

Informing Local Emergency Response Through Standard Health Care Data Reporting

DISCUSSION PAPER

OVERVIEW OF PROPOSAL

In a health-related disaster, efficient, timely, and reliable data collection on cases and health system capacity can provide critical situational awareness around the extent of the health threat and its likely course and aftermath. This data can be used to optimize use of regional health systems' capacity to treat those sick or injured by the disaster. In an infectious disease-related emergency, diagnostic test results and transmission data can also inform prompt analysis and response by on-the-ground responders, public health agencies, and other decisionmakers.

Temporary [data collection authorities](#) were granted to the Department of Health and Human Services during the COVID-19 pandemic. However, the federal agencies, as well as state, local, and territorial public health data systems faced fundamental challenges in bringing together reliable and timely data to inform responses, due to fragmented and outdated reporting systems without the ability to interface routinely and securely with now-widespread electronic health care data systems. The result was incomplete and delayed situational awareness for both immediate response and analysis for future planning, as well as reporting burdens on stretched health care providers.

Many health care systems and some states and localities were able to produce timely data through reliance on standardized electronic data used by health care organizations for their clinical care. Hospitals have electronic health record systems (EHRs) with clinical information on individuals both presenting with symptoms as well as tested and confirmed cases. Laboratories have laboratory information systems (LIS) in place with information on the date and results of individuals' tests, along with the potential to store limited patient information sent with the clinician's orders for testing services, such as key patient demographics and location. Indeed, now that the public health emergency (PHE) has ended, ongoing CMS reporting requirements for hospitals is providing continued insights into trends in serious COVID-19 cases, complications, and their impact on health systems (although there are no longer clinical laboratory reporting requirements at the federal level).

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Building on these health care electronic data capabilities and programs for electronic data reporting supported by the Centers for Medicare and Medicaid Services (CMS) and the data interoperability work done by the Office of the National Coordinator for Health Information Technology (ONC), a standardized health care data reporting system could aggregate this type of data to quickly return actionable regional "heat map" information to local and state health care organizations and public authorities to use for resource allocation and patient load management (for example, showing which intensive care units (ICUs) are close to capacity). This system could also provide standardized reports of the locally aggregated data to federal public health and emergency response agencies (including facility-level data as required for emergency response), enabling more informed analytics for forecasting and allocating response resources and, in a pandemic or bioterrorism event, better understand the pathogen. This system could provide standardized infrastructure ready for reporting data that would be useful in an emergency – providing critical situational awareness for public health offices even if they have not been able to modernize their own electronic data systems, and for health care organizations and local responders to enable effective collaboration. Such a system could be extended to address important public health concerns outside of emergencies as well, such as flu monitoring or critical medical product shortages. More routine, non-emergency use of these reporting systems would also have the benefit of ensuring that the system will function smoothly in an emergency as well.

Key Features of CMS-Supported Data Reporting to Inform Emergency Response

Building on its programs for health care data reporting, CMS could serve as implementation entity within the federal government responsible for standard, efficient, and reliable health care data collection in a public health emergency.

CMS already has established mechanisms to enable nationally consistent data reporting through existing electronic health care data systems. These mechanisms are supported by existing authorities, including CMS Condition of Participation (CoP) authorities, Clinical Laboratory Improvement Amendments (CLIA) authorities, and HHS authorities under the PREVENT Act if needed. CMS also has established “notice and comment” rulemaking processes for obtaining stakeholder and expert input, and supports many collaborative activities with health care providers and state and local authorities to improve care, which would help assure transparent and effective implementation. CMS also has the ability to share data in appropriate ways to other federal departments and agencies such as CDC and ASPR.

In particular, CMS could contract with a third-party entity to support standard electronic data collection from health care organizations, including clinical laboratories, and aggregation of such data into timely reports of case results, laboratory results, and (where necessary) key subgroup data across different subpopulations. Several

major technology companies already have similar, private systems for de-identified hospital and health care data. The reports would only include aggregated, deidentified data, and would comply with health care data privacy and security requirements. **This reporting program would be a public-private collaboration to provide standard reports based on existing health care electronic data systems, allowing automation, easing burden and confusion, improving the quality of reporting, and providing a valuable and reliable bi-directional flow of de-identified, aggregate information to support emergency response.**

CMS should support a process through its rulemaking and related programs to incorporate public comment, health information technology standards implementation, existing private efforts to help health care organizations share and assess gaps and opportunities to improve population health, and guidance from public health agencies to establish an efficient infrastructure for timely and reliable emergency data reporting. This process can be advanced through a set of key uses cases, as summarized below, clarifying what electronic data would need to be collected, how it will be shared and used while ensuring privacy and security of health information, and how reporting burden for health care providers and laboratories can be minimized.

Key Health Data Reporting

During and after the COVID-19 PHE, [CMS required hospitals to report key COVID-19 electronic data](#) using a standard approach to better understand both disease dynamics to combat spread and changing health system resource needs. Some of the most critical and urgently needed data in a health emergency is agnostic to the particular type of disaster and concerns hospital bed and ICU occupancy along with inventory, burn rate, and potential shortages of critical supplies and medical products. During mass casualty events, blood availability and operating room space are of critical importance. For some health emergencies, such as a radiological event or infectious disease, more information on case rates for relevant symptoms or diseases will also be important to forecast health effects and health care needs over time. While it is impossible to fully pre-specify what data elements will ultimately be required in these scenarios,

this public-private collaboration could identify key feasible data elements that should be reported in different types of health-related disasters, ensure in advance that the “pipes” are in place to allow data to flow, and to clarify the key analyses based on any submitted data that will be provided back. This will enable data flows and supporting analysis to be turned on immediately. Examples of such data elements include:

- Total hospital bed and ICU bed census, capacity, and capability;
- Staffing shortages;
- Commonly used inventory/supplies that may experience significant competition and supply chain constraints/shortages in most disaster types

- Confirmed patients seeking emergency care or hospitalized with relevant diagnoses/injuries
- Confirmed deaths due to relevant diagnoses/injuries
- Laboratory tests performed and positive tests (when case rates are relevant to response planning)

CMS is already engaging with health care stakeholders to provide key COVID-19 data that will be valuable for health care planning beyond the PHE, through established electronic reporting mechanisms and authorities. **Reflecting public comment in its [fiscal year 2023 Inpatient Prospective Payment System final rule \(FY 2023 IPPS\)](#), CMS described standard data reporting requirements for hospitalized cases, staffed bed counts and occupancy, PPE on hand, and staff shortages.** These data would enable better-informed modeling for the Federal government to provide additional capacity and supplies where most needed, and data visualizations at the local level to help regional leaders optimize patient care across sites. Such information flows outside of disasters will help ensure that the system is up to date and clearly understood, allowing additional data flows based on emergency circumstances to be quickly “turned on.”

While valuable, such hospital-level reporting occurs for cases that have progressed to emergency department or hospital admission. **Laboratory test reporting, potentially including negative tests to assess positivity rates, could provide more forward-looking awareness in some types of PHEs, providing more insights about the extent of current cases and how fast it is spreading, and where more cases may be coming to support advance planning.** Traditionally, infectious disease test results are reported to local and state agencies based on local requirements, and state public health agencies then report aggregate data to CDC. This currently requires considerable manual reporting effort and customized data sharing agreements for stretched health care providers and laboratory personnel, and can result in delays, non-standardized reports, and gaps that limit actionability. In contrast, the system described in this paper has the

potential to provide actionable information quickly to local, state, and territorial entities as well as health care providers, potentially eliminating the need for some of this reporting, particularly during emergencies.

CMS, using its CLIA authorities, required high- and medium-complexity clinical laboratories to [report certain data to the federal government](#) during the COVID-19 public health emergency. In future emergencies where such laboratory data are critical for guiding emergency response, instead of again use its CLIA authorities CMS could use Department of Health and Human Services (HHS) authorities provided under the [PREVENT Act](#) to require rapid and accurate reporting of laboratory test results for high- and medium-complexity labs, as well as CLIA-waived point-of-care labs. Relevant data elements that are already reliably incorporated in laboratory electronic record systems include:

- Test type
- Date of test
- Result of test¹

Response planning for certain emergencies may also benefit from laboratory test reporting that includes patient information such as demographics and neighborhood of residence, that may not be reliably captured by laboratories. (Any reporting out to support local and national response would consist only of aggregated, deidentified data according to privacy and security standards, at the level of demographic and geographic groups.)

Because laboratories generally do not engage directly with patients, they must rely on ordering providers to supply any required patient demographic information. To further support the provision of such information when appropriate, CMS could develop a testing coordination and management payment for ordering prescribers, or similar financial supports, to provide such patient information as part of the test order, as well as support for laboratories to update their systems to receive and transmit such information automatically.

¹ In some emergencies, non-traditional testing sites may be used for POC testing. During the COVID-19 PHE, these sites often used non-instrumented rapid antigen tests. In future situations where information from such testing sources may be valuable for situational awareness, a least-burdensome approach might consider requiring those sites to report individual positive results and total tests performed rather than reporting all negative tests individually.

Path to Implementation Through Key “Use Cases”

Different uses of data to inform different types of emergency response should be explored in advance of actual emergencies, to assure smooth implementation with reliable data when needed. For example, case reports from health care organizations with information on key co-morbidities, treatments, and outcomes are likely to be valuable for situational awareness and predictive analytics in emergencies that represent new or poorly understood threats. Some uses will benefit from limited key data from all hospitalized cases, but others may be adequately served through data from a subset of representative health systems. The following are examples of potential use cases for hospital and clinical laboratory data:

- **Hospital and facility standard electronic reporting:** Regional situational awareness of health system response capacity, through information on cases in emergency departments and admitted to hospitals, available hospital beds, and hospital supplies and staffing
 - Supports “heat map” of current status and trends related to local health care response capacity
 - Allows local responders to appropriately direct patients and emergency responders to hospitals with capacity to care for them, as well as helping to prioritize resource allocation
 - Standardizes required data: admissions, staffed bed counts and occupancy, relevant supplies on hand, actual or expected staff shortages
- **Laboratory standard electronic reporting:** More complete and earlier situational awareness of public health burden, through information on laboratory testing and results – particularly for infectious diseases or other threats where serious cases may not be immediately apparent (e.g., radiation exposure)
 - Supplemental data could be achieved, as described in the previous section, with support for standard electronic transmission or verification of this information from ordering providers
 - Supplementing data on test results with patient location (zip code or similar) would help local responders better understand if differences in positive cases are due to over- or under-testing
 - Other supplemental data, including some patient demographics, allows local responders to understand what communities are most affected, which can influence where continued spread may occur
- **Forecasting and analytics:** Understanding what to expect next, and learning more about how to combat the threat
 - Gives public health experts (e.g., [CDC’s Center for Forecasting and Analytics](#)) and private entities (e.g., academic research groups, data analytic companies) timely and reliable aggregated, deidentified reports of case and laboratory test data (as described above) that can be used to develop more timely and accurate local “weather forecasts” and further insights into patterns of threat burden and course
 - Enables suppliers and decision-makers to understand where the threat is heading and if certain communities may be more at risk, to focus efforts and prevent or mitigate those adverse outcomes
 - Allows more rapid learning about an emerging public health threat by providing additional reliable ground-level information
- **Connecting local responders to those at risk:** A CMS-based electronic data infrastructure for aggregate reports to inform local emergency response could potentially be extended to provide more assistance to at-risk individuals in each local jurisdiction
 - A current example of this is the [emPOWER program](#), which uses CMS claims data to identify at-risk populations (e.g., those dependent on electricity-based life-sustaining medical devices, those requiring regular facility-based dialysis treatment) to provide guidance for local planning in the event of a disaster such as a hurricane leading to major regional power outages.
 - Some regions have implemented supplemental data privacy and security protections to use the emPOWER infrastructure to enable individual-level data on those at risk (i.e., location

information for those using critical medical equipment affected by a power outage) to be shared with relevant local responders like fire departments or emergency medical services, to enable faster and more effective action to assist those at risk in the emergency.

- For local public health and health care organizations able to provide sufficient privacy protections (e.g., as envisioned in the [Trusted Exchange Framework and Common Agreement](#), or TEFCA), this approach could enable timely public

health and emergency responder notification about cases that could benefit from rapid response, e.g., reportable infectious disease cases. Such secure information transmission to local entities could occur using the CMS-guided framework to add data elements that “stay local,” without providing additional patient-specific information to CMS or its contractor.

Establishing Data Elements and Standards

In previous emergencies, delays have been common before data is forthcoming, as the precise data elements required are identified across diverse information systems and data sharing approaches are developed locally across over 3000 state, local, and territorial public health authorities. In the absence of pre-established data elements, data use agreements, and communication pathways, parties have to resort to ad-hoc systems, which can create delays and additional challenges and confusion when national reporting requirements are imposed. But this approach reflects data sharing capabilities that predate recent progress in electronic data standards and the growing importance and capacity of health care organizations to detect and respond to public health threats. Progress on data exchange standards and health care provider experience with CMS electronic reporting requirements would enable a more efficient and comprehensive system with consensus-based, pre-defined basic data elements established and tested for various types of disasters that can be incorporated into ONC and CMS interoperability requirements for electronic health records, and built into electronic record systems and health care electronic reporting systems.

CMS should use notice and comment rulemaking ahead of potential emergencies to anticipate needed data and the most efficient collection mechanisms. This rulemaking process can be aligned with ongoing Federal interagency activities involving CMS, ONC, CDC, the Administration for Strategic Preparedness and Response (ASPR), and other public health agencies to advance health care data interoperability for addressing public health and

disaster response priorities. **Whenever possible, reporting should aim to enable direct capture from electronic records based on ONC-endorsed standards with United States Core Data for Interoperability (USCDI) and USCDI+ for public health data elements, minimizing provider administrative burden and avoiding duplicative reporting.** The CMS rulemaking process would provide substantial opportunities for public-private collaboration to work out key details of the PHE reporting mechanism, including:

- The minimum data elements that immediate action use cases will require, where benefits for informing public and private emergency response exceed the administrative and other costs associated with standard electronic reporting
- Identifying the least burdensome ways to obtain critical response planning data – for example, determining if additional key data from prescribers on patient characteristics can be combined with standardized and interoperable data elements that laboratories already obtain reliably in conjunction with a diagnostic test performance
- Determining whether reporting should differ across providers and laboratories that likely have different capabilities, e.g., high and medium-complexity laboratories versus CLIA-waived sites, or different types of hospitals

The reliability and impact of the emergency data sharing activities could be guided by a set of principles that can be implemented through this process, where:

- The purpose and uses of reported data are clear, including clear benefits to participating organizations;
- Proprietary and sensitive information is safeguarded;
- The electronic data reporting process is standardized and streamlined to minimize administrative burden and maximize data consistency, building on ONC's existing and ongoing interoperability efforts and electronic data standards and CMS quality and safety reporting requirements; and

- An effective mechanism for deidentified data sharing is implemented, including the provision of timely analytics and insights from the aggregated data to local disaster relief officials and health care organizations.

NEXT STEPS

More Informed Emergency Response Reflecting Health Care Capabilities

Advance planning for coordination between mostly private health care providers and local, regional, and national public response authorities and support systems has not kept pace with progress in health care electronic data standards and with continuing improvements in availability and use of diagnostics and therapeutics in responding to health threats.

A clear example of this gap is the potential for health care electronic data systems to better inform public and private emergency response. **A standardized reporting system with a single entity responsible for data collection, and with the capacity to rapidly analyze and securely distribute the aggregated, deidentified data for actionable insights, is critically needed for emergencies.** This system could also be extended outside of PHEs to inform responses to ongoing health challenges, with the benefit of ensuring the system functions well when emergencies strike.

This approach could augment voluntary programs such as the CDC's National Syndromic Surveillance Program (NSSP), which could focus on providing additional detail and insights beyond a baseline standard approach. This approach would allow health care organizations to move to automated reporting, standardized across state, territorial, and local entities, for data reporting that truly allows data to only be collected once, efficiently and securely, for appropriately use by public and private responders and decisionmakers.

As a next step, relevant use cases need to be more fully developed, building on existing collaborative processes involving CMS and other Federal agencies and private and state stakeholders. This process would help assure that core public health needs are addressed, avoiding the need and burden for state or local public health agencies to impose additional requirements in most emergencies. It would also help health care organizations and electronic record vendors make needed adjustments without avoidable burden – and potentially enable further progress to use interoperable electronic health care data effectively to improve care and public health.

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