THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700
Philadelphia, PA 19103-7077
215.575.9050 Phone
215.575.4939 Fax

901 E Street NW, 10th Floor
Washington, DC 20004
202.552.2000 Phone
202.552.2299 Fax
www.pewtrusts.org

July 16, 2020

Secretary Alex M. Azar II
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar,

Thank you for recently releasing guidance on reporting COVID-19 lab results as part of an effort to ensure that federal, state, and local public health authorities have the data they need to inform public policy decisions and mitigate the spread of this pandemic. The guidance requires the collection and reporting of some de-identified patient data and recommends the collection and sharing of expanded contact information. These additional data elements will better position public health authorities and policy makers to respond to the pandemic within communities and appropriately tailor public health interventions.

The Pew Charitable Trusts is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care. Pew's health information technology initiative focuses on advancing the interoperable exchange of health data and improving the safe use of electronic health records (EHRs).

For public health authorities—such as the Centers for Disease Control and Prevention (CDC) as well as state and local health departments—to effectively respond to the COVID-19 pandemic, they require timely information on the disease's spread throughout different communities. State and local health departments rely on this information to, for example, make quarantine recommendations and trace the spread of disease by contacting and interviewing individuals that have tested positive.

Through this guidance, published in June, the Department of Health and Human Services (HHS) seeks to ensure that the public health authorities receive the information they need to conduct contact tracing and analyze the spread of COVID-19 to inform future interventions.

The guidance states that all laboratories, including non-traditional facilities that may utilize point of care testing (e.g. drive-through or walk-up sites), must report the data they have for every patient to the local or state public health department. The data must be reported to the public health authority in the methodology determined by state or local mandate within 24-hours of the result being available. Regardless of the mechanism through which the public health authority receives the lab report, they are then required to share de-identified result information to the CDC. The guidance takes effect August 1, 2020.

In addition, the guidance includes different requirements for two types of information:

1. de-identified data that must be reported to state and local health departments and CDC; and
2. identifiable data that should, albeit is not required, be collected and sent to state and local health authorities.

Required data elements

The guidance establishes a basic set of information required to be collected throughout the lifecycle of the test, and reported both to the local or state health department and to the CDC. Some of those required data elements include: the test result; date; device identifier; patient age, race, ethnicity, sex and residential zip code; and other data elements.

For the CDC to receive this information, all data elements must be collected by the provider and included in the initial lab order so that the lab can successfully transmit the information to public health authorities. Laboratories can only share information they receive and, similarly, public health authorities rely on these facilities to share the data. In addition, when other types of facilities use point of care testing, they are also responsible for transmitting this information to public health authorities.

The exchange of this non-identifiable information can have important public policy ramifications. For example, the incorporation of device identifiers can help public health authorities take action in the event certain tests don't work as effectively as initially thought. A test may have higher false negatives than others on the market; having the device identifier can then help authorities to better understand the inaccuracies in the data they have and take appropriate actions, such as maintaining closures or contacting individuals to be re-tested. While HHS does not define the term "device identifier" in the guidance, the department should clarify that this refers to device identifiers as defined in Food and Drug Administration (FDA) regulations. FDA has identified standards for device identifiers, which refers to the brand and model of a product, through the unique device identification system. As COVID-19 viral and antibody tests obtain FDA clearance in the future, these diagnostics will have device identifiers and should be reported. In the interim, some tests—such as laboratory developed tests—lack these identifiers.

These data elements, given their centrality to data exchange writ large, are also referenced by the regulations from the Office of the National Coordinator for Health Information Technology (ONC). That office maintains a set of data elements—called the U.S. Core Data for Interoperability (USCDI)—that are deemed essential for data exchange. Starting in mid-2022, the USCDI will be available via standard software tools—called application programming interfaces (APIs)—to extract data from EHRs. The USCDI already includes unique device identifiers for implanted products. HHS should examine how these tools—and any necessary revisions, such as by adding the device identifiers of diagnostics to the USCDI—can support laboratory reporting.

HHS should assess and advance any health information technology improvements needed to ensure the exchange of this critical data, and educate ordering providers on their obligations to collect and share this information with laboratories. Similarly, HHS should examine whether

barriers exists among state and local health departments to receive data electronically, and address gaps that result in faxed test results.

Recommended data elements

In addition to those data required for reporting, HHS in the guidance also encourages the collection and sharing of identifiable data with local or state public health authorities. These data elements include, among other information, patients': name; street address; phone number; and date of birth. These data elements are listed only as "should be collected," rather than as required, meaning that opportunities remain to omit this information. However, just like with the required information, labs can only send data to public health authorities that they have already received from ordering providers.

Public health authorities require this information to contact the infected individual and interview them to further trace to whom the person may have inadvertently spread the virus. However, research suggests that lab reports to public health authorities often lack this contact information. Research from 2013 indicated that laboratories only sent phone numbers in approximately half of reports to public health authorities, and when they were included, the numbers often referred to an ordering physician and not a patient.[1] Public health officials have indicated that the same issues continue at the same rate with COVID-19.[2] That omission forces public health authorities to spend time locating a phone number, for example, while the virus spreads unaddressed. The use of pop-up testing sites may accelerate the omission of these data, as those types of facilities may not have the protocols or infrastructure needed to document this critical information.

Just like the required data elements, this contact information is also part of the demographic data listed in the USCDI. Given that EHRs will be able to share this information in a standard manner, the USDCI should serve as the roadmap for what demographic data all health information technology systems should use. The USCDI also contains email addresses, which could serve as another contact mechanism for patients. Therefore, HHS should further expand the demographic data listed in the lab guidance and work with state and local governments to accelerate the use of demographic data in the USCDI as the core information that must be shared alongside test results.

While these recommended data elements can help with COVID-19 response, they also will assist public health authorities in mitigating the effects of other public health threats. Therefore, HHS should examine further expanding this guidance to other lab reports, and work with state and local governments to secure the capture and sharing of this data. However, in order to facilitate this benefit to public health, it is foundational that all data elements be included in the initial lab order placed by the ordering provider and retained during specimen collection and analysis. HHS should, therefore, educate health care providers on the importance of collecting and transmitting this information. This will likely need to involve training to ensure that ordering providers are aware that these elements are mandated in an initial order, and guidance for hospitals and labs to update EHRs and laboratory information systems to include and exchange these elements.

Conclusion

The new guidance from HHS provides much needed clarity on the data elements that should be shared as part of COVID laboratory results to accomplish essential public health activities—including contact tracing. In implementing this guidance, HHS should:

- Ensure that all testing sites—including pop-up facilities—adhere to the guidance to guarantee that all lab results contain this information;
- Evaluate an expansion of these requirements to apply to additional lab reports—including those for reportable diseases;
- Collaborate with health care providers, laboratories, and state and local public health authorities to transition recommended data elements into a requirement; and
- Use ONC regulations—particularly the USCDI—as a guidepost to the data that should be exchanged.

Thank you for releasing this guidance to encourage greater data sharing for public health purposes. Should you have any questions or if we can be of assistance, please contact Ben Moscovitch at 202-540-6333 or bmoscovitch@pewtrusts.org.

Ben Moscovitch
Project Director, Health Information Technology
The Pew Charitable Trusts

---

[1] B. Dixon et al., "Electronic Health Information Quality Challenges and Interventions to Improve Public Health Surveillance Data and Practice," *Public Health Reports* 128, no. 6 (2013): 546-53, http://europepmc.org/article/PMC/3804098.

[2] American Medical Association, "AMA COVID-19 Daily Video Update: Why It's Essential to Improve Data Collection and Reporting," June 4, 2020, https://www.ama-assn.org/delivering-care/public-health/ama-covid-19-daily-video-update-why-it-s-essential-improve-data.