Duke | MARGOLIS CENTER for Health Policy

Advancing Bacterial Diagnostic Coverage, Reimbursement, and Utilization

Roundtable Takeaways | June 2022

Duke-Margolis hosted a private roundtable to discuss barriers that limit bacterial diagnostics' coverage, reimbursement, and utilization, and to consider policy approaches to advance the role of bacterial diagnostics in patient care and among efforts to combat drug-resistant infections and antimicrobial resistance (AMR). Takeaways from the private roundtable are summarized below.

Policy, Public Health, & Preparedness

- While stakeholders respond to infectious diseases, including AMR and COVID-19, the worst case is that diagnostic test are ignored—yet they continue to be intermittently ignored.
- Diagnostic tests become the first option when therapeutics and vaccines are unavailable or may be ineffective.
- Hospitals are not incentivized to allocate resources toward diagnostic testing for public health purposes (for example, to guide infection prevention and control efforts by identifying patients who are colonized with potentially threatening bacteria).
- There is a gap between diagnostic test innovation and funding for clinical trials—startups develop promising emerging technologies, but their opportunities for funding to conduct clinical trials is especially limited.

Recommendations

- Stakeholders ought to establish and communicate about the value of diagnostic tests in the context of public health preparedness while strategies are being developed to improve public health responses and health care surge capabilities.

DISCLAIMER: The opinions and conclusions expressed or implied herein, summarized by authors at Duke-Margolis, do not necessarily represent the opinions and conclusions of every roundtable participant, nor do they represent the official view of, nor an endorsement, by any organization with which roundtable participants were affiliated.

Coverage & Reimbursement

- Diagnostic tests ought to be available to patients in an equitable fashion.
- Hospitals evaluate new diagnostic tests that have the potential to add value to patient care in a cost-effective manner.
- There are fewer opportunities for diagnostic tests to create cost-savings in the ambulatory care setting.
- Subacute diagnostic testing in the outpatient setting is not incentivized and using a diagnostic test typically costs substantially more than prescribing an antibiotic.
- Discussions about diagnostic tests' coverage are challenging without robust data and clinical guidelines regarding diagnostic testing.
- Payers determine reimbursement rates for diagnostic tests despite limited evidence regarding the impact of diagnostic tests.

Recommendations

- Providing diagnostic test developers with additional transparency regarding reimbursement rate setting may encourage additional diagnostic test development.
- Stakeholders can consider designing coverage and reimbursement practices around diagnostic tests that direct clinicians to prescribe or not prescribe therapeutics (taking a "companion therapeutics" approach), as opposed to current coverage and reimbursement practices (the "companion diagnostics" approach).

Diagnostic Stewardship & Health Care Operations

- Rapid diagnostic tests might only add value if they result in similarly rapid treatment escalation or de-escalation.
- Many diagnostic tests must be performed and interpreted by specialized laboratory and clinical staff in order to ensure antimicrobial stewardship best practices are being followed.
- Appropriate diagnostic stewardship includes ensuring the evidenced-based decision is the easiest decision for the clinician to order and execute within the electronic medical record (EMR).

Recommendations

- Public health authorities and health care systems ought to establish and update local or regional antibiograms and appropriate health information technology so that diagnostic tests provide actionable clinical information.
- Stakeholders can consider how to integrate diagnostics tests into both clinical and HIT systems without creating disruption.

Clinician Behavior

- Adoption of diagnostic tests will improve when clinicians and patients want to use diagnostic tests and feel they are in their best interest.
- Diagnostic tests and the system in which diagnostic tests are used must be designed so that clinicians are comfortable taking actions that may go against their instinct.
- Diagnostic test utilization is heavily impacted by socio-behavioral factors and health system operations.
- Clinicians, payers, and patients all need to better understand the use and value of diagnostic tests.

Recommendations

- Advancing diagnostic stewardship requires educating varied clinicians about the use of diagnostic tests, particularly those with less training such as physician assistants and nurse practitioners.

Pre-Market Evidence Development

- Diagnostic tests must be supported by evidence that both clinicians and payers find compelling.
- Diagnostic test developers spend more developing evidence for payers than they spend developing evidence for regulatory approval.
- Although using RWD and RWE to augment regulatory decision making regarding diagnostic tests is possible, there are multiple challenges and diagnostic test developers may not know what RWD will be useful and acceptable to regulators.
- There may be opportunities to update and shorten regulatory evaluation pathways for diagnostics tests (in the context of COVID tests regulatory timelines were arguably too

long: 7-8 months for an EUA request rejection and 4 months for an EUA request approval).

Recommendations

- Policy researchers can investigate the FDA's current REW-related guidances and consider how they apply to diagnostic test development and whether public-private partnerships might advance RWE-based approaches to studying diagnostic tests.

Post-Market Evidence Development

- Clinical utility studies of diagnostic tests may not be feasible until 2 – 4 years following diagnostic tests' regulatory approval.
- Clinical guidelines and cost-effectiveness studies (for example, ICER reports) that recommend diagnostic testing are impactful to payer decision-making.
- Better communicating the value of diagnostic tests may depend on defining and studying specific use cases in the hospital or outpatient setting, such as leading syndromes like inpatient respiratory infections and outpatients UTIs.

Recommendations

- Because formal clinical guidelines can take years to develop, there may be opportunities to publish more flexible and less rigorous, but evidence-based guidance for the ID expert community (not for the general clinicians or patients).
- Policy researchers can investigate potential performance measures related to indications like pneumonia or sepsis which reliably indicate that a health care facility is (a) using antibiotics appropriately, (b) lowering costs, and (c) mitigating antibiotic resistance.
- Policy researchers and health systems ought to measure how 24-hour hospital microbiology labs impact patient outcomes as compared to labs that close overnight, which might provide additional evidence of diagnostic test value.

This project is supported by the Wellcome Trust. The opinions and conclusions expressed or implied are those of the authors and do not necessarily represent the official views of, nor an endorsement, by the Wellcome Trust.