CHARTER

Tri-Agency Task Force for Emergency Diagnostics

Authority

The Tri-Agency Task Force for Emergency Diagnostics (TTFED) with members from Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Centers for Medicare and Medicaid Services (CMS) is established to develop a process to collaborate on future emergency diagnostic response needs. During emergencies the TTFED will convene quickly to provide timely recommendations to laboratories for rapid implementation of *in vitro* diagnostic (IVD) assays authorized for use under FDA's Emergency Use Authorization (EUA) authority. Agency specific actions and matters will continue to fall under each member agency's respective statutory authorities. The TTFED will in no way involve itself in decision-making that is under the jurisdiction of a member agency.

Background

During public health emergencies, it is critical for IVD assays to be implemented quickly into clinical and public health laboratories for rapid patient care. The implementation of these assays in the U.S. healthcare system is dependent on laboratories understanding the IVD assay Instructions for Use and being able to apply them to the samples they are receiving for testing. In addition, laboratories need clear guidance on application of Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations for these assays.

Where adequate diagnostic tools are not available to meet response needs, it is imperative that diagnostics be developed and deployed under appropriate regulatory authority (e.g., EUA) to meet diagnostic demand and provide information about disease progression. Medical devices marketed in the U.S. are subject to regulatory controls in the Federal Food, Drug, and Cosmetic Act (FFDCA) and associated regulations, including premarket requirements for submissions such as 510(k), PMA, De Novo, and postmarket requirements once devices are on the market.

In addition, section 564 of the FFDCA authorizes FDA to issue an EUA for emergency use of an unapproved product or an unapproved use of an approved product.[1] An EUA may only be issued after the Secretary of HHS issues the requisite declaration[2] that circumstances exist justifying the authorization of emergency use of the medical product, in consultation (to the extent feasible and appropriate given the applicable circumstances) with the Assistant Secretary for Preparedness and Response (ASPR), the Director of the National Institutes of Health (NIH), and the Director of CDC, provided other statutory criteria are met.

1. Unless otherwise specified, the terms "approved product" and "FDA-approved product" refer to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the FFDCA or section 351 of the Public Health Service (PHS) Act, as applicable. For purposes of this document, an "unapproved product" refers to a product that is not approved, licensed, or cleared for commercial distribution under section 505, 510(k), or 515 of the FFDCA or section 351 of the PHS Act; an "unapproved use of an approved product" refers to a product that is approved, licensed, or cleared under such a provision but for which the specific use is not an approved, licensed, or cleared use of the product. See section 564(a)(2) of the FFDCA.
2. The HHS Secretary's declaration must be based on one of 4 determinations (including identification of a material threat pursuant to section 319-F of the PHS Act), as described in section 564(b)(1) of the FFDCA.

Because EUA IVD assays are neither cleared nor approved devices and may be made available based on limited analytical and clinical test performance data, conditions may be imposed on their use and additional recommendations may be needed for laboratories within the U.S. healthcare system planning to implement these assays.

Objective and Scope of Activities

Through the TTFED, CDC, FDA, and CMS, where appropriate, intend to coordinate the implementation of EUA IVD assays in laboratories within the U.S. healthcare system, with the ultimate goal of improving responses to public health emergencies. The TTFED was created to facilitate the use of any authorized EUA IVD assay (including CDC, commercial companies or the Department of Defense) and provide a platform to coordinate efforts to identify, establish and implement approaches to effectively and efficiently communicate with each other.

The TTFED will coordinate to provide consultation and recommendations for the implementation of IVD assays authorized by FDA for use under an EUA in laboratories within the U.S. healthcare system. In advance of an emergency, the TTFED will work to define, refine and streamline interagency approaches for the implementation of EUA IVD assays. The TTFED will develop, document, and refine processes and procedures to address gaps in the current EUA implementation system. Gaps will be identified through review of recent emergency response experiences and current practices. This work will occur through biannual meetings (at a minimum). During an emergency, the TTFED will provide a forum for discussion of agent- or response-specific EUA IVD assays to help facilitate rapid implementation of the assays in the U.S. healthcare system.

The focus of the TTFED is for each member, as applicable and appropriate, to

(a) establish efficient communication channels between TTFED members for effective information sharing to facilitate appropriate planning for and recommendations during emergency responses;
(b) formalize and document interagency process and procedures to facilitate an effective and coordinated response for the rapid implementation of EUA IVD assays in response to a public health emergency and distribute these in the three agencies, so that there is an agreed, shared process and a common understanding; and
(c) provide timely recommendations during emergencies to help ensure appropriate implementation of EUA IVD assays in the U.S. healthcare system.

See Appendix B for links to previously established Memoranda of Understanding or Inter-Agency Agreements that facilitate interactions between the Tri-Agency members, including terms for the exchange of non-public information.

Limitations

Specific agency matters will fall under the member agencies' respective statutory authorities. The TTFED will in not involve itself in decision-making that is under the jurisdiction of the member agencies.

Description of Duties

The TTFED will

1. Be composed of at least one participant from each of CDC, FDA and CMS who intends to participate in every meeting of the TTFED (see appendix A for basic membership). Participants should have the following desired subject matter expertise:
    - CMS – Representative(s) will have expertise in CLIA regulations and administration of the CLIA program, including compliance inspections of commercial clinical and public health laboratories. Representatives will serve as primary liaison to CMS from the Division of Clinical Laboratory Improvement and Quality (DCLIQ).
    - FDA – Representative(s) will have expertise in regulatory review of IVDs and EUA authorities.
    - CDC – Representative(s) will have experience in IVD development and implementation of EUA IVD assays, understanding of the U.S. laboratory system and technical expertise in CLIA regulations.

    Each member agency will identify primary and alternate participants for meetings. Additional participants will be invited based on expertise needed to address specific issues associated with the implementation of an EUA IVD assay for a public health response. CDC, Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Division of Laboratory Systems (DLS) will serve as the TTFED Chair and will have responsibility for activation of the task force, facilitating meetings, tracking action items and communicating TTFED activities to external partners. The Chair will also collaborate with participants from the member agencies to develop agenda items.
2. Facilitate the appropriate planning for and response to a public health emergency requiring the availability and use of EUA IVD assays to facilitate efficient and effective communication and coordination between the TTFED members.
3. Invite subject matter experts designated from each agency to participate in the TTFED discussions about implementation of EUA IVD assays authorized for use in laboratories within the US healthcare system during emergencies.
4. Review, and update as needed, the interagency processes and procedures to facilitate an effective and coordinated response for the rapid implementation of EUA IVD assays in response to a public health emergency.
5. Continually evaluate processes between the TTFED members when using some combination of CDC-developed, Department of Defense-developed, or commercially developed EUA IVD assays in laboratories within the U.S. healthcare system during emergencies in order to identify gaps and areas for improvement.

6. Provide advice and recommendations on EUA documents, associated communication and information for laboratories within the US healthcare system for consistency during a response.
7. Provide advice and recommendations on communication and information developed for CLIA (e.g., via oversight letters) with regards to determining CLIA compliance of laboratories conducting specific EUA IVD assays.
8. Provide venue for information-sharing and coordination between CDC, FDA and CMS related to the overall implementation of EUA IVD assays.
9. Provide strategic recommendations for the implementation and quality management of EUA IVD assays (e.g., verification panels, proficiency testing) to facilitate clinical testing by laboratories within the US healthcare system. During an emergency information will be provided to laboratories through appropriate clearance and communication channels such as the Laboratory Outreach and Communication System (LOCS) owned by CDC CSELS DLS.

Recommendations

Will be based on task force member consensus, with input from each agency and appropriate deference to each agency's respective statutory authority and areas of expertise.

Communications

All communications with external partners pertaining to the TTFED objectives, responsibilities (as defined in the section below) and recommendations must be reviewed and approved by each member agency prior to final release. Approval includes each member agency clearance process for communications. Note, this is not applicable to communications related to response activities, including press release information, that are under the jurisdiction of the member agencies.

- The TTFED Chair will communicate the TTFED recommendations to relevant partners, such as the LRN or other CDC programs for sharing with federal, state and local public health laboratories.
- CDC CSELS DLS will assist with communication directed to other clinical laboratories within the US healthcare system.

Charter Updates

The charter will be reviewed and renewed every five years. In addition, as needed changes will be made at any time as agreed to by the three agencies.

Estimated Number and Frequency of Meetings

The TTFED will meet twice yearly; additional meetings will be scheduled as needed. In addition, the TTFED is anticipated to convene at the beginning of any public health situation that is expected to involve a declaration of an emergency by the Secretary of HHS that would allow authorization of IVD assays for emergency use.

Duration and Termination

The TTFED will be an ongoing activity with no specified end date until canceled by any of the agencies with adequate written notice to the other agencies of no less than 30 days.

Membership and Designation

During a public health emergency, each member agency of the TTFED has clear and distinct roles and responsibilities in the response, and ultimately must work in a harmonized approach to successfully support the implementation of EUA IVD assays in laboratories within the U.S. healthcare system:

Centers for Disease Control and Prevention (CDC): In the context of a public health emergency with a clinical diagnostic testing element, CDC is responsible for providing agent-specific subject matter epidemiology, laboratory expertise and guidance to clinicians and laboratories responding to the emergency or potential emergency. In situations where cleared or approved IVD assays are not available and adequate to meet the public health need presented by the emergency and where CDC has an assay that could aid in meeting the diagnostic testing need, CDC would be responsible for developing assays and clinical testing guidance, submitting a request for EUA to FDA and deploying the EUA IVD assays to federal, state and local, and international, public health laboratories such as those in the LRN program.

The DLS within CSELS at CDC has an ongoing relationship with CMS and FDA. DLS will serve as primary liaison to the DCLIQ in CMS. The CDC DLS Associate Director for Laboratory Preparedness will be an ongoing participant of TTFED. The Regulatory Affairs Activity (RAA) within the CDC Office of Laboratory Science (OLSci) in the Office of Laboratory Science and Safety (OLSS) supports CDC compliance with FDA regulations for IVD assays through policy, guidance and consultation activities. RAA/OLSci/OLSS will serve as the primary liaison for the agency to FDA CDRH/OIR. The RAA serves as an agency-level liaison to FDA for regulatory policy, strategy and compliance matters, including those arising in the context of a public health response. The Regulatory Affairs Activity Lead will be an ongoing participant of TTFED. The Director of the OLSci may also participate in response-specific task force meetings and activities. CDC subject matter experts (SMEs) and CDC programs (such as the LRN) develop assays and may request an EUA through coordination with FDA for distribution to qualified laboratories supporting the response. The CDC SMEs will also be responsible for establishing and maintaining laboratory testing guidance and associated algorithms for detection or diagnosis where needed. They may also provide assistance with the confirmation of IVD assay results, consultations regarding testing or results interpretation, and guidance on availability of specimens or organisms that laboratories can

use to create panels for testing to meet CLIA regulations. Participation of CDC SMEs and its Programs in the TTFED will be as needed to support response efforts.

U.S. Food and Drug Administration (FDA): FDA's CDRH/OIR is responsible for the regulation of IVD products that are devices under the FFDCA (see 21 U.S.C. 321(h)). The Office of Counterterrorism and Emerging Threats (OCET) is responsible for developing and coordinating implementation of FDA policies and procedures to facilitate the availability of medical countermeasures, including through use of EUAs. On behalf of the Commissioner, OCET facilitates communications within FDA and with external partners on counterterrorism policy, public health emergency preparedness, and global health security.

As described above, while there is a declaration in place from the HHS Secretary, FDA may issue EUAs if the certain criteria are met. If an IVD assay meets a need unmet by cleared or approved IVD assays in the US (i.e., there is no adequate, approved, and available alternative to the product), there is evidence of effectiveness, and the known and potential benefits outweigh the known and potential risks of such product, then the IVD assay is eligible for an EUA. FDA when issuing an EUA can make designations about the complexity of the test, typically stated in the intended use/indications for use and this may have the effect of changing which CLIA requirements must be complied with.

FDA works with any IVD assay developer, including CDC, commercial companies, and the Department of Defense. Once an EUA has been issued for a specific IVD assay, FDA may authorize modifications to the EUA IVD assay. For CDC developed IVD assays, FDA works with the CDC's identified regulatory lead for the response regarding authorization for use in CDC-designated clinical and public health laboratories supporting the response. For other EUA IVD assays, some may be authorized for use within CDC-designated clinical and public health laboratories, while others may be authorized for use more broadly within the US healthcare system or emergency response healthcare systems outside of the US. FDA consults and/or notifies relevant agencies, including CDC and CMS, of each new EUA IVD assay prior to EUA issuance. FDA is also responsible for publishing notice in the Federal Register of each authorization, termination, and revocation of an authorization.

Centers for Medicare & Medicaid Services (CMS): The CMS Quality, Safety, and Oversight Group (QSOG) mission is to ensure health care quality and safety for the U.S. public through survey, certification, and the public dissemination of information regarding providers' and suppliers' quality of care. The DCLIQ within QSOG is responsible for administering the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. The regulations established under CLIA (42 CFR part 493) were designed to improve the quality and oversight of all laboratories in the US that are involved in the testing of human specimens for health assessment or the diagnosis, prevention, or treatment of disease. Laboratories conducting EUA IVD are not exempt from CLIA. In the event of a public health emergency, the CMS DCLIQ will provide guidance to laboratories on meeting CLIA requirements. CMS DCLIQ will also notify the CLIA Regional and State Agency surveyors, in addition to CLIA-approved AOs and exempt states, of the emergency and of available EUA IVD assays. If the HHS Secretary makes a

declaration that circumstances exist that justify an EUA, IVD assays used in laboratories that meet the criteria for issuance of an EUA remain subject to CLIA regulations.

Subcommittees

The TTFED has the authority to create subcommittees. The subcommittees must report back to TTFED and must not provide advice or work products directly to the agencies.

Record Keeping

The records of the TTFED and established subcommittees shall be managed in accordance with General Records Schedule 6.2, Federal Advisory Committee Records or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. §552.

- The TTFED Chair will record summary recommendations and action items for all meetings and share with the TTFED member agencies. The summaries will include, at a minimum, participant list, any action items discussed, and any recommendations developed.
- All relevant documents will be maintained by the TTFED Chair and will be available upon request to task force participants.

Approved:

CDC Official _____**---/S/---**_____Date___12/21/18_____
Name and Title: Dr. Chesley Richards, M.D., M.P.H., F.A.C.D., Deputy Director for Public Health Science and Surveillance

FDA Official _____**---/S/---**_____Date___2/07/19_____
Name and Title: Jeffrey E, Shuren, M.D., J.D., Director, Center for Devices and Radiological Health

CMS Official_____**---/S/---**_____Date___2/01/19_____
Name and Title: Kate Goodrich, M.D., M.H.S., CCSQ Center Director, Chief Medical Officer

Appendix A

Basic Membership

CDC Participants

Jasmine Chaitram (Associate Director for Laboratory Preparedness, DLS/CSELS. Zoa6@cdc.gov , 404-498-1635)

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CMS Participants:

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Appendix B

Established Memoranda of Understanding (MOU) and Inter-Agency Agreements (IAA)

The following previously established MOUs or IAA that facilitate interactions between the Tri-Agency members.

- FDA MOU with CMS
  https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm217585.htm
- FDA MOU with CDC (through PHEMCE)
  https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm402857.htm
- FDA MOU with CDC
  https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm402130.htm
- Intra-Agency Agreement Between CMS and CDC
  CMS Control Number IA 15-03, CDC IAA Number: IA-15CSELS001