



January 27, 2017

Chesley Richards, MD, MPH, FACP
Director
Office of Public Health Scientific Services
Centers for Disease Control and Prevention
Department of Health & Human Services

Submitted electronically at: <http://www.fbo.gov>

Re: Request for Information – Clinical Decision Support (Solicitation Number: 2017-RFI-CDS-0001)

Dear Dr. Richards:

The American Medical Informatics Association (AMIA) appreciates the opportunity to submit comments regarding this CDC Request for Information (RFI) on Clinical Decision Support (CDS). AMIA is the professional home for more than 5,400 informatics professionals, representing researchers, front-line clinicians, public health experts, and educators who bring meaning to data, manage information and generate new knowledge across the health and research enterprise.

AMIA also provides support for the AMIA Public Health Informatics Working Group,¹ which includes more than 400 individual members. The Public Health Informatics Working Group discusses the application of informatics in areas of public health, including surveillance, prevention, preparedness, and health promotion via AMIAConnect, our online member community, and through in-person and virtual meetings.

AMIA supports this request, and we believe CDC could add value to CDS development in several ways. First, we encourage CDC to consider how it could synthesize and disseminate practical guidance for care delivery organizations on addressing top priority public health/clinical targets. Second, CDC could add value by coordinating and collaborating with other federal agencies, especially on value set management. Third, CDC can play, and has played, an important leadership, funding and coordinating role for CDS.

AMIA recommends CDC pursue these activities with the notion of CDS-as-a-Service as the conceptual goal. Where possible, CDC should use conventional tools and methods of the present web-economy that leverage prevalent information technology and communications infrastructure. By using web-based, plug-and-play functionality, CDC could mitigate the numerous and varied

¹ <https://www.amia.org/programs/working-groups/public-health-informatics>

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implementation challenges related to applying public health information more broadly and frequently within EHRs.

These challenges include:

- **Access** – public health information that may be useful is often not available, or not available in a computable format;
- **Standards** – digital public health information is not standardized in a way that most EHRs can digest easily, and this stems from a lack of consistency in translating knowledge into machine-readable and human-readable formats;
- **Workflows** – Implementing public health information within EHR workflows is complicated. As is true with any type of clinical decision support, it is important to understand when, where, how, and what to communicate to the clinician’s workflow in order to get to desired outcome.

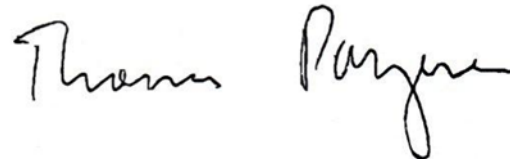
The opportunities for public health and care delivery to work in tandem have never been greater. As care delivery continues its digital evolution, the capacity to integrate relevant and timely public health information only increases. However, such integration will not be easy. CDC must ensure that a coordinated strategy presents stakeholders with a unified vision for how public health CDS can be leveraged.

Below, in Table 1, we outline our recommendations in more detail, and we address CDC’s specific questions related to this RFI. Should you have any questions or require additional information, please contact AMIA Vice President for Public Policy Jeffery Smith at jsmith@amia.org or (301) 657-1291 ext. 113. We, again, thank CDC for the opportunity to comment and look forward to continued dialogue.

Sincerely,



Douglas B. Fridsma, MD, PhD, FACP,
FACMI
President and CEO
AMIA



Thomas H. Payne, MD, FACP, FACMI
AMIA Board Chair
Medical Director, IT Services, UW Medicine
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Enclosed: Full AMIA Recommendations Regarding CDC Request for Information – Clinical Decision Support

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Table 1

	CDC RFI Questions	AMIA Response
1	<p>CDC requests that respondents confirm the completeness and correctness of each of the lists above or provide any missing potential focus areas or stakeholder groups in the CDS development and implementation process.</p>	<p>In discussing this question, we first examined the “list of potential focus areas in the CDS development process.” AMIA recommends CDC order the focus areas in the CDS development process logically as a means to identify missing elements. For example, testing and validation are cited as focus areas, but this step should be preceded by a process to properly identify and scope potentially relevant CDS interventions to address a particular need. This critical identification/scoping step (e.g., to get the CDS 5 Rights² right for the target), should be added explicitly to the focus areas – along with the pertinent knowledge engineering and knowledge management activities. And while “legal considerations” is listed, CDC should consider adding “Governance of shared resources,” as another important element of the CDS development process. As a next step, CDC could be well-served by placing the elements of a development cycle into a logical framework.</p> <p>Additionally, AMIA recommends that CDC leverage other existing frameworks and collaborations related to CDS development, such as those developed by AHRQ’s Patient-Centered Outcomes Research Clinical Decision Support Learning Network (PCOR CDS-LN).³ Specifically, we point towards the PCOR CDS-LN Analytic Framework for Action which may help CDC develop its own rubric using similar concepts. Regardless, AMIA recommends CDS remain connected or enhance connection to this joint AHRQ-PCORI initiative.</p>

² <http://bit.ly/cds5rights>

³ <https://www.pcorcds-ln.org/>

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		<p>In terms of stakeholders, we suggest that CDC likewise develop an overarching model, e.g., considering groups of stakeholders such as: (1) those that develop content for guidelines, including professional societies and guideline stewards; (2) those that use guidelines for CDS tools, such as CDS content vendors and EHR developers; (3) stakeholders that implement CDS tools, such as clinical informatics professionals; (4) patients and care givers; and (5) researchers who can provide evaluation of CDS safety and effectiveness.</p>
2	<p>How can public health add the most value to CDS development and implementation? What role should CDC play? Please describe these opportunities for added value and include examples, where possible, to illustrate (e.g., if there are specific ways CDC could add value in certain domains, such as guidelines development or translation, standards development, convening stakeholders, etc.).</p>	<p>AMIA members believe CDC could add value in several ways. First, we encourage CDC to consider how it could synthesize and disseminate practical guidance for care delivery organizations on addressing top priority public health/clinical targets. We point to the Million Hearts® Hypertension Control Change Package for Clinicians as an example.⁴ This resource uses a logical, structured approach to providing hypertension management change strategies, tools and examples, and could be replicated/adapted for other targets with additional CDC support and coordination. It also illustrates the role of clinical decision support in the broader context of population health quality improvement. It is very valuable for teams considering improvement projects to consider both the technical and non-technical (such as policy changes) strategies that could be leveraged to meet goals.</p> <p>Second, CDC could add value by coordinating and collaborating with other federal agencies, especially on value set management. We encourage CDC to leverage the experience and resources of other federal partners, rather than creating new / separate resources, and we recommend CDC conduct an internal and external landscape review to identify such resources. Part of this work could entail the validation of CDS interventions (e.g., rules,</p>

⁴ Centers for Disease Control and Prevention. Hypertension Control Change Package for Clinicians. Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human Services; 2015. (<http://bit.ly/mhhccp2>)

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		<p>documentation templates, registry/dashboard reports) and making those available for use by other public health entities.</p> <p>On potential outcome of this work could be for CDC to develop mechanisms to facilitate CDS rule validation, especially those rules translated from CDC published guidelines. There may be information loss in the translation process from human readable guidelines to machine readable rules, and CDC should play an audit role if the CDS rules originated from CDC published guidelines.</p>
3	<p>What are some examples of CDS currently being used in EHRs with potential public health implications (e.g., population-based screening, outbreak-specific screening, etc.)? Please describe each tool and how it is used in clinical settings.</p>	<p>AMIA members point to two examples where CDC has played an important leadership, funding, and coordination role for CDS.</p> <p>(1) CDC NCIRD is already heavily involved, through The CDS for Immunization (CDSi) in leading a coordinated effort among public health agencies, EHR vendors, other vendors, and clinicians in developing and promoting consistent, standards-based CDS for the immunization domain.⁵ This work has enabled both commercial and Open Source products to be enabled and supported which are used across public health and the clinical community in EHR and PHR systems.</p> <p>(2) As part of an emerging national strategy to support electronic case reporting (eCR), CDC has funded the Council of State and Territorial Epidemiologists (CSTE) to develop a centralized CDS solution, known as the Reportable Condition Knowledge Management System or RCKMS, to provide computable knowledge as a CDS service that will help</p>

⁵ <https://www.cdc.gov/vaccines/programs/iis/cdsi.html>

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		<p>clinicians and EHR systems determine if a patient meets the criteria for reporting a conditions to State or Local public health authorities, and to whom that report should be made.⁶ Recently, these efforts – which are critical for disease control and national surveillance efforts have been further supported by the Digital Bridge initiative.⁷</p>
4	<p>How is information tailored in EHRs based on public health knowledge (e.g., focused on a particular geographic location or patient population, based on public health alerts received via email or through electronic health records (EHRs), etc.)? Please include any specific challenges or barriers in being able to apply public health information in order to tailor the delivery of care.</p>	<p>AMIA members note that public health knowledge is often presented as CDS or an “Info Button” within EHRs, based on local, national and international guidelines. However, our experience indicates that neither of these pathways are exploited beyond a marginal degree, especially as contextualized by jurisdiction or certain populations within a jurisdiction. Barriers to being able to apply public health information more broadly and frequently within EHRs are many:</p> <ul style="list-style-type: none"> • Access – public health information that may be useful is often not available, or not available in a computable format; • Standards – digital public health information is not standardized in a way that most EHRs can digest easily, and this stems from a lack of consistency in translating knowledge into machine-readable and human-readable formats; • Workflows – Implementing public health information within EHR workflows is complicated. As is true with any type of clinical decision support, it is important to understand when, where, how, and what to communicate to the clinician’s workflow in order to get to desired outcome. <p>AMIA recommends CDC examine ways to improve knowledge engineering of public health information to ensure that guidelines are translated for an electronic environment, and</p>

⁶ <http://www.cste.org/group/RCKMS>

⁷ <http://www.digitalbridge.us/>

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		<p>knowledge representation accurately conveys the right information. This computable knowledge should be aligned with HL7 CDS standards, such as for information retrieval using the ‘Infobutton’ standard of representation using the knowledge artifact standards. Finally, CDC should be cognizant that knowledge maintenance is an on-going challenge, and one that should be considered as an essential part of the CDS development lifecycle.</p>
7	<p>Who should develop and maintain public health CDS tools? How can proof of concept CDS pilots be scaled faster? What resources are needed to achieve this scalability?</p>	<p>AMIA members note a critical concept in development of CDS is that knowledge is separate from tools.</p> <p>Given this tenet, we believe that knowledge is and should be distributed across various stakeholders, including domain-specific professional societies, associations, and public health authorities. An example of this model includes the American Immunization Registry Association, which has worked on CDS development in collaboration with CDC.⁸ Should CDC look to take a leadership role for public health CDS, we recommend it focus on development of tools, such as an external, web-based CDS agent that could be referenced by stakeholders. CDS-as-a-Service, with plug-and-play functionality that removes implementation challenges, would be the conceptual goal.</p> <p>CDC could also play a clearinghouse role by providing curated knowledge from domain-specific experts, and making those knowledge-bases or knowledge engines available. And as stated previously, CDC could provide CDS rule validation, especially for those rules translated from CDC-published guidelines.</p>

⁸ <http://www.immregistries.org/>

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		<p>In order for this approach to scale, CDC must invest in web-based standards and protocols, and establish relationships with knowledge curators.</p>
8	<p>How might the exchange of data and knowledge between EHRs and public health agencies be improved? Please provide examples of how this exchange currently occurs (whether unidirectional or bidirectional) and identify specific challenges or barriers you have encountered.</p>	<p>AMIA members note a disparity in value among stakeholders involved in exchange of data between EHRs and public health agencies. In order to improve data exchange, improvements in value to data producers through simplified reporting and return of data by public health agencies is needed.</p> <p>Most exchange is unidirectional – from the clinical to the public health arena. This exchange is usually legally required (i.e. forced) to engage with national public health authorities as well as those in their service area, which often includes several states and other jurisdictions. Practices and hospitals must collect and supply data to target agencies, but there is no requirement for these agencies to report back to the reporting providers. Patients and their doctors would benefit greatly from bidirectional communication from public health authorities that report back meaningful data in a timely manner, such as intelligence about what is happening in the community.</p> <p>As stated previously, public health authorities need to make information easier to find and use in an electronic environment, and public health data standards must be improved. Bidirectional sharing of immunization information is fairly robust in selected locales, but other public health related interoperability standards must continue to be tested and improved.</p> <p>An important barrier to sharing information is the lack of standard terminology and models using in EHRs for documenting pregnancy status, travel history, and occupational history. Having access to these data in a standardized manner would add immediate value.</p>

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		<p>Another significant barrier is the uneven capabilities and resources with state and local public health agencies to implement the systems required on their end to use the data that is becoming available from clinical systems. AMIA recommends CDC needs to continue to make investments, provide guidance and workforce development, and further help these agencies improve their informatics capabilities.</p> <p>We also note that historic trends in procurement have inhibited exchange through creation of data silos. Varying standards and data requirements, used for specific use cases or programs, has resulted in a disjointed public health infrastructure. AMIA recommends CDC ensure that procurement and acquisition requirements align towards a digital infrastructure capable of supporting multiple programs within a public health agency.</p>
9	<p>How could clinical data and EHRs be more effectively used for public health purposes? How could health information exchanges (HIEs) play a role?</p>	<p>AMIA members note that HIEs will struggle with the same challenges faced by EHRs in terms of public health CDS. Either EHRs or HIEs could be more effectively used if data, such as travel history, pregnancy status, occupational data, etc., were standardized and standards were harmonized.</p> <p>Public health authorities need to rethink their data “needs.” When they require data from practices and hospitals, they usually require that the data elements be defined, structured, and formatted differently from the way the data are collected during the delivery of clinical care. This means that the reporting clinicians (or EHR interface) have to manipulate the data in ways that decrease the accuracy and value of the data elements. Public health authorities believe that they are receiving data that match their intentions, but this is often not the case. The data that public health authorities typically receive may be so distorted by the conversion or double entry processes that they will not serve the purposes of public</p>

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		<p>health. Rather than forcing data collectors to transform data to match public health specifications, public health should redesign its processes – in collaboration with clinical and HIT stakeholders - to accept and use the clinical data to the extent possible in the form and structure that they are routinely collected by clinicians during the care delivery processes. Where transformations are necessary, specific logic should be provided.</p>
10	<p>Where are the opportunities for public health surveillance data to inform clinical decisions? What are the barriers? How would you implement an effective bidirectional feedback loop between a clinical setting and public health agency or CDC?</p>	<p>When a clinician is ‘working up’ a patient, they consider the pre-test probability of a ‘positive’ outcome from the various diagnostic options available. Public health surveillance data provides significant opportunities for estimating pre-test probabilities by reporting on the incidence or prevalence of conditions (e.g. influenza, measles) in the community, or the levels of vaccination in a community. Similarly, heat maps (zip codes of high poverty that impact the social determinants of health) can be used to trigger reminders and inform tools for referrals. Additionally, incorporating environmental data in the EHR (e.g., national weather data, pollen and dust levels) may be very useful for clinicians caring for patients with environmental-related diseases such as COPD and asthma. The environmental data may guide appropriate diagnosis, treatment and management.</p> <p>Barriers to these opportunities have been articulated previously, but we underscore the availability of data, the degree of standardization of these data and the ability of EHRs to digest these data in ways that render the information actionable. Careful attention to clinical and consumer workflow issues – e.g., in context of the CDS 5 Rights – will be essential to ensure that this information enhances rather than distracts from critical activities.</p>
11	<p>Should there be a different approach for CDS in emergency scenarios versus less urgent</p>	<p>AMIA members indicate that there should not be different approaches for CDS in emergencies versus routine scenarios. If CDC can make CDS work for routine scenarios, then these same people, processes and technologies should work for emergencies. Again,</p>

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<p>scenarios (e.g., in outbreak responses such as Zika or Ebola vs. in chronic conditions such as heart disease or stroke)? Why or why not? Please describe in your response how the scenarios should be approached the same or differently.</p>	<p>the CDS 5 Rights framework is a tool for ensuring that information flow and workflow are optimized to the need at hand. We also note that any framework that is put together should not be so rigid that it would curtail or slow such changes in the course of an emergency, pandemic or bioterror threat.</p> <p>A system-agnostic approach to CDS-as-a-Service, that follows a plug-and-play model of integration, separates knowledge from tooling, and relies on improved core standards, would be applicable across outbreaks and routine scenarios.</p>