



**PRESENTATION TO  
FDA Public Workshop - Mobile Medical Applications Draft Guidance  
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**Introduction**

On behalf of the American Medical Informatics Association (AMIA) and its Board of Directors, I am pleased to have this opportunity to present our organization's thoughts on a topic that is of great interest to AMIA. Our organization is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy. AMIA seeks to enhance health and healthcare delivery through the transformative use of information technology. Our 4,000 multidisciplinary members advance the use of health information technology (HIT) in clinical care and research, personal health management, public health, and translational science, working throughout the health system in various clinical care, research, academic, government, and commercial organizations.

Through its draft guidance, the FDA has proposed definitions for a small subset of mobile medical applications that the FDA believes may affect the performance or functionality of currently regulated medical devices and as such, will require FDA oversight. AMIA plans to submit comments in response to the FDA's DRAFT Guidance, and will not address directly the issues included in that forthcoming response. We welcome the opportunity to contribute to your public forum, and to participate in panel presentations regarding clinical decision support -- a critical but complex topic. To support our comments here, we have provided below a set of relevant selected references and resources that have been developed by AMIA or its members.

As I begin my remarks, I would like to acknowledge and thank several AMIA leaders and members for their contributions to AMIA's presentation:

- **David W. Bates, MD, MSC, FACMI**, Senior Vice President for Quality and Safety and Chief Quality Officer Brigham and Women's Hospital and the Brigham and Women's Physicians Organization, Chair AMIA Public Policy Committee

- **Robert Greenes**, MD, PhD, FACMI, Ira A Fulton Chair and Professor of Biomedical Informatics, Arizona State University
- **Rainu Kaushal**, MD MPH, Chief of the Division of Quality and Medical Informatics Weill Cornell Medical Center
- **Gilad J. Kuperman**, MD, PhD, FACMI, Director, Interoperability Informatics, New York-Presbyterian Hospital, Board Chair-elect, AMIA
- **Nancy M. Lorenzi**, PhD, MA, MS, FACMI, Assistant Vice Chancellor for Health Affairs  
Vanderbilt University, Medical Center; Chair, Board American Medical Informatics Association
- **Blackford Middleton**, MD, MPH, MSc, FACMI Corporate Director, Clinical Informatics Research and Development Partners Healthcare System Boston, MA
- **Jerome A. Osheroff**, MD, FACP, FACMI, Principal, TMIT Consulting, LLC
- **Dean Sittig**, PhD, FACMI, Professor, School of Biomedical Informatics, University of Texas Health Science Center at Houston
- **Edward H. Shortliffe**, MD, PhD, FACMI, President and CEO, AMIA

## Key Themes

Although you have asked us to respond to specific questions about clinical decision support, we would first like to emphasize and focus your attention on several **key themes and cautionary remarks**:

**Defining CDS is essential to moving the discussions forward.** Increasingly, individuals are using a growing array of mobile health devices, technology and software applications to access health information and services. In addition, health care and public health professionals are formally and informally integrating mobile technologies and applications into diverse public health practices and clinical care activities. There are various approaches to defining and using terms such as CDS, standalone systems, devices, and mobile apps, and this variation may reflect a lack of agreement; alternate interpretations, and/or the evolution of the topics and their scope. Public and private sector organizations should collaborate to build consensus around working definitions of key terms before we go much farther in discussing regulatory or safety options.

In 2005, AMIA undertook a set of activities relating to clinical decision support (CDS), with funding from ONC and AHRQ. The work culminated in the release of the roadmap for national action on CDS in 2006.<sup>1</sup> In the Roadmap, AMIA said that *Clinical Decision Support (CDS) encompasses a variety of approaches to provide clinicians, staff, patients, and other individuals with timely, relevant information that can improve decision making, prevent errors, and enhance health and health care.* CDS tools and interventions include simple information retrieval, such as access to Medline references, as well as computerized alerts and reminders, clinical guidelines,

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<sup>1</sup> Osheroff JA, Teich JM, Middleton B, Steen EB, Wright A, Detmer DE. A roadmap for national action on clinical decision support. J Am Med Inform Assoc. 2007 Mar-Apr;14(2):141-5. Erratum in J Am Med Inform Assoc. 2007 May-Jun;14(3):389. (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2213467/>).

order sets, patient data reports and dashboards, documentation templates, diagnostic support, therapeutic advice, and clinical workflow tools. We consider CDS software to be any application which brings relevant clinical data and knowledge together to improve clinical decision making by either care providers or patients. In this sense, essentially all healthcare information technology has CDS potential. As a result, it is common and given FDA's interest in CDS, essential to distinguish *generic decision support* (e.g., information resources such as Medline, or antidote details in a poison control system) from *patient-specific* or *proactive decision support* (e.g., diagnostic or therapeutic advisory tools that generate recommendations based on information about a specific patient). Patient-specific CDS can be quite simple (e.g., based on a single rule that fires when a specific set of laboratory criteria occur for a specific patient) or complex (e.g., tools that assist with cancer chemotherapy or radiation therapy planning, or systems to assist with general medical diagnosis).

The book entitled, *Improving Outcomes with Clinical Decision Support: An Implementer's Guide. Second Edition*<sup>2</sup> refines this definition (which was based on the first edition of this guidebook, and which, in turn served as the basis for the definition in the Meaningful Use regulation) to:

“Clinical Decision Support is a process for enhancing health-related decisions and actions with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery. Information recipients can include patients, clinicians, and others involved in patient care delivery; information delivered can include general clinical knowledge and guidance, intelligently processed patient data, or a mixture of both; and information delivery formats can be drawn from a rich palette of options that includes data and order entry facilitators, filtered data displays, reference information, alerts, and others.”

In 2010, as part of a project funded by the Commonwealth Fund, AMIA assessed progress toward the short-term goals within the CDS Roadmap, and recommended activities to continue to improve CDS adoption throughout the US. We found that considerable progress had been made although significant work remained.<sup>3</sup> We urge the FDA and others to re-review our initial proposed framework and subsequent status report findings in the context of today's discussions.

**There is an ongoing need to harmonize and coordinate efforts across the Federal government and between and within the research and practice communities in the public and private sectors.**

The evidence-base in CDS suggests that detailed clinical patient data are often necessary for CDS to be most effective. In addition, the knowledge-base(s) used in CDS applications must be based upon best clinical practices, kept current, and organized and used in a way that provides coherent and sensible CDS. Explanation(s) for CDS advisories or guidance, and ideally

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<sup>2</sup> Improving medication use and outcomes with clinical decision support: a step by step guide. HIMSS. 2009. Co-published by HIMSS, the Scottsdale Institute, AMIA, AMDIS, and the Society of Hospital Medicine. In press for publication early 2012; further details to be posted at [www.himss.org/cdsguide](http://www.himss.org/cdsguide).

<sup>3</sup> Lyman JA, Cohn WF, Bloomrosen M, Detmer DE Clinical decision support: progress and opportunities. *J Am Med Inform Assoc.* 2010 Sep-Oct;17(5):487-92.

linkage(s) to the primary evidence, must be available to the end-user in every case. Achieving health care that is patient-centered and that assures patient safety as well as a high level of quality and cost-effectiveness requires consistent, systematic, and comprehensive application of available health-related knowledge using CDS. The challenge is to implement CDS to drive predictable improvements in health outcomes across a broad array of settings. A core of CDS applications should be broadly implemented and would represent a public and social good. We believe that there is a need to create a generalizable framework to help ensure the safety and effectiveness of HIT systems and applications, including CDS.

**We caution the FDA in focusing narrowly on CDS, or in considering mobile apps in isolation from other CDS delivery methods or contexts.** CDS are likely elements in *all* clinical systems, whether implemented on mobile platforms or on tethered workstations. Their safe and effective use will be dependent on the quality of the associated HIT environment, regardless of whether it is running on a mobile device or in a mainframe setting. There is still a need for development and dissemination of best practices for HIT design and implementation, and these will have a major effect on the quality of CDS implementations as well. Efforts are needed to synthesize the results of existing and future HIT studies to capture, compile, and disseminate best practices and guidelines for designing and implementing such systems in general; these should include usability guidelines, as well as proven technical and organizational issues. With specific reference to CDS there is need for methods to identify best practices on a national level (public-private) that can form an authoritative knowledge base for development and adaptation of CDS.

**We note rapidly emerging and converging technologies and devices along with new and evolving forms of patient care delivery and payment methods (such as medical homes and accountable care organizations).** We envision increasing achievements in personalized medicine and growing pressures for consumer engagement in healthcare decisions. Thus, we anticipate a further blurring of the lines between information delivery channels and mechanisms, devices, and applications intended primarily for use by clinicians and other providers, contrasted with those intended for patients, consumers and their care givers.

**The CMS EHR Incentive Programs provide financial incentives for the "meaningful use" of certified EHR technology and include CDS-related meaningful use objectives.** These existing Federal efforts and programs are likely to add layers of complexity to the questions posed today by the FDA. The Health Data Initiative was launched by DHHS and the Institute of Medicine to help get more value from health data. In addition, DHHS initiated various challenge programs intended to invigorate prototype web and/or mobile communication technology applications to achieve more widespread use and access to health data. Thus, we again urge the FDA to consider creative, flexible and nimble approaches while coordinating its efforts with the work of other government agencies.

We acknowledge that there is great interest broadly in **what kind of regulatory or oversight interventions might be warranted in order to help assure the safe implementation of CDS applications in health care, whether delivered via mobile devices or other means/mechanisms/HIT technology.** AMIA has been tracking these issues for many years. In 1987, the FDA Commissioner published an article summarizing the agency's philosophy and

approach to software regulation, with an emphasis on clinical decision-support programs.<sup>4</sup> Software was viewed as similar to a textbook or other knowledge source, as long as there was no direct computer control of a patient's care (closed-loop system). Thus the FDA stated that the presence of a "learned intermediary" (generally a physician) who interpreted the output from the computer before applying results to a patient meant that the software did not require regulatory oversight. As computing technology advanced in health care, this issue was revisited from time to time. AMIA published a summary article with recommendations in 1997.<sup>5,6</sup>

Subsequently we have seen the increasing adoption and complexity of EHRs, PHRS, HIEs, mobile health, and other HIT systems, with roles in patient-care decision making that may have potential risks to patients and to optimal care, even when the system is not explicitly offering decision support. As a result, issues of software regulation, including the definition and enforcement of best practices, have arisen again in recent years, generally acknowledging the tension between the need to assure patient safety and the need to encourage innovation and production differentiation. Some of the articles cited in AMIA's written remarks further illustrate the concerns and raise the issue of interventions to help assure or promote the safety of clinical IT systems.

Despite current public and private sector efforts, additional research and development is needed to further develop test protocols and methods to assess the integrity of the previously mentioned components of CDS. These efforts would include an investigative focus on the knowledge-base, the inference method(s), and the expression methods (how displayed/integrated with a clinical application, or free standing - including data presentation, human factors and usability). While there is a solid and growing evidence base for the role and implementation CDS, there is still much to learn about how such systems should adapt to different delivery mechanisms, patients, contexts, populations, and clinical domains.

We believe that there will be increased adoption of mobile health technology such as smart phones tablet devices, implantable and wearable sensors, home monitors, and other devices for data collection and reporting, treatment support, and information dissemination in the practice and delivery of health care and public health. As these technologies and applications evolve, the distinctions between them are likely to blur, posing additional challenges if the FDA seeks to provide possible oversight and/or regulation based on vehicle delivery rather than software content and role. Further, as AMIA has stressed in numerous forums, ongoing research is needed to support resolution of several inter-related HIT design and implementation issues. Additionally, we believe that a comprehensive and systematic exploration of the technological considerations as well as the public policy issues is warranted,

AMIA and its members have devoted decades of attention to the technological, ethical, and organizational issues raised by the use of health information technology and software. An

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<sup>4</sup> Young, FE. Validation of medical software: Present policy of the Food and Drug Administration. **Ann Intern Med.** 1987;Apr;106(4):628-9

<sup>5</sup> Miller RA, Gardner RM. Summary recommendations for responsible monitoring and regulation of clinical software systems. **Ann Intern Med.** 1997;127:842

<sup>6</sup> Miller Randolph A., Gardner Reed M., Recommendations for Responsible Monitoring and Regulation of Clinical Software Systems **J Am Med Inform Assoc.** 1997 Nov-Dec; 4(6): 442-457

important challenge is to address these issues while considering regulatory and oversight options that might help to assure that EHR systems and other clinical software is suitably overseen, assessed, and monitored to assure patient safety. We are not persuaded that the simple emergence of mobile technologies, and other technologies that are rapidly evolving, should justify a major rethinking of FDA's role in such oversight and/or regulation.

## **Responses to Specific FDA Questions**

### **Definition of stand-alone (mobile apps/web/desktop) CDS software.**

We suggest that there are several main groupings of CDS software although these are not specific to stand-alone CDS. There are also multiple ways to categorize the purposes of CDS software, again not specific to stand-alone CDS software. For instance:

- CDS targeted at providers and supplying decision support for individual patient-care decisions.
- CDS targeted at providers and supplying decision support for populations of patients.
- CDS targeted at patients and consumers and supplying information to help the individual in lay terms

*Stand-alone* is itself an elusive and poorly defined term, because, to the extent that the devices obtain information from sensors, user input, access to remote EHR data, and other sources, they are not operating in a stand-alone mode. There is clearly a spectrum of "stand-alone-ness".

Also, if *stand-alone* were meant to refer to operation without human intervention, i.e., in a closed loop, such as a pacemaker or an imbedded insulin pump, then this term would encompass a very limited number of devices – most of which would not function on generic mobile devices.

### **What levels of support do these CDS software provide?**

It is not entirely clear what the question means. Referring to our response to the previous question, each of the above categories may provide a wide array of CDS capabilities, ranging from basic to intermediate to advanced, along at least two basic axes: (1) the breadth of coverage and context/patient-specific adaptation capability of the advice within a clinical domain, and (2) the depth of coverage within the clinical domain. For example, CPOE applications often have embedded CDS capabilities, which may range from basic to advanced, and these may or not be accessible on mobile devices.

- Basic: specific classes or subsets of drugs (usually excluding experimental drugs), limited depth of reasoning due to lack of patient data (e.g., only drug-drug interactions; No allergy alerts w/o patient data)
- Intermediate: broader coverage of agents with more complete modeling of drug knowledge-base for improved drug- drug- interaction (DDI) alerting (e.g., categorical alerts based upon drug classes), with deeper inference based upon access to patient data
- Advanced: deep drug knowledge-base with modeling of drug classes and other attributes (route of administration, drug-lab interactions, drug-symptom interactions, etc.), and

sophisticated CDS surrounding drug dosing (pediatric or geriatric dose calculations, renal failure dose calculations) with adaptations based on access to a complete patient data set

On the other hand, if by “levels of support” the FDA means the features, functions, and purpose of CDS, there are various approaches to developing a continuum that can be used to describe these attributes. Some researchers have recommended a multi-step model that provides a framework for clinical decision support-related standards,<sup>7</sup> while others have identified specific CDS intervention types: clinical documentation forms and templates, relevant data presentations, order creation facilitators, time-based checking and protocol support, reference information and guidance, and reactive alerts and reminders.<sup>8</sup> Still other approaches depict CDS capabilities along a continuum such as: answering questions in response to queries, retrieving data; providing information to help make diagnosis and/or treatment decisions; optimizing clinical processes and/or workflow, such as via guidelines or protocols); monitoring actions (such as by providing time based alerts and reminders); and/or focusing provider attention (such as on specific order sets or clinical checklists).<sup>9</sup>

### **What factors should FDA consider in determining the risk classification of different types of software that provide CDS functionality?**

The critical issue is whether the CDS is mediated by a human being or not. The most rigorous attention should be given to applications which, in an automatic and autonomous fashion, provide CDS and intervene directly on patient care parameters (e.g., "Smart Pumps"). This is part of the capacity for the intervention to do harm, but there are others – for example, the nature of the clinical guidance provided, and it’s propensity to cause harm, how the information is presented (i.e. intervention type) and others. We believe that this is a complicated issue and that further discussion is warranted to sort out. However, we offer the following set of options to get the discussion started:

Forms of CDS which interact directly with the patient or consumer provide a moderate amount of risk.

Forms of CDS which provide guidance to the provider but leave it up to the provider to accept or reject the guidance, present a lesser risk to the patient because a qualified clinical professional is always acting as an intermediary between the CDS and the patient.

Forms of CDS that do not make patient specific recommendations, and are always intermediated by the provider are the lowest risk category.

This suggests several categories:

- **Autonomous CDS:** automatic clinical interventions that affect patient care directly without provider oversight

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<sup>7</sup> Sittig DF, Wright A, Ash JS, Middleton B. A set of preliminary standards recommended for achieving a national repository of clinical decision support interventions. AMIA Annu Symp Proc. 2009 Nov 14;2009:614-8.

<sup>8</sup> Osheroff JA, Pifer EA, Teich JM, et al. Improving Outcomes with Clinical Decision Support: An Implementer’s Guide. Health Information and Management and Systems Society. 2005

<sup>9</sup> Greenes, RA. (Editor) Clinical Decision Support: The Road Ahead. Academic Press; 1st edition (December 14, 2006)

- Patient-directed CDS without provider oversight
- Patient-directed CDS with provider oversight
- Human mediated CDS and intended for providers
- Human mediated CDS and not-patient specific

### **What is an appropriate approach for assessing reasonable safety and effectiveness for such factors?**

A coordinated effort between the private and public sectors is needed. Stakeholders, building on existing models and approaches should leverage prior and ongoing research and work in informatics, quality assurance, and patient safety. There needs to be coordinated development of procedures, approaches and processes to ensure the safe and effective use of all types of health information technology, not just CDS. Efforts should encourage system designers and implementers to focus on the use of HIT to contribute to the ultimate goal of improvement in patient care processes and outcomes.<sup>10 11</sup> Additional attention is needed to assure sources of high quality medical knowledge in executable form, and an infrastructure and processes for managing and updating such knowledge and integrating it into applications.<sup>12 13 14</sup> AMIA notes the formation in 2008 of the CDS Federal Collaboratory, a federal community of interest, to focus on CDS as a key health information technology component for improving the quality, safety, efficiency and effectiveness of health care<sup>15</sup> as well as the CDS Consortium<sup>16 17</sup> which was a federally-funded collaboration among leading CDS researchers and practitioners to help increase widespread sharing and adoption of CDS.

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<sup>10</sup> Bloomrosen M, Starren J, Lorenzi NM, Ash JS, Patel VL, Shortliffe EH. Anticipating and addressing the unintended consequences of health IT and policy: a report from the AMIA 2009 Health Policy Meeting. *J Am Med Inform Assoc.* 2011 Jan-Feb;18(1):82-90.

<sup>11</sup> Bloomrosen M, Detmer DE. Informatics, evidence-based care, and research; implications for national policy: a report of an American Medical Informatics Association health policy conference. *J Am Med Inform Assoc.* 2010 Mar-Apr;17(2):115-23.

<sup>12</sup> Greenes R, Bloomrosen M, Brown-Connolly NE, Curtis C, Detmer DE, Enberg R, Fridsma D, Fry E, Goldstein MK, Haug P, Hulse N, Hongsermeier T, Maviglia S, Robbins CW, Shah H. The morningside initiative: collaborative development of a knowledge repository to accelerate adoption of clinical decision support. *Open Med Inform J.* 2010;4:278-90. Epub 2010 Dec 14.

<sup>13</sup> Osheroff J, Teich J, Middleton B, Steen E, Wright A, Detmer D. A Roadmap for National Action on Clinical Decision Support. Report. Bethesda, MD: American Medical Informatics Association; 2006.

<sup>14</sup> Goodman KW, Berner ES, Dente MA, Kaplan B, Koppel R, Rucker D, Sands DZ, Winkelstein P; AMIA Board of Directors. Challenges in ethics, safety, best practices, and oversight regarding HIT vendors, their customers, and patients: a report of an AMIA special task force. *J Am Med Inform Assoc.* 2011 Jan-Feb;18(1):77-81. Epub 2010 Nov 12.

<sup>15</sup> [http://healthit.hhs.gov/portal/server.pt/community/healthit\\_hhs\\_gov\\_cds\\_collaboratory/1230](http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_cds_collaboratory/1230) Accessed 09/09/11

<sup>16</sup> [http://healthit.ahrq.gov/portal/server.pt?open=514&objID=5562&mode=2&holderDisplayURL=http://wci-pubcontent/publish/communities/a\\_e/ahrq\\_funded\\_projects/cds\\_projects/cds\\_projects/clinical\\_decision\\_support\\_consortium.html](http://healthit.ahrq.gov/portal/server.pt?open=514&objID=5562&mode=2&holderDisplayURL=http://wci-pubcontent/publish/communities/a_e/ahrq_funded_projects/cds_projects/cds_projects/clinical_decision_support_consortium.html). Accessed 09/09/11

<sup>17</sup> See: <http://www.partners.org/cird/cdsc/>  
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## Summary

The health sector faces an expanding array of clinical information systems for potential use in a broader range of settings. Growing evidence demonstrates that electronic health records (EHRs) can improve the quality and safety of patient care and promote efficiencies in overall care delivery.

From the research and evidence available today we believe that quality and performance measurement, reporting, and improvement require the use of EHRs integrated with evidence-based CDS. This foundation can result in improved care across the continuum of providers and care settings as well as better measurement of performance and outcomes. However, there has been limited diffusion and adoption of these advanced EHRs with the capacity for widespread performance measurement and improvement. AMIA does not fully understand why the FDA has singled out “stand-alone” CDS that is delivered as “mobile medical devices” and potentially subject to FDA oversight any more than other kinds of clinical software environments. Mobility seems incidental to the questions we have raised in this document. In addition, we believe that it is essential that the FDA make sure that any oversight efforts support and integrate well with the broader and fast moving HIT and CDS context, including the ONC’s and CMS’ HIT adoption efforts,— e.g. MU-related regulations, certification and oversight.

CDS and HIT can improve care processes and outcomes, but they can also cause harm. We need to bring together multiple federal and private stakeholders (including informatics experts, CDS/HIT users, and many others) to figure out how to minimize potential harm. Any FDA CDS regulatory or oversight actions should unfold in this broader context.

AMIA thanks the FDA for its attention to an important public policy issue. As a source of informed, unbiased opinions on policy issues relating to the national health information infrastructure, the uses and protection of clinical and personal health information, and a variety of public health considerations, AMIA appreciates the opportunity to contribute to your discussions. AMIA again wishes to thank you for convening this meeting and for inviting public remarks. Please feel free to contact us at any time for further discussion of the issues we have raised.

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