

November 29, 2016

The Honorable Sylvia M. Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's recommendations pertaining to the improvement of health care by providing a funding mechanism for postmortem examinations and the improvement of safe communication and follow-up of diagnostic test results to providers and/or patients.

BACKGROUND

During the November 18-19, 2015 CLIAC meeting, the Committee was provided an overview of the Institute of Medicine (IOM) Report: *Improving Diagnosis in Health Care*. During the April 13-14, 2016 CLIAC meeting, the Committee suggested that a workgroup be formed to discuss the issues surrounding the IOM report to provide background information and input to CLIAC for its consideration in making recommendations to HHS Agencies. During the November 2-3, 2016 CLIAC meeting, the Committee was provided an update on two workgroup topics: 1) the role of autopsies in the health care quality process; and 2) guidelines for safe communication of sub-critical (non-life threatening) abnormal laboratory results.

The Committee discussed the need to provide funding for designated subset of health care systems to conduct routine postmortem examinations on appropriately defined categories of patient deaths. The Committee also discussed the opportunities and challenges for empowering laboratory professionals to participate in efforts to improve communication of abnormal laboratory results. After deliberation on the issues, the Committee voted to provide the following recommendations to HHS.

CLIAAC Autopsy Recommendation

The CLIAAC supports the IOM recommendation that Department of Health and Human Services (HHS) provide funding for a designated subset of health care systems to conduct routine postmortem examinations on appropriately defined categories of patient deaths (for example, those listed in the College of American Pathologists Guidelines for Non-Forensic Autopsies). These funds should be directly linked to proposals for data acquisition, including standardization of autopsy procedures and reporting (including death-certificates), with the expressed goal of understanding the value of autopsies for improving individual and health system outcomes.

CLIAAC Communication of Test Results Recommendation

Recommendation 1a

CMS should convene a multidisciplinary group* to

- Generate a report describing a process for health care institutions to improve safe communication and follow-up of diagnostic test results to providers and/or patients with clear guidelines on timelines for communicating those results; and
- Provide an implementation and evaluation plan for the process.

Examples of guidance for the report include:

- The 2015 VHA policy on communicating test results, http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3148.
- A similar project was the CDC's *Core Elements of Hospital Antibiotic Stewardship Programs*, <http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>.

*may include, but is not limited to, representatives from CMS, FDA, CDC, diagnostic industry representatives, relevant approved accrediting organizations, informaticians, human factors engineers, laboratory directors/professionals, clinician end-users, patient/consumer representatives, health IT developers/vendors, and other relevant professional organizations.

Recommendation 1b

CMS should recommend health care institutions create an interdisciplinary team comprised of clinical and diagnostic health care professionals, health IT, and other safety/human factors experts. This team should conduct periodic institutional self-assessments to address areas of risk and improvement related to safe communication and follow-up of diagnostic results.

Examples of guidance include:

- *Test Results Reporting & Follow-up* ONC SAFER Guide, <https://www.healthit.gov/safer/guide/sg008>.
- Additional guidance could be obtained from the report in Recommendation 1a.

CLIAC appreciates the significant and continuing efforts made by HHS and its operating divisions to improve health care quality through both an increase postmortem examinations and through effective communication of test results. Thank you for your consideration.

If you have any questions regarding CLIAC's recommendation, please feel free to contact me via email at rarnaout@bidmc.harvard.edu or by telephone at 617-538-5681.

Sincerely,



Ramy A. Arnaout, M.D, D. Phil
Chairperson
Clinical Laboratory Improvement Advisory Committee (CLIAC)

cc:

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Director, CDC

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