HLN
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Response to Request for Information:
Clinical Decision Support

Centers for Disease Control and Prevention

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HLN Consulting, LLC, offers the following responses to CDC's CDS RFI questions:

1. 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.

With respect to the focus areas listed, we note that CDC indicates that they are in no particular order. In fact, we suggest that it is worth some additional thought on CDC's part as to the order that these topics might be addressed, and the inter-relationship between them. When ordered properly, these items offer a sensible progression through an already fairly complicated topic. Here is one suggested order that might bring some additional coherence to this list, as well as some additions/suggestions/clarifications in **bold**:

- Strategic planning for CDS (nationally)
- Clinical workflows **that require or may benefit from CDS**
- CDS-friendly **clinical** guideline development (Structured guidelines amenable to CDS development)
- CDS Standards (*e.g.,* **API,** Transport, Structure, Content, Format)
- **Identification and development of CDS tools**
- Testing and validation of CDS tools
- **Identification, development, and validation of CDS rules**
- CDS tool housing, dissemination, and maintenance
- Partnerships – internal & external (**internal and external to what? CDC? Perhaps rephrase as National and State/Local Health Departments**)
- Funding (receiving or distributing)
- **Governance of shared CDS resources**
- Legal considerations
- Communication channels

With respect to the stakeholder list, we note that **professional societies and other stewards of clinical guidelines and/or CDS rules** are missing from the list.

2. 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.).

There is an immense amount that CDC and public health at large can do to promote and enable CDS. We offer just two examples of many which we are directly involved in that are promoted and funded at least in part by CDC:

CDS for Immunization (CDSi): CDC NCIRD is already heavily involved 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.[1] 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. Our own Open Source Immunization Calculation Engine (ICE) is currently deployed in public and private healthcare settings and in 2017 will be integrated into VistA, the EHR used by the Department of Veterans Affairs.[2]

Reportable Condition Knowledge Management System (RCKMS): 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 to help clinicians determine if a patient meets the criteria for reportable conditions at the State or Local levels and, if so, how and to whom that report should be made. Building upon existing Open Source products and standards, HLN has developed the CDS shared service and administrative tools to be used by State and local jurisdictions to manage their reporting specifications and rule sets for their reportable conditions. This is in parallel to CSTE's considerable effort working with jurisdictions to develop default reporting specifications that can be adopted as is or used as a baseline by jurisdictions to develop their own reporting specifications.

These are but two examples. CDC has been instrumental in the success of both and should continue to show the leadership, funding, and coordination services for other domain areas as well. At the same time, CDC should encourage the community to use successful implementations, particularly those that leverage Open Source solutions, rather than encourage too many varying solutions to proliferate.

3. 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.

See the examples identified above. Our Open Source ICE product is currently in production within at least one major EHR and PHR product. Here are some additional details of the use of these products in the clinical setting:

CDS for Immunization (CDSi): The primary use case for this functionality is at clinical sites that provide immunization services in either the public or private sectors, including ambulatory and in-patient settings. While for many years this was largely a function of

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[1] See https://www.cdc.gov/vaccines/programs/iis/cdsi.html as well as a good descriptive summary of the entire domain area at "Clinical Decision Support for Immunizations (CDSi): A Comprehensive, Collaborative Strategy, "*Biomedical Informatics Insights*, Suppl. 2, October 2016. < http://www.la-press.com/clinical-decision-support-for-immunizations-cdsi-a-comprehensive-colla-article-a5971-abstract?article_id=5971>

[2] See https://www.hln.com/ice/

pediatric medicine, immunization is becoming more and more an important part of both adolescent and adult medicine with the addition of more and more vaccines (in fact, there has been a rapid growth in the number of vaccines over the past 20-30 years). The schedule used by clinicians to determine if past immunizations are valid and what immunizations might be due now or in the future continues to get more complicated, making CDS a useful, and even necessary, feature of clinical care. In the typical workflow, a clinician using an EHR will retrieve a patient's record which triggers a query to an Immunization Information System (IIS) to ensure that the local EHR representation of the immunization history is correct. CDSi can be used by an EHR in one of two ways: The response from the IIS might return an evaluation and forecast based on the information it has for the patient, or the EHR might just incorporate any missing immunizations into its local record and apply its own CDS logic to evaluate and forecast any immunizations due. The forecast is then used by the clinician to determine if in fact immunizations are to be administered at that encounter. Any immunizations administered are then transmitted back to the IIS for incorporation into the consolidated immunization history for that patient which will affect the forecast the next time the record is accessed by the clinician. The evaluation of a patient's immunization history can also facilitate both public health and clinical settings with Reminder/Recall functionality that further promotes the likelihood that patients remain up-to-date with their vaccinations.

Reportable Condition Knowledge Management System (RCKMS): All states have a set of conditions (though not the same set) that are reportable to state and/or local public health agencies, yet the process used to report these conditions is overwhelmingly manual (usually via FAX). The new process for electronic case reporting (eCR) being developed for national deployment will allow an EHR to incorporate within its system a set of standard terminology codes (*e.g.,* LOINC, SNOMED) to be used to "trigger" a suspected case report for a reportable condition. The case report will be generated automatically by the EHR either immediately or periodically (once a day, twice a day) based on the matching of a trigger code within a patient's record. The Electronic Initial Case Report (eICR) will then be transmitted to a central CDS service (RCKMS) to determine if the data represents a reportable condition in that clinician, laboratory, or patient's jurisdiction. An electronic Reportability Response is then returned to the EHR with the CDS response and instructions as to whether the condition is reportable, and, if so, to whom and how. The state or local public health agencies also receive the electronic Reportability Response with the eICR and are notified of reportable conditions for case follow-up.

CDSi is used fairly extensively within EHR systems today. eCR is still in its infancy but once the infrastructure is in place it is expected to have wide-scale use.

4. 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 vie 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.

IIS must support query/response from EHRs to fulfill Meaningful Use Stage 3 requirements of the CMS EHR Incentive Programs. The response requirements from an IIS must include a valid evaluation of the patient's immunization history and forecasting of immunizations due now or in the future. Many IIS already support this functionality and many more will support it at scale by the January 1, 2018 start date of Stage 3. Even without local CDSi capabilities within EHR products, this query/response capability will significantly improve the level of CDSi experienced by clinicians, with strong public health support and involvement.

5. Have you previously worked with public health agencies around CDS development (this could include anything from "translating" guidelines into structured decision algorithms, to defining standards, to developing or piloting CDS tools)? If so, please describe that experience.

In the two projects described above in our response to question #2, HLN has worked significantly with State and local public health agencies. We convene a Subject Matter Expert workgroup to help guide the development of CDS rules for ICE with State and local public health representatives actively involved. Through CSTE, the RCKMS project engaged *many* State and local public health representatives actively in its focus groups, workgroups and pilot projects. HLN is also involved in the Digital Bridge project which is currently focused on eCR. Finally, through our more than 20 years of experience supporting IIS, we have actively worked with State and local public health agencies (currently in New York City and Rhode Island; previously in California and Philadelphia as well) on CDSi solutions.

6. What are the challenges you face in the CDS development and implementation process? How do those challenges affect you? How would you ameliorate or eliminate those challenges?

The challenges are many and include:

- Knowledge engineering – the heart of any set of CDS rules – is complex, and there is not always agreement on what the resulting rules should be. Clinical guidelines are rarely written in a form that is computable, so some interpretation is usually necessary. There is a progression of clinical knowledge from narrative, to semi-structured content, to more structured content that becomes rules; at any stage of the process errors and disagreements can be introduced.
- The CDS knowledge itself is not static. Depending on the domain area rules may need to be updated frequently as medical and public health knowledge advances.
- The information to make fully-informed CDS decisions is not always available in the information system when a decision is needed. For example, immunization schedules

for high-risk patients are sometimes different than routine schedules, but the information to determine whether or not a patient is high-risk may not be available.

- CDS systems are expensive to develop and maintain. Open Source and collaborative projects may help share that cost but there are consequences to doing so as well. Open Source products are neither commercial products which are enhanced based on what the marketplace demands, nor "custom developed" products which are enhanced based strictly on what the funder requests and pays for. Usually everyone benefits from changes, but is unclear who should pay the bill.
- The management and coordination of a governance process for the software and rules requires effort and funding, even more so if it is to be conducted fairly and efficiently and will be sustainable in the long run.

There are no easy answers to these challenges, but clearly additional funding, strong support through leadership for initiatives, collaboration, and coordination can minimize duplications of effort and unnecessary variations in interpretation.

7. 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?

This is a difficult question as public health is a diffuse, disjoint collection of thousands of agencies at the local, State and Federal levels. Coordination among these many moving parts is very difficult. Priorities differ, funding is inconsistent, and expertise and resources vary from agency to agency. Several attempts have been made to coordinate public health technical infrastructure, the most recent (and failed) attempt being the Public Health Community Platform. It is difficult for public health agencies to pool their funds to support common goals as the administrative, contracting, procurement, and funding origination often works against such collaboration due to administrative compliance requirements, fear that an agency will not get its "money's worth" if it cannot control an entire project, and legislative constraints that create disincentives for leverage.

CDC should provide the leadership, coordination services, and in some cases resources to enable and facilitate collaboration and joint projects among public health agencies to further specific CDS objectives. As an example, the American Immunization Registry Association (AIRA) – funded largely by cooperative agreements with CDC NCIRD – convenes and facilitates "Joint Development and Implementation" activities through a standing workgroup and sponsored projects across the IIS community.

Domain-specific associations and professional societies may be a good option for much-needed shared resources and infrastructure. As an example, the Association of Public Health Laboratories (APHL) operates its Informatics Messaging Services platform (AIMS) to provide public health agencies with interoperability and other data management services for a fee that would otherwise be prohibitive for them to arrange and support on their own (it is

coincidentally the hosted platform for RCKMS).[3] As another example, the American Immunization Registry Association (AIRA) has a long history of promoting and facilitating joint development and implementation activities among IIS across the country.[4]

It may not be useful to focus so much on *public health* CDS tools specifically but rather on CDS tools *in general*. Closer collaboration between the clinical, analytical, research and public health communities may provide better opportunities for leverage that might further CDS overall. Without this close collaboration scalability may be more difficult.

8. 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.

Several examples are already identified above for unidirectional and bidirectional data exchange. In many instances, data often appears to be unidirectional from EHRs to public health agencies, with limited data provided from public health agencies to EHRs (e.g. syndromic surveillance, case reporting). If limited data is being returned back to EHRs or regulations/new initiatives are implemented without stakeholder feedback, buy-in from healthcare providers and EHR vendors will be limited. The response to additional requirements from public health may be felt as a burden, with a focus on minimal compliance rather than keeping in sight the goal of assisting public health in the larger effort of improving the population's health. Initiatives with healthcare providers and EHR vendor feedback appear to be the most successful.

The coordination between public health and EHRs that is provided by CDC can be quite limited – in fact, it often appears that the various CDC branches and projects are often not aware of each other's efforts in certain areas and are not coordinated with each other in a comprehensive way. One example of this phenomenon is the loose connection between the large eCR/Digital Bridge project and a smaller, but somewhat related Automated Clinical Decision Support Service (ACDS) effort focused on a few specific communicable diseases. This is somewhat understandable given the distributed nature of CDC but it makes coordination between public health and EHRs even harder. At minimum, CDC should establish a clearinghouse of information related to CDS and public health (perhaps a new Digital Bridge project?) and an active and relentless communication campaign to promote its use and consultation.

9. How could clinical data and EHRs be more effectively used for public health purposes? How could health information exchanges (HIEs) play a role?

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[3] https://www.aphl.org/programs/informatics/Pages/aims_platform.aspx
[4] http://www.immregistries.org/resources/joint-development

Use of clinical data in multiple contexts is the foundation of the Nationwide Interoperability Roadmap.[5] In a CDS context, we have provided examples above that are driven by clinical data:

- Public health use of clinical data about immunizations drives various processes that ensure that the population is properly immunized for vaccine-preventable diseases, including identification of gaps of coverage by geography, race/ethnicity, or sub-population.
- Public health use of clinical data about emerging conditions drives case reporting and management for notifiable conditions.

We believe that the foundational elements are defined and starting to be put into place for clinical data to be more effectively used for public health purposes. The public health measures defined within the CMS EHR Incentive Programs as well as standard promulgated by the Office of the National Coordinator for Health Information Technology (ONC) go a long way to promote adoption. One significant barrier, however, continues to be 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. CDC needs to continue to make investments, provide guidance and workforce development, and further help these agencies improve their informatics capabilities.

Health information exchanges can play a key role by providing the infrastructure necessary to quickly and securely transport data between clinical sites, public health agencies, and other types of authorized users, and in some cases to improve the quality of data being sent (depending on the capabilities of the HIE).

10. 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?

Public health surveillance data – both identified and de-identified – can provide important elements to a clinical decision. Knowledge of emerging conditions in a particular location or among a particular sub-population may alert a clinician to evaluate clinical results or suspicions differently. Environmental data can have a profound impact on how patient data is assessed and considered. We are not epidemiologists, so we leave the details of these observations to others.

11. Should there be a different approach for CDS in emergency scenarios versus less urgent 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.

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[5] https://www.healthit.gov/policy-researchers-implementers/interoperability

We have no opinion on this issue. CSTE's RCKMS Content Vetting Workgroup for eCR is trying to develop reporting specifications in a way that provides meaningful, timely and accurate notifications to public health agencies while trying to reduce the 'noise' of excessive information being sent them that they cannot use or analyze in a timely manner. This is especially important with urgent scenarios where time is of essence and with jurisdictions that do not have the resources to work with large quantities of data. In addition to defining the rules in such a way to balance these two factors, the default reporting specifications are being developed to contain 'optional' criteria that allow jurisdictions to eliminate or include criteria that increase or decrease the level of sensitivity of their rules depending on preference.