Clinical Decision Support Workshop Meeting Summary

August 25 – 26, 2009
Office of the National Coordinator for Health Information Technology
Department of Health & Human Services, Hubert Humphrey Building
200 Independence Ave. S.W.
Washington, DC 20201

This document summarizes the proceedings of a Clinical Decision Support (CDS) Workshop held by the Office of the National Coordinator for Health Information Technology on August 25-26, 2009, in Washington, DC. The CDS Workshop was a widely attended gathering of subject matter experts who shared their thoughts on a series of topics related to advancing the utility, usability, and meaningful use CDS. Attendees represented a broad spectrum of expertise, including clinical informatics, quality improvement, patient advocacy, provider, payor, knowledge vendor, and electronic health records (EHR) system vendor perspectives.

The intent of CDS is to provide clinicians, patients (and their family members, where appropriate), and other individuals involved in the increasingly team-based processes of health care with generally applicable knowledge and person-specific information that is intelligently filtered and organized, and that is presented in effective formats at appropriate times, to enhance health and health care. CDS includes, but is not limited to, computerized alerts and reminders to care providers and patients, patient data reports and summaries, documentation templates, advice to promote more accurate and timely diagnoses, contextually relevant reference information, and other tools that enhance decision making in clinical workflow.

The Office of the National Coordinator for Health IT (ONC) is committed to promoting the advancement of CDS. Over the course of several years, ONC has facilitated a variety of activities to catalyze progress in CDS development and deployment in support of enhanced health and care. Three noteworthy milestones in these efforts are represented by the development of: a "CDS Roadmap" in 2006[i]; policy recommendations for advancement of CDS recommended to the Secretary of Health and Human Services (the Secretary) by the American Health Information Community (AHIC) in 2008[ii]; and the formation of the CDS Government Collaboratory, also in 2008. The Collaboratory is an active network of professionals from multiple Departments and Agencies of the Federal Government, whose work relates to the development and deployment of CDS in support of health and health care.

On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act (ARRA) (Public Law 111-5). Two specific titles of ARRA (Title XIII in Division A and Title IV in Division B of the law) may, together, be referenced as the Health Information Technology for Economic and Clinical Health (HITECH) Act. HITECH authorizes an unprecedented investment in the advancement of health information technology to support care for every American, including: a $2 billion appropriation to support a variety of grants programs and other activities to advance the nation's health information technology infrastructure; and authorization of an estimated $45 billion in Medicare and Medicaid incentives for providers who demonstrate meaningful use of certified EHR technology.

CDS Workshop Summary

A part of ONC's portfolio of activities to advance CDS, the August 25-26, 2009, CDS Workshop was convened to gather a wide range of input and to promote discussion across various stakeholder perspectives. The purpose of the workshop was not to reach immediate conclusions, modify a specific document, or make policy or planning recommendations to ONC

or any other public or private organization. Thus, this meeting summary presents a sample of individuals' statements made and ideas expressed during the workshop. This document does not claim to present a majority or consensus opinion on any topic nor represent the position or policies of any federal agency. The information captured here is made available for the information of the public, including all stakeholders in CDS development, deployment, and use.

The August, 2009, CDS Workshop consisted of a series of short framing presentations followed by group discussion on the general topic or theme of the presentations. Framing presentations were given by David Bates, Paul Tang, Jonathan Teich, Jane Metzger, Helen Burstin and Jon White. Workshop proceedings, as described in this document, represent the thoughts and perspectives of individual workshop attendees and not ONC or any other federal or non-federal organization.

CDS Workshop Framing Presentations

The Vision of Meaningful CDS

In a framing presentation regarding the state of the art and vision for CDS, David Bates noted that advanced EHR systems with CDS functionalities have the potential to offer numerous benefits to the safety and quality of patient care, including improving the rate at which patients receive preventive services recommended by clinical guidelines, as well as the potential to facilitate superior financial performance, based on the best return on investment models currently available. While the promise of CDS is great, trials of CDS have produced mixed results and a number of challenges in implementing CDS remain unresolved. Nevertheless, the potential of CDS to improve health care outcomes affirms that truly meaningful use of electronic health records includes the meaningful use of effective CDS.

Dr Bates observed that in both the US and the UK, trials of EHRs including CDS functionality have demonstrated improvement in specific domains, such as increased use of appropriate preventive services and decreased errors in medication orders. He also noted that trials of CDS to improve care for patients' chronic clinical conditions have had mixed results.

Implementation of CDS varies across different healthcare settings and is characterized, Dr Bates noted, by a number of distinct challenges. Acute care settings experience a large degree of variability when implementing CDS. This variability is typically related to the scope of each implementation, rather than vendor capabilities. Ambulatory settings tend to lag acute care settings in implementation of CDS. A key challenge facing broad CDS implementation is a lack of a standard or other generally accepted definition of core CDS functionalities that should exist in a given setting. While there is general consensus that all EHRs should contain some form of drug-to-drug and drug-to-allergy checking, usability concerns arise when tools provide too much information with too little specificity. User acceptance is improved when CDS is initially implemented in a limited form and ramped-up over time. Movement to team-based care, supported by informatics solutions such as patient registries to identify patients at highest risk also support improved patient care quality.

CDS & Meaningful Use of EHR systems

Paul Tang framed CDS against a backdrop of the meaningful use of EHR systems and current recommendations for the 2011 meaningful use criteria. Recommended meaningful use criteria are intended to shift attention away from EHR software toward outcomes of care, including the quality and cost of care. The use of CDS to help achieve quality improvements is both explicit and implied in many of the meaningful use recommendations. Without CDS, measures of health priorities as defined by meaningful use are less likely to meet quality targets or improve over time.

As required by the current text of the authorizing statute, in order for eligible professionals and hospitals to earn meaningful use incentive payments, they must use a certified EHR in a meaningful manner, exchange electronic health information to improve the quality of care, and report on clinical quality measures using a certified EHR. The statute also requires that meaningful use criteria become more stringent over time. The Health IT Policy Committee's 2009 CDS-related recommendations for meaningful use criteria for the 2011 payment year include:

- Capturing clinical data in a standard, coded manner
- Utilizing computerized provider order entry
- Implementing drug-drug, drug-allergy, and drug-formulary checks
- Implementing one CDS rule for a priority condition
- Setting patient reminders per patient preference
- Performing medication reconciliation at transitions of care

Dr Tang noted that the recommended requirement to capture data in a standard, coded manner in 2011 lays the foundation for more advanced CDS-related criteria in 2013 and 2015. The CDS recommendations of the Policy Committee for those later years is not completely formulated at this time; most proposals to advance specific CDS elements in recommended meaningful use criteria should consider focusing on those later time frames rather than 2011.

The Range and Scope of CDS: Making use of varied types of CDS in multiple practice settings

In a framing presentation regarding the breadth of CDS types and functions, Jonathan Teich noted that while CDS is well known as an aid in drug-to-drug, drug-to-allergy, and drug-to-formulary checking, other types of CDS may potentially achieve greater impact. In addition, different practice types/specialties have different priorities for CDS. Given the variety of CDS uses and priorities, definitions or criteria for meaningful use of CDS may need to reflect a broad spectrum of CDS types.

When broadly defined as "information that is filtered to circumstance and displayed to best effect", CDS may take many different forms. At least a dozen different types of CDS have been identified, including:

- Relevant data displays
- Smart documentation forms
- Order facilitators (order sets, order consequents, order modifiers)
- Extended-time guideline and protocol followers
- Targeted reference, including contextually relevant medical references or info buttons
- Reactive alerts
- Task assistants for tasks such as drug dosing and acknowledging laboratory results
- Diagnostic suggestions
- Patient summaries for hand-offs between clinicians
- Procedure refreshers, training, and reminders
- Performance dashboards with prompts for areas needing attention
- Tracking and management systems that facilitate task prioritization and whole-service management

Dr Teich observed that this wide variety of CDS types suggests a need for tools to facilitate the optimal selection and use of CDS. A CDS knowledge framework would assist in identifying which types of CDS are most useful for specific types of problems or objectives. Additionally, a communication mechanism for sharing the best knowledge available would help clinicians determine how best to use CDS as a tool in providing care.

Scope of CDS: Expanding Specialties and Settings

In a framing presentation regarding the scope of CDS, Neil Calman noted that, in the same way that having a Global Positioning System (GPS) in a car widens a driver's potential driving range, CDS is the "value add" application in EHR systems that increases opportunities for improving healthcare quality. The successes and lessons learned from the Institute for Family Health's (IFH's) implementation of CDS as part of their EHR system provide a valuable case study in assessing the real-world usefulness of CDS.

Efforts to ensure the ongoing clinical relevance and utility of CDS, Dr Calman stated, should factor in the expertise of clinicians, clinical leaders, and content experts. IFH, which provides health care services in multiple sites in New York City and the upper Hudson Valley, has been using an electronic health record system since 2002. IFH focused on early wins and teamwork rather than financial incentives to drive its implementation of CDS. Early wins promoting the adoption of CDS by clinicians included reminders to administer flu vaccines and depression screenings. Teamwork also played a key role in IFH's implementation of CDS, as CDS alerts were delivered to both nurses and physicians.

Dr Calman noted that CDS should ideally be used to provide clinicians with information they perceive as helpful. Active engagement by clinicians and rapid turnaround of system changes at IFH has ensured that CDS interventions are current and clinically relevant. IFH focused much effort on maximizing the specificity of CDS interventions and fine-tuning them to the local patient population, thus minimizing alert fatigue while maximizing clinical utility. By helping to define the CDS logic for several hundred CDS interventions, clinical leaders and content experts addressed the complex task of identifying the criteria for triggering CDS interventions. IFH noted that clinicians are highly motivated by CDS-driven data that visibly trends patient care quality outcomes over time.

Dr Calman shared the observation that quality improvement initiatives may require system changes and additional resources to handle increased demand for services related to CDS interventions. For example, if you remind clinicians to administer depression screenings, you will need to plan ahead for additional psychological services to care for patients identified as needing these services. Some improvement initiatives require "clusters" of CDS interventions such as interventions that provide alerts to perform a test, ensure that test results are obtained and inform the subsequent treatment plan. IFH plans to get patients engaged in CDS by providing a pre-visit summary that would allow a patient to review a list of things that the system will recommend prior to the visit so that they can decide what is important to them.

CDS Implementation and Usability: Challenges and Success Factors

Jane Metzger shared that few organizations have EHRs that can deliver CDS, and even fewer organizations implement more than the most basic CDS functions. At the same time, there is a small but growing number of organizations that are making extensive use of CDS. While use of CDS should be the norm and not the exception, implementing CDS in a way that is useful to clinicians and complements existing clinical workflows is a significant challenge to the widespread, optimal use of CDS.

Ms. Metzger observed that current uses of CDS tend to focus on errors of commission (such as adverse drug events) or omission (condition and prevention management) with less focus given to clinical appropriateness or cost. Professionals and facilities often start with implementing what's easiest, rather than focusing on larger safety issues, such as drug dosing for patients with renal compromise. Hospitals that use CDS commonly implement order sets and check for drug interactions and drug allergies. Primary care settings generally focus on health maintenance and may use electronic prescribing with embedded medication alerts. Exemplary hospital CDS implementers often utilize homegrown applications or have made major modifications to commercial EHR systems. In addition, organizations that are using CDS well

generally have a strong culture of quality and safety as well as a process-driven infrastructure for implementing quality improvements.

Ms. Metzger noted that making good use of CDS is not trivial, and that this challenge will only increase as the next round of CDS adopters will include smaller organizations with fewer resources and less expertise in terms of customizing or building out their EHR software. Given this understanding, CDS needs to move closer to "out of the box" functionality. While vendors have evolved their products considerably in the last 3-5 years, maintenance of CDS implementations over time continues to require significant investments of time and resources. EHR vendors have been reluctant to become knowledge vendors and, while facilities may receive CDS "starter sets" with their EHR applications, CDS is often "high touch" from that point on. Operationalizing CDS requires new processes, as evidenced by emerging roles such as Medical Director of CDS and Pharmacy Informaticist, to effectively configure and test systems, validate effectiveness, address updates in a timely manner, and ensure system-wide accountability.

Another critical factor Ms Metzger noted for ensuring the effective use of CDS is the timing of CDS interventions. For example, the least effective time to provide alerts intended to support optimal order selection is after a provider has already entered and signed off on a patient's clinical orders. To optimize usability and acceptance, CDS should be delivered at an opportune point before the cognitive effort of making those decisions has been completed.

Looking forward, Ms Metzger noted, the role and use of CDS may be redefined and influenced by a variety of factors. Advances in health information exchange (HIE) will offer providers and facilities more complete data and create opportunities to increase the effectiveness of CDS. However, national patient safety and quality improvement goals are needed to provide focus for CDS use. Hospitals and physician practices report a large number of quality measures to numerous accrediting and oversight bodies. One health system reported that its hospitals reported the same information, in slightly different ways, to as many as ten different organizations, suggesting room for standardization. In addition, clinical effectiveness research should provide additional knowledge and facilitate appropriate application of CDS. The role of CDS should also be expanded by moving CDS earlier in the clinical workflow, thereby increasing CDS' usefulness beyond today's reactive alerting capabilities and providing CDS at a point in time when clinicians are formulating decisions and plans of action.

End-to-End CDS: The Path from Guidelines to CDS Measurement

In a framing presentation regarding the relationship between CDS and Quality, Helen Burstin noted that although the development of CDS and quality measures have not been coordinated to date, they share a common basis in systems of evidence and are both designed improve patient care outcomes. The establishment of clear, specific guidelines should assist in better aligning CDS with quality measures. Additionally, health IT systems should leverage a "global standard" dataset to support both CDS and quality measurement.

Dr Burstin observed that lack of guideline specificity in terms of periodicity, definition of terms such as "high risk", and ambiguity of "action" terms have contributed to the lack of coordination between CDS and quality measurement. Measures also tend to focus on aspects of guidelines that are measurable today, rather than other targets that may have greater impact but which are currently harder to quantify. In the future, it is anticipated that CDS will help drive care process steps and that quality measurement will increasingly focus on the measurement of patient outcomes.

It will be helpful, Dr Burstin noted, to focus CDS and quality measures around clinical items where there is a good evidence base, opportunities for clinical improvement, and relationship to a priority or high-impact area of care. The National Priorities Partnership of the National Quality

Forum (NQF) has identified candidate national priorities, some of which have been incorporated into meaningful use recommendations. The establishment of a common data set is a key area for collaborative development by CDS and Quality professionals. NQF's Health Information Technology Expert Panel has begun this work, but in order for health IT systems to leverage a common dataset for both CDS and quality measurement, significant effort will be required to harmonize measures and harmonize across sites of care. Some stakeholders, including providers, will look at quality for individual patients. Subsequently, this data will be aggregated to look at the quality of care for communities. Data flow will not be a one-way "report-out", but rather a bidirectional flow between sites to share key pieces of data – such as immunization histories and patterns of illness in the community – that are important to the provision of quality patient care.

Sharing and Reuse of CDS Knowledge, Interventions and Experience

Jon White described several current and ongoing knowledge-sharing efforts, including the following:

- The National Guidelines Clearinghouse is currently available as a web-based resource with an effort underway to codify some of these guidelines.
- The Eisenberg Clinical Decisions and Communications Science Center translates comparative effectiveness research into materials and products that can be used by consumers, clinicians, and policy makers.
- Healthfinder.gov is a consumer-facing web-based tool that is based upon US Preventive Services Task Force recommendations.
- AHRQ has funded two major CDS contracts, has recently released two white papers on CDS, and held a CDS town hall last year.

Dr White noted that the concept of a CDS repository to support the sharing and re-use of CDS content has been suggested on a number of occasions. The mission of such a CDS repository would be to improve healthcare for all Americans. The notion of a CDS repository stimulates a number of questions about sharing knowledge, including:

- What do people want and need?
- How do we share?
- What standards will be necessary to guide such an effort?
- Of the many things that are possible and the subject of research and pilots, what do we share?
  - o broad knowledge?
  - o quantitative guideline measures?
  - o generic interventions?

Dr White observed that if CDS knowledge is shared, it is equally important to share the details regarding implementing a CDS intervention such as what, how, when, to whom, and under what circumstances an action should be taken.

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CDS Workshop Participant Discussion

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Robust participant discussions followed each short framing presentation during the August 25-26, 2009 CDS Workshop. For the convenience of the reader, comments across multiple workshop sessions have been aggregated into common themes. As noted in the workshop summary section, above, this document presents a sample of individuals' statements made and ideas expressed during the workshop. This document does not claim to present a majority or consensus opinion on any topic, nor does it represent the position or policies of any federal agency. The information captured here is made available for the information of the public, including all stakeholders in CDS development, deployment, and use.

CDS should support team-based care

Multiple participants discussed the observation that many EHRs are structured so that the data from each discipline goes into its own "silo." A team approach has an enormous impact on

patient care and significant implications for CDS. To optimize CDS effectiveness in a team environment, multiple team members must utilize the same underlying data. Every patient deserves evidence-based care and every clinician deserves ready access to timely, relevant knowledge and patient-specific data at the point of care. In the firmly held view of many participants in the workshop discussions, CDS incorporated into team-based workflows and communication should become the norm, not the exception. As virtualization of care becomes commonplace, and with the advent of the medical home, it was noted that new roles and teams of providers will continue to care for patients after discharge from the hospital.

There may be many new needs for CDS, based on the involvement of participants in the care process beyond professionals with prescriptive privileges and pharmacists. New audiences for CDS over time may well be expected to include patients, case managers, and others as new models of team-based, information-driven care emerge to achieve high-value, accessible, affordable care for all Americans. Informatics solutions, such as patient registries that identify patients with chronic conditions at highest risk for developing such conditions or other complications, are important tools that support team-based care. The concept of gathering data and providing recommendations to the team can, from an information science perspective, readily extend to the patient, the patient's family, and other participants in the broader care team such as but not limited to pharmacists and health educators.

A culture of quality improvement is important to effective use of CDS
Multiple participants raised and discussed the observation that clinical professionals' practices, acute care, and other organizational or facility-based providers, need to have a culture that is focused on quality improvement, coupled with the right tools to make it happen. Sharing current outcomes data with providers can demonstrate room for improvement, which in turn can initiate the culture necessary for the successful application of CDS tools.

Clinician engagement in CDS planning and implementation is critical to success
Multiple participants discussed the observation that clinician engagement in the pre-planning, implementation, testing, deployment, and ongoing evaluation of CDS is imperative. The users of systems need to be at the table and they need to feel a sense of ownership of the systems that are being implemented. There is not likely a single approach for successfully implementing CDS for all providers. While many successful sites have "stars" that drive implementation, different micro-dynamics exist in multiple groups and settings that affect implementation strategies.

Different perspectives exist regarding the optimal pace and complexity of CDS implementation. Participants noted that conventional wisdom suggests that, while there is a long list of things that may facilitate complex decision-making, the underlying infrastructure to do this will be built by starting with the simpler things first, then progressing to more complex things. The alternative or counterbalancing point, it was noted, is that clinicians need (and want) the most CDS assistance for non-routine care that raises issues with which they are less familiar. This was discussed as a potential argument for starting with high CDS functionality rather than low. Participants noted that many providers tend to implement basic EHRs without implementing advanced functions such as CDS. If CDS were included in the initial deployment of EHRs, it may be more likely that providers and facilities will both use and continue to build additional CDS content over time.

User adoption depends upon implementation of highly usable systems
Multiple participants noted that common usability challenges associated with CDS implementations include presenting CDS interventions in a manner that compliments clinical workflows, avoiding alert fatigue, and presenting the right CDS at the right point in time to the person most suited to act upon it.

Participants discussed that care should be taken to avoid underestimating how challenging it can be for busy clinicians to capture data at the point of care. Evaluation and management codes have changed the level of detail required for clinical notes to support them, and the implementation of CDS has the potential to do the same. Discussions noted the importance of

ensuring that the data that clinicians are asked to capture is relevant to clinical decisions and that the subsequent CDS interventions based upon that data provide high clinical value. It was noted that it would be helpful to have a consistent way of collecting user experiences with CDS to guide enhancements and improvements.

In the perception of workshop participants, CDS has not yet been incorporated into the mainstream medical decision making process. Discussions noted that CDS should be included in medical education, so providers are well prepared to utilize CDS in practice. Many providers generate electronic documentation at the end of the day because they don't want a computer to interfere with patient visits. In this scenario, computer-based CDS interventions are delivered well after the patient encounters have concluded. Some participants suggested that providers currently performing documentation in this manner may benefit from education regarding best practices for incorporating computers into clinical practice. Alternatively, some participants suggested that incorporation of computers into care will naturally follow implementation of systems that provide high value to clinicians at the point of care.

In designing usable systems, multiple participants noted that it will be beneficial to incorporate lessons from adult learning theory, which suggests considering such questions as:
- when should the reminder be presented to the clinician?
- when is the clinician most receptive?
- how do I get the reminder delivered at the optimum moment?
- what actions, information, and notices are uniquely appropriate to specific clinical roles – such as MD, RN, or health tech?

Greater CDS specificity can reduce alert fatigue
Participants discussed that critically analyzing how, when, and why each CDS intervention will occur; redesigning processes to take full advantage of CDS; and raising the specificity of alerts reduces the "noise" level of nuisance alerts. This in turn would be expected to shift user perception of CDS from being annoying to being very useful. Discussions noted that identifying the scenarios and triggering data points for when CDS interventions will display requires significant effort by clinicians who will be using the system, and that clinician involvement is critical to the long-term success of CDS implementations. Additionally, discussions surfaced the idea that the specificity of CDS interventions should be maximized for different localities with differing disease patterns and health priorities.

While participants observed that there is general consensus that all EHRs should contain some form of drug-to-drug, and drug-to-allergy checking, many tools give too much information, which is problematic from a usability perspective. Discussions noted that user acceptance improves when CDS systems initially provide limited support and ramp up over time.

Multiple participants noted that the knowledge base for drug-drug interactions is such that if you turn on "all" alerts, so many alerts fire that it grinds clinical workflow to a halt. Discussions noted that there is not yet an easy or clear way to identify a subset of highest-value, highest-priority rules that will improve patient safety without impeding workflow. If a provider office or hospital chooses not to turn on all drug-drug interaction alerts in order to decrease the number of alerts that do not need to be acted upon, there is concern that this may lead to increased liability exposure. Discussions noted that it would be helpful to specify the top drug-drug and drug-allergy interactions, as well as the top drug dosing guidelines, for use within CDS in the meaningful use matrix.

Discussions noted that accommodating "fuzzy" health maintenance intervals can be helpful, as they give the provider a chance to take action before being reminded. One example discussed was to allow for reminders at 18 months rather than only reminding clinicians at exactly 12 months. On the other hand, it was noted that there is a science to the periodicity of providing reminders. Checking at 18 months for something that should happen at 12 months risks intervals growing to 2 years, which may not be clinically acceptable.

Other fields offer computer interaction principles that can be leveraged

Participant discussions noted that healthcare delivery involves many cognitively complex scenarios. Research conducted by psychologists and human factors engineers has shown that people behave significantly differently when under stress and in a hurry. Discussions noted that systems should be consciously designed to take such factors into account.

Participant discussions noted that CDS designers and the clinical users of CDS systems need to be in sync. Participants observed that other industries utilize well-established design principles that healthcare has not yet widely embraced. There are many examples of human-automation interaction in other fields (nuclear power, space aviation, etc.) that we can draw upon. As in other fields, it is possible to end up with over-reliance or under-reliance on electronic systems over time. Discussions noted that systems need to provide transparency and appropriate context for recommended actions.

Promote collaborations among stakeholders that can support effective use of CDS

Participant discussions noted that progress toward the effective development, use, and evaluation of CDS can be achieved by collaborations among stakeholders, including knowledge vendors, clinical care providers, EHR vendors, guidelines authors and developers, payors, quality improvement professionals, EHR implementation professionals, public health professionals, patient advocates, and others. With meeting the meaningful use clinical outcomes as a goal, participants noted that it would be helpful to identify actions to be taken by each stakeholder.

Different stakeholders possess different core competencies. EHR vendors design software to support clinician workflow. Knowledge vendors, guideline developers, and CDS professionals deal with evidence and content. Bringing stakeholders together to share case studies and experiences in using CDS to address specific clinical challenges was discussed as an activity that can provide valuable learning opportunities. Participants discussed that leveraging expertise from both the field of quality improvement and the field of clinical informatics may help achieve improved patient care outcomes.

Participants offered several suggestions about how new or existing organizations may help meet people where they are and give them a compelling reason to move to where we need them to be in 2011 and 2013. Examples include:

- The 2008 CDS American Health Information Community (AHIC) recommendations included idea of a forming a national CDS alliance as a public-private, multi-stakeholder entity to focus on CDS. Participants in this August, 2009, CDS workshop noted this may be a useful mechanism to consider for promoting knowledge sharing among stakeholders. Several participants expressed concern that any new organization may need to be public/private to assure the needed breadth of expertise and perspectives for its products to be accepted and trusted.
- Workshop participants noted that it could be helpful to leverage the National Institutes that are responsible for specific diseases to build some of these collaborations. For example, the National Heart, Lung and Blood Institute (NHLBI) has established a National Knowledge Network for cardiovascular disease which brings together knowledge generators, specialty societies, performance measurement, and CDS professionals.

Discussions noted that there has been a fairly clear distinction in the market between electronic health record vendors, who focus on building highly configurable tools, and knowledgebase vendors, who focus on the development of synthesized content which may be used to inform the development of CDS interventions. The fact that CDS tools do not "prescribe" what CDS interventions to implement nor how they are implemented provides a great deal of flexibility. At the same time, the logic configuration and data mapping required to build CDS interventions within electronic systems is not trivial. Collaboration between the EHR vendors and knowledge

vendors – along with the development of clear standards for CDS content interchange – could streamline this process.

Including CDS in the definition of meaningful use of EHRs is important
Discussions noted that the structure of meaningful use recommendations developed by the Health Information Technology Policy Committee (HITPC) focuses on the implementation of EHRs, then moves to EHR-enabled processes, and then to health care outcomes. Inherent in this progression is the need for a core data set that supports both CDS and quality measurement. Some participants thought there should be more specific CDS requirements within the meaningful use matrix, even though CDS is an implied prerequisite for some of the quality goals.

Specific comments participants made regarding CDS and meaningful use include:
- There is a difference between 1) having CDS available, 2) using CDS, and 3) demonstrating that it has some influence on the process and outcomes of care. This natural progression could be mirrored in meaningful use criteria.
- Selecting scenarios or settings where meaningful use has the greatest impact and rallying EHR and CDS development around achievable goals relating to these scenarios could be a useful strategy.
- In system validation, it would be helpful to ask how clinicians feel about a product as well as assessing its basic functionality.
- Requiring physicians to submit encoded Clinical Document Architecture (CDA) documents – or some other standard format – would support the assessment of quality measures required by meaningful use.
- Caution is indicated regarding what is considered to be necessary frequency of alerts and other requirements to support the consistent implementation of guidelines. For example, some participants expressed the opinion that requiring medication reconciliation with every visit may not be practical or efficient.
- The CDS specifications should be directed toward goals rather than specific technologies; then, for a given goal (e.g., better health maintenance), the fulfillment of that goal can come from any number of CDS intervention types.
- There should be a core set of CDS functionality present and that core should be relevant to all clinical practices and specialties.
- Focusing on CDS at the point of care is an important contributor to the achievement of meaningful EHR use. For example, CDS allows for compliance checking 100% of the time rather than just 10% with a chart pull.
- In a market basket approach (where you could choose *n* targets that are relevant to your practice from a larger set), targets could come from a broad menu.

Meaningful Use should allow for variations in CDS techniques, objectives, and localization of goals.
Participant discussions noted that the recommendations for meaningful use criteria developed by the HITPC contemplate requiring in 2013 a broader view of CDS, both in determining key targets and optimal techniques. For example, team-based approaches and registry functions are important to chronic disease management. In the inpatient environment, patient fall risk reduction, pressure sore prevention, and anticoagulation management are important areas of focus

Participants expressed a need to strike a balance between being prescriptive about CDS and encouraging creativity. Participants felt that providers and facilities need variability in what CDS they choose to implement. Discussions noted that specifying this too tightly may decrease CDS's local applicability and stifle innovation. We also risk letting perfection become the enemy of the good.

Participants observed that it will be important to permit a range of types of CDS to achieve meaningful use objectives. Discussions surfaced the idea that sometimes objectives can be best achieved using less common, but effective types such as:

- Effective delivery of external information, such as knowledge of an emerging infectious disease
- Asynchronous CDS, such as CDS-related communications with patients
- Support for organizational decisions, such as staffing decisions
- Identification of facility-based information that may affect patient care (e.g., physical proximity of rooms in cases of infection control)
- Face sheets, smart forms, task assistants, and other nonstandard, but available, CDS technologies and intervention types
- Closed-loop CDS, where a machine automatically takes actions based on patient parameters (although some participants expressed concern about actions being taken without human confirmation)

The HITECH Act specifically mentions EHRs as a foundational element. However, workshop participants noted that EHRs may not necessarily be the source of the most effective CDS at all times. There was observed to be a need to think about how to get the best quality and safety value at all times, which may extend the appropriate range of CDS to non-EHR-based contexts, or to broader EHR contexts, such as registries, informational tools, workup advisors, dosing programs, guideline-based ordering tools, and task assistants.

Specialties and different practice types must not be overlooked
Participant discussions noted that as virtualization of care happens, there may be many new needs for CDS that involve new players with new requirements to achieve a high-performing healthcare system. Discussions noted that implementing CDS to address the unique but focused needs of specialty practice areas may be beneficial.

Participant discussions noted that newborn screening is an obvious target for CDS in that over 4 million children are screened per year across the United States. Specific follow up interventions are expected as the standard of care, and action sheets to guide follow up care have already been developed. Discussions also noted that emergency departments could benefit from CDS to support decreased time to pharmacologic intervention for myocardial infarction patients and decreased time to treatment for pneumonia patients.

Participants observed that the logic used to drive what are essentially medically equivalent CDS interventions across multiple care sites can vary widely, suggesting that variations in experiences and workflow may make it more difficult to share CDS interventions. Discussions noted that it would be helpful to identify varieties of CDS that are appropriate to different settings.

Provide effective guidance and best practice examples
Multiple participants expressed the opinion that we should be cognizant that there are providers and facilities out there saying "just tell me what to do to qualify for the incentive payments". Workshop participants noted that such facilities and providers would benefit from pre-populated, pre-configured solutions that are tied to evidence and to quality measures. It was noted in discussions that if there is a lack of guidance in terms of what health IT functionality is required, providers and facilities may opt to wait to implement technology until the penalties kick in, especially in cases where there is a lack of resources to implement technology.

In addition, discussions included a recognition by participants that CDS is not the only way to improve clinical outcomes. It was noted that people with other areas of focus will likely promote education, academic detailing, etc. as options alongside, or instead of CDS. Participants noted that collecting good practices for different settings – and putting them in a form than can be taught or shared – may smooth the adoption process.

Incentives and drivers can promote CDS adoption
While workshop participants expressed an opinion that there is general agreement that CDS is conceptually important, paying for it is another matter. Even in cases where providers are not

required to pay for the systems, CDS systems require time for use, and the lost productivity may be a barrier to adoption.

Participants commented that it may be helpful to align financial incentives with quality outcomes, because what gets measured gets done. It was noted by participants that if the quality measures currently recommended by Health IT Federal Advisory Committees are eventually implemented by the Secretary as criteria for meaningful use payment incentives, this would have the effect of attaching substantial financial incentives to performance achievement on quality measures. Participants speculated that, in such an event, intermediaries may evolve to help providers meet meaningful use quality objectives using a variety of tools and methods, including CDS. Participants observed that this could provide a starting point and the number of quality measures can grow over time.

Several participants noted that one way to achieve increased utilization of CDS could be to pay for it. Many payment reforms start with changes in Medicare payment approaches, which are, in turn, adopted by other payors. Discussions noted that when payment is at stake, practices and behaviors change rapidly. However, participants also expressed a concern that payment criteria be set up to recognize that there are some things that can be influenced by clinicians and other things that require patient behavioral changes.

It was also noted in discussions that the absence of financial incentives can create a culture that responds to things other than money. Discussions noted that clinicians can be highly motivated by viewing reports and graphs that depict patient care outcomes. Identifying national priorities, goals, and targets was suggested as a source of focus for CDS implementations. The discussions noted that candidate areas for priority focus, identified by the National Quality Forum's National Priorities Partnership, can be leveraged to this end.

Providing liability protection or advantage may speed CDS adoption
Participant discussions surfaced a concern that increased data availability through electronic exchange of health information and from the use of CDS could potentially increase risk of liability. The concern expressed by participants in the discussions is that providers and hospitals should have considered, but did not consider, some piece of information that was technically available to them at the time a decision was made. There was also discussion of concerns about potential liability risk related to an audit trail of overridden CDS alerts. In participants' experience, CDS exemplar facilities have not turned off audit trails but have worked through issues of transparency.

As a possible way to address liability concerns, some participants suggested that the government may be able to set liability limits for providers who are making good faith efforts to employ technologies to improve care – not only to ensure that the availability of CDS does not increase liability, but perhaps to consider liability incentives for facilities using CDS. Discussions made specific note of drug-drug interactions. As noted earlier in this summary, participants expressed that it would be useful to have a "short list" of alerts that provide the greatest gains in medication safety, approved by the federal government or other notable body, would greatly help providers who are trying to balance the benefits and usability of systems with perceived liability risk.

Patients have a role to play in CDS
Participant discussions noted that one way to improve outcomes may be to engage patients. Discussions noted that it could be helpful to accelerate the timeline for establishing as a fundamental requirement that provider health IT utilize patient-provided data. Participants noted that data must flow in both directions to support effective clinician-patient communication. Pain assessments and quality of life indicators should, participants noted, come from the patient rather than the doctor. Waiting room time and patient intake time can be used to gather and respond to patient data as a patient is typically in the office 45 minutes for a 15-minute visit.

Several participants expressed a concern that in our eagerness to improve quality through CDS, we must remember that the patient should drive the agenda for the clinical encounter. Discussions noted that CDS should support the patient, and that pre-identified quality measures may not reflect the patient's top priority for the visit.

Translating guidelines into CDS is complex, so we should be able to leverage collective efforts
Participants observed that transforming evidence into actionable recommendations is not trivial. Currently, participants observed, this is being done in a variety of ways by multiple entities employing persons with varying types and levels of specific training. Discussions noted that there is not currently a way to easily share guidelines that have been codified in a manner that supports CDS interventions, nor do we have a way to accredit guideline developers to ensure that they follow required principles.

Participants noted it would be helpful to create a mechanism for facilities to share information about how they have dealt with the ambiguities and fuzzy deadlines within clinical guidelines and how they have instantiated inclusion and exclusion criteria. Identifying the inclusion and exclusion criteria that build the numerator and denominator for a given quality measure is a complex task. Additionally, identifying electronic sources of these data is not trivial. Discussions noted that it would be helpful to work with developers to avoid creating multiple exclusion criteria that are not statistically important.

Participants noted that having vendors translate guidelines into each vendor's "system speak," would be valuable to the providers and facilities that use those products. Currently, CDS implementation staff within each provider practice and acute care facility are essentially doing the same "knowledge to CDS" translation step. This represents a significant opportunity for standardization and re-use of content through the development of a *lingua franca* for clinical guidelines.

Opportunities for data standardization
Participant discussions noted that data collection and exchange of health information are important first steps in initiating CDS and many other advances. Items identified in the discussions as big wins include medication prescribing, medication dosing, checking for drug interactions, and chronic disease management. It is imperative that the right data be captured in electronic format in order to employ CDS to support improvements in these areas.

Discussions noted that both CDS and quality measurement share improved patient care outcomes as a goal and both depend on the availability of detailed patient data. Efforts are underway by NQF's Health Information Technical Expert Panel to identify a quality dataset. By leveraging this work, multiple participants noted that it is hoped that a core dataset can be identified that will support both CDS and quality measurement. An alternate perspective offered by other participants is that trying to force CDS and quality measurement into the same dataset could be problematic. A single missing data element may significantly affect the intervention that a CDS system presents to a clinician, but it may not significantly affect quality measurement. Another difference is that CDS primarily relies upon the availability of real-time data, whereas quality measurement can utilize retrospective data.

Participants in workshop discussions noted that leading vendors are attempting to capture and assemble data into a structured health maintenance profile, rather than structuring every data element within every clinical note. Participant discussions observed that this approach deserves additional exploration as a potential pragmatic way to capture required patient data. There is a semantic granularity mismatch problem where clinicians are interested in maximizing documentation to code for reimbursement, while guidelines may rely on data that is less granular.

An observation arose in discussions that while many ancillary providers collect important data elements, many of these are not reviewed by other providers or used as a basis for CDS.

Examples noted in the workshop discussion included: a pharmacist, therapist or nurse may document that a patient is having adverse reactions to a treatment; a pharmacist or nurse documents a patient's reactions to medications; and a therapist captures a decrease in range of motion that could be a precursor to things like pressure ulcers. To the degree that we can enhance datasets for the quality measures and CDS, we should recognize the entire team's contribution to the record.

As an alternative to heavily formatted data, it was discussed that it would be useful to explore the machine learning techniques that may provide roughly similar sensitivity as some quality measures. Natural language processing technologies were noted in discussions to be progressing in functional utility as well.

Translation of knowledge into codified structures and mechanisms for dissemination of codified knowledge are key to sharing and reuse of CDS interventions
When the concept of sharing knowledge was developed twenty yrs ago, the only available option was to build your own systems. Now, as noted in the discussions, although ready-made systems are available, problems arise in knowledge dissemination. In a growing vendor marketplace, it is likely that multiple models for disseminating knowledge will exist over time. However, a definitive model and associated standards for sharing codified knowledge does not yet exist. Implementation teams in provider offices and acute care facilities should not each have to reinvent the wheel by uniquely translating guidelines into actionable CDS interventions. In addition, sharing structures could help to capture user experiences in order to improve both the CDS interventions and the underlying guidelines.

The group discussed multiple potential methods for developing codified knowledge that could be widely distributed, including the possibility of leveraging a meta-society of medical specialties, or a peer-review group. The Guidelines International Network (GIN) will hold its 2010 meeting in Chicago. This group has talked about forming regional chapters. A North American chapter of GIN was discussed as a potentially interesting place to start developing codified knowledge that can be shared.

To meet the need of accessing knowledge within US Preventive Services Task Force (USPSTF) guidelines in a codified way, AHRQ has recently issued a Request for Task Order that will take USPSTF guidelines, and turn them into logic statements or pseudo code. These will be reviewed by the CDS Government Collaboratory and eventually made available to the public.

Workshop participants discussed that each vendor has different standards for importing CDS into their systems. Until CDS standards are available, participants expressed that sharing will be problematic. Discussions noted that development of such standards would be helpful preparation for the potential 2013 and 2015 meaningful use criteria contemplated by the HITPC's currently adopted recommendations.

The CDS Services Standard is an emerging Health Level 7 (HL7) standard that will allow provider offices and acute care facilities to receive CDS by exchanging clinical data with a server. Discussions noted that while this type of "black box" approach avoids some issues related to sharing CDS interventions, it raises new issues related to trust. Discussions noted that software vendors would prefer to receive pseudo code that they could implement into their own CDS tools rather than subscribe to a black box service. Given that providers and facilities may branch off at different levels of knowledge representation, participants observed that perhaps what is developed should support multiple levels of knowledge representation.

The Food and Drug Administration (FDA) has issued guidance that indicates that they may begin looking at CDS as a device. Multiple participants expressed concerns that defining CDS as a medical device could have significant impact on its development.

CDS & Quality need to quickly incorporate evolving evidence

Participant discussions noted that both CDS and quality guidelines need a fast cycle for the uptake of new medical knowledge. Guidelines are a representation of our best knowledge at a certain point in time. Participants noted the desirability of a tighter process for converting guidelines into CDS that can more quickly respond to changes in medical knowledge.

Guidelines development processes that incorporate feedback from clinical users were discussed as being helpful in identifying when there are challenges in the field related to guidelines. At provider offices and acute care facilities, keeping CDS interventions current with best medical knowledge and adjusting interventions based on user feedback to ensure good usability was noted to require the availability of clinical and system maintenance resource staff.

Discussions noted a need for evidence based documentation systems and evidence based interdisciplinary national guidelines that operate from a common dataset. To the degree that we can enhance the dataset for the quality measures, participants noted we should also recognize the entire teams' data contributions.

Specific ideas that stakeholder groups may consider for focused development/action

The experts and stakeholders in attendance at the workshop expressed a wide variety of opinions about the most important action areas for CDS. Each of these topics could lend itself to further exploration and possible actions by private or public groups. During the course of the workshop, participants proposed a number of specific ideas and suggestions for the advancement of CDS. A partial list of the expressed suggestions follows:

- Identify a "short list" of the most important drug-drug, and drug-allergy interactions to support with CDS. This will necessitate the development of a model for rule creation/review/editing.
- Develop a reference of best CDS practices and exemplary implementation sites
- Build a library of CDS reference implementations, by practice type, as a starting point that others could emulate.
- Develop a "usability checklist" that identifies standard wait times of no longer than X seconds, etc.
- Collect good practices and exemplars associated with incorporating a computer into the exam room during ambulatory patient visits.
- Build a national health IT simulation lab, similar to the national driving simulator, to help providers assess the functionality and usability of EHR and CDS systems. Products could be configured to address specific patient scenarios, and users could "test drive" them to assist vendors in improving their products while giving providers information on which systems are the most functional and usable.
- Develop a vendor-independent certification for "expert implementers of Health IT systems"- similar to a Good Housekeeping seal or Angie's List.
- Develop an accreditation for guideline developers to ensure that they follow required principles in translating guidelines into codified knowledge and CDS interventions.
- Develop a robust set of use cases to test the hypothesis that a common data set could service both CDS and quality measurement.
- Develop a list of CDS intervention types with key parameters, as a first step in standardization and sharing of CDS across disparate EHR systems.

While the intent of the workshop was not to formulate immediate conclusions, but instead to foster discussion and collect input from the diverse interests represented, the discussion topics and ideas put forward during the CDS Workshop may facilitate future CDS advancement if acted upon by various stakeholder groups. Workshop participants validated their interest in CDS as an integral part of a broad set of tools and mechanisms needed to improve health and healthcare in the US, and suggested that actions to advance CDS will likely arise from a variety of public and private collaborations.

ONC CDS Workshop Participants

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[i] The CDS roadmap is available at: http://www.amia.org/files/cdsroadmap.pdf.

[ii] Deliberatively developed over the course of 2007 and early 2008 by an ad hoc planning group spanning several workgroups of the AHIC, the CDS recommendations that were unanimously accepted by the full AHIC in April, 2008, are available from the ONC programmatic website at: http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848182_0_0_18/2008%20AHIC%20CDS%20Recommendations%20-%20FINAL.pdf.