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 25, 2022, and was attended by representatives from the following agencies:

<table>
<thead>
<tr>
<th>Agency</th>
<th>Description</th>
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<tbody>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>DoD</td>
<td>Department of Defense</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>IHS</td>
<td>Indian Health Service</td>
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<tr>
<td>NIH/NBIB</td>
<td>National Institutes of Health/National Institute of Biomedical Imaging and Bioengineering</td>
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<td>NIH/NLM</td>
<td>National Institutes of Health/National Library of Medicine</td>
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<td>NIH/NCI</td>
<td>National Institutes of Health/National Cancer Institute</td>
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<td>ONC</td>
<td>Office of the National Coordinator for Health Information Technology</td>
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<td>OASH</td>
<td>Office of the Assistant Secretary for Health</td>
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<tr>
<td>VA</td>
<td>Department of Veterans Affairs</td>
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The aims of this meeting were to: (1) listen to a presentation from the Food and Drug Administration on the regulation of in vitro clinical tests, (2) provide agency updates related to diagnosis improvement efforts, and (3) receive updates from the Subcommittee on Using HIT to Improve Diagnosis and discuss next steps.

A select sample of agency activities is outlined in the table on the next page.
<table>
<thead>
<tr>
<th>Agency</th>
<th>Update</th>
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| AHRQ/ Improvement and Patient Safety | • Diagnostic Safety Building Contract  
  o Posted our 7th Issue Brief on the AHRQ website: [Improving Education – A Key to Better Diagnostic Outcomes](#)  
  o [TeamSTEPPS for Diagnosis Improvement](#) is now posted on the AHRQ website  
  o Completed the pilot testing of our resource – Measure Dx: A Resource To Identify, Analyze, and Learn From Diagnostic Safety Events. Posted to website on July 19.  
  o Completed pilot testing of our resource – Calibrate Dx: A Resource to Improve Diagnostic Decisions. Reviewing revised resource and hope to post in the Fall.  
  
  • Diagnostic Safety Grants  
  o Posted a new NOFO – Diagnostic Centers of Excellence: Partnerships to Improve Diagnostic Safety and Quality (R18). Plan to award 8 grants under this mechanism.  
  
  • Diagnostic Error in Medicine (DEM) Conference  
  o AHRQ will be presenting on the 4 resources from the Diagnostic Safety Contract as a plenary session during SIDM 2022.  
  
  • EPC Program  
  o The contractor is currently working on the final draft of the Report.  
  
  • Common Format for Event Reporting – Diagnostic Safety  
  o AHRQ released the Common Formats for Event Reporting – Diagnostic Safety (CFER-DS) Version 1.0. The Event Description, Users’ Guide and Glossary, and Form are all available [here](#). Public comment is being collected through NQF. Additional supporting material are anticipated in Fall 2022. |
| IHS | • Enhanced Adverse Event Reporting Capabilities  
  o IHS Safety Tracking and Response (I-STAR) is deployed and used agency-wide. Current projects include working on overdue events and development of standardized reporting at the facility, area, and national level.  
  
  • Division of Patient Safety  
  o Creation and redesign of Total Systems Safety strategy at national level that aligns with the IHI’s framework and national action plan for patient safety.  
  
  • Diagnostic Errors Focus  
  o Initiated improvement project to better identify and facilitate the reporting of diagnostic errors through voluntary event reporting (I-STAR). |
### NIH/NIBIB
- **RADx MARS- Mobile Application Reporting**
  - NIBIB in collaboration with ONC launched [RADx® MARS](#) – Mobile Application Reporting through Standards project to address the unmet need of shifting in COVID testing, to ensure accurate and appropriate reporting on at-home testing results.

### NIH/NCI/HSIRB
- **New SBIR Awarded Contracts**
  - All three SBIR contractors who are working on social determinants of health are presenting their research in a 3-part webinar called “Addressing Social Risks in Cancer Care Delivery.” The webinars will be available [here](#).

### ONC
- **USCDI + (United States Core Data for Interoperability)**
  - ONC has launched a new initiative, the USCDI+ Program, which will build on the concept on the United States Core Data for Interoperability (USCDI)* to ensure that essential health data for a wide range of use cases is standardized, harmonized, and supported across an interoperable health IT infrastructure.

Following agency updates and a presentation from the Food and Drug Administration on the regulation of in vitro clinical tests, the IAWG Subcommittee discussed committee goals and identified next steps for the discovery and development 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 before the next IAWG meeting, scheduled for November 3, 2022, at 10 a.m. EST.