Federal Interagency Workgroup:
Improving Diagnostic Safety and Quality in Healthcare
November Meeting Summary

Workgroup Goal: Established by Senate Report 115-150. The Senate Committee on Appropriations requested "AHRQ to convene a cross agency working group that will propose a strategy to enhance scientific research to improve diagnosis in healthcare, as outlined in the 2015 NASEM report." (NASEM = National Academies of Sciences, Engineering, and Medicine.)

Workgroup Summary: The latest workgroup meeting occurred virtually on November 3, 2023, and was attended by representatives from the following agencies:

AHRQ	Agency for Healthcare Research and Quality
CDC	Centers for Disease Control and Prevention
DoD	Department of Defense
FDA	Food and Drug Administration
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
NIH/CC	National Institutes of Health Clinical Center, Office of Patient Safety and Clinical Quality
NIH/NLM	National Institutes of Health, National Library of Medicine
OASH	Office of the Assistant Secretary for Health
ONC	Office of the National Coordinator for Health Information Technology
SAMSHA	Substance Abuse and Mental Health Services Administration

The aims of this meeting were to:

1. Provide new or significant updates on activities federal participants have undertaken related to improving diagnosis;
2. Hear a CDC presentation, Intersection of Diagnostic Stewardship & Public Health Measurement to Improve Practice: *Clostridioides difficile* (CDI) as a Case Study; and
3. Have an opportunity to bring up any other issues that would benefit from group discussion.

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AHRQ, Center for Quality Improvement and Patient Safety	• Diagnostic Safety Building Contract
	  ○ We published three new issue briefs to the AHRQ website:
	  ▪ Reimagining Healthcare Teams: Leveraging the Patient-Clinician-AI Triad To Improve Diagnostic Safety
	  ▪ Pediatric Diagnostic Safety: State of the Science and Future Directions
	  ▪ Strategies for Improving Clinician Psychological Safety in Reporting and Discussing Diagnostic Error

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	○ We completed the evaluation of MeasureDx in 11 healthcare organizations. Results show that healthcare organizations, including those relatively new to diagnostic safety improvement work, were able to use Measure Dx to guide their efforts to detect, analyze, and learn from diagnostic safety events. • Diagnostic Safety Grants ○ We funded seven new diagnostic safety-focused grants and have posted two new standing notices of funding opportunity: ▪ AHRQ Understanding and Improving Diagnostic Safety in Ambulatory Care: Incidence and Contributing Factors (R01) ▪ AHRQ Improving Diagnostic Safety in Ambulatory Care: Strategies and Interventions (R18) • Patient Safety Learning Laboratories ○ We funded three PSLL grants in fiscal year 23 that focus on improving diagnostic safety. • Diagnostic Error in Medicine (DEM) Conference ○ We presented at a plenary session during the SIDM 2023 meeting, as well as at a workshop on the psychometric testing of the Teamwork Assessment tool that is part of our TeamSTEPPS for Diagnosis Improvement Curriculum. The Baylor contract team also presented on the evaluation of MeasureDx as well as oral abstracts on two different issue briefs. • Contract To Implement and Evaluate MeasureDx, CalibrateDx, and the Toolkit for Engaging Patients To Improve Diagnostic Safety ○ We awarded a new contract to implement and evaluate these resources. Each resource will be implemented in at least 50 healthcare organizations. • Contract To Implement and Evaluate TeamSTEPPS for Diagnosis Improvement ○ We awarded a new contract to implement and evaluate this resource in at least 60 healthcare organizations.
CDC	• Division of Laboratory Systems ○ **Clinical Laboratory Outreach To Advance Diagnostic Excellence:** DLS is working to implement a project to reduce underdiagnosis and undertreatment of severe hypercholesterolemia in a medically underserved population. DLS, along with the CDC Division of Heart Disease and Stroke Prevention, the National Association of Community Health Centers, and the Million Hearts Initiative™, is working on this effort with Zufall Health, a federally qualified health center, and LabCorp, a national reference clinical lab.

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	The in-person project kickoff meeting, held September 15, 2023, established steps forward for connecting with clinicians and patients to promote informed healthcare decisions. Approaches include addition of a lab note that contextualizes the result for the clinician and patient, links to educational resources, inclusion of additional information within the patient portal, and public service announcements. This project is intended to develop a sustainable process, be adaptable to other healthcare settings, and be applicable to other medical conditions. ○ **Health Equity and Diagnostic Excellence:** DLS published *When Positive is Negative: Health Literacy Barriers to Patient Access to Clinical Laboratory Test Results*. This manuscript describes how the use of systematic approaches that account for poor health literacy skills and include culturally and linguistically appropriate planning and availability of resources is warranted at individual and population health levels (e.g., human-centered design of patient portals). ○ **Clinical Laboratory Improvement Advisory Committee Regulations:** CDC, the Centers for Medicare & Medicaid Services, and FDA are all part of the clinical laboratory regulatory program, CLIA (Clinical Laboratory Improvement Amendments). The federal Clinical Laboratory Improvement Advisory Committee (CLIAC) has established two new workgroups to be convened by the end of 2023. The Next Generation Sequencing Workgroup is charged with providing input to CLIAC for consideration in making recommendations to HHS on education, training, experience, and competencies that CLIA should require to qualify personnel performing next-generation sequencing bioinformatic data analysis and interpretation. In addition, the Biosafety Workgroup is charged with providing input to CLIAC for consideration in making recommendations to HHS on potential additions to the CLIA regulations and the need for solutions that will improve the safety of laboratory professionals, their colleagues, and the environment. During the April 2023 meeting, CLIAC made 31 recommendations related to potential updates to the CLIA regulations on use of data as a specimen, remote testing, a new type of CLIA laboratory certificate, and opening of the CLIA statute to all oversight of CLIA Certificate of Waiver sites. See Clinical Laboratory Improvement Advisory Committee (CLIAC) at https://www.cdc.gov/cliac/. ○ **Collaboration With Division of Healthcare Quality and Promotion on a Blood Culture Contamination NQF Laboratory Measure:** The National Quality Forum (NQF) Blood Culture Contamination (BCC) measure received full endorsement in January 2023. DLS is developing a communications plan to reach the

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	nation's laboratories, laboratory and clinical professional organizations, and Hospital and Laboratory Accreditation programs to educate them about the measure, standardize the clinical laboratory's approach to handling BCC, and optimize blood culture collection. The BCC measure will support the DHQP's Hospital Acquired Bacteremia measure, which is undergoing NQF review. Standardization will allow a national benchmark to be developed to monitor the quality of collection across hospitals. In addition, a secondary submeasure to monitor blood culture single-set collection as a proxy for volume will be evaluated. DLS is partnering with Indiana Hospital Association on a statewide process improvement plan to implement the national BCC safety measure. This partnership will allow DLS to understand the challenges and barriers to adopting the measure in individual institutions and to develop tools to assist in addressing these issues. Tools that have been developed include: ▪ Blood Culture Contamination: An Overview for Infection Control and Antibiotic Stewardship Programs Working With the Clinical Laboratory. ▪ Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals. DLS also presented at two meetings to increase awareness and encourage uptake of the national measure: ▪ ASM Microbe Symposium; June 2023 ▪ Indiana Hospital Association Meeting; August 2023 Data collection to measure uptake is planned to occur through DHQP/National Healthcare Safety Network in 2024. • Division of Healthcare Quality Promotion ○ **Core Elements:** Based on the successful models of Core Elements of Antibiotic Stewardship and Hospital Sepsis Program Core Elements in facilitating change in U.S. healthcare, CDC is working with leaders in the field to scope and draft a Core Elements document focused on improving diagnosis in hospitalized patients.
FDA	• Assessment of a pharmacist-led transitions of care (TOC) service using an admissions-enhanced patient risk evaluation approach: the ICARE program. ○ Project is ongoing, with an anticipated end date of mid-November 2023.

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	• Oral Anticoagulation Surveillance and Improvement through Stewardship (OASIS), an ongoing project that is in Year 2.
	• IVD Updates
	  ○ FDA issued a proposed rule aimed at helping to ensure safety and effectiveness of laboratory developed tests (LDTs). The proposed rule seeks to amend FDA regulations to make explicit that in vitro diagnostic products are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the in vitro diagnostic is a laboratory. Along with this amendment, FDA is proposing a policy under which the agency intends to provide greater oversight of LDTs, through a phaseout of its general enforcement discretion approach to LDTs.
	  ○ On October 31, 2023, FDA will host a webinar to provide information on the proposed rule regarding LDTs.

HRSA	• Medical Claims Review Panel
	  ○ Annual review of malpractice claims paid shows a similar pattern as previous years with regard to failures in diagnostic safety and quality and repercussions related to financial payouts; up to one-third of all cases that end in a claim have a diagnostic failure in terms of team function. Discussions have opened up with OASH for addressing trends by engagement of the ASH and Secretary.
	
	• Training Initiatives
	  ○ The findings of the MCRP, and subsequent efforts by HRSA's Bureau of Primary Health Care, have resulted in ongoing programmatic developments for trainings of the HRSA-supported federally qualified health centers (FQHCs), via a national training contract with ECRI. These trainings have reached much of the FQHC sites and providers therein. Ongoing planning for additional trainings on importance of diagnostic safety is in process.

IHS	• Existing Activities Regarding Diagnostic Safety
	  ○ Voluntary adverse event report via I-STAR. IHS is continuing to optimize this effort, as they are focused on root cause analysis standardization to help in identifying events to increase culture, safety, and reporting.
	  ○ Development of a dashboard aligning the World Health Organization Primary Health Care framework for HIS, which will include clinical tracer conditions.

ONC	• Provisions of the 21st Century Cures Act ○ In the rule we hope to finalize before the end of the year, ONC seeks to implement provisions of the 21st Century Cures Act and make updates to the ONC Health IT Certification Program (Certification Program) with new updated standards, certification criteria, and implementation specifications. We have received responses to multiple requests for information (RFIs) to inform

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	potential future rulemaking. RFI topic areas include electronic prior authorization, lab interoperability, predictive decision support interventions, and advanced Fast Healthcare Interoperability Resource (FHIR®) capabilities. Elements that were in the proposed rule include: ▪ Enhanced information blocking regulations in response to feedback from affected parties. ▪ Adoption of United States Core Data from Interoperability (USCDI) Version 3 to replace USCDI Version 1 as the standard by January 1, 2025. ▪ Electronic case reporting using HL7® Consolidated Document Architecture and HL7 FHIR-based specifications. ▪ Clinical decision support with several new transparency requirements for Health IT Modules that enable or interface with technology intended to support decision making based on predictive models or algorithms. ▪ Revision to the "Transmission to Public Health Agencies – Electronic Case Reporting" criterion to adopt consensus-based, industry-developed electronic standards and implementation guides. ▪ Health IT tools that support patient-directed privacy requests for data the patient deems sensitive (e.g., through a patient portal).

Following agency updates was a presentation by CDC, "The Intersection of Diagnostic Stewardship & Public Health Measurement To Improve Practice: *Clostridioides difficile* (CDI) as a Case Study." Three individuals in the Division of Healthcare Quality and Promotion presented. Joseph Lutgring, M.D. presented "History of CDI Testing and Role for Diagnostic Stewardship and Recent Studies on Means To Implement Diagnostic Stewardship for CDI." Alice Guh, M.D., M.P.H, FIDSA, presented "U.S. Epidemiology of *Clostridioides difficile* Infection (CDI) and Limitations of Current NHSN CDI Measure." Kristina Betz, M.D., Ph.D., presented "Update on the New NHSN *C. difficile* Digital Quality Measure." Afterward, the group had an open discussion on these topics.

The next IAWG meeting is scheduled for March 1, 2024, at 10 a.m. EST.