

May 13, 2021

The Electronic Health Record Association is pleased to share our experience and perspectives to advance public health data infrastructure.

The EHR Association's nearly 30 member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our focus is on collaborative efforts to accelerate health information and technology adoption, assist member companies with regulatory compliance, advance information exchange between interoperable systems, and improve the quality and efficiency of patient care through the use of technology.

EHRs have been engaged with public health reporting ever since state and federal level electronic reporting requirements emerged for syndromic surveillance, electronic laboratory reporting, immunization reporting/queries, and case reporting in particular. Inclusion of certification criteria into ONC's Certification Edition with defined standards for three of these reporting requirements (syndromic surveillance, electronic laboratory reporting, and immunizations) aimed to align reporting and ease implementation. CMS introduced performance measures in which providers were not required to select all capabilities towards their Promoting Interoperability score. At the same time, states/jurisdictions implemented variations on the standards used in certification to address local and state policies that impacted when and what to report.

When the COVID pandemic reached the U.S., public health was confronted with new data requirements that the then-current reporting infrastructure was not prepared to support immediately. Examples include:

1. Operational statistics on volumes, beds, supplies, and other resources -- some that could be sourced by EHRs, while others could be sourced by other health IT, such as logistics and bed management systems.
2. More data on patients who contracted COVID-19 that, in the absence of a robust electronic case reporting infrastructure, resulted in alternative data collection methods such as submission requests for full HL7[®] CDA[®] C-CDA CCD (CCD) documents, and expansion of electronic laboratory reporting and immunization reporting.
3. Rapid deployment of vaccine codes ahead of vaccine availability with incomplete data, e.g., not-yet-established expiration dates.
4. Available appointments for COVID-19 vaccinations at state levels for mass vaccination programs.

Throughout, data requirements varied by local, state, and federal levels creating challenges for providers and their EHR vendors to respond in the timelines requested. With the need to communicate

quickly while learning what was needed, challenges arose with not all stakeholders hearing and understanding the same messages and requests.

This led the EHR Association to establish an EHRA COVID-19 Taskforce that began, on behalf of its members, to reach out to various agencies to create a common communication platform allowing EHR developers to be informed, ask questions, and help establish consistency and/or clarity in information-sharing. We reached out to the CDC and the office of the HHS CIO as operational data collection started; members shared information on data requirements for CCD submissions; we reached out to CDC, FDA, and states as electronic laboratory reporting data requirements were established, and worked with the HL7 community to rapidly establish guidance on how to communicate that in a standard fashion; the CDC reached out to explore enhanced reporting using the new HL7 FHIR standards; members participated in various research initiatives and shared their learnings; and as vaccine administration came closer, we reached out to the CDC to learn more about plans.

These multiple outreach initiatives all led to ongoing meetings that began to also include AIRA, to keep information flowing. When we had opportunities for early awareness and to review and discuss plans, our members were able to be better prepared, while agencies and jurisdictions were better informed on opportunities and challenges for support and preparation from EHR developers. We very much appreciate all of the agencies' representatives who have responded and engaged to help us serve our clients better during that time.

The challenges we encountered along the way can be summarized as follows:

- Short-turnaround requests for large volumes of historical data
 - Ensuring consistent & complete reporting
 - Minimum necessary data sets vs. full CCD data requests
 - Real-time reporting implementations within 24 hours for providers who had not needed to report before
 - Device identification collection, when source data and systems were not geared to collect that information
- Aligning measures and reporting across requesters
 - Variant measure definitions
 - Duplicate reporting requests
 - Competing requests
- Right-sized reporting and transaction content
 - Ask at Order Entry questions being required for data that is better supported using case reporting, while case reporting was not widely deployed
- State variations
 - Non-vaccine therapeutics reporting through immunization interface
 - Consent requirements
 - Priority group definitions
 - Confusion around the use and expected integration of VAMS vs. EHRs

- New and variant reporting systems
- Data quality
 - Patient identification and matching for vaccine administration queries across jurisdictions, limiting the ability to provide a holistic patient vaccination record

Considering our experience, we recommend focusing on the following areas, in order to enhance the public health infrastructure to be better prepared for the future:

- **Drive adoption of standards based electronic reporting**
 - We appreciate CMS proposal -- in its recent Inpatient and Long-Term Care Prospective Payment System NPRM -- to require all four fundamental public health reporting mechanisms. We suggest that CMS work with ONC and the healthcare community to additionally recognize a common case reporting standard beyond the currently established reference to supporting USCDI v1 referencing vocabulary standards in the 2015 Certification Edition Cures Update, but not a report format standard such as the HL7 Electronic Initial Case Reporting standard.
- **Align data requirements across jurisdictions**
 - We recognize the need for variant data requirements considering the unique and specific data needs for each jurisdiction. We strongly encourage collaboration to establish a common data set that includes all data of interest across jurisdiction promoting re-use, while not requiring everybody needs the same data. This will enable increased and improved standardization. Consistent data collection and reporting formats can then be established where actual content may vary. Adding new and critical data can be more easily accommodated rather than point-to-point by jurisdiction.
- **Right-size data transactions to purpose**
 - We understand the challenges that occurred in the absence of widely deployed case reporting and the interest to use other, already existing reporting vehicles to attempt to gather such data. Unfortunately, those alternatives, such as electronic laboratory reporting, are not well suited to support data beyond what is needed for the specific workflow at hand. We urge that data not necessary for the specific workflow at hand be managed through case reporting that has a focus on gathering relevant and critical data from the patient's record, pertinent and necessary for the reportable condition at hand. This would also reduce the need for large data requests through vehicles such as CCD documents that frequently include more than necessary.
- **Address incremental data requirements**
 - The COVID pandemic has clearly demonstrated that there is a need to be able to quickly collect data considered relevant or necessary for ongoing reporting. The wide availability of national networks and introduction of HL7 FHIR-based APIs are enabling

an infrastructure to query for additional data. We are encouraged and supportive of the HL7 SANER project that is forging an approach to enable both measurement and supporting data queries to address incremental data requests.

- **Include health information networks**

- Understanding and clarifying the role of HIEs and national networks is important as well, as they have the ability to find a patient's relevant data across participating data sources. This may be focused on enabling a national level data sharing agreement for, e.g., case reporting, avoiding point-to-point agreements, or the ability to submit and access patients' records through the networks. The public health capabilities are currently underutilized and should be taken advantage of. We also suggest that encouraging participation in networks, including support for Direct, has tremendous value. Being connected before an emergent need arises enables data to flow more quickly to new points of need. Preparation for a natural disaster or public health emergency would be enhanced when systems are already connected.

- **Enable real-world data research**

- While ongoing public health reporting works with well-defined data sets that are event-specific (e.g., electronic laboratory reporting) or condition-specific (e.g., case reporting), novel outbreaks in particular require exploratory research to gain critical understanding. Individual EHR Association members have been active in supporting such initiatives, and identified challenges, particularly with clarity on consent requirements and the resulting venues by which accommodate the various data interests. We recommend that real-world data-based exploratory research should be addressed closely together with public health enhancement to enable a robust environment to understand novel data needs during all stages of an outbreak, from initial awareness to initial assessment of impact of alternate courses of action, e.g., guidance, existing and/or experimental treatments, etc.

- **Establishing a surge process and infrastructure**

- We recommend that as part of infrastructure enhancements to establish a more robust base, consideration be given to processes that can be enacted when a response surge is needed, one that engages all critical stakeholders from the start into the response planning. From an EHR perspective, as well as for other health IT that provide critical data sources, early engagement is critical to accelerate response. Established response plans that address local, state, and federal levels, including the role of the health IT suppliers of the critical data source, are essential.

- **Clarify privacy and consent requirements**

- Beyond the considerations already referenced, we suggest there is also a need for clarity on data retention, particularly when more data than usual/necessary is being collected. We recommend clear guidance on duration and how data removal is then

managed.

- **Patient identification and matching**

- For any public health infrastructure improvements to yield optimum value, patient identification and matching is essential, even as data is being de-identified along the way: data must be associated with the right patient to get the relevant perspectives, while also being able to manage authorizations to access identified data. This is particularly evident where patients interact with multiple providers contributing to the same data sets, as well as enabling a complete immunization record regardless of where the patient has obtained them. We continue to advocate for progressing the ability to improve patient matching and use of unique identifiers that can be used across the system. We also reference the recent publication of the Patient ID Now Coalition's [Framework for a National Strategy on Patient Identity](#).

The EHR Association and its members strongly believe in the importance of a robust public health infrastructure. We welcome any opportunity to be engaged as early as possible to address opportunities to make necessary improvements.