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Evaluation of the Implementation of CDC's Health Alert Related to the FDA LeadCare Recall From the State Health Department Perspective

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Abstract

On May 17, 2017, the Food and Drug Administration (FDA) issued a safety recall for the Magellan Diagnostics' LeadCare Testing Systems due to the potential for inaccurately low blood lead test results when used with venous blood samples. The Centers for Disease Control and Prevention (CDC) announced a health alert with retesting recommendations because those with a blood lead level of concern may have been missed and not connected to the appropriate follow-up services. A qualitative evaluation of 9 state childhood lead poisoning prevention programs' experiences is presented in this report. Interviewees reported using a variety of media and notification methods to inform key stakeholders about the recall and recommendations. Challenges experienced by programs in responding to retesting recommendations include incomplete and out-of-date lists of LeadCare users; missing or inaccurate information in their surveillance database; not having large laboratories and hospitals consider contacting persons for retesting to be within their purview; and having limited staff members to conduct emergency response activities. Two of the 9 states report subsequent challenges with their retesting rates. The retesting recommendations were generally viewed positively. The interviewees' comments provide insight into steps CDC might take to better serve state and local lead programs. Programs' experiences have led to a better understanding of the roles of their program when emergency events occur, their relationship with stakeholders as related to the blood lead testing and reporting process, and areas of improvement in surveillance databases. Public health agencies at all levels have important roles to play in preventing lead exposures and providing needed services when exposures occur. Programs may achieve long-term benefits by improving surveillance systems and having a better understanding of laboratory practices. CDC will continue to provide timely information and recommendations to state and local public health agencies to inform both routine and emergency response activities.

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On May 17, 2017, the Food and Drug Administration (FDA) issued a Class I recall for Magellan Diagnostics' LeadCare Testing Systems and the Centers for Disease Control and Prevention (CDC) simultaneously announced a health alert with blood lead retesting recommendations.[1,2] CDC currently funds 48 state and local childhood lead poisoning prevention programs (CLPPPs) to implement prevention activities with the objective of increasing blood lead testing of children younger than 6 years and improving surveillance and follow-up.[3] The overall goal is to reduce and prevent childhood lead poisoning.

Funded programs receive blood lead test results and associated demographics from health care providers and/or laboratories. Health care providers and laboratories use various methodologies including point-of-care (POC) devices such as LeadCare analyzers, as well as high-complexity methods such as inductively coupled plasma mass spectroscopy and graphite furnace atomic absorption spectroscopy to analyze blood lead levels.[4]

Following the CDC health alert, on May 18, 2017, CDC's CLPPP hosted a conference call with state and local CLPPP cooperative agreement recipients. On this call, recipients raised questions about the scientific basis of the recall and concerns about how to implement the retesting recommendations. To help CDC understand how the LeadCare recall affected program implementation and to document the lessons learned about the recall response, a 2-pronged approach was used: case studies and interviews. Detailed case studies are described in the Mason et al article in this special issue. This report describes the results of semistructured interviews with staff from state health department CLPPPs to shed light on their experiences, needs, responses, and lessons learned.

Approach

Nine state health departments' CLPPP staff members who were actively involved in implementing CDC retesting recommendations were invited to participate in an in-depth semistructured phone interview. Interviewees were recruited on the basis of their active participation on an informational conference call concerning the recall and retesting recommendations hosted by CDC on May 18, 2017. The interviewees included 5 program managers, 3 epidemiologists, and 1 program surveillance coordinator. The interview questions included 5 areas: (1) When did the program learn about the FDA recall? (2) What were the program's needs and concerns after learning about the LeadCare recall? (3) What are the program's unmet needs with respect to its ability to respond to the LeadCare recall? (4) Did the interviewee have additional comments about the LeadCare recall? and (5) Did the interviewee have additional comments about CDC's response to this event? This evaluation was reviewed and deemed nonhuman subjects research by the Centers for Disease Control and Prevention institutional review board.

The semistructured interview approach allows both the interviewer and the interviewees to request or provide more details for greater clarification when appropriate. The interviews

were recorded following verbal agreement from the recipient. The recordings were transcribed into electronic documents and analyzed using thematic analysis.[5,6] This inductive approach is used to organize findings to reveal patterns and themes within the collected qualitative information.

Findings

A majority (n = 7; 78%) of programs first learned of the LeadCare recall and recommendations for retesting through the FDA advisory and/or the CDC Health Alert Network. Two programs (22%) had previous knowledge that suggested there might be a problem with using LeadCare systems to analyze venous samples based on previous customer notifications from Magellan Diagnostics.[7,8] One of these 2 programs had received a data request from the FDA a few weeks prior to the recall announcement but was not aware of any specific issues about the use of LeadCare devices. Four interviewees (44%) received the FDA and CDC announcements while attending a CDC-hosted CLPPP training course outside of their state. Those who were at the training found it helpful to be around colleagues to discuss what was known and what steps may be taken next.

It was difficult for many programs to determine how severe the issue was in their state. One program indicated that providers and laboratories in their state “were confused on how serious it (the recall) was.” Nonetheless, objectives to respond to the recall were similar across programs, that is, to (1) notify providers and laboratories that may be using the LeadCare analyzers about the recall and recommendations and (2) notify anyone who may have been affected by the recall to get retested.

A few programs had already taken precautions against using LeadCare devices to analyze venous blood samples prior to the recall. Three programs (33%) had previously informed laboratories and providers that venous samples analyzed by LeadCare devices were not to be used for confirmation of capillary blood lead test results. Interviewees reported these decisions were made after they learned about guidelines for blood lead screening using POC devices from the Advisory Committee for Childhood Lead Poisoning Prevention.[4] Thus, the recall did not present an urgent concern for these programs. As stated by one interviewee: “We had already stopped allowing LeadCare venous here in the state from guidelines from CDC and the advisory committee to send elevated results to CLIA- (Clinical Laboratory Improvement Amendments) certified laboratories for high-complexity testing.”

Three overarching themes emerged from the interviewees’ responses: (1) What their program’s initial responses were immediately after learning about the LeadCare recall? (2) What challenges their program and program staff experienced in implementing their responses? and (3) What their thoughts and perspectives were about CDC’s retesting recommendations? To ensure that this evaluation had enough participants to get rich qualitative information about the interviewees’ experiences, we checked coded themes across all interviewees and concluded that saturation was reached with the 9 interviewees (ie, the interviews reached a point where the same themes were observed throughout the interviewees’ responses and no new data/themes emerged).[9]

Initial responses following the LeadCare recall

Interviewed programs reported using multiple media outlets and types of notifications to inform providers and laboratories about the recall and recommendations including state health alert systems (67%), contacting providers (67%), contacting laboratories, or contacting identified laboratories that use LeadCare systems (44%), sending letters to identified families (11%), circulars (11%), conference calls (11%), and postings on their own program Web site (11%). Some programs relied on health care providers, whereas others worked with their stakeholders to announce CDC's retesting recommendations, identify laboratories that were using LeadCare devices, and begin contacting individuals who needed retesting. At least 3 programs enlisted the help of partner organizations in their state, such as Medicaid, the refugee program, and the Department of Children and Families, to help locate children who needed a retest. Five of the programs (56%) created and provided supporting materials to further assist health care providers and laboratories in following the retesting recommendations. Programs developed and shared frequently asked questions sheets with health care providers and laboratories, as well as information sheets related to the issue, scripts to be used when contacting individuals and families, letter templates, and protocols to complete the retesting recommendations. Despite the various approaches taken, in some cases, it was reported that pertinent information did not always reach essential personnel who had a role to play in carrying out the recommendations. For example, in one state, communications were handled through a central phone bank that transferred callers to the wrong program personnel.

Some programs sought to communicate directly with known LeadCare users in their state. The level of effort required for a program to contact laboratories or providers depended on, in large part, if the program either had or was able to obtain a list of LeadCare analyzer customers. One of the main difficulties programs expressed was not having complete information on who owned and used LeadCare Testing Systems. Those without complete information reached out directly to laboratories and clinics to inquire about the use of LeadCare analyzers at the site. Ultimately, 8 programs (89%) were able to identify providers and laboratories that were using LeadCare analyzers to test venous samples. One interviewee indicated that the use of LeadCare devices to analyze venous samples was not employed in their state because of prior training received from Magellan on the appropriate use of LeadCare Testing Systems.

Challenges identifying individuals for retesting

Programs that had the necessary information available in their surveillance database were quickly able to identify individuals that required retesting; they then shared this information with the respective health care providers and laboratories. At various lengths in time (from less than 1 hour to several months) since learning about the recall, 5 programs (56%) successfully identified individuals for retesting. These programs contacted the individual patients (or respective families) themselves, contacted the patient's provider, or shared a list of the individuals with local health departments. Conversely, several interviewees (n = 4; 44%) spoke of issues identified with their surveillance database or procedures receiving blood lead test reports. Some programs received very limited information with LeadCare results, that is, missing or inaccurate information on sample type (venous or capillary blood

test), a lack of information about adults (which was needed to identify pregnant or lactating women to retest), and whether the health care provider associated with the test result was operating under a larger laboratory. Programs also indicated that the recall revealed issues in the quality of their blood lead surveillance data. One of the interviewees stated their program's experience attempting to identify individuals that may have been affected by the recall shows "how broken sometimes systems are."

Two programs did not collect any information on how the blood samples were analyzed, which resulted in their inability to determine which venous samples may be associated with LeadCare and which ones were tested using acceptable higher complexity methods. Six of the programs (67%) experienced missing data issues and outdated contact information needed to inform the individuals or laboratories about the retesting recommendations. One program resolved its issues with missing data fields by contacting providers directly to determine the specific test type, as well as updating addresses by partnering with their state's Medicaid office.

Other challenges programs faced included conducting surveillance on "highly transient populations," which made it difficult, if not impossible, to track individuals. Another challenge reported involved tracing analytic methods used for blood lead tests. For example, one program discovered a case where a child's venous blood sample was referred to multiple out-of-state laboratories, which created difficulty in determining how the test was analyzed; it was therefore unable to ensure timely follow-up for that child. Approximately half of the interviewees (n = 4; 44%) mentioned having limited staff time to dedicate to implementing the retesting recommendations. One program experienced challenges with its ability to securely share data with laboratories across the state. Another program encountered an issue when investigating its surveillance data for individuals who may be affected by inaccurate blood lead test results, with one particular laboratory providing results with systematic errors identified. Programs that were able to identify specific individuals to retest faced subsequent challenges with retesting rates. Retest percentages were not generally known; however, 2 programs reported rates of less than 20% for all groups retested.

Program perception of CDC's retesting recommendations

Overall, CDC's recommendations were viewed positively. The recommendations were seen as appropriate and sufficiently specific by most interviewees. However, because CDC is not a regulatory agency and has no enforcement authority, several interviewees reported difficulty in getting providers to comply with recommendations. Four programs (44%) believed it was the responsibility of health care providers and laboratories to identify and contact patients; thus, these programs fulfilled their roles by notifying the appropriate health care providers and laboratories of FDA's recall and CDC's retesting recommendations. However, because of the large number of children serviced, it was reported that hospital laboratories and clinics generally were not receptive to taking on responsibility for identifying patients who should be retested. For example, 3 state public health agencies experienced significant pushback or even outright refusal from hospital laboratories or clinics to accept responsibility for identifying children who needed to be retested. Hospitals justified not taking on this task because they are not primary care providers or their leaders

did not believe it was important to identify individuals for retesting. One program reported that hospitals may be hesitant to implement the retesting recommendations about inaccurate results because it could create a sense of distrust in the community.

There were some misconceptions about what role CDC could play in events of this type, as well as some suggestions on how CDC might better serve state and local CLPPPs. For example, one program stated that more information from CDC on retesting guidelines for adults was needed, although the interviewee acknowledged that responsibility for addressing adult lead exposure is not in the CDC CLPPP's purview. One program contacted the National Institute for Occupational Safety and Health (NIOSH) for recommendations on adults. One participant would have liked for CDC to explicitly state what activities programs were expected to do to ensure a "more uniformed response across the country," whereas another looked upon CDC's recommendations as having set the parameters so that CLPPPs "were all kind of doing the same thing." Overall, programs understood that CDC's CLPPP can only "recommend" and not "require" specific actions.

It was suggested that CDC could have been more helpful in explaining "the why" of the retesting recommendations, for example, why a venous blood lead test result of less than 10 μg/dL was chosen as the cutoff value. Three programs (33%) expressed concerns about not testing children older than 6 years. One of these categorized the recommendation that only children younger than 6 years at the time of the alert be retested as "a serious oversight." Another suggestion for CDC was to provide a better and more sustained opportunity for discussion and questions to be asked and answered by CLPPPs and subject matter experts.

Despite challenges faced by programs in carrying out the blood lead retesting recommendations, the problems experienced led to potentially long-term benefits for individual programs. Benefits noted include enabling programs to (1) improve missing data in surveillance system; (2) better understand laboratory practices; (3) implement, or recognize the need to implement, surveillance system quality control or assurance practices; and (4) resolve previously unrecognized problems with laboratory reporting.

The experiences of programs interviewed point to one important lesson learned that may be helpful for some programs in preparing for future public health responses. As pointedly stated by one interviewee, "Having quality surveillance data and having good points of contacts at all of the facilities is absolutely critical to any kind of response like this."

Discussion and Conclusion

One aim of these interviews was to retrospectively examine the experiences, challenges, and successes of state lead poisoning prevention programs with regard to the implementation of the FDA recall of LeadCare Testing Systems and the response to CDC's blood lead retesting recommendations for children and currently pregnant or lactating women. A second aim was to identify areas in which the federal government, namely, CDC's CLPPP, might better serve programs when similar emergency events occur.

The experiences of programs that participated in the semistructured interviews had some clear successes and challenges. Some were unique to the individual program, but others

reflected common experiences across CLPPPs. For example, findings from both the interviews and case studies suggest that a program's ability to respond effectively to emergency events is driven in large part on having the right tools and processes in place (see the Mason et al article in this special issue). Revisiting blood lead test results months or years after they were originally reported is a nontrivial task for CLPPPs. However, having a comprehensive and complete surveillance system helped programs quickly identify individuals recommended for retesting, whereas a greater level of effort was required by programs that reported data quality issues. Collectively, findings from the interviews suggest that having a thorough and collaborative infrastructure in place was helpful for taking immediate action.

Strong partnerships with key stakeholders can enhance the ability of programs to respond to issues. Various partners have assisted CLPPPs in creating more complete surveillance databases and improving their ability to reach health care providers across their states. Programs that had missing or outdated information were able to collaborate with partner organizations to improve data completeness and quality. Programs partnered with stakeholders that work with children, families, and refugees to reach targeted at-risk individuals. One program partnered with health care providers and hospitals to identify other health care providers and stakeholders to contact. Thus, partnerships with stakeholders can provide the necessary infrastructure that can quickly mobilize to create and implement plans of action for such emergencies.

Findings from the interviews suggest that it is important for CLPPPs to identify, understand, and assign the roles of stakeholders in lead poisoning prevention activities prior to an emergency event occurring in order to ensure that shared responsibilities can be carried out. As a result of this experience, some programs have a better understanding of the essential role of blood lead surveillance efforts in their state. Thus, this experience will ultimately strengthen surveillance systems, improve data management and quality assurance protocols, and prepare supportive tools to assist health care providers and laboratories in their states. Understanding the respective roles of each entity allows for a workforce ready to respond to emergencies.

The majority of programs were satisfied with the FDA and CDC responses. Some of the programs believed that it was their responsibility to identify individuals for retesting, and others believed it was their responsibility to share the FDA and CDC announcements and rely on local providers to implement the retesting procedures. Federal, state, and local public health agencies have a shared responsibility for protecting the health of all citizens from lead. These agencies, along with key stakeholders, must make every effort that those who have or may have been exposed to lead are properly diagnosed and appropriately treated. Collectively, public health agencies at all levels have important roles to play in preventing lead exposures and providing needed services when exposures occur. CDC's CLPPP will continue to provide timely information and recommendations to state and local public health agencies to inform both routine and emergency response activities.

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Implications for Policy & Practice

- Lead poisoning prevention programs can perform regular quality control and assurance on their surveillance system for both their routine operations and when they need to respond to an emergency event.
- State and local CLPPP staff may want to consider the important role that key stakeholders can play at each step of the blood lead collection, blood lead analysis, case referral, and data reporting processes. Programs can set practical expectations for the participation of stakeholders based on the reasonableness with which execution of a detailed task can be undertaken by a particular stakeholder. Specifically, CLPPPs might consider that large hospitals or independent laboratories may not have the resources to contact large numbers of individuals for whom the laboratory performed blood lead analysis.
- Programs can examine whether their surveillance system is designed to collect all information needed to identify children in their database for retesting and consider sharing with all entities in the blood lead collection, analysis, and reporting chain the importance of reporting accurate and complete data.
- Our evaluation indicates that maintaining strong partnerships and regularly discussing blood lead testing method issues with personnel from laboratories serving their jurisdiction may help lead poisoning prevention programs improve surveillance efforts.