Federal Interagency Workgroup:
Improving Diagnostic Safety and Quality in Healthcare
March 2024 Meeting

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 March 1, 2024, 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
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
NIH/NCI	National Institutes of Health/National Cancer Institute
NIH/NLM	National Institutes of Health/National Library of Medicine
ONC	Office of the National Coordinator for Health Information Technology
OASH	Office of the Assistant Secretary for Health
SAMHSA	Substance Abuse and Mental Health Services Administration
VA/VHA	Department of Veterans Affairs/Veterans Health 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 presentation by the Society to Improve Diagnosis in Medicine (SIDM) on Addressing the Root Causes of Health Inequity,
3. Hear a presentation by the Centers for Disease Control and Prevention (CDC) on A Prototype for Clinical Laboratory Outreach to Providers and Patients: Reducing the Risk for Heart Disease, and
4. Provide 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 a new issue brief to the AHRQ website: Current State of Diagnostic Safety: Implications for Research, Practice, and Policy.
	  ○ We published a paper in the journal *Diagnosis*: The PRIDx framework to engage payers in reducing diagnostic errors in health care.
	  ○ We will share Measure Dx evaluation results during a session at the Institute for Healthcare Improvement Patient Safety Congress in May.
	
	• Contract to Implement and Evaluate TeamSTEPPS for Diagnosis Improvement
	  ○ The recruitment for training on TeamSTEPPS for Diagnosis Improvement will begin soon.
	
	• AHRQ Blog
	  ○ We will post a blog during Patient Safety Awareness Week about the results of four diagnostic safety grants we awarded in 2019.

CDC	• Division of Laboratory Systems (DLS)
	  ○ Clinical laboratory outreach to advance diagnostic excellence:
	  ▪ DLS is working with Zufall Health and HealthEfficient to increase diagnoses and guideline-recommended followup for severe hypercholesterolemia in a medically underserved population. Zufall Health is a federally qualified health center, and HealthEfficient is a health center controlled network. DLS is also working with the CDC Division of Heart Disease and Stroke Prevention, the National Association of Community Health Centers, and the Million Hearts Initiative™. A pilot study has launched that provides consistent messaging to physicians and patients about laboratory test results that indicate severe hypercholesterolemia. Evaluations of the message (product), processes, and timeliness of making diagnoses and prescribing statins is underway to assess prospects for sustaining this approach and scaling to other medical conditions and healthcare systems.
	  ▪ The Clinical Laboratory Partners Forum (CLPF) is a network led by CDC that connects CDC, the Food and Drug Administration (FDA), and the Centers for Medicare & Medicaid Services (CMS) with organizations that represent a broad spectrum of the clinical laboratory and diagnostic testing communities. On May 22, 2024, CLPF will host a focused meeting on the Implementation of the CKD-EPI 2021 eGFR Equation Re-fit without Race Co-efficient. Presenters will include the National Kidney Foundation and the DLS Diagnostic Excellence Team.

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	○ Clinical Laboratory Improvement Advisory Committee (CLIAC) Regulations ▪ CDC, CMS, and FDA are all part of the clinical laboratory regulatory program, CLIA. CLIAC, a federal advisory committee, has established two new workgroups that were 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. 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. ▪ During the November 2023 meeting, CLIAC made 10 recommendations related to potential updates to the CLIA regulations to recognize histotechnicians, histotechnologists, and pathology assistants as testing personnel; activities to address the top CLIA laboratory deficiencies; the role of the laboratory in diagnostic and antibiotic stewardship; and standardization of test result communication. See Clinical Laboratory Improvement Advisory Committee (CLIAC). ○ Collaboration with Division of Healthcare Quality and Promotion (DHQP) on a National Quality Forum (NQF) laboratory measure for blood culture contamination (BCC): ▪ The NQF BCC measure received full endorsement in January 2023. DLS is developing 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, which is undergoing NQF review. 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.

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	▪ DLS partnered with the 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. DLS is also partnering with VA Hospital Systems Laboratories and sharing best practices and lessons learned. ▪ DLS developed tools that include Blood Culture Contamination: An Overview for Infection Control and Antibiotic Stewardship Programs Working With the Clinical Laboratory and Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals. ▪ DLS recently presented at two meetings to increase awareness and encourage uptake of the national measure: CLIAC presentation, November 2023; and CDC OneLab Network Event, December 2023. ▪ DLS will continue to develop communication and educational tools in 2024. Data collection to measure uptake is planned to occur through DHQP and the National Healthcare Safety Network in 2024. • Division of Healthcare Quality Promotion 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 for the diagnosis of 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 between 2016 and 2022. Concerns have been raised that this testing may lead to inappropriate antibiotic use. CDC has shared findings with CMS 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 to health centers and clinics.

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	• Patient Safety Awareness Week
	  ○ HRSA Event: Cornerstones of Clinical Care: Empathy, Creativity, and Imagination as the Foundation for Effective Provider-Patient Communication. This year's Patient Safety Awareness Week program will explore how providers and staff can get to the heart of patient stories to improve clinical care and address disparities in provider-patient relationships. Guest speaker Jay Baruch, M.D., is an emergency physician and award-winning author, lecturer, and medical educator. The presentation will provide tools and inspiration to rethink patient and family engagement. The Bureau of Primary Health Care is cohosting the event with AHRQ, CDC, CMS, Indian Health Service, NIH, and National Practitioner Data Bank. The program will be held Wednesday, March 13, 2:00-4:00 p.m. ET.
	
	• Population Health Management: A National Learning Series
	  ○ More than a dozen HRSA-funded National Training and Technical Assistance Partners are collaborating on a webinar series throughout March. Each webinar will focus on strategies for developing, evaluating, and supporting effective healthcare delivery models. Coordinators will ensure webinar materials are practical, enhancing skills directly related to training recipients.
	
	• HRSA New Resources in Spanish
	  ○ The Bureau of Primary Health Care introduced a Spanish translation of the Progressive Action Conditions Library and a Spanish glossary of common Health Center Program terms. The latter promotes uniformity and avoids misinterpretation of Spanish-language materials.

NIH/NCI	• Telehealth Research in Cancer Care ○ NCI published a Notice of Special Interest to highlight the interest of NCI's Division of Cancer Control and Population Sciences in receiving investigator-initiated applications for research on the use and impact of telehealth in cancer-related care. The applications also would address the implications of telehealth policy changes on cancer care access, outcomes, and health equity.
ONC	• Sync for Genes Finalized ○ Sync for Genes, a project that sought to advance standards and tools to effectively integrate genomic information into clinical workflows, delivered its final report. The report includes a toolkit that highlights resources to help advance genomic data sharing for research and patient care. To help organizations, the Sync for Genes Resources Toolkit (PDF, 351 KB) aggregates the insights and outputs developed across all project phases.

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	• Trusted Exchange Framework and Common Agreement (TEFCA) and Qualified Health Information Networks (QHINs™)
	  ○ On December 12, 2023, HHS recognized the first organizations to become designated QHINs under TEFCA. A QHIN is a network of organizations working together to share data. QHINs will connect directly with each other to ensure interoperability between the networks they represent.
	
	• ONC HTI-1 Rule and Artificial Intelligence (AI)
	  ○ Algorithm transparency was one of the key features of the HTI-1 rule finalized at the end of the year. ONC established the first-of-its-kind transparency requirements for the AI and other predictive algorithms that are part of certified health information technology.
	
	• FAVES (fair, appropriate, valid, effective, and safe)
	  ○ FAVES is our quality framework describing the characteristics of "high-quality" algorithms and communicates how we may get the best out of predictive models in healthcare:
	  ▪ Fair (unbiased, equitable): Model does not exhibit biased performance, prejudice, or favoritism toward an individual or group based on their inherent or acquired characteristics. The impact of using the model is similar across same or different populations or groups.
	  ▪ Appropriate: Model is well matched to specific contexts and populations to which it is applied.
	  ▪ Valid: Model has been shown to estimate targeted values accurately and as expected in both internal and external data.
	  ▪ Effective: Model has demonstrated benefit and significant results in real-world conditions.
	  ▪ Safe: Model use has probable benefits that outweigh any probable risk.

VA	• VHA Directive 1088 on Communication of Test Results
	  ○ Dr. Singh co-led and worked with the Office of Primary Care on revising VHA Directive 1088 on communication of test results, which was released July 11, 2023. This directive requires VA providers to communicate normal test results to patients within 14 days after the result becomes available or within 7 days when results require followup action. This directive will lead to more efforts to improve test result communication to VA patients and providers.
	• Manuscript Publication in *Digestive Diseases and Sciences*
	  ○ Citation: Khalaf N, Ali B, Liu Y, Kramer JR, El-Serag H, Kanwal F, Singh H. Emergency presentations predict worse outcomes among patients with pancreatic cancer. Dig Dis Sci. 2024 Feb;69(2):603-614. https://pubmed.ncbi.nlm.nih.gov/38103105/.

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	• Manuscript Publication in *JAMA Network Open*
	  ○ Rajan SS, Sarvepalli S, Wei L, Meyer AND, Murphy DR, Choi DT, Singh H. Medical home implementation and follow-up of cancer-related abnormal test results in the Veterans Health Administration. JAMA Netw Open. 2024 Mar 4;7(3):e240087. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10940951/.
	
	• Forthcoming Manuscript
	  ○ Manuscript forthcoming titled "Development and Implementation of a Digital Quality Measure of Emergency Cancer Diagnosis."

Before agency updates, Dr. Ron Wyatt from SIDM gave a presentation on "Addressing the Root Causes of Health Inequity." A takeaway from this presentation is that to advance diagnostic equity, we must: (1) engage clinicians, (2) create community partnerships, and (3) focus on connected care. Connected care focuses on whom you serve (e.g., protected characteristics, populations at high social risks, geography, inclusiveness, and vulnerable populations and communities).

After agency updates, Dr. Ira Lubin gave a presentation from CDC on "A Prototype for Clinical Laboratory Outreach to Patient Care Providers and Patients: Reducing the Risk for Heart Disease." Overall, this presentation looked at an opportunity to develop and evaluate a prototype for clinical laboratory outreach. Open discussion ensued among group members on these topics, followed by next steps.

The next IAWG meeting is scheduled to occur on July 26, 2024, at 10 a.m. EDT.