

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

Workgroup Goal: Established in response to [Senate Report 115-150](#). The Senate Committee on Appropriations requested that “AHRQ 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 stands for “National Academies of Sciences, Engineering, and Medicine.”)

Workgroup Summary: The latest workgroup meeting occurred virtually on July 14, 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
HIS	Indian Health Service
NIH/NBIB	National Institutes of Health/National Institute of Biomedical Imaging and Bioengineering
NIH/CC	National Institutes of Health Clinical Center, Office of Patient Safety and Clinical Quality
NIH/NCI	National Institutes of Health/National Cancer Institute
ONC	Office of the National Coordinator for Health Information Technology
OASH	Office of the Assistant Secretary for Health
VA	Department of Veterans Affairs

The aims of this meeting were to (1) receive updates from the IAWG Subcommittee on Best Practices for Utilizing Patient Portals for the Release of Tests Results and discuss next steps, (2) provide agency updates related to diagnosis improvement efforts, and (3) have an open discussion on any pertinent items among the workgroup members.

Agency	Update
AHRQ/Center for Quality Improvement and Patient Safety	<ul style="list-style-type: none"> • Diagnostic Safety Building Contract <ul style="list-style-type: none"> ○ We published a new issue brief, Diagnostic Safety Across Transitions of Care Throughout the Healthcare System: Current State and a Call to Action. Several others will be posted over the next few months. ○ We published an article in the <i>Journal of General Internal Medicine</i>, Managing Interruptions to Improve Diagnostic



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	<p data-bbox="565 239 1308 306">Decision-Making: Strategies and Recommended Research Agenda.</p> <ul style="list-style-type: none"> <li data-bbox="516 312 1414 422">○ We published a two-issue-brief series on Patient Experience as a Source for Understanding the Origins, Impact, and Remediation of Diagnostic Errors. <ul style="list-style-type: none"> <li data-bbox="565 453 1146 485">▪ Volume 1: Why Patient Narratives Matter <li data-bbox="565 489 1101 520">▪ Volume 2: Eliciting Patient Narratives <li data-bbox="469 562 1333 667">● Patient Safety Learning Laboratories (PSLLs) <ul style="list-style-type: none"> <li data-bbox="516 596 1333 667">○ We will fund new PSLLs in FY23. Some of these will be on diagnostic error. <li data-bbox="469 705 1317 810">● Society to Improve Diagnosis in Medicine (SIDM) Conference <ul style="list-style-type: none"> <li data-bbox="516 739 1317 810">○ We will present at a plenary session during the SIDM 2023 meeting. <li data-bbox="469 848 1393 953">● Diagnostic Safety Grants <ul style="list-style-type: none"> <li data-bbox="516 882 1393 953">○ We will fund new diagnostic safety and quality grants by the end of FY23 in response to two RFAs.
CDC	<ul style="list-style-type: none"> <li data-bbox="469 968 1414 1875">● Division of Laboratory Systems (DLS) <ul style="list-style-type: none"> <li data-bbox="516 1001 1406 1509">○ Clinical laboratory outreach to advance diagnostic excellence: A novel clinical laboratory outreach approach will launch later this year. The goal will be to reduce missed and delayed diagnoses for severe hypercholesterolemia and increase the use of evidence-based guideline-recommended cholesterol-lowering therapy. DLS is working to implement an approach that will reach out to clinicians and patients once a test result is available. DLS is working on this effort with the CDC Division of Heart Disease and Stroke Prevention, the National Association of Community Health Centers, and the Million Hearts Initiative™, along with Zufall Health, a federally qualified health center, and LabCorp, a national reference clinical laboratory. This project is intended to develop a sustainable process that is adaptable to other healthcare settings and applicable to other medical conditions. <li data-bbox="516 1514 1414 1875">○ Leveraging of the total testing process across patient care and laboratory settings to support diagnostic excellence: DLS recently published The Clinical Laboratory Is an Integral Component to Health Care Delivery: An Expanded Representation of the Total Testing Process. This manuscript expands on the traditional model of the total testing process to include contemporary elements of patient care and clinical laboratory practice, such as the use of data, quality practices, and patient, clinician, and laboratory professional engagement. Examples are provided that illustrate how this model can be used to understand and optimize the testing

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	<p>workflow across clinical laboratory and patient care settings to support diagnostic excellence and healthcare decisions.</p> <ul style="list-style-type: none"> ○ Health equity and diagnostic excellence: DLS published Effective Access to Laboratory Test Results: A Health Equity Issue that Enhances Diagnostic Excellence. This manuscript describes health inequities relevant to accessing patient portals by people with limited English proficiency and potential solutions to address this challenge. ○ Clinical Laboratory Improvement Advisory Committee (CLIA) regulations: CLIA has three workgroups focused on looking at the current CLIA regulations to determine how they may be specifically updated to reflect how laboratory testing is performed currently. This includes remote testing, next generation sequencing and other technologies, and expansion of point-of-care testing. During the November 2022 meeting, CLIA 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 (CLIA). ○ Collaboration with 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 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 blood culture contamination, and optimize blood culture collection. <p>The BCC measure will support the Division of Healthcare Quality and Promotion's Hospital Acquired Bacteremia measure, which is undergoing NQF review. The measure will standardize the clinical laboratory's approach across the country to handling blood culture contamination and optimize blood culture collection. Standardization will allow a national benchmark to be developed to monitor quality of collection across hospitals. In addition, a secondary submeasure to monitor blood culture single set collection as proxy for volume will be evaluated.</p> <ul style="list-style-type: none"> ● Division of Healthcare Quality Promotion <ul style="list-style-type: none"> ○ Safety and Healthcare Epidemiology Prevention Research Development (SHEPheRD) Program: Previously reported contract awarded beginning in FY23 to University of Maryland investigators: Using an Electronic Health Record-Based

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	<p data-bbox="565 243 1409 310">Diagnostic Stewardship Intervention to Optimize the Treatment of Respiratory Viral Infections Including COVID-19.</p> <p data-bbox="565 348 1382 453">Update: University of Maryland has been working with EPIC to optimize the design of the prescriber order entry form within the electronic health record.</p>
<p data-bbox="201 468 277 499">CMS</p>	<ul style="list-style-type: none"> <li data-bbox="467 468 1398 758"> <p data-bbox="467 468 1230 499">• RFI-0872 [American College of Emergency Physicians]</p> <ul style="list-style-type: none"> <li data-bbox="516 506 1398 758"> <p data-bbox="516 506 1398 758">○ Patients with symptoms consistent with a possible emergency health condition should not be expected to self-diagnose before deciding whether to come to the emergency department (ED). Even as experienced emergency physicians, we cannot determine a patient’s final diagnosis (or whether they have an emergency or nonemergent medical condition) based on the patient’s symptoms when they first present to the ED.</p> <p data-bbox="565 800 1398 1045">Many conditions share very similar symptoms, and a full workup and examination (sometimes with additional diagnostic tests) are frequently required before the ultimate diagnosis becomes clear. Claims denials violate the PLP standard, but they are not the only bad practice by payers that discourage provider participation in programs such as Medicaid and the Children’s Health Insurance Program.</p> <li data-bbox="467 1087 1398 1339"> <p data-bbox="467 1087 1057 1119">• RFI-1129 [Organization/Medical Imaging]</p> <ul style="list-style-type: none"> <li data-bbox="516 1125 1398 1188"> <p data-bbox="516 1125 1398 1188">○ Decreasing variability in diagnostic accuracy between readers and facilities.</p> <li data-bbox="516 1199 1398 1339"> <p data-bbox="516 1199 1398 1339">○ Access to imaging drugs: Expanding inclusion and addressing inequities are essential to address longstanding disparities in care. One way to achieve this goal is to expand access to accurate and innovative diagnostic radiopharmaceuticals.</p> <p data-bbox="565 1381 1398 1633">Medicare’s current reimbursement policy for diagnostic radiopharmaceuticals packages the radiopharmaceutical with the scan and thus financially penalizes the hospital who may want to perform the tests. This policy 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.</p> <li data-bbox="516 1644 1398 1883"> <p data-bbox="516 1644 1398 1883">○ To improve access to diagnostic advanced technologies and outcomes of those living with conditions such as prostate cancer, advanced breast cancer, neurologic conditions such as Parkinson’s and other movement disorders, Alzheimer’s, or neuroendocrine tumors, CMS needs to eliminate or contemporize their hospital-based payment and coverage policies for advanced imaging technologies.</p>

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NIH/NIBIB	<ul style="list-style-type: none"> • The Medical Imaging and Data Resource Center <ul style="list-style-type: none"> ○ NIBIB’s Medical Imaging and Data Resource Center (MIDRC) initiative may help address image-based diagnostic tools using artificial intelligency (AI) methods, especially for fair and ethical aspects. <ul style="list-style-type: none"> ▪ NIBIB posted A detailed overview of MIDRC: the quest to develop fair and ethical algorithms in medical imaging. ▪ Recently, MIDRC released an online tool to help AI researchers identify potential bias from 29 sources, with corresponding mitigation strategy for consideration: Roadmap to fair AI: revealing biases in AI models for medical imaging. • Potential Diagnostic Technologies <ul style="list-style-type: none"> ○ Two new scientific highlights on new potential diagnostic technologies are available: <ul style="list-style-type: none"> ▪ How the combination of advanced ultrasound and AI could upgrade cancer diagnostics. ▪ Ultrasound selfies: with little training, patients could produce high-quality medical images at home.
NIH/NCI/ Health Systems and Interventions Research Branch	<ul style="list-style-type: none"> • Telehealth in Cancer Care <ul style="list-style-type: none"> ○ Since the issuance of NCI’s Notice of Special Interest on Telehealth in Cancer Care, two awards have been made: (1) A telehealth intervention to improve initiation of mental health treatment among depressed older adults with cancer (R21) and (2) Evaluation of a telehealth oncofertility care intervention in adolescent and young adult cancer patients: a stepped wedge cluster randomized controlled trial (R01).

The group started by discussing updates from the IAWG Subcommittee on Best Practices for Utilizing Patient Portals for the Release of Test Results. A draft was sent before the meeting for members to review. After a high-level overview, workgroup members shared comments and publications to potentially include. The current plan is for the IAWG Subcommittee to continue to incorporate edits for the final draft to AHRQ. After this discussion, agencies provided updates and group members had an open discussion.

Next Steps: The next IAWG meeting is scheduled for November 3, 2023, at 10 a.m. EDT.