Federal Interagency Workgroup:
Improving Diagnostic Safety and Quality in Healthcare
July 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 July 26, 2024, and was attended by representatives from the following agencies:

AHRQ	Agency for Healthcare Research and Quality
ASTP/ONC	Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology
CDC	Centers for Disease Control and Prevention
DoD	Department of Defense
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
NIH/NIBIB	National Institutes of Health/National Institute of Biomedical Imaging and Engineering
NIH/CC	National Institutes of Health/Clinical Center
NIH/NCI	National Institutes of Health/National Cancer Institute
NIH/NLM	National Institutes of Health/National Library of Medicine
OASH	Office of the Assistant Secretary for Health
VA	Veterans Health Administration

The aims of this meeting were to:

1. Provide new and significant updates on activities federal participants have undertaken related to improving diagnosis;
2. Listen to a presentation from NIH/CC and HRSA titled "MCRP Data, Experience, and Insights";
3. Listen to a presentation from AHRQ on "Reflections on History of the IAWG and Vision of the Future"; and
4. Have an opportunity to bring up any other issues that would benefit from group discussion.

Agency	Update

AHRQ/ Center for Quality Improvement and Patient Safety	• **Diagnostic Safety Capacity-Building Contract**
	  ○ We posted a new issue brief, Cognitive Load Theory and Its Impact on Diagnostic Accuracy.
	• **Diagnostic Safety Grants**
	  ○ We will award five new diagnostic safety grants by the end of fiscal year 2024, in addition to three other grants funded earlier in the year.
	• **Contract To Implement and Evaluate MeasureDx, CalibrateDx, and the Toolkit for Engaging Patients To Improve Diagnostic Safety**
	  ○ We are in a prerecruitment phase; recruitment will start in the fall. Anyone interested in learning more about being a test site should reach out to Margie.
	• **AHRQ Blog**
	  ○ We posted a blog during Patient Safety Awareness Week about the results of four diagnostic safety grants we awarded in 2019.
	• **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. The training is underway, and more information can be found on the TeamSTEPPS training website.
	• **Contract Supporting a Diagnostic Safety Grantee Learning Community**
	  ○ We are supporting a contract to create a learning network of our diagnostic safety grantees. This contract will also prepare white papers/issue briefs on different diagnostic safety issues.
	• **NASEM Workshop**
	  ○ We are supporting a NASEM Workshop on Advancing Equity in Diagnostic Excellence To Reduce Health Disparities. The Workshop will be held on September 23-24 in Washington, DC.
	• **Special Supplement of *Academic Emergency Medicine***
	  ○ We are supporting a special supplement in *Academic Emergency Medicine* focused on the science of errors in emergency care. This special issue will publish original reports that focus on all aspects of errors relevant to emergency care. Topics include error definition, cognitive processing, diagnostic hypothesis generation, treatment, and communication with patients and other providers. We hope to focus particularly on diagnostic error. We are planning a summer 2025 release of the special issue.

Agency	Update
ASTP/ONC	• **Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule** o The HTI-2 proposed rule aims to advance interoperability, improve transparency, and support access, exchange, and use of electronic health information through proposals for: ▪ Standards adoption; ▪ Adoption of certification criteria to advance public health data exchange; ▪ Expanded uses of certified application programming interfaces, such as for electronic prior authorization, patient access, care management, and care coordination; and ▪ Information sharing under the information blocking regulations. o The rule proposes to establish a new baseline version of the United States Core Data for Interoperability. It would update the ONC Health IT Certification Program to enhance interoperability and optimize certification processes to reduce burden and costs. The proposed rule would also implement certain provisions related to the Trusted Exchange Framework and Common Agreement (TEFCA), which would support reliability, privacy, security, and trust within TEFCA.
CDC	• **Division of Laboratory Systems** o Clinical laboratory outreach to advance diagnostic excellence: ▪ DLS is working to increase diagnoses and guideline-recommended followup for severe hypercholesterolemia in a medically underserved population. DLS is working with the CDC Division of Heart Disease and Stroke Prevention, the National Association of Community Health Centers, and the Million Hearts® Initiative, in conjunction with Zufall Health, a federally qualified health center, and HealthEfficient, a Health Center Controlled Network. Using an iterative plan, do, study, act approach, the team developed and implemented a prototype to measurably improve diagnosis and followup for severe hypercholesterolemia within the Zufall Health System. The prototype includes outreach to clinicians and patients when cholesterol results are reported. Efforts are underway to sustain the approach that was developed and explore scaling successes to other clinical settings and medical conditions. A report detailing this work is being prepared. ▪ The Clinical Laboratory Partners Forum (CLPF) is a network led by CDC that connects CDC, the Food and Drug Administration, and the Centers for Medicare & Medicaid Services with organizations that represent a broad spectrum of the clinical laboratory and diagnostic testing communities. On May 22, 2024,

Agency	Update
	CLPF hosted a meeting on Implementation of the CKD-EPI 2021 eGFR Equation Re-Fit Without Race Co-efficient. Dr. Víctor De Jesús introduced the topic. Then, Dr. Nancy Cornish and Dr. Rex Astles presented on Screening for Chronic Kidney Disease: The Essential Role of Clinical Laboratories in Public Health. Elizabeth Montgomery, National Vice President, Learning Strategies and Population Health Programs, National Kidney Foundation, presented on Laboratory-Driven Collaborative Approaches To Improve Chronic Kidney Disease Care. After the presentations, the forum members participated in an open discussion on early detection of chronic kidney disease. o Collaboration with Division of Healthcare Quality Promotion (DHQP) on a National Quality Forum laboratory measure for blood culture contamination: ▪ CDC, CMS, and FDA are all part of the clinical laboratory regulatory program, CLIA. The federal Clinical Laboratory Improvement Advisory Committee (CLIAC) established two new workgroups that were convened by the end of 2023 and met in early 2024. 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 the potential additions to the CLIA regulations and the need for solutions that will improve the safety of laboratory professionals, their colleagues, and the environment. The workgroups will continue to meet in 2024 and will present reports to CLIAC at a future meeting. ▪ During the April 2024 meeting, CLIAC made four recommendations. One recommendation was related to the applicability of CLIA personnel requirements to preanalytic testing. Two recommendations were related to the use of clinical standards to improve laboratory quality. The last recommendation was to create a new workgroup to explore the current and future intersection between artificial intelligence and machine learning in the clinical laboratory, specifically regarding implementing and

Agency	Update
	deploying tools in the clinical laboratory. More information is at CLIAC: Clinical Laboratory Improvement Advisory Committee. ▪ The National Quality Forum Blood Culture Contamination (BCC) measure received full endorsement in January 2023. The Division of Laboratory Systems has developed a communications plan to reach the 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 DHQP's Hospital-Acquired Bacteremia (HOB) measure. The measure will standardize the clinical laboratory's approach across the country to handling BCC and optimize blood culture collection. 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 partnered with the Indiana Hospital Association on a statewide process improvement plan to implement the national BCC safety measure. This partnership will help DLS understand the challenges and barriers to adopting the measure in individual institutions and to develop tools that will assist in addressing these issues. DLS is also partnering with VA Hospital Systems Laboratories and sharing best practices and lessons learned. Tools that have been developed include Blood Culture Contamination: An Overview for Infection Control and Antibiotic Stewardship Programs Working With the Clinical Laboratory and Prevent Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals. ▪ Development of communication and educational tools will continue in 2024. Data collection to measure uptake is planned to occur through DHQP/National Healthcare Safety Network in 2024. A video demonstration on how to properly collect blood cultures for phlebotomy for clinical laboratories and nursing personnel is being created for public use and will be available in fall 2024. This video will also be used in CDC infection control and prevention training programs for rural hospitals. • **Division of Healthcare Quality Promotion** o Core elements for hospital diagnostic excellence

Agency	Update
	▪ DHQP has sought and received feedback from internal CDC partners and external partners, including CMS, FDA, AHRQ, The Joint Commission, other federal agencies, and professional societies. The next step is to move this effort forward through CDC clearance. o Testing practices that are not FDA approved ▪ CDC has been notified that providers, including those at nursing homes, have been using urine multiplex molecular tests to diagnose urinary tract infection. This testing is not FDA approved and is being performed at private laboratories as laboratory-developed tests. CDC has investigated this practice using CMS data and can confirm that this testing is occurring, and its use has increased from 2016-2022. Concerns have arisen that this testing may lead to inappropriate antibiotic use. CDC has shared findings with CMS, has presented an abstract at the SHE spring 2024 meeting, and is planning to publish these findings to alert the clinical community about these testing practices.
HRSA	• **Risk Management and Patient Safety Resources** o On behalf of HRSA, ECRI is providing free risk management and patient safety resources, including email newsletters. Each edition includes hot topics from clinical risk management and healthcare news and is provided every other week at no cost to health centers and clinics. Recent materials sent to all federally qualified health centers (FQHCs) include: • Catching Patients Before They Fall: Reducing Fall Risk for Patients of All Age Groups. • Environmental Modifications of the Health Center or Free Clinic. • Screening Patients for Fall Risk. • Education for the Patient and Caregiver on Fall Prevention at Home and in the Community. People who do not have access or want to attend a free, live demonstration of the website can email Clinical_RM_Program@ecri.org or call (610) 825-6000, ext. 5200.
IHS	• **Enhanced Adverse Event Reporting Capabilities** o In August 2020, IHS implemented the IHS Safety Tracking and Response (I-STAR) system, based on the RLDatix platform. In FY2024, enhancements were made related to documenting root cause

Agency	Update
	analyses directly into the platform. The goal was to increase data aggregation and analysis across the enterprise to identify trends, including issues in diagnostic safety. • **Electronic Health Record Modernization** o IHS is deploying an enterprise EHR (Oracle Health) that will increase the capability to assess diagnostic safety, including use of patient registries, global trigger tools, and enterprisewide data collection/aggregation. • **World Health Organization Primary Health Care Dashboard Development** o The Office of Clinical Performance and Health Impact is working with the Office of Quality to implement the WHO PHC framework to measure IHS's performance across 14 operational levels. One class of measures, clinical tracer conditions, will increase capacity in the system to monitor enterprise clinical performance. Some measures under consideration are also directly related to diagnostic performance.
NIH/NIBIB	• **Authorization of Multiplex Tests** o NIH collaborates with diagnostics manufacturers on obtaining authorization of multiplex tests. As of June, 15 duplex tests (combining flu A/B and COVID-19) have successfully gone through this program and received emergency use authorization.
VA	• **Manuscript Publication** o Development and implementation of a digital quality measure of emergency cancer diagnosis, recently published in the *Journal of Clinical Oncology*, highlights missed diagnostic opportunities in patients who presented to emergency rooms but were later diagnosed with cancer. Two-thirds of the cases reviewed showed missed opportunities for earlier diagnosis based on prior medical records. • **World Patient Safety Day** o Working with the World Health Organization on several initiatives for World Patient Safety Day, which this year focuses on diagnostic safety and will occur on September 17. Messaging related to this event will be shared as it comes out for the group to consider participating.

After agency updates, NIH/CC and HRSA gave a presentation titled "Medical Claims Review Panel (MCRP) Data, Experience, and Insights." This presentation highlighted what the MCRP involves, data on healthcare centers covered by HHS that cases come from, and insights from the cases seen.

Overall observations included:

1. Marked growth in HRSA-supported FQHC patient visits per year and
2. Decrease in the number of claims per 1 million HRSA-supported visits per year.

Despite good quality overall, HRSA-supported FQHCs represent about 84 percent of the total claims reviewed by the MCRP in the last 12 years and about 88 percent of total payments. In addition, insights drawn from case observations suggested trends and areas of focus for improving diagnostic safety and quality.

Key findings revealed that at least 30 percent of claims primarily involve diagnostic errors, particularly in outpatient care, with contributing factors including human cognitive issues and systemic access challenges. Recommendations for improvement include enhancing provider-patient communication about indicated workup and leveraging technology for better tracking of patient care. The discussion also emphasized the need for collaboration with federal agencies and community health organizations to address these concerns effectively.

After this presentation, AHRQ reflected on the history of the IAWG and the vision for the future. Collaboration among this group is critical to propel the work in this space forward. Future focus areas for suggestion included:

- The evolving role of AI in diagnosis.
- Data interoperability and EHR development.
- Health disparities and social determinants of health.
- Advancements in testing, telehealth, and specific areas such as maternal and mental health.

AHRQ conducted a poll to gather input from members regarding their preferences for future meeting topics and involvement in additional initiatives. Open discussion ensued among group members on these topics, followed by next steps. The next IAWG meeting is scheduled to occur on October 4, 2024.