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

Workgroup Goal: Established in response to 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 March 2, 2023, and was attended by representatives from the following agencies:

AHRQ	Agency for Healthcare Research and Quality
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
DoD	Department of Defense
FDA	Food and Drug Administration
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
NIH/NBIB	National Institutes of Health/National Institute of Biomedical Imaging and Bioengineering
NIH/NLM	National Institutes of Health/National Library of Medicine
NIH/CC	National Institutes of Health/Clinical Center's Pediatric Consultant Service
ONC	Office of the National Coordinator for Health Information Technology
SAMHSA	Substance Abuse and Mental Health Services Administration
VA	Department of Veterans Affairs

The aims of this meeting were to (1) provide agency updates related to diagnosis improvement efforts, (2) receive updates from the IAWG Subcommittee on Best Practices for Utilizing Patient Portals for the Release of Tests Results and discuss next steps, and (3) listen to a presentation from the Gordon and Betty Moore Foundation and National Academies of Sciences, Engineering, and Medicine.

A select sample of agency activities is outlined in the table that follows.

Agency	Update

AHRQ/ Improvement and Patient Safety	• Diagnostic Safety Building Contract
	  ○ Published an article in the *Journal of General Internal Medicine*, Advancing Diagnostic Equity through Clinician Engagement, Community Partnerships, and Connected Care.
	• Diagnostic Safety Grants
	  ○ Posted two new funding opportunities: AHRQ Understanding and Improving Diagnostic Safety in Ambulatory Care: Incidence and Contributing Factors (R01) and AHRQ Improving Diagnostic Safety in Ambulatory Care: Strategies and Interventions (R18).
	• EPC Program
	  ○ Released the final report *Diagnostic Errors in the Emergency Department: A Systematic Review*.
	• Common Formats for Event Reporting – Diagnostic Safety
	  ○ Released the Common Formats for Event Reporting – Diagnostic Safety (CFER-DS) Version 1.0 and additional technical specifications, which were made available September 1, 2022, and January 19, 2023. Public comment is now being collected through the Patient Safety Organizations Privacy Protection Center.

CDC	• Division of Laboratory Systems
	  ○ Health Equity and Diagnostic Errors: DLS envisioned and is supporting the launch of a laboratory outreach initiative that is engaging clinicians and patients to reduce missed and delayed diagnoses for severe hypercholesterolemia. The initiative also aims to increase the use of evidence-based guideline-recommended cholesterol-lowering therapy within medically underserved communities.
	
	DLS is partnering with the CDC Division of Heart Disease and Stroke Prevention in establishing a collaboration with Million Hearts® and the National Association of Community Health Centers. A prototype process will soon be launched with Zufall Health, a designated federally qualified health center, and HealthEfficient, a health center-controlled network, in collaboration with LabCorp, a national reference laboratory. This prototype is intended to serve as a model scalable to other healthcare settings, clinical laboratories, and medical conditions.
	  ○ Clinical Laboratory Improvement Advisory Committee Regulations: CLIAC has three workgroups focused on looking at the current Clinical Laboratory Improvement Amendments (CLIA) regulations to determine how they may be specifically updated to reflect how laboratory testing is performed currently. Focus areas include remote testing, next generation sequencing and other technologies, and expansion of point-of-care testing.

Agency	Update
	During the November 2022 meeting, CLIAC made recommendations related to 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). ○ Collaboration with the Division of Healthcare Quality Promotion on a blood culture contamination National Quality Forum (NQF) laboratory measure: The NQF blood culture contamination measure received full endorsement by the committee in January 2023. DLS is now embarking on a communications plan to reach the nation's laboratories to education them about the measure, standardize the clinical laboratory's approach to handling blood culture contamination, and optimize blood culture collection.
CMS	• RFI-0872 [ACEP] ○ Patients with symptoms consistent with a possible emergency health condition should not be expected to self-diagnose before deciding whether to go to the emergency department (ED). Even experienced emergency physicians cannot determine a patient's final diagnosis (or whether they have an emergent or nonemergent medical condition) based on the patient's symptoms when they first present to the ED. Many conditions share very similar symptoms, and a full workup and examination (sometimes with additional diagnostic tests) is frequently needed before the ultimate diagnosis becomes clear. Claims denials violate the prudent layperson standard, but they are not the only bad practice by payers that discourages provider participation in programs such as Medicaid and CHIP. • RFI-1129 [Organization/Medical Imaging] ○ Decreasing variability in diagnostic accuracy between readers and facilities. ○ Access to Imaging Drugs: Expanding inclusion and addressing inequities are essential to address longstanding disparities in care. One way to do so is to expand access to accurate and innovative diagnostic radiopharmaceuticals. Medicare's current reimbursement policy for diagnostic radiopharmaceuticals packages the radiopharmaceutical with the scan. This policy financially penalizes hospitals that may want to perform the tests. It thus exacerbates already limited access to positron emission tomography and single-photon emission computerized tomography procedures that are crucial to guiding accurate diagnosis and treatments that may improve outcomes.

Agency	Update
	• To improve access to diagnostic advanced technologies and outcomes of those faced with living with conditions such as prostate cancer, advanced breast cancer, neurologic conditions (e.g., Parkinson's and other movement disorders, Alzheimer's, neuroendocrine tumors), CMS needs to eliminate or contemporize their hospital-based payment and coverage policies for advanced imaging technologies.

FDA	• Mentored Implementation and Dissemination of Anticoagulation Stewardship (MIDAS) Program
	  ○ The project is completed, and the Playbook is available for download at no cost from the Anticoagulation Forum website.
	• Preventable Harm From Pediatric Outpatient Medication Errors: Measure Development
	  ○ Project completed on December 31, 2022. Final report submitted to FDA.
	• Assessment of pharmacist-led transitions of care service using an admissions-enhanced patient risk evaluation approach—the ICARE program
	  ○ Project is ongoing.
	• Oral Anticoagulation Surveillance and Improvement through Stewardship (OASIS)
	  ○ Project is ongoing.

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. The HRSA Bureau of Primary Health Care (BPHC) is managing ongoing efforts to address this issue.
	• Training Initiatives
	  ○ Above findings of the review panel and the resulting efforts from BPHC have resulted in ongoing programmatic developments for trainings of HRSA-supported federally qualified health clinics via a national training contract with ECRI.

Agency	Update

NIH/NIBIB	• Pulse Oximeter Performance
	  ○ Followup: NIH MedlinePlus recently published an article to provide further information regarding what to know about using the devices and what affects their accuracy.
	• Home Test to Treat
	  ○ NIH launched Home Test to Treat, a pilot COVID-19 telehealth program.
	• Make My Test Count
	  ○ NIH launched MakeMyTestCount.org last December (news coverage: https://www.verywellhealth.com/how-to-report-rapid-test-results-6951432), which was officially adopted by FDA as part of their guide for over-the-counter (OTC) at-home COVID-19 test results. (FDA press release: https://www.fda.gov/news-events/press-announcements/fda-roundup-february-7-2023)
	• Technology Accelerator Challenge for Maternal Health
	  ○ NIH has awarded a total of $1 million in prizes to the winners of the NIH Technology Accelerator Challenge for Maternal Health. The winning technologies designed and developed diagnostic tests and platform technologies to reduce maternal morbdity and mortality.

ONC	• TEFCA Interoperability Work
	  ○ On Monday February 13, ONC unveiled the first six networks that have been approved to be onboarded as qualified health information networks, or QHINs, under TEFCA, the government's framework for a nationwide health information exchange. Last year, ONC released TEFCA, or the Trusted Exchange Framework and Common Agreement. TEFCA is ONC's path to broad and deep interoperability that will promote rich sharing of medical information between and among providers, which is essential for improving diagnostic processes.
	• USCDI+
	  ○ The ONC USCDI+ initiative to support the identification and establishment of domain- or program-specific datasets that will operate as extensions to the existing United States Core Data for Interoperability (USCDI) is continuing to work with federal partners. They are working to advance the use of interoperable datasets that extend beyond the core data in the USCDI in order to meet agency-specific programmatic requirements. In particular, ONC is working closely with CMS to improve measure set reporting, including measures that support improvements in diagnostic accuracy.

Agency	Update

SAMHSA	• Screening Tools
	  ○ Long COVID + Behavioral Health Symptoms Advisory + Guide, primarily aimed at primary care clinicians (in clearance)
	  ○ National Guidelines for Child and Youth Behavioral Health Crisis Care
	  ○ Evidence Based Practice Advisories from SAMHSA
	• Centers of Excellence funded by SAMSHA, including:
	  ○ Serious Mental Illness Advisor (American Psychiatric Association). This is an ongoing education site for clinicians regarding diagnosis and treatment of serious mental illnesses. It also includes a consultation model for complex cases.
	• National Center of Excellence for Eating Disorders (UNC) developed an SBIRT screening tool for eating disorders.

Following agency updates, the group discussed updates from the IAWG Subcommittee on Best Practices for Utilizing Patient Portals for the Release of Tests Results. The committee identified next steps for the interview phase of their collaborative work. The current plan is to prepare a white paper on best practices for organizations and patients related to the release of test results directly to patients. The IAWG Subcommittee will look to formalize next steps prior to the next IAWG meeting that is scheduled for July 14, 2023, at 10 a.m. EDT.

After this discussion was a presentation from the Gordon and Betty Moore Foundation and National Academies of Sciences, Engineering, and Medicine on NAM's workshop series on Advancing Diagnostic Excellence.