Federal Interagency Workgroup:
Improving Diagnostic Safety and Quality in Healthcare
October 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 October 4, 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/NCATS	National Institutes of Health/National Center for Advancing Translational Science
NIH/NCI	National Institutes of Health/National Cancer Institute
NIH/NLM	National Institutes of Health/National Library of Medicine
SAMHSA	Substance Abuse and Mental Health Services Administration
VA	Department of Veterans Affairs

The aims of this meeting were to:

1. Provide new or significant updates on activities federal participants have undertaken related to improving diagnosis,
2. Listen to a presentation from the National Quality Forum (NQF), Exploring the Use of AI in Quality Measures for Diagnostic Excellence,
3. Listen to a presentation from the IAWG Subcommittee on Artificial Intelligence (AI), and
4. Discuss what each agency is doing relevant to the use of AI in diagnostic safety and quality.

Jenna Williams-Bader and Elizabeth Drye discussed how NQF is approaching the assessment of quality measures that incorporate AI methods. They shared their experience to date and key lessons learned.

The Subcommittee on AI proposed a mission, goals, and strategies to guide our examination of AI in improving diagnostic safety and quality.

General Updates

Agency	Updates
AHRQ, Center for Quality Improvement and Patient Safety	• **New Issue Briefs From the Diagnostic Safety Capacity Building Contract:** o Learning from AHRQ's Diagnostic Safety Culture Survey at a Tertiary Care Health System in Brazil: A Case Study o Diagnostic Stewardship as a Model To Improve the Quality and Safety of Diagnosis (coauthored by CDC colleagues) o State of the Science and Future Directions To Improve Diagnostic Safety in Older Adults o Documenting Diagnosis: Exploring the Impact of Electronic Health Records on Diagnostic Safety o Electronic Test Result Communication in the Era of the 21st Century Cures Act (informed by the Workgroup) o The Patient's Role in Diagnostic Safety and Excellence: From Passive Reception Toward Co-Design o Diagnostic Excellence in U.S. Rural Healthcare: A Call to Action • **Diagnostic Safety Grants** o We awarded eight new diagnostic safety grants during fiscal year (FY) 2024. • **Common Format for Event Reporting – Diagnostic Safety (CFER-DS)** o In August 2024, we awarded a contract to conduct an evaluation of CFER-DS version 1.0, including its ease of use and substantive value to providers and Patient Safety Organizations (PSOs). • **Contract To Implement and Evaluate Measure Dx, Calibrate Dx, and the Toolkit for Engaging Patients To Improve Diagnostic Safety** o We will soon be recruiting sites for this project. If anyone is interested in learning more about being a test site, let Margie Shofer know. • **AHRQ Blog** o We posted a blog for World Patient Safety Day that discussed AHRQ's diagnostic safety work in addition to other topics. • **Contract Supporting a Diagnostic Safety Grantee Learning Community** o We are holding our first hybrid meeting on October 24-25 for grantees and other organizations with an interest in diagnostic safety. The first day of the meeting is in person for Diagnostic Safety Center of Excellence grantees. Day 2 will be virtual for other diagnostic safety grantees and others, *including IAWG members.*

Agency	Updates
	• **NASEM Workshop** ○ We supported a NASEM Workshop on Advancing Equity in Diagnostic Excellence To Reduce Health Disparities. The workshop was on September 23-24 in Washington, DC. Proceedings will follow.
ASTP/ONC	• **USCDI +** ○ USCDI v4 is available for use in certified electronic health records (EHRs) and will be required in 2028. Important elements that will assist and improve the diagnostic process include a structured Patient Summary and Care Plan with conclusions and working assumptions that will guide the patient's treatment and recommendations for future treatment. This dataset will enrich the data we get from EHRs.

CDC, Division of Laboratory Systems	• **Clinical Laboratory Outreach To Advance Diagnostic Excellence**
	  ○ At this time, data are being analyzed to determine what outcomes were achieved to increase appropriate diagnosis and followup for severe hypercholesterolemia at Zufall Health, a federally qualified health center.
	
	• **Collaboration With Division of Healthcare Quality Promotion on a Blood Culture Contamination NQF Laboratory Measure**
	  ○ Development of communication and educational tools continues.
	  ○ 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 finalized 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.
	  ○ DLS and DHQP worked together in a leadership role, along with FDA (Disruptions in Availability of BD BACTEC Blood Culture Media Bottles - Letter to Health Care Providers | FDA), in the federal government's response to the BACTEC blood culture bottle shortage.
	  ○ After being notified of a shortage of a critical diagnostic supply (i.e., BD BACTEC is the source of approximately half of the U.S. supply of blood culture bottles) in early July, CDC notified the clinical laboratory and clinician community on July 15 with a Laboratory Outreach Communication System (LOCS) call. CDC also issued a subsequent health advisory, Disruptions in Availability of Becton Dickinson (BD) BACTEC™ Blood Culture Bottles.
	
	• **Division of Healthcare Quality Promotion Core Elements for Hospital Diagnostic Excellence**
	  ○ Based on the successful models of Core Elements of Antibiotic Stewardship and Hospital Sepsis Program Core Elements in facilitating change in U.S. healthcare, on September 17, CDC, the Centers for Medicare & Medicaid Services (CMS), and AHRQ released the Core

Agency	Updates
	Elements of Hospital Diagnostic Excellence (DxEx). This release is a significant step toward enhancing patient safety. It was informed by the clinical and patient community, peer-reviewed literature, and adaptation of features of effective quality improvement programs. • **Multiplex Molecular Tests** o CDC has been notified that providers, including those at nursing homes, have been using urine multiplex molecular tests to diagnose urinary tract infections. 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 increased between 2016 and 2022. There are concerns that this testing may lead to inappropriate antibiotic use. CDC has shared findings with CMS and has presented an abstract at the Society for Healthcare Epidemiology of America spring 2024 meeting. A manuscript describing these findings is currently under review with a journal.
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 FY 2024, we made enhancements related to documenting root cause analyses directly into the platform to increase data aggregation and analysis across enterprise to identify trends, including issues in diagnostic safety. • **Dashboard Development** o The Office of Clinical Performance and Health Impact is working with the Office of Quality to implement the World Health Organization Primary Health Care framework to measure IHS 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. • **EHR Modernization** o IHS is deploying an enterprise EHR (Oracle Health) that will increase the capability to assess diagnostic safety, including the use of patient registries, global trigger tools, and enterprisewide data collection/aggregation.
VA	• **Manuscript Publication** o Machine Learning to Enhance Electronic Detection of Diagnostic Errors

After routine updates, the group presented work specific to AI and diagnosis that facilitated a discussion on AI to improve Diagnostic Safety and Quality.

Group Discussion on AI: Summary of Agency Work in of AI and Key Question or Priority To Guide Workgroup Activity

Agency	Actions Around AI

AHRQ, Hamid Jalal	• A new contract for the Common Formats for Diagnostic Safety will look at identifying diagnostic errors using natural language processing.
	• Two related notices of funding opportunity:(mentioned by Chris Dymek)
	  ○ Using Innovative Digital Healthcare Solutions to Improve Quality at the Point of Care
	  ○ Examining the Impact of Artificial Intelligence (AI) on Healthcare Safety
	• The PSO National Patient Safety Database is looking at adverse events triggered by use of AI.
	
	Key Question or Priority: What specific AI tools have the greatest potential to improve diagnostic safety in the near future?

ASTP/ONC, David Hunt	• Leading Edge Acceleration Projects ○ ASTP announced two awards under the Leading Edge Acceleration Projects in Health Information Technology (IT) funding opportunity. One of the areas of special interest recently announced is to develop innovative ways to evaluate and improve the quality of healthcare data used by AI tools in healthcare. The other is to accelerate adoption of health IT in behavioral health settings.
CDC/DLS, Ira Lubin	• CDC is looking at the prospect of using AI/machine learning by leveraging lab data, EHR data, and population health packages and other data sources to detect significant public health diagnoses, such as chronic kidney disease, sepsis, and severe hypercholesterolemia.

CDC/DHQP, Cliff McDonald	• Work to integrate clinical decision support into routine EHR (Epic) to support diagnosis, in this case, specific to infections/antibiotics/testing for community-acquired pneumonia.
	• Recent JAMA paper on examples across Hospital Corp. of America(HCA)/Inspire stories about using regressive partitioning* to look back historically for pneumonia and urinary tract infection diagnoses to predict risk of resistant bacteria and optimize antibiotic selection.
	• Chat text about two recent papers from the CDC-funded INSPIRE study by Susan Huang's group:
	  ○ Stewardship Prompts to Improve Antibiotic Selection for Pneumonia: The INSPIRE Randomized Clinical Trial
	  ○ The INSPIRE Randomized Clinical Trial and Stewardship Prompts to Improve Antibiotic Selection for Urinary Tract Infection: The INSPIRE Randomized Clinical Trial
	
	* Regression partitioning is a decision tree analysis method frequently incorporated into machine learning. The cluster-randomized trial design used it to evaluate the safety and effectiveness of the intervention. This method may be a best practice for evaluating future AI interventions.

Agency	Actions Around AI
	Key Question or Priority: Where can we at the federal level best innovate with AI in diagnosis, but also evaluate the safety and effectiveness of AI-supported diagnosis?
Indian Health Service, Philippe Champagne	• Working with large language models (LLMs): can it help sort through records and data for learning? • Working on a policy for how they will use AI, what the rules of the road are for data protection, and what tools are allowed to be used. **Key Question or Priority: What AI/LLM models would be allowed for use by the government that preserves data privacy?**

VA, Hardeep Singh	• Machine learning to identify medical records with higher risk of diagnostic error.
	• Paper on quality measure for emergency presentation of cancer diagnosis.
	• AI in clinical diagnosis for visual diagnosis, although some of the other areas are more problematic (ultimately rely on exam).
	• Chat text: Here are the papers mentioned.
	  ○ Artificial Intelligence in Clinical Diagnosis
	  ○ Development and Implementation of a Digital Quality Measure of Emergency Cancer Diagnosis
	  ○ Machine Learning to Enhance Electronic Detection of Diagnostic Errors

VA, Reena Duseja	• Tech sprint: 3-month competition. Theme: how to reduce clinician burnout (two tools - ambient dictation, community care document processing).
	• Now starting pilots focusing on two vendors. Have robust evaluation of AI tools to determine usefulness.
	• Ongoing AI projects:
	  ○ Use of AI tools to detect anomalies that might indicate patient safety events
	  ○ AI tools using legacy databases to classify harm
	  ○ Risk prediction models for 90-day mortality (e.g., percutaneous coronary intervention, acute kidney injury)

NIH, Gurvaneet Randhawa	• Notice of special interest, NCI: Use of digital health and machine learning tools. Broad scope of research, including diagnosis. Including sensor technologies, software as a medical device, smart phone, AI/LLM algorithms. • Opportunity to collaborate: ASPE ECHO trust funds. AI and diagnostic safety and quality could be part of that. • Consider challenges that could be lower budget and higher impact.

NIH, Qi Duan	• Analysis of imaging and AI/ML growth in funding:
	  ○ NIBIB is leading amount of funding. Including CDS, human error detection, radiology perception, medical imaging.
	
	• AI portfolios at NIBIB:
	  ○ Computation, modeling, data science

Agency	Actions Around AI
	○ Source, detection, reconstruction, signal, and image formation ○ Data standard and large data resource ○ Clinical decision support ○ Human error detection ○ Radiology perception/performance model • Medical Imaging and Data Resource Center (MIDRC Model) ○ Foster AI/ML innovation through data sharing for rapid and flexible collection, analysis, and dissemination of imaging and associated clinical data. ○ Use sequestered data for independent regulatory approval evaluation of AI medical imaging software. • Part of NIH data ecosystem: ○ Cochaired NIH Scientific Data Council. ○ Participating in trans-NIH initiations for AI and AI readiness. • AI initiatives: ○ Bridge2AI ○ AI/ML Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) through Ethical, Multimodal AI • Other federal efforts: ○ National AI Research Resource (NAIRR) ○ ARPA-H Biomedical Data Fabric (BDF)
	• Assorted links from NIH Reporter: ○ Unobtrusive and Continuous Monitoring of Cognitive Changes Using Smartphones ○ Developing and Evaluating Multi-Modal Clinical Reasoning Models for Automated Diagnosis Generation ○ Reliable Question-Answering Frameworks for Clinical Decision Support Using Domain-Specific Large Language Models

The meeting concluded with general announcements.

Next Workgroup meeting: January 17, 2025.