Point-of-Care Testing for STIs:

Barriers and Opportunities from Test Development to Adoption

NASEM Committee on Prevention and Control of STIs in the US

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What is a Point-of-Care Test?

Family Practice

- "A test to support clinical decision making performed by a qualified member of the practice staff nearby the patient…"
- "…during or very close to the time of consultation"
- "…to help the patient and physician to decide upon the best suited approach"
- "…the results should be known at the time of clinical decision making."

STI testing: broader range of users, settings and methods for delivering test results

Schols et al. International definition of a point-of-care test in family practice: a modified e-Delphi procedure. *Fam Pract.* 2018;35(4):475-480.

Point-of-Care Testing: The Potential

What can POC STI testing do?

- Empower health care providers to make informed decisions during patient visit
  - Increase diagnostic capacity
  - Guide delivery of timely and appropriate treatments
- Improve health care access in remote areas or areas with provider shortages
- Facilitate patient self-testing
- Enable new or growing models of delivering care (e.g., pharmacist-based testing, home health, telehealth, retail clinics)

Point-of-Care Testing: The Challenges

What is the reality of POC testing?

- Poor understanding of clinical needs and end-user perceptions
- Limited evidence of impact of testing on patient outcomes
- Lack of awareness of test availability or test value by providers
- Concerns about costs and reimbursement
- Concerns about changes needed to effectively implement and manage POC testing programs
- Concerns about impact on workload/workflow
- Need for improvements in quality assurance and user training
- Need for data connectivity

Challenges with adoption/implementation are limiting the potential impact of POC testing!

Device Development Approaches

	Technology-Driven	Clinical Needs-Driven	Value-Based
Characteristics	• Motivated by desire to push technological capabilities • No clinical focus but shared understanding of key challenges: multiplexing, signal detection, sample preparation, device integration, miniaturization, cost	• Motivated by desire to solve clinical problem • Needs reflect clinical or "user" perceptions • Process can result in identification of technical specifications	• Motivated by desire to achieve outcomes(clinical, process, economic) and benefits for all stakeholders • Goes beyond clinical perceptions to consider system-level needs and broad stakeholder perspectives • Context is important
Limitations/Barriers	• Limited use of biological samples • No clear performance targets • Long time horizon for applying advances toward clinical application • Career factors can prevent sustained attempt to solve difficult problems	• "Expressed" clinical needs might not capture all aspects of problem • Needs assessments assume test is best solution to clinical problem • Pressure to demonstrate outcomes; clinical performance isn't enough • Guiding implementation also important	• Definitions of value vary • Working within specific contexts in resource-intensive • Value concepts and methodologies are new and evolving • Evidence can be difficult or costly to obtain to support value propositions
Decision Factors for Investment in Development (developer/funder)	• Novelty • Potential to impact a range of applications • Diversification of technology portfolio • Potential to leverage developments from another field	• Detailed definition of clinical needs and technical specifications • Appropriate partnerships to ensure access to clinical samples/study design expertise • "Match" between enabling technology and performance rqmts • Ability to use technology platform for other clinical applications	• Recognized value drivers for proposed test within care pathway • Adopter decision processes that allow value to be demonstrated • Clear approach to develop evidence that is needed to demonstrate value

Clinical Needs-Driven

Improving Information Resources for Developers

Decision Factors for Investment in Development

- Detailed definition of clinical needs and technical specifications
- Appropriate partnerships to ensure access to clinical samples/study design expertise
- "Match" between enabling technology and specifications
- Ability to use technology platform for other clinical applications

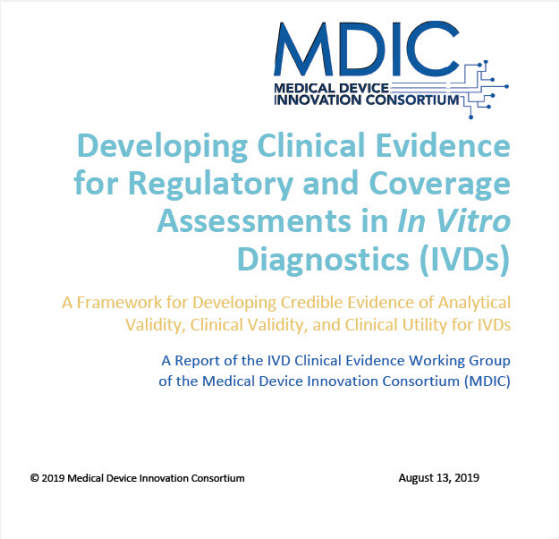
Produce and disseminate detailed performance requirements for a range of clinical needs related to STI testing; verify unmet needs in high-impact contexts of use; create tools to evaluate devices at early stages of development relative to needs

Create more opportunities for collaboration with STI researchers

Create resources to inform developers about changes to evidence requirements and appropriate study design

The regulatory landscape is changing!

FDA: Focus on advancing innovations; making clinical trials more efficient; producing more product-specific guidance; using real-world evidence
EU: (MDR/IVDR) Stricter evidence and post-market surveillance requirements; challenges with implementing changes could negatively impact innovation and test availability in the near term
IMDRF: Accelerating international medical device regulatory harmonization



Value-Based

Decision Factors for Investment in Development

- Recognized value drivers for high impact contexts
- Adopter decision processes that allow value to be demonstrated
- Pathway to develop evidence needed to demonstrate value

Improving Information Resources for Developers

Identify and communicate value drivers for POC STI testing that capture the perspectives of all stakeholders

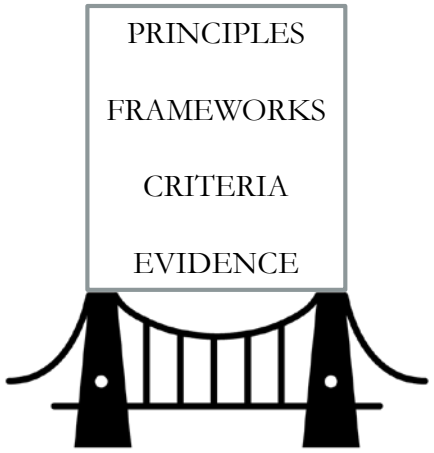
Develop value frameworks and structured decision processes to support value-based adoption decisions for introducing POC STI tests

Develop tools to assess likelihood of implementation success and guide implementation of POC STI testing in high-impact settings

What is the Value Proposition for POC STI Testing?

The Value Proposition for STI Testing

Role of public health/health services researchers?



Creating Value Propositions

manufacturer

Providing guidance on evidence needed to demonstrate value of STI tests

Working on coverage, reimbursement, and policy challenges

payer

Evaluating Value Propositions

provider

Understanding and guiding adoption decisions within provider organizations

Developing tools to assist with implementation planning

Developing metrics and tools to evaluate implementation success

Defining Value for Technology Adoption

ISPOR Task Force Report

A Health Economics Approach to US Value Assessment Frameworks—Introduction: An ISPOR Special Task Force Report [1]

Peter J. Neumann, ScD[1,], Richard J. Willke, PhD[2], Louis P. Garrison Jr, PhD[3]*

[1]Center for the Evaluation of Value and Risk in Health, Tufts Medical Center, Boston, MA, USA; [2]International Society for Pharmacoeconomics and Outcomes Research, Lawrenceville, NJ, USA; [3]The Comparative Health Outcomes, Policy, and Economics Institute, University of Washington, Seattle, WA, USA

VALUE IN HEALTH 21 (2018) 119–123

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ADx | AdvaMedDx Vital Insights | Transforming Care

AdvaMed Advanced Medical Technology Association

The value proposition for point-of-care testing in healthcare: HbA1c for monitoring in diabetes management as an exemplar

Christopher P. Price & Andrew St John

Price & St. John (2019): Scandinavian Journal of Clinical and Laboratory Investigation, DOI:10.1080/00365513.2019.1614211

A Framework for Comprehensive Assessment of the Value of Diagnostic Tests

May 2017

https://www.advamed.org/issues/payment-health-policy/value-initiative

Spanning the Development/Adoption Gap

The MaRS EXCITE Program (Ontario)

Excellence in Clinical Innovation and Technology Evaluation

The MaRS EXCITE program:

- provides developers with an early indication of fit with healthcare system
- supports developers in understanding evidence needed to meet key stakeholder requirements with a focus on a single, harmonized evidence generation (regulatory/ reimbursement)
- has a process that includes "conditions of adoption" analysis:
  - identifying relevant systemic barriers to adoption
  - supporting system changes necessary for implementation

EXCITE International: not-for-profit global collaboration of key stakeholders — innovators/industry, regulators, payers, health systems, patients, scientists and end-users — working together in the premarket space to change the paradigm of health technology innovation and adoption.

https://www.marsdd.com/service/mars-excite/

http://www.exciteinternational.com/site/about

Thank You!

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