JHU Center for Development of Point-of-Care Tests for Sexually Transmitted Diseases

All Hands Scientific Meeting

Natcher Center
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Our mission is to drive the development of appropriate POC technologies for STDs through collaborations that merge scientific and technological capabilities with clinical need.
Why Diagnose and Treat STIs?

- >110 M prevalent STIs, U.S. 2008; >20% in 15-24 yr
- 19.7 M incident STIs in U.S. 2008; 50% in 15-24 yr
- PID, ectopic pregnancy, infertility, Cervical CA
- HIV transmission and acquisition facilitation
- Health care cost: ~$15.6 billion ($11.0-$20.6 B)

- CT: $516.7 M; NG $162.1 M
- HBV $50.7 M; HIV $12.6 billion; HPV $1.7 billion
- HSV-2 $540 M; Syphilis $39.3 M; TV $24.0 M
- HIV >80% of total

350 million (M) prevalent cases of curable STIs are estimated worldwide:
- 100M chlamydia (CT)
- 36M gonorrhea (NG)
- 187M trichomonas
- 36M cases of syphilis
- 34M HIV infections

Include viral STIs: 2,993,200,000
• 1.42 million cases of CT (0.7% increase)
• 334,826 cases of GC (4% increase)
• Half of CT / GC in adolescent girls 15-19 yr
• 15,667 cases of syphilis: (11.1% increase)
  • unchanged in women; 15% ↑ in MSM, 4% ↑ MSW

• All STDs have significant health disparities issues with rates often 10-20 times higher in African Americans

  • African Americans are 12-13% of the population, but account for >50% of all HIV cases, 71% of GC cases and almost half of chlamydia and syphilis cases
Our Goals

We are keenly interested moving some diagnostic testing for STDs outside of the laboratory and into sites outside a regular clinic or doctor’s office.

Our long-term goals are to address the epidemics of STDs in the U.S. and in resource-poor settings by development and better use of POC tests, so as to address health inequity and improve the sexual health of individuals.
Welcome to The Center for Point-of-Care Tests for Sexually Transmitted Diseases

In 2007, the National Institute of Biomedical Imaging and Bioengineering (NIBIB) created The Point-of-Care Technologies Research Network (POCTRN) to drive the development of appropriate point-of-care diagnostic technologies through collaborative efforts that simultaneously merge scientific and technological capabilities with clinical needs. The Network also provides parallel educational activities that advance evidence-based medical practice in point-of-care testing in critical care, primary outreach, and low-resource environments, including global health settings.

The NIBIB gave grants to four Centers to build expertise in the development of integrated systems that address unmet clinical needs in point-of-care testing. A major aspect of the function of each Center is the creation of multidisciplinary partnerships necessary to move technologies from an early stage of development into clinical testing. Each of the four Centers will serve as a resource to the technology development and clinical communities in their respective areas, as well as coordinate activities across areas as a Network.

Each Center within the POCTRN will perform or facilitate five different Core functions:

- Conduct in-house clinical testing of prototype point-of-care devices.
- Collaborate with physical scientists, biochemical scientists, computational scientists, and engineers on exploratory technology development projects.
- Complete clinical needs assessments in areas anticipated to advance the field of POC testing and disseminate this information to the technology development community.
- Provide training to technology developers on clinical issues related to the development of point-of-care devices.
- Provide an adequate administrative structure to ensure that the large, complex Center projects are effectively managed.
Specific Aims: POC for STDs

1. To develop a “Center of Excellence for the Development and Testing of POC Tests for STDs
2. To use clinical drivers of technology progression for introducing and expanding existing POC STD technologies, by providing assistance and feedback in an iterative fashion to developers
3. To implement functioning components that work together and with other members of the NIBIB POCTRN, to implement a smooth transition along a pipeline from developmental prototype assays through in-house and pilot testing
Center Pipeline

Established Adaptable Technology

Innovative New Technology

Technology Watch Database

Meetings & Presentations

Solicitations & Funding

Needs Assessment

Training & Education

Iterative Clinical Testing

Testing in clinics, low resource setting, patient

FDA clearance/CE mark/Over-the-counter (OTC)
Components

- Administrative Component
- Clinical Needs Assessments and Health Impact Analysis component for clinicians, end-users, and other appropriate stakeholders
- Components for 1) collaboration with physical scientists, biochemical scientists, computational scientists, and systems engineers on exploratory technology for prototype development projects and
- 2) industry for testing of more mature POC assays in clinical situations and in resource poor countries in order to enhance use of POC tests in settings such as emergency departments, home testing, and to advance clinical acceptance and use of such tests
Components

• Component to provide **training** to technology developers across various career levels on clinical and process issues as well as needs related to the development of point-of-care devices in an iterative fashion.

• The training center has endeavored to **educate** STI POCT stakeholders about issues associated with developing diagnostics that will be practical, affordable and still profitable to the developers.
Components

• Development of POC Tests within the Center- At University of Maryland at Baltimore Campus- Our project with Professor Chris Geddes has been to develop both a *Chlamydia trachomatis* and *Neisseria gonorrhoeae* low cost, ultra rapid, sensitive assays, test them clinically and then commercialize the technology using the Microwave Accelerated Metal Enhanced Technology (MAMEF).

• Development of POC Tests with in the Center- At Hopkins Whitaker School of Engineering, Professor Tza-Huei Wang and his JHU BioMEMS Group developed a microfluidic device for delivering low-cost and mobile nucleic acid amplification chlamydia test -a bioanalytic platform based on the principles of droplet magnetofluidics
Components

• Collaboration with the Cincinnati Children’s site provides access to a population of adolescent patients seeking care at a large, urban, academic medical center

• Demonstration of the acceptability and effectiveness of self-testing for STDs among women using a POC STD tests; the benefits of women learning their STD results at the time of testing; and the acceptability of self-collected vaginal swabs

• Demonstrated that using privacy shelters and vans are acceptable settings to men and women to collect genital samples for STD testing

• POC testing resulted in improved antibiotic stewardship
• STD testing outside the Clinic via Internet Recruitment - We have successfully translated our internet recruitment STD IWTK into public health practice, which allows a participant to collect a sample at home and mail it to our laboratory for testing.

• Modernization allows a HIPAA-compliant site and secure login w/password protection. Participant can obtain his/her results in a secure manner online.

• A Risk Quiz allows a participant to assess risk of STDs.

• Trichomonas Home POC Test and HIV self home POC test evaluated.
STD Testing in Resource-Limited Settings Component

- Site at the Infectious Diseases Institute (IDI) at Makerere University College Health Sciences in Kampala, Uganda
- Focused on syphilis detection in pregnant women
- Rapid POC treponemal lateral flow assays can be used to diagnose patients. Both the Trinity and Alere SD Bioline tests met the WHO accuracy standard
- The IDI POC STD site has also screened more than 15,000 pregnant women as part of a clinical trial to improve syphilis partner notification, testing, and treatment (NCT02262390)
- Asymptomatic STD infections are being measured in HIV-infected key populations.
We have conducted studies in ED setting to evaluate performance and feasibility of integrating FDA approved POC tests for STDs into clinical practice (CT/NG), with a focus on patient self-testing and use of tablet based kiosks for HIV.

We developed and optimized a kiosk based platform for obtaining consent for HIV testing in the ED.

To streamline STD testing in the ED, we evaluated self-testing of a POC test for *Trichomonas*, demonstrating high level of patient and provider acceptability of self-testing with tablet guided facilitation, and showed excellent performance of the assay and high level of patient and provider concordance (98%).
Technology Watch Database
(Filling the Pipeline)

• To identify best technologies for development of POCT for STDs “cast a wide net” inclusive of all POCT/enabling technologies

• “Tech-Watch” database (TDB) describes each commercial system’s technical approach, current level of development and its current performance characteristics.

• Worked with POC technologies to determine which obstacles are critical for advancement of the technology for market applications and where tactical support (funding, samples) of greatest benefit

• The TDB was built for use as a tool for technology developers to locate technologies which may be similar to ones they are developing or technologies which may be able to be married with their technology to improve it.

• The database is being placed on an external server so that it can be accessed by anyone interested in following POCT
Companies with whom we have worked

- We have interacted by phone call, web meetings, or in-person meetings with companies in the form of teleconferences and technology placement discussions, materials requests, support of funding efforts, and signed CDAs.

- **2014-5** PearlDX, TPG Biotech, Boston Microfluidics, Strategic Health Adventures/BioInsight Diagnostics, LLC, Alere, Wako, Cannon, Diassess, Click Diagnostics, Inc, Drop Diagnostics, DNA Electronics, Research Media-Mexico, Luminostics, NPExPty, Ltd, NextGenArrays, AquilaDiagnostic Systems, Inc, Diagnostics for All (DNA), Poccadot, TriQuint, Axxin, ProPath, NexGen, Cellgen Diagnostics, Chromologic, 3idx, Cognivault, TwistNostics, NPLEX Pty Ltd, MDLogix, APBiocode, iTIRF-labs, Diainecode, Qiagen.)

- **2015-6** NPLEX, Neoterix, Diassess, Novel Microdevices, Great Basin, Maxim Biomedical, Sores UW, Al Biosciences, UT Dallas Nano-Thermal Bioengineering Laboratory, Xagenic Inc, Laura Sagle (U of Cincinnati), Cranfield Health UK, Canon, Northwestern University, In Health, Strategic Health Adventures/BioInsight, tpg.com, Alere, Wako, Luminostics, Click Diagnostics

- **2015-6: Companies we have sent clinical samples or DNA to:** Al Biosciences, Alere Scarborough, Atlas Genetics, Canon Life Sciences, Diassess, Luminostics, Maxim Biomedical, University of Northwestern, University of Washington, Planet Innovation,
Solicitations

- **Funding Complete:** Paratus, Cel Gen, McMaster, CIGHT/NWU, McFall CIGHTS/NWU

- **Funded/Active:**
  - Dr. Raja, Luminostics (anticipated completion 8-1-16)
  - Dr. Ellington, University of Texas (anticipated 8-1-16)
  - Dr. McFall Northwestern University (completion 11-16)

- **Under Review:** Two other awards are pending approval by NIBIB anticipated to begin in June 2016 with completion dates around the end of the year
Summary: STDs are prevalent and beg for rapid POC tests to be able to diagnose and treat infected persons immediately to prevent adverse sequelae

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Questions?

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STD Related Papers in 2015-16


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OP ED

Posters and Invited Oral Presentations: 31