov/sites/default/files/acds-lessons-in-cds-implementation-deliverablev2.pdf (Accessed July 26, 2017)

3 Available at: http://wiki.siframework.org/Health+eDecisions+Project+Charter+and+Members. (Accessed July 26, 2017)

4 Available at: http://wiki.hl7.org/index.php?title=Clinical_Quality_Information_Work_Group (Accessed August 08, 2017)

process was to enable local health IT systems to more easily integrate robust CDS rules into local health IT systems, potentially broadening adoption of CDS and leading to improved patient care and outcomes. These structured recommendations, developed for all 50 of the U.S. Preventive Services Task Force A and B recommendations[5] and all 12 recommendations relevant to meaningful use measures that must be reported to the Centers for Medicare and Medicaid Services, became known as eRecommendations (Raetzman et al., 2011). These eRecommendations leverage standard data elements, coding systems, and value sets developed for performance reporting under meaningful use for health IT to identify patients for whom a clinical recommendation applies and action should be taken. Throughout the project, the format and content of eRecommendations were vetted extensively with multiple stakeholders. Broad stakeholder feedback, which included health care provider organizations, guideline developers, EHR, and CDS suppliers, indicated wide interest in the eRecommendation work and belief that the project materials could deliver significant value. CDS needs to be specifically tested in an electronic environment, as paper-based systems invariably require some degree of judgment in application, whereas CDS, by definition, is triggered not by judgment, but by data.

CLINICAL PRACTICE GUIDELINES

The 2011 IOM report, *Clinical Practice Guidelines We Can Trust*, discussed some of the evidence showing the benefits of CDS, but also noted the existence of a few studies offering contrasting results. One such study, for example, found that CDS designed to improve diabetes and coronary artery disease care among primary care physicians resulted in limited effectiveness. Although reminders increased the odds that participants followed recommended care, adherence to quality measures remained low and significant variability in practice persisted (Sequist et al., 2005). A 2004 evaluation of a guideline-based computerized educational tool found no significant difference in guideline knowledge between physician groups with and without access to the tool (Butzlaff et al., 2004), while a 2002 study of CDS to aid implementation of CPGs for the management of asthma and angina by primary care practitioners found that CDS had no significant effect on consultation rates, process of care measures including prescribing, as structured for that program, or any patient reported outcomes for either condition (Eccles et al., 2002).

5 Available at https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/ (Accessed April 15, 2017)

One of the limitations that existed at the time of the 2011 report was that even basic EHRs—those with the ability to record patient demographic and health data and manage prescription order entry, laboratory, and imaging results—let alone those with CDS capabilities, were scarce. One study summarizing the evidence related to EHRs reported that the quality of the data on hospital EHR adoption is generally poor, and that, at the time, only approximately five percent of hospitals had computerized physician order entry, which is just one crucial element of EHRs. (Jha et al., 2006). The situation was slightly better in ambulatory care settings, with some 17 percent of ambulatory care clinics having basic EHR capabilities and 4 percent using a comprehensive EHR (DesRoches et al., 2008). The HITECH Act, the associated stages of satisfying meaningful use criteria, and accompanying financial incentives have largely addressed that shortcoming.

Moreover, since CDS implementation has been advancing in a number of places under different circumstances, a new evaluation environment has emerged. For example, the Veterans Health Administration has had CDS in place for more than a decade; it may be an environment for determining some of the benefits and challenges relevant to accelerating effective CDS more broadly.

HIMSS CDS101

The Healthcare Information and Management Systems Society (HIMSS) developed CDS101 to provide a broad and concise overview of CDS, including implementation challenges and strategies to overcome them, for health care organizations interested in implementing CDS within their health IT infrastructure. CDS101 includes a downloadable,[6] customizable C-Suite level presentation that outlines the challenges and leadership commitment needed to ensure a successful CDS program, and it provides detailed discussions of the promise and perils of CDS adoption. The CDS101 program provides a range of scenarios for how CDS is deployed in various health care environments and a toolbox that describes the types of CDS interventions and success factors for CDS interventions. The toolbox lists what HIMSS calls the "CDS Five Rights":

1. Right information
2. Right person
3. Right CDS intervention format

6 http://www.himss.org/sites/himssorg/files/HIMSSorg/Content/files/TypesOfClinicalDecisionSupportPresentation.ppt (Accessed April 14, 2017)

4. Right channel
5. Right point in workflow

In creating CDS101, HIMSS paid particular attention to discussing what have been called the grand challenges in CDS (Sittig et al., 2008), which are to:

- Improve the human–computer interface to support rather than interrupt the clinical workflow.
- Disseminate best practices in CDS design, development, and implementation.
- Summarize patient-level information intelligently and automatically to create one or more brief summaries pertinent to the current situation and that can provide all key data needed for optimal decision making.
- Prioritize and filter recommendations to the user in a manner that accounts for the competing influences that impact clinical decision making and prioritizes delivered recommendations.
- Create an architecture for sharing executable, plug-and-play CDS modules and services in a cloud-based environment to which any EHR system could "subscribe" without the need to recreate clinically proven CDS.
- Prioritize CDS content development and implementation, rather than continue doing so on an ad hoc basis, based on a number of factors, including patient impact, cost, availability of reliable data, implementation difficulty, and acceptability to clinicians.
- Create internet-accessible CDS repositories of high-quality, evidence-based, tested CDS knowledge modules that would support local deployment of content, allow for local customizations, and enable rapid upgrades of context with the development of new knowledge (Sittig et al., 2009). Establishing this repository would reduce the need for every health care organization to develop its own rules and procedures.
- Use free-text information to harvest valuable information in EHRs to drive CDS.
- Mine existing large clinical databases to create new CDS.

AHRQ PCOR CDS INITIATIVE

Building on its long history of investments to advance CDS, including the CDSC and GLIDES project (GuideLines Into Decision Support), AHRQ established the Patient-Centered Outcomes Research (PCOR) CDS Initiative in 2016 to promote the dissemination and implementation of PCOR CDS findings and develop tools to help CDS become more shareable, health IT

standards-based, and publicly available and to create reusable CDS modules and tools and a CDS repository.[7] According to AHRQ, PCOR-based CDS helps patients and their care teams apply evidence from patient-centered outcomes research to enhance care processes and their results. Approaches include promoting shared decision-making, incorporating patient reported outcomes, factoring in patient preferences to generate patient-specific recommendations for care, and others. This initiative will have four main components: PCOR CDS Learning Network, CDS Connect, two funding opportunities to scale existing CDS and develop new CDS, and an evaluation effort for the overall initiative.

The PCOR CDS Learning Network, based at RTI International, is building a community of researchers, clinicians, professional societies, and others to accelerate collaborative learning opportunities and advance patient-centered CDS. The Learning Network will create content and a collaboration hub containing information that promotes understanding of patient-centered CDS, disseminates patient-centered evidence and practice, disseminates best practices for incorporating evidence into patient-centered CDS, and shares information on approaches to dissemination, development, implementation, and evaluation of patient-centered CDS. The Learning Network's stakeholders will contribute to the creation of relevant technical standards, policies, legal frameworks, and market analyses aimed at creating momentum for widespread adoption of patient-centered CDS. The strategic foci of the Learning Network will be to provide stakeholders with a broad array of up-to-date information relevant to patient-centered CDS, to provide information and services that enable stakeholders to connect and collaborate, and to foster the collaborative development and application of concepts, frameworks, policies, and standards for patient-centered CDS while recognizing that not all PCOR findings are suitable for implementation in CDS. A key concept underlying this work is that, at a minimum, patient-centered CDS includes an element of patient choice, whether direct or by proxy.

One of the first activities of the PCOR CDS Learning Network was to identify barriers and facilitators to the dissemination of PCOR-based CDS (Richardson et al., 2016). A critical artifact that grew out of this effort is the Analytic Framework for Action (AFA) (Figure 2–1). The AFA provides a means by which the CDS community can organize the findings and recommendations of the PCOR CDS Learning Network, and it represents the lifecycle of activities that must occur to disseminate PCOR through CDS, measure its impact,

7 Available at: https://cds.ahrq.gov/ (Accessed April 12, 2017)

and create a learning system. Throughout the process of prioritizing evidence for dissemination via CDS, authoring CDS interventions, implementing those interventions, measuring the decisions and outcomes from those interventions, and learning from the CDS experience at each step, it will be important to recognize and manage external factors, such as the marketplace, policy, legal, and governance factors that affect developing, dissemination, and implementation processes for patient-centered CDS.

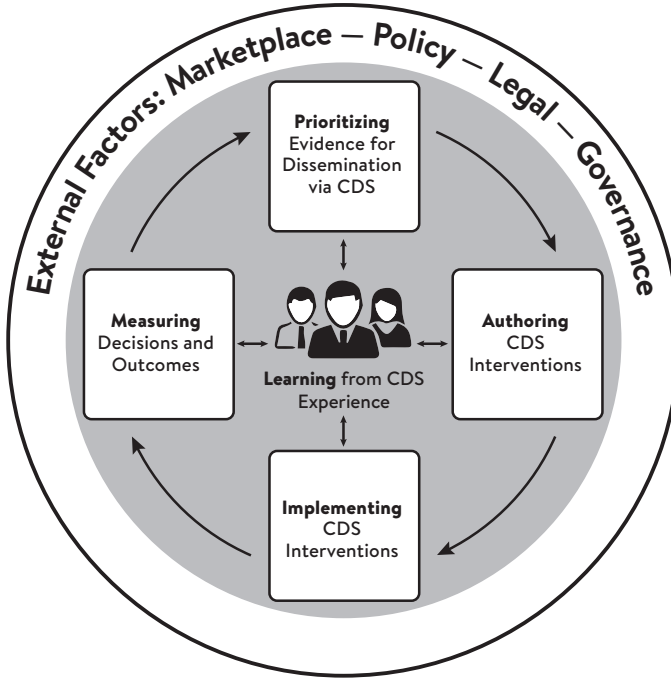

FIGURE 2–1 | PCOR CDS Learning Network Analytic Framework for Action

SOURCE: Lomotan, E. "Accelerating Evidence into Practice: AHRQ's Patient-Centered Outcomes Research Clinical Decision Support Initiative." Optimizing Strategies for Clinical Decision Support: Meeting 3. February 10, 2017.

CDS Connect, led by MITRE, will demonstrate a web-based repository service that will enable the broader PCOR CDS community to identify evidence-based standards of care, provide a tool to promote a collaborative model of CDS development, and translate and codify information into an interoperable standard. The repository will offer structured data, aggregated resources, and the ability to leverage the international standard Clinical Quality Language. As a demonstration, CDS Connect is focusing on CDS related to cholesterol management.

SUMMARY OF KEY ISSUES

As Jonathan Teich noted in his presentation to the first workshop, these and other efforts have shown that to be useful and accepted CDS needs to be several things. "It needs to be smart. It needs to be aware of the context and be like the guru down the street that can actually give you answers," said Teich. "It needs to be filtered and sensitive to the patient." CDS, he added, needs to provide alerts that are useable within the workflow so that the user's experience is clean and easy, and it needs to be shareable, valuable, safe, and perhaps, above all, CDS must become an important part of a learning health system.

In a recent review of the field, Blackford Middleton and colleagues noted that CDS has evolved dramatically over the past 25 years and will likely evolve just as dramatically or more so over the next 25 years (Middleton et al., 2016). They suggest that this evolution is inevitable given the explosion of biomedical knowledge and the pressure to improve the quality of care and lower costs in value-based care. While the projects described above, as well as others, have made significant progress in demonstrating how to develop effective CDS for specific cases, widespread adoption of CDS to improve care has not occurred. As numerous speakers at the three workshops noted, there are multiple challenges that the field still needs to address to realize this vision, including those involving authoring CDS, the technical implementation of CDS, operations, and scaling and spreading the value proposition. These challenges will be discussed more fully in the next chapter.

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3

PRIORITIES FOR ACCELERATING CDS PROGRESS

Through the project working groups, various implementation challenges were assessed related to widespread adoption and use of equitable, scalable, sustainable, and accountable CDS that can be deployed in large systems as well as single physician practices. Four primary priorities were identified for realizing the vision for CDS that will ultimately make a difference at the level of individual patient-centered care, and also contribute to a learning health system and improved population health:

- **Development of CDS content** that distills the wealth of information and clinical guidelines into a few action items that will have the biggest impact on patient-centered care.
- **Learning from CDS implementing experience,** including that related to incorporation into the EHR and delivery to the practitioner in a way that provides optimal support for the recommended clinical decisions.
- **Practical strategies for embedding CDS** in real-world environments that considers change management, people management, measurement of use, and usability considerations.
- **Explication of the value proposition** that fosters scale and spread of CDS through the development of clearinghouses and web-based repositories of CDS artifacts that can be shared, evaluated, and continuously improved through feedback from clinicians and patients.

Reports from the workgroups assigned to these challenges, delivered by the workgroup leaders, and the subsequent discussions among all of the workshop attendees were the major focus of the project's second meeting, and the contents of those reports are discussed in this chapter.

CREATING, MANAGING, AND CURATING CONTENT[8]

One important barrier to widespread CDS use is the relative lack of effective and shareable reference CDS content that can be easily adopted across health care organizations and health IT systems. Beyond medication CDS, there is relatively little effective CDS content that has been disseminated in a widespread manner. There are vendors for CDS interventions including rules, order sets, and documentation templates but these interventions often take significant effort to implement within health care systems because different EHR systems and health care systems utilize different underlying patient data models and CDS integration mechanisms.

Consequently, CDS content creation and implementation usually involves at each health care organization either a laborious configuration of external licensed content or a laborious reinvention of the wheel as the organization creates its own content. Additionally, maintenance and curation of the CDS content usually takes a lower priority compared with meeting requests for new content creation, especially when content is developed and managed locally; as such, existing content often becomes outdated, with corrective action only taken if users identify and report a problem. While the creation of CDS content in-house is an expensive and resource-intensive endeavor, sharing CDS content, either with peers or through the licensing of vendor content, is presently perceived to be equally or more expensive; thus this duplication of effort at each site has persisted.

On the subject of CDS content standardization, there are at least four important technical challenges to sharing CDS content: insufficient standardization of patient data representation; insufficient standardization of CDS knowledge representation; insufficient standardization of CDS integration mechanisms; and a need to align with broader standardization initiatives. With regard to patient data representation, different EHR systems, and in many cases different health care organizations using the same EHR system, differ in how they represent patient data. Because CDS relies on inferencing using patient data, this heterogeneity in patient data representation poses an immense obstacle to sharing CDS. With regard to CDS knowledge representation and CDS integration mechanisms, different EHR systems generally use different approaches, making it extremely difficult to use CDS content developed in one EHR system in another. Moreover, such sharing is often quite difficult even for different health care organizations

8 This section is based on the workgroup report of Kensaku Kawamoto, Associate Chief Medical Information Officer, Director of Knowledge Management and Mobilization, Assistant Professor of Biomedical Informatics, University of Utah Health Sciences Center and chair of the content development workgroup, and the ensuing discussion.

using the same EHR system. Current CDS knowledge representation approaches typically have limited capacity to efficiently manage local differences in clinician preferences and workflows. Finally, even if standardization along these technical axes was achieved for CDS, there must be strong alignment with standardization efforts in other aspects of health IT, such as electronic clinical quality measurement or data exchange. Otherwise, the required implementation effort will be increased, and vendor buy-in is likely to be diminished.

At the second meeting, Kensaku Kawamoto began his presentation by reminding the attendees that the Arden Syntax for medical logic modules was developed in 1990 (Hripcsak, 1991) and the Roadmap for National Action on Clinical Decision Support was published, as noted in the previous chapter, in 2006. Even this many years later, sharing of effective CDS is still limited. In the workgroup's view, there is a great deal of work to build from to reach the desired state of widespread sharing of effective CDS content. The field is at a tipping point.

Given that health care is a business and investment decisions are made based on financial calculations, the workgroup called for a strong business case for CDS content creation. Fee-for-service reimbursement policies, Kawamoto said, are a significant barrier in this regard because they provide no incentive to improve the quality of care through the use of CDS. As an example, he cited the common practice of ordering lumbar magnetic resonance imaging (MRI) for patients with lower back pain, the number of which would likely be reduced with effective CDS. The potential game changers, he added, could be the Centers for Medicare and Medicaid Services' (CMS) merit-based incentive payment system, alternative payment models, and physician-focused payment models that would make investments in CDS an "existential imperative." Creating that existential imperative will involve developing a business case for CDS content using incentives, such as sponsored projects and challenges.

Kawamoto and his colleagues recently demonstrated that implementing CDS for sepsis management in the inpatient setting reduced length of stay and produced an average savings of $5,000 per patient, which at his institution would equal savings of $500,000 per year (Lee et al., 2016). Demonstrating this type of return on investment, with hard numbers obtained from demonstrations at multiple institutions using multiple EHR platforms, would produce the impetus for change. While such efforts are likely to focus on demonstrations conducted under the auspices of CMS programs, Kawamoto added that it makes sense to look at instituting financial incentives for the health care system at large.

Brian Alper, founder of DynaMed and vice president for innovations and evidence-based medicine development at EBSCO Health, noted that it should be possible to create a business case even in a fee-for-service payment model.

This could be possible if CDS is viewed as not just a technological feature but also as a service that helps patients make informed decisions about their health care. In his opinion, CMS's recently approved physician-focused payment model for Medicare may enable this type of valuation for CDS. Joshua Mandel, research scientist in biomedical informatics at Harvard Medical School and in the Department of Biomedical Informatics at Boston Children's Hospital, added that the incentive for using CDS should focus on the outcomes that CDS can help providers achieve, rather than for simply using CDS. Kawamoto agreed with this idea because it eliminates the argument that such incentives are for a process measure rather than appropriate care and outcomes. Blackford Middleton noted that return on investment should also include some metric for the social goods that accrue with knowledge sharing, which he acknowledged will require new modeling work.

Roberto Rocha, clinical informatics director at Partners Healthcare, remarked that at least some of the return has to accrue to frontline clinicians. Too often, he said, the clinician is making a big investment in terms of the time it takes to input the information that is needed to produce decision support. All the while, this investment may or may not produce a return for that clinician. Kawamoto noted that, at his institution, it is the physicians who make the ultimate yes or no decision when it comes to adding new CDS to the EHR. Usability, added Jeff Cohn, a physician with Broadlands Family Practice, has to be a primary focus for CDS content to reduce alert fatigue and provider resistance. In that regard, he asked if it might be necessary to explore whether there would be a benefit to targeting different clinicians differently. "A primary care physician might need a different type of alert than say a nurse or a specialist, for example," he said.

Moving on, Kawamoto discussed the second key issue this workgroup addressed: the need for efficient, standards-based CDS content sharing. The main barrier here, according to the workgroup, is that sharing CDS content is either more expensive or perceived to be more expensive than creating content de novo at each institution, with the one exception being CDS relevant to knowledge-based medication-related CDS content. The concern here is that while ONC has sponsored several efforts that have worked as pilot demonstrations, the demonstrations were not as effective when scaled because of a lack of specificity on the information model. Examples of past and present efforts include the Health eDecisions initiative that resulted in the development of standards for knowledge artifacts and CDS services, the ONC- and CMS-sponsored Clinical Quality Framework initiative to harmonize Health eDecision standards with measurements, and the development of the Fast Healthcare Interoperability Resources (FHIR) specification for exchanging health care information electronically. Using FHIR as an

example, Kawamato said that it is enabling promising interoperability projects, but each project requires so many decisions on specific actions to take that "we are not going to get true interoperability unless we solve that issue."

As is the case with the need to demonstrate a return on investment for CDS deployed across multiple platforms at multiple institutions, CDS developers need to create content based on clear standards. What happens today, said Kawamoto, is that standards are not always defined clearly enough, so a developer will make a decision that enables content to work within systems at the test institutions but are not scalable nationally. The HL7 Clinical Quality Information Work Group initiative is harmonizing decision support standards and those for electronic clinical quality measures. The workgroup recognized that while this effort has made significant strides toward standardization, this work has not yet achieved the necessary level of detail in the standards and how they are applied to clinical decisions, said Kawamoto. He noted that the Clinical Quality Language standard for logic expression has been well-received by the community and CMS is moving forward with an initiative to promulgate this quality measurement program.

Another effort, called OpenCDS, is being implemented by the Department of Veterans Affairs in its eHMP program, but this open-source standard will be useful, said Kawamoto, only for specific use cases or where adding another tab to the EHR makes sense. "In cases where it does, I think this is very powerful, and vendors are adopting it, which makes it very attractive for implementing," he said. A second program, CDS Hooks, provides decision support services for specific use cases, and there is an effort to harmonize this approach with FHIR.

In Kawamoto's opinion, the most promising approach is to provide EHR support for CDS. Epic, for example, has a capability called the Best Practice Advisory Web Service that operates within Epic's native rules authoring environment. His hope is that every vendor could provide a similar web-based CDS content delivery service supported by the native architecture of that vendor's EHR. The main challenges here, said Kawamoto, relate to performance issues—it currently takes six or seven seconds for the EHR to retrieve and package patient data, send it to the web service, and retrieve and answer.

Middleton noted that while the focus on accessing web services has been on how to enable EHRs to reach out to access those services, research on the EHR context is also needed to define insertion points and hooks. Such research would create spaces in the EHR into which CDS information displays would fit naturally within the context of the provider's workflow and in a team-based care model. Creating these insertion points and hooks will require additional dialog with EHR vendors, he said. One challenge will be to develop secure application program interfaces (APIs), the set of routines, protocols, and tools

that will enable CDS content developers to create applications that will interact with EHRs, in much the same way that computer operating systems have APIs that enable third-party developers to create external programs that work on top of those operating systems.

With regard to action priorities, the workgroup concluded there is still a need to develop, validate, and adopt standards and tools for CDS sharing, including important building blocks such as value sets and mapping tools. As an example, Kawamoto described a hypothetical situation in which a sepsis decision algorithm requires information on a patient's white blood cell count. A mapping tool needs to know which internal code denotes white blood cell count.

The second action priority is to seed the marketplace with useful CDS content. Kawamoto explained that justifying the decision to deploy CDS at an institution would be easier if a significant starter set of CDS content, such as for the U.S. Preventive Services Task Force A and B recommendations, existed for immediate inclusion in the EHR. Sumi Sexton, a physician whose practice joined the Privia Medical Group, noted that the expense of acquiring CDS content can be too high for a small practice such as hers.

The content development workgroup's third key issue was the need to discover and disseminate CDS best practices, with the main barriers being insufficient guidance on the creation of effective CDS and the fact that providers view much of the current CDS as a nuisance because of "alert fatigue." Kawamoto said that the field has learned a great deal about effective CDS from clinical trials and various meta-analyses, and particularly from the AHRQ Patient-Centered Outcomes Research Decision Support Learning Network described in chapter 2. Nonetheless, he said, more work remains to discover and disseminate best practices. The workgroup called for the nation to make an investment in CDS research, particularly for multisite randomized, controlled trials, and to establish a robust, interoperable CDS marketplace within the context of business incentives to improve care quality. A potential initial place to start addressing the challenges of CDS content development, the workgroup concluded, would be to integrate standards of CDS Web services within EHR vendors' rule authoring platforms.

LEARNING FROM CDS IMPLEMENTATION

Several comments focused on CDS technical implementation challenges. Currently, there are various implementation approaches across health systems and vendors, resulting in different implementation of each CDS system. With the variability in approaches, there is also little crosscutting evidence on how:

- CDS performs **in real-world environments** (e.g., whether CDS users provide better care than control groups);
- CDS implementation designs accommodate **actual workflow patterns**; or how
- CDS implementation models **are validated and compared**.

Nor are there mechanisms that enable health systems and researchers to regularly monitor and study system use and usability over time to determine what is working and what is missing (e.g., lack of sufficient data to support CDS logic).

While traditionally CDS, including rules engines and interaction software, has been embedded natively as part of the EHR, hybrid systems that utilize cloud-based services in real time are becoming increasingly more common. The development of implementation standards, especially for the cloud, has the potential to reduce the vendor implementation workload and provide common base content for every vendor. However, standards development efforts, especially for standards developed based on real-world experimentation and trial use, are insufficient.

As Scott Weingarten, chair of the technical implementation workgroup reported, this workgroup primarily took an industry or vendor perspective on the issues it was charged to address. The reason for this, he explained, is that every EHR vendor has a product roadmap, and if the vendors are being asked to implement standards that will enable CDS integration, they may have to alter the product roadmap and make a decision about whether to do so, absent a federal mandate. He noted, too, that the workgroup had representatives from six EHR vendors and five content developers accounting for the major shares of their respective markets.

The technical implementation workgroup concluded that the large number of EHR native rule engines, each with its own approach and workflow, creates a difficult environment in which to develop scalable CDS content. Mapping across these different systems is difficult and expensive, and making content changes to reflect new knowledge is perhaps no less difficult. The workgroup then concluded that implementing CDS in a cloud-based environment offers the best opportunity to achieving the desired outcome of scale and spread. Toward that end, using a standards-based, Web API approach makes sense in that it will reduce EHR vendor work, CDS content vendor work, and implementation costs.

Marc Overhage, chief medical informatics officer at Cerner, added that even with a web- or cloud-based CDS service, it will still be necessary to establish local EHR mechanisms for integration. These mechanisms can help access the necessary data, rule sets, and care plans that have to interact with CDS for it to be effective and fit within the workflow of the provider. Todd Rothenhaus, senior

vice president and chief medical officer at athenahealth noted the challenge of keeping web-based systems synchronized with primary sources of information. Based on what he has seen at various health IT conferences, Howard Strasberg, vice president for medical informatics at UpToDate/Wolters Kluwer Health, said it appears that a web-services approach is rapidly gaining traction among EHR vendors.

When it comes to deploying a web-based system, standards will be essential for success on a large scale, the workgroup concluded. In addition to enabling scale and spread across multiple EHR and technology platforms, standards are necessary to create systems that are sustainable, maintainable, and updatable. They will also reduce maintenance costs, Weingarten noted. Members of the workgroup agreed on the importance of standards but also noted that standards can be constraining. At least one member of the workgroup was concerned that standards are not yet mature enough for implementation.

James Tcheng wondered if there is a need for what he called an "uber authority," a single source of truth from which all CDS derive. From his perspective as chair of the digital steering committee of the American College of Cardiology, Tcheng noted that this organization, like other specialty colleges in the medical profession, is responsible for authoring clinical guidelines. However, in his opinion, the College has struggled to convert these paper guidelines into computable guidelines, in large part because there is no standards-based pathway for creating computable guidelines that could be used in any EHR context. "If I was on the authoring side of trying to create CDS, I do not want to work with 35 different vendors and 35 additional institutions or enterprises in the CDS field. I would like to create a knowledge representation that others can then consume," said Tcheng.

Jonathan Teich, a practicing emergency medicine physician at Brigham and Women's Hospital, noted that when he led the AHRQ Roadmap for National Action on Clinical Decision Support project, vendors supported the idea of a standard framework set by a governmental authority but were concerned with how it would survive over time. He added that one advantage of FHIR is that it has taken off by itself and become a de facto standard. David Bates, senior vice president and chief innovation officer at Brigham and Women's Hospital, suggested that a central authority for standards to act as a clearinghouse could be in order, but not for content. In fact, he said, having the specialty societies set guidelines is not ideal because they inevitably develop recommendations beneficial to their members, not necessarily patients.

Vindell Washington, who at the time of the meeting was the National Coordinator for Health Information Technology at ONC, said that ONC

established the Interoperability Standards Advisory as a public-private partnership rather than create a set of standards itself. He noted, though, that the Advisory has come under pressure to be more declarative and to develop a rating system for these standards.

In considering priorities for action, the implementation workgroup noted the importance of expanding the evidence base for implementation science around CDS. It is critical, the workgroup concluded, to conduct research and evaluation of real-world deployments of CDS in clinical environments spanning the gamut from small physician practices to large health systems and across a variety of workflows and to determine if there are models of implementation that are more efficient and successful than others. Research is also needed to understand usability, physician satisfaction, and the effect of CDS deployment on physician burnout over time, as well as whether each individual CDS intervention improves care outcomes. Some CDS, for example, may not produce measureable benefits over time and should therefore be removed from cloud-based (and local) repositories.

Another priority action the workgroup identified was the need for the development of standards related to cloud-based implementation. This effort should involve federal and industry partners. Examples of such standards include the SMART on FHIR®, an open-source set of specifications for integrating apps within EHRs and health information exchanges, and CDS Hooks.[9] Additional priorities included sharing best practices about implementation and integration, and considering how the field can make the case that CDS will help reach incentives already in place for providing high quality and less costly or more cost-effective care. As Weingarten noted, there was disagreement between the workgroup participants on whether or not CDS implementation should be driven by the market or by incentives for using CDS.

PRACTICAL STRATEGIES FOR EMBEDDING CDS

To be effective, CDS must be integrated into, and supportive of, the clinical work environment. This includes attending to timing the presentation of interventions, providing concise yet sufficient information to drive action clearly on the screen, and making it easy for the user to understand the recommendations and take optimal actions, all without overly interrupting clinical workflow. There has been much discussion about usability principles, but not enough practical guidance and examples. Nonetheless, evidence suggests that providers are more

9 Available at: http://docs.smarthealthit.org/ (Accessed August 21, 2017)

likely to follow suggestions when they are delivered in ways that have better usability. Currently, CDS works well in some institutions but has low or even negative impact in others. Factors that need to be carefully addressed during implementation include:

1. **Design/workflow factors**
   - CDS that is too nonspecific and generates **too many low-impact alerts**;
   - **Failure to show** the clinical user the **underlying data and rationale** leading to a clinical recommendation; and
   - CDS that excessively **interrupts workflow and demands a change in plan**, as opposed to providing information earlier in the care process before decisions have been made.

2. **Lack of standard/repeatable implementation across institutions**
   - **No easily-accessed store of good exemplars of CDS design** that can be used as reference for new implementations;
   - **Basic operational components**—including triggers, notifications, and action items—are known to some experts, but **not widely known and not easily available** as standard sets and templates; and
   - **No agreement across EHR vendor systems about where to place available CDS trigger points**; some systems, for example, provide drug dose checking as soon as an order is entered, while others wait until a full session of multiple orders is ready to be signed.

3. **Communication/implementation factors**
   - **Failure to understand the range of stakeholders** whose workflow could be affected by an intervention; and
   - **Failure to include users and stakeholders** (clinicians, quality leaders, and often patients/consumers) in design and configuration early in the process.

4. **Measurement limitations**
   - EHRs and CDS systems **not providing sufficient and easily accessible data to allow measurement** of whether given CDS interventions are being used, are triggering consistently and appropriately, are generating recommendations, and are being accepted or excepted appropriately; and
   - **Difficulty in determining whether a given CDS intervention has impacted health decision making, outcomes, and patient experience**; thus, it is difficult to distinguish effective CDS interventions from ineffective ones.

5. **Priority-setting factors**
   - Providing optimal CDS has often **not been a priority for vendors**, compared to supporting documentation requirements for the current regulatory and reimbursement environment; and
   - **Patient-facing CDS and shared decision-making tools have not been prioritized**, which further slows the understanding and development of effective CDS of this type.

While there have been many efforts to codify CDS logic, the field has paid less attention to making it easy, shareable, implementable, usable, trackable, and measurable, said Jonathan Teich, who chaired the operations workgroup. The development of vendor-specific APIs represent a good step in the right direction, he said, and this workgroup focused on actions needed to make the CDS more universal and practical, he explained.

Before presenting the operations workgroup's findings, Teich briefly described the typical CDS process (Figure 3–1) that starts with a trigger, some piece of data that starts the logic process resulting in either no action or the decision to present something to the user and perhaps notify the user if the user is offline at the time. The CDS presentation can be an alert, an order set, a care plan facilitator, or decision tool. The EHR supplies data that informs the CDS.

With regard to operational problems and priorities, the workgroup noted that triggers need to be more precise to avoid alert fatigue, and presentations need to not only suggest an action but also state the reasons for a recommended intervention, including relevant data and information supporting the action. According to the workgroup, action items need to be understandable and presented in a form that can be readily absorbed by the user. In addition, there should be an effort to collect and codify examples of good practices to educate CDS developers, and the field needs to publish usability evaluations of EHR and CDS systems.

The workgroup referenced the recommendations of the National Quality Forum (NQF) expert panel, which concluded there are approximately a dozen trigger points in the standard workflow that are appropriate places to initiate live CDS processing (National Quality Forum, 2010). Some EHR vendors, said Teich, have provided trigger points at some of those places, but there is little consistency across vendors. "It is clear that if all of the major vendors of EHRs had a consistent set of trigger points, it would be easier to write both embedded and cloud-based CDS to support that," said Teich. "This is something that I would suggest could be standardized that would facilitate CDS without actually controlling what is in the CDS itself."

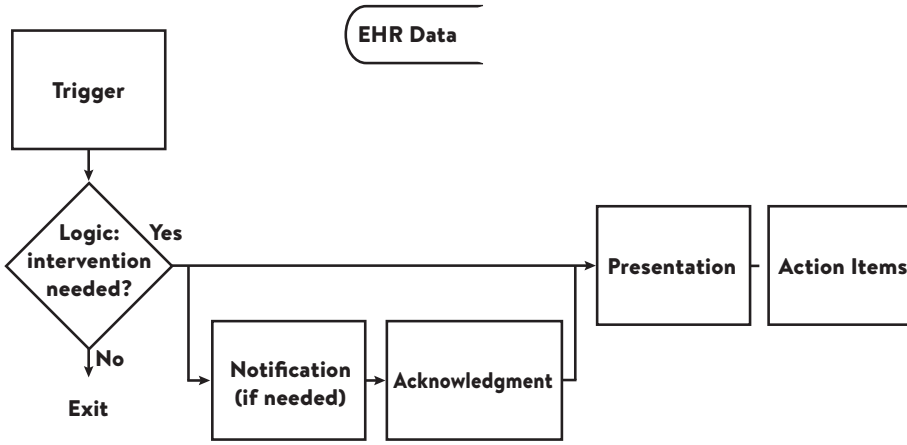

FIGURE 3–1 | CDS core components

SOURCE: Reproduced from: Osheroff JA, Teich JM, Levick DA et. al., *Improving Outcomes with Clinical Decision Support: An Implementer's Guide*, 2nd edition. HIMSS Press, 2012.

The ability to extract discrete data from an EHR and send it to CDS is fairly well developed, the workgroup noted, but there is still work to be done on the reverse process (i.e., CDS returning a recommended action to the EHR). Vendors, Teich explained, need more proof that these actions are supported by evidence and have been validated. They have also expressed concern that CDS input does not adversely affect the fundamentals of the EHR. The workgroup suggested that just as with trigger points, the field could develop a set of standard actions that CDS systems would ask the EHR to perform. Having services in the EHR to support such standardized actions could make it easier to reuse and spread both embedded and cloud-based CDS. The workgroup also suggested that the field should create model CDS built on core elements that would include an order set, several different alerts, and a clinical pathway that users could modify for specific clinical conditions. CDS needs to be specifically tested in an electronic environment, as paper-based systems invariably require some degree of judgment in application, whereas CDS, by definition, is triggered not by judgment but by data.

In terms of exemplary CDS, the workgroup concluded that much of the success results from high-caliber implementation and communication. Too often, stakeholders are not involved early in the implementation process, governance is inconsistent, and patients are not involved where appropriate. It is important, said Teich, "to make sure that the computer is not making policy before people know what the policy is and that people have a reasonable place to come back

with feedback from something that is or is not working well." Collaboration among CDS proponents, users, and vendors must become routine, the workgroup noted, and the field should collect best practices to educate and facilitate implementation.

Going forward, measurement is essential. "We want to make sure that the CDS is working," said Teich. To optimize CDS and increase adoption and acceptance, it will be critical to determine which interventions are firing at the appropriate times and are then accepted by the clinical care team and patients and changing care for the better. This capability will be important at both the local and national scale if the goal is to reduce the burden on providers and health systems to each identify important lessons on their own.

The operations workgroup noted that while developers are relying more on usability science, they do not have specific examples of what works best in the context of how to reduce alert fatigue, how to trigger alerts at appropriate times, and how to create alerts that are not so full of information as to be unreadable on the computer monitor. Another deficit currently is that some systems lack the ability to follow through easily on a recommended action, such as ordering a particular test or prescribing a specific medication. A potential solution, the workgroup noted, would be to develop a resource of good practices that systems and providers could use when starting to implement their own CDS systems. Another solution would be to evaluate the usability of EHR and CDS systems in enough depth to enable users and developers to identify which specific tasks their systems do well and which ones need improvement. One workgroup member, David Bates, noted that even when he accepts an alert, he cannot tell if the system actually accepted and followed through on any actions he might take as a result of the alert, something he counts as a usability issue.

These standards would not dictate specifics of a CDS but act as templates that would provide a common starting place and format. The example Teich gave was how all iPhone apps have a similar look to them. Certification may be an avenue to encourage or facilitate standardization. Standardization would help enable reusable CDS in that way that the Pyxis medication dispensing system enables a new drug to be added in a simple and straightforward process. Currently, Teich said, a new CDS intervention requires a year's worth of committee work to implement in an EHR. "It is very hard to leverage good work done elsewhere," he said. "It is very hard for hospital A to make an intervention that actually works and for hospital B to pick it up." The idea is not so much to have one repository of CDS but one standard for any repository.

With regard to implementation, the workgroup stressed the importance of communication and getting all stakeholders involved early in the implementation

process. It may be useful, the workgroup noted, to convene vendor-user group meetings to share concerns and create priority lists for vendors. The workgroup also suggested that EHR vendors include logging and analysis tools in EHRs to determine how often and under what circumstances CDS fired and what the response of the clinical staff was to an alert. As a final note, this workgroup agreed with the other workgroups on the need for payment and regulatory reform to change the financial incentives

During the ensuing discussion, Middleton noted that a missing operational piece in most systems is knowledge management—providing information about the provenance of the knowledge going into CDS and having the ability to update that information when needed. He also suggested that one approach to standardization of CDS would be for EHR vendors to create a style guide so that CDS developers can create alerts that make it easier to navigate within a given EHR. Sexton suggested that alerts could be tied to continuing medical education credits and board recertification, an idea that several meeting participants also endorsed.

EXPLICATING THE CDS VALUE PROPOSITION[10]

As was apparent throughout the other presentations, despite a substantial national investment in health IT, there continues to be a struggle to articulate and demonstrate the health IT value proposition. Looking at the issue of CDS use from a macro level, the workgroup focused on the CDS marketplace noted that the articulation, dissemination, and adoption of an industry-scale value case for CDS is critical to its long-term use. Some prior experience in this respect is offered in the development of a tool developed by the National Academy of Medicine's Digital Learning Collaborative[11] in conjunction with the Healthcare Financial Management Association[12] (HFMA) to provide a systematic mechanism for assessing the costs and benefits of EHR implementation, alternate approaches to implementation, and models of use (Adler-Milstein et. al, 2014).

There are a number of challenges to creating a competitive market for CDS. A 2015 analysis of the CDS marketplace (Figure 3–2) conducted for ONC (Discern Health, 2015) found there was a good supply of new knowledge generated by

10 This section is based on the workgroup report of Blackford Middleton, Chief Informatics and Innovation Officer, Apervita, Inc. and chair of the scaling and spreading the value proposition workgroup and the ensuing discussion.

11 Available at: https://nam.edu/programs/value-science-driven-health-care/digital-learning/ (Accessed July 26, 2017)

12 Available at: https://www.hfma.org/ (Accessed July 26, 2017)

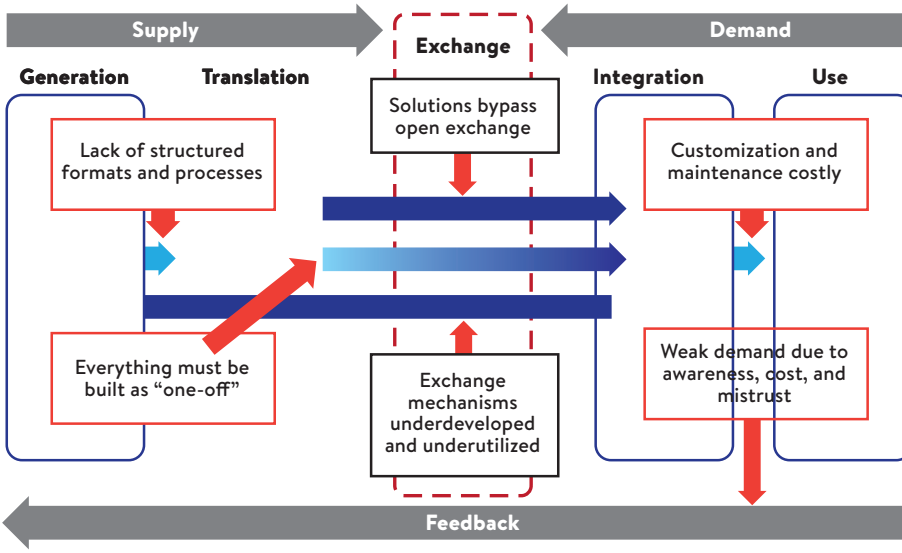

FIGURE 3–2 | Current state of the CDS marketplace
SOURCE: Discern Health, 2015

the nation's biomedical research enterprise but a lack of structured formats and processes to extract a structured output that could represent core knowledge elements. As a result, the knowledge that would go into CDS needs to be extracted manually from the literature and inputted into CDS manually, an expensive and time-consuming process that must be repeated every time research generates new knowledge. This analysis also found that demand was weak because of cost of customization and maintenance, as well as lack of awareness and mistrust of CDS. The remedy for the disconnect between the supply of information and demand for that information in the form of CDS was to create a two-sided exchange or marketplace for buyers and sellers of CDS. In the ideal state, standards and automation will support efficient translation of knowledge into CDS, reducing costs. On the demand side, efforts to raise awareness of the benefits of CDS and increase trust, coupled with the lower cost of creating CDS and the availability of standards and automation to reduce the costs of customizing and maintaining CDS, will stimulate demand. At the same time, competition in the marketplace would lead to better products and multiple options, further lowering costs, which together with feedback that contributes to a continuously learning system, would further drive demand.

When presenting the scaling and spreading the value proposition workgroup's findings, Middleton noted that because of its operational and technical issues, CDS is at times still viewed as a hindrance to clinical care instead of as a tool

for improved quality of care. Improvements in implementation, content, and operations could increase the value of CDS tools, as would increased interoperability with EHRs and other workflow systems. The hassles of adoption and sharing must also be reduced. Clinicians and institutions may favor robust CDS that is also integrated and bundled with EHR systems, particularly when they meet the "five rights" of effective CDS discussed in chapter 2. An additional challenge is that a sales model problem exists. According to Overhage at the third meeting, vendors do not know how to sell $100,000 items (the cost of standalone CDS); for health systems, it is easier to buy an entire health IT system that includes knowledge instead of only purchasing one CDS resource. A clear business case is needed in order to get a toolset or vision in the company to create an infrastructure.

However, according to Middleton, a major barrier to CDS adoption (even if interoperability reduced hassles in adoption, and trust in CDS resources are achieved) is that the health care industry is not fundamentally designed to focus on or reward optimal decision-making focused on quality and safety. Health care financing is heavily weighted toward documentation of observations as the basis for determining and auditing payments. The result is that EHRs and health care transactions are developed to support documentation of specific observations and not support documentation or facilitation of decision-making. Observations useful for supporting payment but not useful or less useful for decision-making or patient care are valued and prioritized, while observations that are most relevant to decision-making and documentation of the decision-making are not valued or prioritized. Although national attention is gravitating toward payment incentives that reward greater effectiveness and efficiency in outcomes—the aims of CDS—actual practices are still heavily oriented to fee-for-service.

According to the scaling and spreading the value proposition workgroup, health care service provision is more optimally done with a focus on decision-making. Patients seek guidance in health care decision-making. Though sometimes fully delegating to the health care professional, patients often actively participate in their own health care decision-making. Aligning decision-making with individual values and preferences is important for patient satisfaction, personalized health care, patient engagement, patient adherence, and quality of health care in the view of the recipient.

To address the numerous challenges to distribution, the workgroup developed guiding principles for creating a marketplace supportive of CDS being widely adopted by health systems and providers. In such a "post-EHR world," said Middleton, vendors need access to externalized data to keep their customers happy

and enable them to provide appropriate care and to externalized knowledge-based tools and services. The guiding principles articulated by the workgroup are:

- CDS distribution should be anchored in the basic principles of being **actionable/reportable, integrated** into the workflow, **interoperable**, and **available** as a web service.
- Each CDS intervention should have **a value proposition** for each of the different purposes and variety of sizes and types of health care organization, across care settings, for which it is targeted. This value statement must include how CDS will benefit the care of a given patient both at the time of care and extending over time through the accrual of secondary benefits.
- **Quality reporting** as a byproduct of CDS tools should be expanded and measurement should be embedded as a tracer and transparent byproduct of CDS technology.
- CDS should support providers' success as health care delivery and payment models increasingly **emphasize outcomes** as opposed to volume of services performed.
- Health care financing should be reoriented to **reward providers** for documenting decision-making based on CDS, in addition to clinical observations, the impact of those decisions on patient outcomes, and the value patients place on those outcomes.
- Industry should work closely with federal partners, patients and families, and representatives from professional societies to **advance awareness**, understanding, and application of CDS strategies and **address legal barriers** to CDS use and knowledge sharing.
- Industry, in collaboration with multiple partners, should take a lead in developing **industry regulation and certification** efforts as they relate to assessing and defining an appropriate regulatory framework for CDS.

With regard to this last item, Middleton expressed his concern about efforts at the Food and Drug Administration (FDA) to consider software as a medical device and regulate it as such. In his opinion, CDS is not autonomous, that is, there is a learned intermediary who has to decide whether to act on CDS-generated alert. He acknowledged the argument that a clinician may not always have time to exercise his or her judgment about a given alert, and said that careful thought needs to be given about the appropriate boundary conditions for when a regulated CDS service should be considered a medical device. In this respect, the 21st Century Cures Act provides clarification that software/data used within the context of an electronic health record does not necessarily

constitute an FDA-regulated device, thereby supporting use of the electronic health record as a vehicle for decision support.

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AGENDA FOR CDS ADOPTION AND USE

Over the duration of the meeting series, all of the workgroups identified next steps relevant to their particular topics. Key themes related to CDS adoption and use emerged that crossed the boundaries of the specific workgroups. Through a series of discussions with the project's steering committee, subcommittee workgroups, and meeting participants, held between the second and third meeting, a comprehensive list of actions for optimizing strategies for CDS adoption and use was identified. These priorities for action then served as the focus for the third meeting's presentations and discussions, which in addition to considering these priorities also aimed to identify organizations that would be well situated to take lead roles in their implementation.

The organizations listed in some instances include specific examples representative of larger groups of organizations with similar characteristics, such as integrated delivery systems, academic medical centers, or specific physician or other clinical specialty societies. The lists are intended to be illustrative and name some evocative examples, not to be exhaustive or imply that *only* those organizations listed could take leadership roles, and not to imply that any of the specifically named example organizations have committed to carrying forward the roles for which the workgroup identified them as examples of potential leaders.

Against this backdrop of compelling opportunities emerged the common themes noted in chapter 1:

- Much like in-person peer learning (e.g., grand rounds with residents), CDS should serve as a tool to help clinicians at the front line think through options at the point of care.
- Current challenges include the various pathways for implementation of CDS within different health care organizations, lack of standards and incentives to use and improve CDS, poor data quality, and gaps in the evidence.

- One of the greatest challenges for scaling CDS adoption is its limited financial business case. It remains difficult to demonstrate the return on investment of CDS, especially against many competing priorities at the delivery system level.
- Current CDS lacks measurement practices and standards. Evaluation of current and future CDS should assess whether it measurably improves quality, health outcomes, safety, cost, and physician productivity.

Throughout the meeting series, the participants expressed an interest in focusing on these themes to identify strategies to move CDS implementation into action and help the field address longstanding challenges associated with CDS adoption and use. As Kensaku Kawamoto asked during the first meeting, "How do we help ensure that we are not here in 10 years having these same discussions?" It was this question, and the overarching drive of the meeting participants that led to efforts to identify actionable next steps and approaches to implement them.

In this respect, participants were motivated to offer their views on actionable collaborative next steps that could be initiated over the next five years. Although the summary below represents views of the authors, not the NAM, they are intended to move forward the discussion in a way that complements and enhances clinical practice, and they will require commitment by multiple stakeholders at the federal level, by the EHR and CDS vendor community, and by health delivery systems.

DEVELOP, TEST, ESTABLISH, VALIDATE, AND APPLY STANDARDS

1. Establish CDS technical standards

- Develop coordinated activities in support of standard intervention templates, methods, artifacts, and intervention repositories.
- Develop a standard set of each of the core CDS operational elements such as EHR trigger points, action items, and supporting data, leveraging existing work such as the 2012 NQF expert panel report and existing Health Level Seven international standards (HL7), so that CDS can be developed with confidence that these elements will be present in each EHR environment.
- Establish repeatable conventions, such as the FHIR and APIs, to pass data and context/situational info from the EHR to the CDS and to accept recommendations from the CDS back to the EHR in the appropriate context.
- Establish an entity of appropriate stakeholders to resolve governance issues and drive EHR vendor acceptance for support of CDS standards.

Potential leaders for such an effort include the HL7 workgroup, the CDS work group, integrated health systems, the HL7 Clinical Quality Information Workgroup, the AMIA, HIMSS, primary care practice community stakeholders, and federal agencies.

2. **Engage federal leadership for CDS standards innovation and maturation**
   - Have relevant federal agencies dedicate at least a critical minimum of support, reliably year over year, to foster the development and maturation of technical standards essential to achieving seamless interoperability of CDS with EHRs and other health IT used daily to support health care delivery.

Federal agencies would be the potential leaders of this activity.

3. **Create a CDS technical information resource**
   - List, describe, and validate existing CDS constructs, such as SMART on FHIR®, CDS Hooks, FHIR Clinical Reasoning module and industry standard APIs, and develop objective criteria on standards validation models.

Potential leaders of this effort would include the HL7 and CDS workgroups and federal agencies.

ENCOURAGE DELIVERY SYSTEM ADOPTION, USE, AND ASSESSMENT

4. **Disseminate best practices**
   - Convene one or more small expert groups to cultivate, plan, and direct the publication of actionable implementation guides that draw upon existing public, private, and cooperative efforts to articulate and delineate best practices in: implementation and platform integration approaches for several types of delivery systems; CDS management approaches for organizing multistakeholder CDS implementation and governance committees, and for clinicians and health systems of various sizes/resources; and usability recommendations for usable, practical, workflow-supportive CDS for various situations and objectives that are straightforward and readily adopted by designers and system configuration teams.
   - Develop education toolkits for health delivery systems implementing and using CDS.

Potential leaders for such an effort include HIMSS, medical specialty societies, AMIA, and federal agencies.

5. Create a national CDS repository

- Develop and organize a national network of "choose and use" repositories of downloadable or service-accessible CDS interventions. The repository concept does not prescribe a single federal repository but rather a standard format that allows multiple entities to supply repositories. Providers should be able to download artifacts and use them with a minimal amount of customization. The same concept can be used to allow providers to select from a catalog of CDS services. Key considerations for a nationwide CDS repository infrastructure will include funding sources, duration, and sustainability.
- Create CDS building blocks such as a "starter pack" of logic and operational items, value sets, and detailed clinical models that cover a meaningful portion of the high-priority CDS targets of the health care community.

EHR and CDS vendors and federal agencies are potential leaders/funders of this activity.

6. Measure CDS usage

- At a delivery system level, measure (both pre and postimplementation) such items as number of times occurring, supporting data provided, user response, and other relevant clinical measures regardless of application and independent of application platform.
- Over the longer term (2020 and after), the capacity to measure at the delivery system level will allow for the assessment of CDS at a national level, specifically the ability to measure CDS success by pervasiveness of adoption; assessment of override rates; the feedback of end users and patients about how and when the CDS was presented; the beneficial difference it made in overuse, underuse, and misuse of tests and treatments; and how CDS contributed to the quality outcomes that matter, such as those defined by the Institute of Medicine (now the National Academy of Medicine) definition of quality: patient-centeredness, effectiveness, safety, timeliness, efficiency, equitability[13]; and Quadruple Aim criteria.

13 Institute of Medicine. 2001. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: The National Academies Press. https://doi.org/10.17226/10027

Potential promoters of this activity would be patient safety organizations (PSOs), vendors, integrated health systems, and federal agencies.

7. Develop tools to assess CDS efficacy

- Convene, fund, develop, and make publicly available tools and metrics for assessing CDS performance in the dimensions of quality, safety, and transparency of CDS, and for assessing ongoing performance and impact of CDS.
- Potential leaders of this activity include integrated health systems, The National Committee for Quality Assurance (NCQA), the Institute for Healthcare Improvement (IHI), and federal agencies.

8. Publish performance evaluations

- Publish evaluations of usability and effectiveness of vendor EHR CDS implementation with sufficient detail to facilitate purchasing decisions and postpurchase configuration and monitoring work by providers.

The AMIA, Institute for Clinical and Economic Review (ICER), IHI, Patient-Centered Outcomes Research Institute (PCORI), Institute for Safe Medication Practices (ISMP), American EHR Partners, and federal agencies are potential leaders of this activity.

9. Market CDS to stakeholders

- Articulate a macro-level, industry-scale CDS value proposition as well as distinct value propositions on the use of CDS for different end-users such as individual practitioners and integrated health systems.
- Develop partnerships with multiple stakeholders, including industry, federal representatives, patients and families, and professional societies, to better inform both the private and public domains of CDS value. An engaged public informed about the cost, quality, safety, and satisfaction benefits of CDS can make the case to the government of the value of CDS. Societies are positioned to review data, report back, and translate the value of CDS to public domains.

Potential leaders of this activity include HIMSS, vendors, professional societies, medical education organizations, patient advocacy organizations, and federal agencies.

10. Promote financing and measurement to accelerate CDS adoption

- Have available from the federal government a system of strong financial incentives for the adoption and implementation of CDS, supported by information

about how specific CDS could help in improving care effectiveness, efficiency, and quality performance.
- Incorporate CDS into the Medicare Access and CHIP Reauthorization Act (MACRA) Quality Payment Program by leveraging the APMs track to drive incorporation and standardization of CDS. This action would reward participants in advanced APMs for deploying, adopting, and adhering to evidence-based best practices that facilitate standardization, reduce variation that is without value, and promote achievement of national benchmark results for quality, patient experience, and health professional engagement and alignment for better care.
- Pilot alternative approaches to health care financing in which the basis for payment is centered on documenting decisions rather than documenting observations.

Potential leaders of this activity include federal agencies, integrated health systems, and ICER.

ESTABLISH A NATIONAL CDS INFRASTRUCTURE

11. Create a legal framework for CDS
- Convene a small, interdisciplinary group of experts in a public-private partnership to explore and address the legal concerns surrounding: adoption of CDS; creation of CDS public and private repositories/services; professional and institutional liability when using CDS; liability of authors, creators, and investigators producing CDS logic and interventions; and the FDA's approach to CDS within its overall regulatory strategy for clinical software. Outputs of this interdisciplinary, multistakeholder group could include a framework of criteria for development and deployment of CDS resources and services which, when met, would provide clinicians assurance they could reasonably rely on those CDS resources and/or services.

Potential leaders could include AMIA, The Brookings Institution, the NAM, IHI, the Duke-Margolis Center for Health Policy, HIMSS, College of Healthcare Information Management Executives (CHIME), American Health Lawyers Association, and federal agencies.

12. Develop a multistakeholder CDS learning community to inform usability
- Facilitate the routine engagement of end-users and key stakeholders—including providers and their staff, EHR and CDS vendors, and patients and

families—throughout the CDS design specification and implementation process.
- Develop a mechanism to collect feedback from providers and other users about efficacy, design questions, configuration tips for other users, and suggested changes to specific CDS interventions and CDS in general.
- Link patient-generated data to CDS technologies in order to generate alerts and recommendations based on the clinical and nonclinical needs of patients, including their preferences, lifestyle factors, environmental and public health issues, social determinants of health, and goals for care.

Potential leaders of this activity include HIMSS, PSOs, vendors, the Society for Medical Decision Making, the NAM, Intermountain Healthcare, Kaiser Permanente, Brigham and Women's Hospital, other integrated health systems or academic medical centers, and federal agencies.

13. Establish an investment program for CDS research

- Establish a national investment in a variety of research projects focused on CDS, such as multisite pragmatic cluster randomized controlled trials and implementation research—either as stand-alone projects or incorporated into other research studies conducted within real-world environments—to evaluate the optimal approaches for delivering CDS in diverse, representative clinical settings, especially:
  - the use of implemented tools within real-world environments;
  - implementation of CDS resources within various workflow and implementation models;
  - comparison and validation of various CDS implementation models; and
  - feedback on CDS use, efficacy, and usability over time to determine what is working and what is missing.

Potential leaders for this activity could include federal agencies, PCORI, IHI, the NAM, ICER, the Duke Clinical Research Institute, Duke Center for Health Informatics, the American Cancer Society, the American Heart Association, and provider societies such as the American College of Physicians and the American Academy of Family Physicians.

MOVING AHEAD

While there is important benefit to federal leadership for developing regulations, providing guidance, and funding research, advancement toward adoption

of CDS relies on engagement, leadership, and collaboration among multiple sectors and stakeholders. Industry could have a leadership role in helping to identify and test standards; knowledge from front-line users is crucial to understanding priorities, usage, workflow, and design; and professional societies are positioned to disseminate best practices and guidelines. Additionally, a convening authority for standard-setting might offer a vehicle for customer voices to motivate changes with vendors, as well as facilitate collaboration between societies, multiple vendors, and different specialties to develop building blocks for improvement.

The Steering Committee and meeting participants shared a common vision that CDS is an essential tool for health care that holds great potential for improving health delivery and outcomes. A common observation was that many participants have been engaged in trying to improve CDS for years in their own systems and throughout a number of national initiatives, and despite frustration at the pace of adoption, a number of key factors, including the emergence of new technological and policy advancements, as well as the increased willingness for collaboration across sectors, foster a health ecosystem more open to the acceleration of CDS use. Specifically, they see opportunities for:

- **increased engagement of stakeholders** in the design, implementation, and use of CDS;
- the **incorporation of new knowledge**, including patient-reported outcomes and contextual information, into CDS;
- a renewed focus on **clinical decision support for health care teams**;
- the **creation of new multistakeholder partnerships** to develop practical implementation tools and lead standardization and regulatory efforts;
- the development and deployment of CDS **for public health response**; and
- the strengthening of the **CDS implementation evidence base**.

With near-universal use of EHRs throughout hospitals and office practice settings, the time is at hand for modest investments by multistakeholder partnerships to refine technical standards, develop and create governance approaches to facilitate quality, consistency, effectiveness, and efficiency for health care teams and their patients.

By taking into account the current environment, engaging multiple stakeholders, and committing to the priorities of action identified through this work, the adoption and use of CDS may be better developed, implemented, used, and shared thus delivering on its potential to facilitate patient and clinician engagement, enhance care delivery, accelerate system-wide continuous learning, and improve health care outcomes.

APPENDIX A

MEETING SERIES AGENDAS

Leadership Consortium for a Value & Science-Driven Health System

OPTIMIZING STRATEGIES FOR CLINICAL DECISION SUPPORT: MEETING NO. 1

❖

– Sponsored by the Office of the National Coordinator for Health Information Technology –

❖

March 16, 2016
National Academy of Sciences Building
Lecture Room
2101 Constitution Ave NW
Washington, DC

MEETING GOAL

Explore issues and opportunities to take the **real-time application and use** of Clinical Decision Support (CDS) to the next level in informing health and health care decision making.

Meeting Objectives:

1. **Current status:** Describe current and emerging CDS practices.
2. **Validation:** Identify approaches to validating CDS resources.
3. **Spread and scale:** Consider implementation challenges and strategies at a national scale.

8:30 am Coffee and light breakfast available

9:00 am Welcome, introductions, and meeting overview

Welcome from the NAM

- *Michael McGinnis,* National Academy of Medicine

Welcome from the ONC

- *Andrew Gettinger,* ONC

Opening remarks and charge

- *James Tcheng,* Duke University School of Medicine, Steering Committee Chair

9:30 am CDS progress in a learning health system

Presenters highlight the progression of CDS initiatives to date, including strategies for adoption and use of CDS within a learning health system.

- *Jonathan Teich,* Brigham and Women's Hospital/Harvard University, Elsevier Clinical Solutions, and OpenMRS/Bahmni
- *Charlotte Weaver,* health care executive

10:15 am A vision for CDS adoption and use

Participants reflect on the ONC *Health IT Enabled Quality Improvement* vision report, as well as a strategic plan for its future.

- *Tejal K. Gandhi*, National Patient Safety Foundation, *moderator*
- *Kensaku Kawamoto,* University of Utah
- *Scott Weingarten*, Cedars-Sinai Health System

11:15 am Break

11:30 am Implementation at the front-line: barriers & approaches

Front-line decision-makers discuss CDS implementation challenges and strategies.

- *Suzanne Bakken*, Columbia University, *moderator*
- *Hugh Bonner III*, Saint Francis Hospital
- *Kathryn Bowles,* Visiting Nurse Service of New York

12:30 pm Luncheon presentation: addressing CDS governance

Presenters explore outstanding governance issues and their impact on data exchange, real-time CDS application, and use.

- *David Bates*, Brigham and Women's Hospital
- *Blackford Middleton*, Apervita Inc.

1:30 pm Continuously learning: approaches for scale and spread

Participants discuss CDS best practices and approaches for dissemination of lessons learned within and across health systems.

- *Edwin Lomotan*, Agency for Healthcare Research and Quality, *moderator*
- *Thomas Graf*, The Chartis Group
- *Steve Peters,* Mayo Clinic

2:30 pm Agenda setting: identifying next steps for moving ahead

Participants consider outstanding issues for consideration and propose meeting topics and additional stakeholders for the remaining meetings in the series.

- *Michael McGinnis,* National Academy of Medicine

3:00 pm Summary and next steps

Comments from the Chair

- *James E. Tcheng,* Duke University School of Medicine

Comments and thanks from the NAM

- *Michael McGinnis,* National Academy of Medicine

3:30 pm Adjourn

Leadership Consortium for a Value & Science-Driven Health System

OPTIMIZING STRATEGIES FOR CLINICAL DECISION SUPPORT: MEETING NO. 2

❖

– Sponsored by the Office of the National Coordinator for Health Information Technology –

❖

October 27, 2016
National Academy of Sciences Building
Lecture Room
2101 Constitution Ave NW
Washington, DC

MEETING FOCUS

Opportunities and practical strategies for improving clinical decision support (CDS) practices and adoption.

Core questions:

4. **Action plans.** What are the key insights from the four working groups: CDS content, system integration, operations, and spread?
5. **CDS advancement.** What are the key priorities for next steps?
6. **Leadership.** What can ONC (and NAM) do to accelerate progress?

Anticipated outcome: Identification of key elements for expanded CDS adoption and use.

8:30 am Coffee and light breakfast available

9:00 am Welcome, introductions, and meeting overview

Welcome from the National Academy of Medicine (NAM)

- *Michael McGinnis*, NAM

Welcome from the Office of the National Coordinator for Health Information Technology (ONC)

- *Vindell Washington*, ONC

9:15 am Project vision and progress

The NAM and ONC have partnered to explore practical strategies for improving CDS practices and adoption. In this session, Steering Committee Chair Dr. James Tcheng will discuss progress to date, including the effort of four workgroups focused on CDS content, implementation, operations, and spread; and outline the vision for continued engagement and action.

Presenter:

- *James Tcheng,* Duke University School of Medicine, Steering Committee Chair

9:30 am Workgroup reports

CDS content:

- *Kensaku Kawamoto*, University of Utah

CDS technical implementation:

- *Scott Weingarten*, Cedars-Sinai Health System

10:30 am Break

10:45 am Workgroup reports (continued)

CDS operations in real-world environments:

- *Jonathan Teich*, Harvard University, Elsevier Clinical Solutions, and OpenMRS/Bahmni

Fostering CDS spread:

- *Blackford Middleton*, Apervita Inc.

12:00 pm Working lunch: common themes from workgroups

Facilitator:

- *James Tcheng*, Duke University School of Medicine, Steering Committee Chair

2:00 pm Identifying priorities for moving forward

Participants will discuss finalizing the priorities for action and consider topics and additional stakeholders for inclusion during the remaining meeting in the series.

- **Facilitator:** *Michael McGinnis,* National Academy of Medicine

2:30 pm Summary and next steps

Comments from the Chair

- *James E. Tcheng,* Duke University School of Medicine

Comments and thanks from the NAM

- *Michael McGinnis,* National Academy of Medicine

3:00 pm Adjourn

Leadership Consortium for a Value & Science-Driven Health System

OPTIMIZING STRATEGIES FOR CLINICAL DECISION SUPPORT: MEETING NO. 3

❖

– Sponsored by the Office of the National Coordinator for Health Information Technology –

❖

February 10, 2017
Keck Center
Room 100
Washington, DC 20001

MEETING FOCUS

Opportunities and practical strategies for improving clinical decision support (CDS) practices and adoption.

Core questions:

7. **CDS advancement strategies**. What are the key priorities for next steps?
8. **CDS advancement responsibilities**. What organizations will take the lead in implementing the identified action steps?
9. **CDS progress targets and monitoring**. What do meeting participants hope to see accomplished in five years? In 10 years? How should this be tracked?

Anticipated outcome: Elements of a roadmap for expanded CDS adoption and use

8:30 am Coffee and light breakfast available

9:00 am Welcome, introductions, and meeting overview

Welcome from the NAM
- *Michael McGinnis,* National Academy of Medicine

Welcome from the ONC
- *Andrew Gettinger*, ONC

Opening remarks and charge
- *James Tcheng,* Duke University School of Medicine, Steering Committee Chair

9:15 am Optimizing CDS Use & Adoption: A Call for Action

Dr. James Tcheng presents an overview of the *Optimizing Strategies for Clinical Decision Support* project, and resulting list of proposed Priorities for Action.

- *James Tcheng,* Duke University School of Medicine, Steering Committee Chair

9:30 am Priorities for Action: An Industry Response

Representatives from the EHR vendor industry discuss the implementation strategies and leadership needed to advance the proposed Priorities for Action.

- *Jonathan Teich*, Harvard University, Elsevier Clinical Solutions, and OpenMRS/ Bahmni, *moderator*

Panel of Discussants:
- *James Doyle,* Epic
- *Marc Overhage*, Cerner
- *Todd Rothenhaus*, athenahealth

Q&A and open discussion

10:45 am Break

11:00 am Priorities for Action: Addressing Next Steps in the Field

Front-line decision-makers discuss the implementation strategies and leadership needed to advance the proposed Priorities for Action.

- *Suzanne Bakken*, Columbia University, *moderator*

Panel of Discussants:
- *Hugh Bonner III*, Saint Francis Hospital
- *Jeffrey Cohn,* Broadlands Family Medicine Residency
- *Sumi Sexton,* Premier Primary Care Physicians

Q&A and open discussion

12:00 pm Luncheon presentation: The AHRQ PCOR CDS Initiative

A session focused on how the AHRQ PCOR CDS Initiative might serve as a resource for advancing the proposed Priorities for Action; provide a forum for further discussion, and the infrastructure for future engagement and dissemination of CDS advancements.

- *Edwin Lomotan*, Agency for Healthcare Research and Quality, *moderator*
- *Rob McCready,* CDS Connect, MITRE Corporation
- *Barry Blumenfeld*, PCOR CDS Learning Network, RTI International

Q&A and open discussion

1:00 pm Priorities for Action: Partnering with Professional Societies

Professional society representatives discuss the implementation strategies and leadership needed to advance the proposed Priorities for Action.
- *Tejal K. Gandhi*, National Patient Safety Foundation, *moderator*

Panel of Discussants:
- *Dino Damalas*, American College of Cardiology
- *Angie Fagerlin*, Society for Medical Decision Making
- *Doug Fridsma*, American Medical Informatics Association

Q&A and open discussion

2:00 pm Identifying strategies for moving forward

Participants discuss finalizing the Priorities for Action within their own organizations and future steps for moving forward CDS progress.

- *James Tcheng,* Duke University School of Medicine, Steering Committee Chair

2:30 pm Summary and next steps

Comments from the Chair

- *James E. Tcheng,* Duke University School of Medicine

Comments and thanks from the NAM

- *Michael McGinnis,* National Academy of Medicine

3:00 pm Adjourn

APPENDIX B

MEETING SERIES PARTICIPANTS[14]

Brian S. Alper, MD, MSPH, FAAFP, Founder, DynaMed; Vice President, Innovations and EBM Development, EBSCO Health

Brian Anderson, MD, Strategic Account Executive, Kyruus

Suzanne Bakken, PhD, RN, FAAN, FACMI,* Alumni Professor of Nursing; Professor, Biomedical Informatics, Columbia University

JoAnna Baldwin, MS, Senior Policy Advisor, Centers for Medicare and Medicaid Services

David W. Bates, MD, MSc,* Senior Vice President and Chief Innovation Officer, Brigham and Women's Hospital

Andrew Bazemore, MD, MPH, Director, Robert Graham Center, American Academy of Family Physicians

Barry Blumenfeld, MD, MS, Senior Physician Informaticist, RTI International

Hugh Bonner III, MD,* Associate Director, Saint Francis Family Medicine Residency Program, Saint Francis Healthcare

Kathryn H. Bowles, PhD, RN, FAAN, FACMI, vanAmeringen Professor in Nursing Excellence and Director, Center for Integrative Science in Aging, University of Pennsylvania School of Nursing

14 Listed alphabetically

* Planning committee member

Aziz Boxwala, MD, PhD, Co-CEO, Elimu Informatics Inc.

Tiffani Bright, PhD, Director of Informatics Development, Institute for Informatics, Washington University School of Medicine

Jeffrey Cohn, MD, Physician, Broadlands Family Practice

Dino Damalas, MBA, Chief Operating Officer, American Academy of Orthopaedic Surgeons

James Doyle, Research and Development Product Lead, Epic

Joshua Duncan, MD, FAAP, Chief Resident, General Preventive Medicine Residency, Uniformed Services University of the Health Sciences

Patricia C. Dykes, PhD, RN, FAAN, FACMI, Senior Nurse Scientist; Program Director, Center for Patient Safety Research and Practice; Program Director, Center for Nursing Excellence, Brigham and Women's Hospital,

Shahram Ebadollahi, MS, MBA, PhD, Vice President, Innovations and Chief Science Officer, IBM Watson Health Group

MaryAnne Elma, MPH, Senior Director, Guidelines and Clinical Tools/Apps, American College of Cardiology

Angie Fagerlin, PhD, Professor and Chair, Department of Population Health Sciences, University of Utah; Research Scientist, Salt Lake City Veterans Affairs Center for Informatics Decision Enhancement and Surveillance

Valerie Florance, PhD, Director, National Library of Medicine Extramural Programs, National Library of Medicine, National Institutes of Health, U.S. Department of Health and Human Services

Rebecca Freeman, PhD, RN, PMP, Chief Nursing Officer, Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services

Doug Fridsma, MD, PhD, FACP, FACMI, President and Chief Executive Officer, American Medical Informatics Association

Tejal K. Gandhi, MD, MPH, CPPS,* President & Chief Executive Officer, National Patient Safety Foundation, NPSF Lucian Leape Institute, and Certification Board for Professionals in Patient Safety

Andrew Gettinger, MD, FCCP, FCCM, Chief Medical Information Officer; Director, Office of Clinical Quality and Safety, Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services

Thomas Graf, MD, Vice President and Chief Medical Officer, Horizon Blue Cross Blue Shield of New Jersey

Leslie Kelly Hall, Senior Vice President, Policy, Healthwise

Sarah Hampton, CORE Program Specialist, Association of American Medical Colleges

Aisha Hasan, MBA, Senior Advisor to the National Coordinator, Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services

Amy Helwig, MD, MS, FAAFP, Chief Quality Officer & Vice President, Quality Improvement and Performance, UPMC Health Plan

Tonya Hongsermeier, MD, MBA, Chief Medical Information Officer, Lahey Health

Betsy L. Humphreys, MLS, Former Deputy Director, National Library of Medicine, National Institutes of Health, U.S. Department of Health and Human Services

Joseph Hutter, MD, MA, U.S. Public Health Service Medical Officer, Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services

Meredith Josephs, MD, MPH, FAAFP,* Senior Medical Director and Senior Director, Clinical IT and Training, Privia Health

Steven Kator, MD, MS, FACP, Clinical Informaticist, Veterans Health Administration, Cochief Medical Informatics Officer, U.S. Department of Defense/U.S. Department of Veterans Affairs Interagency Program Office

Kensaku Kawamoto, MD, PhD, MHS, Associate Chief Medical Information Officer, Director of Knowledge Management and Mobilization, Assistant Professor of Biomedical Informatics, University of Utah Health Sciences Center

Keith G. Larsen, RPh, Medical Informaticist, Intermountain Healthcare

Jennifer Lee, MD, Deputy Under Secretary for Health for Policy and Services, Veterans Health Administration, U.S. Department of Veterans Affairs

Joy Lewis, MSW, MPH, Senior Health Policy Consultant, Kaiser Permanente Institute for Health Policy

Edwin A. Lomotan, MD, FAAP,* Medical Officer and Chief of Clinical Informatics, Health IT Division, Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality

Erin Mackay, MPH,* Associate Director, Health Information Technology Programs, National Partnership for Women & Families

Paul Magelli, MS, MBA, Chief Executive Officer, Apervita, Inc.

Joshua Mandel, MD, Health IT Ecosystem Lead, Verily; Research Scientist, Biomedical Informatics, Harvard Medical School, and Department of Biomedical Informatics, Boston Children's Hospital

Thomas C. Mayes, MD, Clinical Professor, Department of Pediatrics, University of Texas Health Center at San Antonio

John D. McGreevey III, MD, FACP, Associate Professor of Clinical Medicine, Associate Chief Medical Information Officer, University of Pennsylvania Health System

Blackford Middleton, MD, MPH, MSc, Chief Informatics and Innovation Officer, Apervita, Inc.

Rachel Nelson, MHA, JD, Deputy Director, Office of Clinical Quality & Safety, Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services

J. Marc Overhage, MD, PhD, Chief Medical Informatics Officer, Cerner Corporation

Steve Peters, MD, Vice Medical Information Officer, Medical Director, Knowledge Delivery Center, Mayo Clinic

Robert Phillips, MD, MSPH, Vice President, Research and Policy, American Board of Family Medicine

Ernie Ratcliff, Vice President, Technology Engineering, Reed Elsevier

Andrew Robie, MD, Medical Director, Unity Health Care

Roberto Rocha, MD, PhD, Clinical Informatics Director, Partners eCare, Partners Healthcare; Assistant Professor of Medicine, General Internal Medicine and Primary Care, Brigham and Women's Hospital, Harvard Medical School

Todd Rothenhaus, MD, FACEP, Senior Vice President and Chief Medical Officer, athenahealth, Inc.

Hoda Sayed-Friel, Executive Vice President, Meditech

Sumi Sexton, MD, President, Premier Primary Care Physicians; Associate Deputy Editor, American Family Physician, Associate Professor, Department of Family Medicine, Georgetown University School of Medicine

Shaman Singh, MD, Clinical Lead, Office of Connected Care, Veterans Health Administration, U.S. Department of Veterans Affairs

Julia Skapik, MD, MPH, Internist and Medical Officer, Office of Clinical Quality and Safety, Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services

Jack Starmer, MD, MMHC, Vice President and Associate Chief Medical Information Officer, Community Health Systems

Howard Strasberg, MD, MS, Vice President, Medical Informatics, Wolters Kluwer Health

Katherine Szarama, PhD, Presidential Management Fellow, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services

Paul Tang, MD, MS, Vice President, Chief Health Transformation Officer, IBM Watson Health Group

James E. Tcheng, MD, FACC, FSCAI, FESC,* Professor of Medicine, Interventional Cardiologist, Duke University School of Medicine

Jonathan M. Teich, MD, PhD,* Department of Emergency Medicine, Brigham and Women's Hospital/Harvard University; Chief Medical Information Officer, Elsevier Clinical Solutions; Clinical Architect, OpenMRS/Bahmni

Lauren Thompson, PhD, MHSA, Director, U.S. Department of Defense/U.S. Department of Veterans Affairs Interagency Program Office

Charlotte Weaver, RN, MSPH, PhD, Former Senior Vice President and Chief Clinical Officer, Gentiva Health Services

B. Vindell Washington, MD, MHCM, FACEP, Former National Coordinator, Health Information Technology, Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services

Jeff Weinfeld, MD, MBI, FAAFP, Physician, MedStar/Georgetown

Scott Weingarten, MD, MPH,* Senior Vice President, Chief Clinical Transformation Officer, Cedars-Sinai Health System

Michael Wittie, MPH, Public Health Analyst, Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services

Adam Wright, PhD, FACMI, Senior Scientist, Brigham and Women's Hospital, Associate Professor of Medicine, Harvard Medical School

Michael Zaroukian, MD, PhD, MACP, FHIMSS, Vice President and Chief Medical Information Officer, Sparrow Health System

APPENDIX C

EDITOR BIOGRAPHIES

James E. Tcheng, MD, FACC, FSCAI, is a Professor of Medicine, Department of Medicine, Division of Cardiology, and Professor of Community and Family Medicine (Informatics), Department of Community and Family Medicine of the Duke University School of Medicine. Dr. Tcheng received his MD from the Johns Hopkins University School of Medicine (Baltimore, MD) and completed his residency in medicine at Barnes Hospital/Washington University (St. Louis, MO). He completed fellowship training in cardiology at Duke University and joined the faculty of Duke in 1988. Dr. Tcheng is a practicing interventional cardiologist and faculty of the Duke Clinical Research Institute (DCRI) and the Duke Center for Health Informatics (DCHI). He serves as Director of the Duke Cardiovascular Databank and Director of Performance Improvement for the Duke Heart Center. He previously was the Medical Knowledge Architect responsible for the implementation of clinical decision support across the Duke Health System. He is currently faculty of the Medical Device Epidemiology Network (MDEpiNet) Coordinating Center of the DCRI. In addition, he is Chair of the Informatics and Health IT Task Force of the American College of Cardiology, is a member of the ACC National Cardiovascular Data Registry Management Board, and the ACC/AHA Task Force on Clinical Data Standards. He is an accomplished educator and is the 2015 recipient of the Duke Master Clinician/Teacher award. Dr. Tcheng has led a number of informatics initiatives spanning professional societies, regulatory and other government agencies, industry, and non-governmental organizations to develop clinical data standards and interoperability solutions, and to integrate structured reporting into clinical workflows. His current work focuses on harmonizing the clinical definitions and informatics of cardiovascular clinical data elements across academia, regulatory agencies, the life sciences industry, professional societies, and standards organizations, to improve the capture, communication, interoperability, and analysis of health care information.

Suzanne Bakken, RN, PhD, FAAN, FACMI, is the Alumni Professor of Nursing and Professor of Biomedical Informatics at Columbia University. She directs the Precision in Symptom Self-Management (PriSSM) Center and the Reducing Health Disparities Through Informatics (RHeaDI) pre- and post-doctoral training program and also leads a federally funded program of informatics research focused on advancing health equity for Latinos. In 2015–2016, she served as the AAN/ANA/ANF Distinguished Nurse Scholar-in-Residence at the National Academy of Medicine where she focused on the intersection of data science and health equity. Dr. Bakken is an elected fellow of the New York Academy of Medicine, American Academy of Nursing, and American College of Medical Informatics, and is a member of the National Academy of Medicine.

David Bates, MD, MSc, is an internationally known expert in medication safety, patient safety, evaluation, and clinical informatics, and has also done extensive work on improving efficiency, quality, and on assessing HIT adoption and issues around interoperability. He has done some of the leading work demonstrating the effects of implementation of CPOE on medication safety. He also has published on the effects of sleep on errors and adverse events. He is a primary care provider and is Chief of the Division of General Internal Medicine and Primary Care at Brigham and Women's Hospital. He served as external lead for patient safety research for WHO and has served as PI of many proposals from AHRQ on using HIT to improve safety and quality.

Hugh Bonner, MD, is a graduate of Haverford College and the University of Pennsylvania School of Medicine. He completed his Family Medicine Residency at Christiana Care Health System in Wilmington, Delaware. Dr. Bonner was in private practice for many years and during that time, served as a preceptor, regularly teaching residents. In 2006, he joined the faculty at Saint Francis Healthcare. Dr. Bonner has a special interest in evidence-based medicine and geriatrics. In addition to a busy clinical practice, he oversees the nursing home experience for second- and third-year residents, supervises residents conducting home visits, and teaches on the inpatient service. Dr. Bonner is a past president of the Delaware Academy of Family Physicians. He continues to serve on the Board of the DAFP as an alternate delegate from Delaware to the American Academy of Family Physicians Congress of Delegates. Dr. Bonner serves as the Director of Medical Grand Rounds at Saint Francis Healthcare.

Tejal Gandhi, MD, MPH, CPPS, is Chief Clinical and Safety Officer, Institute for Healthcare Improvement (IHI), where she leads IHI programs

focusing on improving patient and workforce safety. Dr. Gandhi was President and Chief Executive Officer of the National Patient Safety Foundation (NPSF) from 2013 until 2017, when the Foundation merged with IHI. She continues to serve as President of the Lucian Leape Institute, a think tank founded by NPSF that now operates under the IHI patient safety focus area. She is President of the Certification Board for Professionals in Patient Safety. Dr. Gandhi was formerly the Executive Director of Quality and Safety at Brigham and Women's Hospital, and Chief Quality and Safety Officer at Partners Healthcare. In these roles, she led the efforts to standardize and implement patient safety best practices across hospital and health systems. Throughout her career, Dr. Gandhi has been committed to educating other clinicians on the topic of patient safety. She has been an invited speaker for numerous organizations, has mentored physicians in post-doctoral study, and has frequently served on national and regional committees and boards. She was included in *Modern Healthcare*'s 100 Most Influential People in Healthcare in 2014, 2015, and 2016 and was also one of their 2015 Top 25 Women in Healthcare. She is also a member of the Aurora Health Care Board of Directors. Dr. Gandhi's research interests focus on patient safety and reducing error using information systems. In 2009, she received the John M. Eisenberg Patient Safety and Quality Award for her contributions to understanding the epidemiology and possible prevention strategies for medical errors in the outpatient setting. Dr. Gandhi is a board certified internist and Associate Professor of Medicine at Harvard Medical School, and is a Certified Professional in Patient Safety. She received her MD and MPH from Harvard Medical School and the Harvard School of Public Health, and trained at Duke University Medical Center. Her undergraduate training at Cornell University was in biochemistry.

Meredith Josephs, MD, MPH, FAAFP, is a clinical informatician with expertise using health information technology to support clinicians and maximize the quality of patient care. Dr. Josephs is Senior Medical Director and Senior Director, Clinical IT & Training at Privia Health. Dr. Josephs is working to optimize the implementation and use of electronic health records, clinical decision support, and telehealth for Privia practices. Dr. Josephs is a graduate of the University of Maryland School of Medicine and the Franklin Square Family Medicine Residency Program. She is a fellow of the American Academy of Family Physicians and is board certified in both Family Medicine and Clinical Informatics. Dr. Josephs received her Master's in Public Health from the George Washington University and a Graduate Certificate in Biomedical Informatics from the Oregon Health & Science University.

Kensaku Kawamoto, MD, PhD, MHS, is Associate Chief Medical Information Officer, Director of Knowledge Management and Mobilization, and Assistant Professor of Biomedical Informatics at the University of Utah. Dr. Kawamoto earned his BA in biochemical sciences from Harvard University, and he earned his MD, PhD in biomedical engineering with a focus on biomedical informatics and MHS in clinical research from Duke University. At the University of Utah, Dr. Kawamoto chairs the Clinical Decision Support committee and is a leader of the University's Interoperable Apps and Services (IAPPS) initiative, which is a multi-stakeholder effort to enable standards-based, interoperable applications and software services to improve health and health care. Dr. Kawamoto is also engaged in the development and leveraging of predictive models to address important health care needs, and he is a Co-Solution Architect of the Value Driven Outcomes (VDO) framework for analyzing and improving care value. Beyond the University of Utah, Dr. Kawamoto co-chairs the Clinical Decision Support Work Group of Health Level 7 International (HL7), the primary standards development organization in health IT. He also served as Co-Initiative Coordinator for the Clinical Quality Framework initiative (http://www.cqframework.info), which was a public-private partnership sponsored by the Office of the National Coordinator for Health IT and the Centers for Medicare & Medicaid Services to develop and validate a harmonized set of interoperability standards for clinical decision support and electronic clinical quality measurement. Dr. Kawamoto also founded and directs OpenCDS (www.opencds.org), which is a multi-institutional initiative to enable advanced, standards-based, and open-source clinical decision support and electronic clinical quality measurement at scale. Dr. Kawamoto is a member of the U.S. Health IT Advisory Committee, which provides guidance to the U.S. Office of the National Coordinator for Health IT on policies, standards, implementation specifications, and certification criteria related to health information technology.

Edwin Lomotan, MD, FAAP, serves as Medical Officer and Chief of Clinical Informatics for the Health IT Division in the Center for Evidence and Practice Improvement at the Agency for Healthcare Research and Quality (AHRQ). His areas of focus include clinical decision support, child health informatics, and health IT safety. He currently leads AHRQ's CDS initiative, which aims to accelerate evidence into practice through CDS and to make CDS more shareable, standards-based, and publicly available. Before joining AHRQ, Dr. Lomotan was Health IT Branch Chief in the Office of Quality and Data in the Bureau of Primary Health Care at the Health Resources and Services Administration (HRSA). While at HRSA, he led the Health Center-Controlled Network grant program, which was aimed at improving health care quality through health IT

at community health centers across the country. Dr. Lomotan is board-certified in pediatrics and clinical informatics. He received his medical degree from the University of Pittsburgh. He completed his pediatrics residency and informatics fellowship at Yale University. He also spent several years in community pediatric practice in Connecticut before joining federal service in 2010.

Erin A. Mackay, MPH, is the Associate Director of Health Information Technology Policy and Programs at the National Partnership for Women & Families. Ms. Mackay manages the Consumer Partnership for eHealth, a coalition of consumer and patient advocacy organizations working to advance health IT in ways that meet the needs of individuals and their families. Ms. Mackay also directs the GetMyHealthData initiative, a national effort which helps patients gain access to their health information in electronic formats, offers educational resources to patients and providers, and advocates for advancements in policy and practice. In these roles, Ms. Mackay advocates for health IT policies and practices that enhance patient access and use of health data, facilitate care coordination and communication, address health disparities, and improve health outcomes.

Blackford Middleton, MD, MPH, MSc, FACP, FACMI, FHIMSS, is Chief Informatics and Innovation Officer at Apervita, Inc., and Past-Chair of the Board of Directors of the American Medical Informatics Association (AMIA), and the Healthcare Information Management and Systems Society (HIMSS). He is also Instructor in the Harvard T.H. Chan School of Public Health in the Departments of Health Policy and Management, and Policy Translation and Leadership Development. Previously, he was a Professor of Biomedical Informatics and/or of Medicine at Stanford, Harvard, and Vanderbilt Universities, and he held executive leadership roles at MedicaLogic/Medscape, Partners Healthcare System, and at Vanderbilt. Dr. Middleton's work is focused on clinical informatics – the applied science surrounding strategy, design, implementation, and evaluation of clinical information systems in complex environments. Currently, he is Co-Chair of the AHRQ-funded PCOR Clinical Decision Support Learning Network. From 2013-2014, he was Assistant Vice Chancellor for Health Affairs, and Chief Informatics Officer (CIO), at Vanderbilt University Medical Center, and responsible for information technology supporting clinical informatics, educational informatics, research informatics, and financial systems. Prior to joining Vanderbilt, he was Corporate Director of Clinical Informatics Research & Development (CIRD) at Partners Healthcare System, Boston, and Assistant Professor of Medicine at Brigham and Women's Hospital, Harvard Medical School. His work at Partners HealthCare focused on building an advanced

informatics infrastructure to support translational research, and the development and implementation of knowledge-based tools for cloud-based clinical decision support, knowledge engineering, population management, and comparative effectiveness research. While at Partners he also was Co-Founder of the Center for Information Technology Leadership (CITL) and led its research in value-based technology assessment until 2010. He serves on the CAHIIM (Commission on Accreditation for Health Informatics and Information Management Education) Health Informatics Accreditation Council (HIAC), and the HL7 Advisory Council. He also serves on several Editorial Boards. He served as a member of the National Quality Forum Health IT Advisory Council (HITAC) from 2010-2012, and served on the NQF Measure Variation Expert Panel as Co-Chair.

Jonathan Teich, MD, PhD, has been deeply involved with clinical decision support (CDS) and EHR design for over twenty years in a variety of academic, industry, government, and provider settings. He is a practicing Emergency Physician at Brigham and Women's Hospital, Assistant Professor of Medicine and Emergency Medicine at Harvard, and Clinical Design Leader for Health Information Systems in Developing Countries with the OpenMRS Community. Dr. Teich founded the Clinical Informatics R&D department at Partners Healthcare, developing two generations of innovative electronic health records, CPOE, and CDS systems. He helped found HEALTHvision, a startup that developed some of the first Internet-based health information exchanges, and served as Chief Medical Informatics Officer for Elsevier, where he helped lead the vision, strategy, and design for knowledge-based tools and CDS directly supporting clinical practice and healthcare delivery. Dr. Teich has authored over 100 papers, books, and editorials in medical informatics and health care information systems. He is a co-author of the book *Improving Outcomes with Clinical Decision Support: An Implementer's Guide*. He co-chaired the HHS-sponsored *Roadmap for National Action on Clinical Decision Support*, and from 2009-2012 he served as a subject-matter expert on CDS for the Office of the National Coordinator (ONC). Dr. Teich serves on a variety of industry and government councils on CDS, knowledge delivery, patient safety, and quality. He has served on the board of directors of AMIA, HIMSS, and the eHealth Initiative.

Scott Weingarten, MD, MPH, is Senior Vice President and Chief Clinical Transformation Officer at Cedars-Sinai. He is a Professor of Medicine at Cedars-Sinai Health System. Board certified in internal medicine and a Fellow of the American College of Physicians, Dr. Weingarten has published approximately 100 articles and editorials on health care quality improvement, clinical decision

support, and related topics, and has authored numerous chapters on improving the quality of patient care in some of the leading internal medicine textbooks. He has given more than 300 presentations on clinical decision support and related topics throughout the United States and internationally. Dr. Weingarten has held positions on myriad national committees dedicated to improving patient outcomes, including those of the Institute for Medical Quality, the American Heart Association's "Get With The Guidelines" program, and the quality improvement committee of the board of directors of St. Joseph's Health System. He is currently a Board Director for the Scottsdale Institute. At Cedars-Sinai, he has been awarded both the President's Award and the Golden Apple Teaching Award, and was Alumnus of the Year for 2009. Dr. Weingarten was the Co-Founder, President, and Chief Executive Officer of Zynx Health, which is the leader for order sets and care plans for electronic health records. Dr. Weingarten sold Zynx Health to the Cerner Corporation and later to the Hearst Corporation. He is a Co-Inventor of three software patents granted by the United States Patent and Trademark Office. Scott is also Chairman of the Board of Stanson Health. After graduating from UCLA's medical school, Dr. Weingarten completed his internship, residency, and fellowship in internal medicine at Cedars-Sinai. He later participated in a National Center for Health Services Research Fellowship at the RAND/UCLA Center for Health Policy Study. During the fellowship, he also earned an MPH at the UCLA Fielding School of Public Health.

Marianne Hamilton Lopez, PhD, MPA, is Research Director of the Value-Based Payment Reform portfolio at Duke-Margolis. In this role, she manages the center's activities aimed at identifying barriers and facilitating implementation of new value-based payment models for pharmaceuticals, including gene therapies and medical devices. She oversees the *Developing a Path to Value-Based Reimbursement for Medical Products Consortium* and partners with Duke University faculty, scholars, and external health experts to advance this work. Prior to joining Duke-Margolis, Dr. Hamilton Lopez was a Senior Program Officer with the National Academy of Medicine's Leadership Consortium for a Value & Science-Driven Health System and provided strategic direction and oversight of the Consortium's Science and Technology portfolio and Clinical Effectiveness Research Innovation and Digital Learning Collaboratives. She was a Senior Manager at AcademyHealth; a Public Health Community Advisor for the United States Cochrane Center; and the Federal Women's Program Manager and American Indian/Alaska Native Employment Program Manager for the National Institutes of Health.