

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

All Hands Scientific Meeting



Natcher Center
NIH, Bethesda, MD
June 9, 2016

Charlotte A. Gaydos, MS, MPH, DrPH
Professor

Division of Infectious Diseases
Johns Hopkins University
Baltimore, MD

<http://hopkinsmedicine.org/medicine/std>



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?

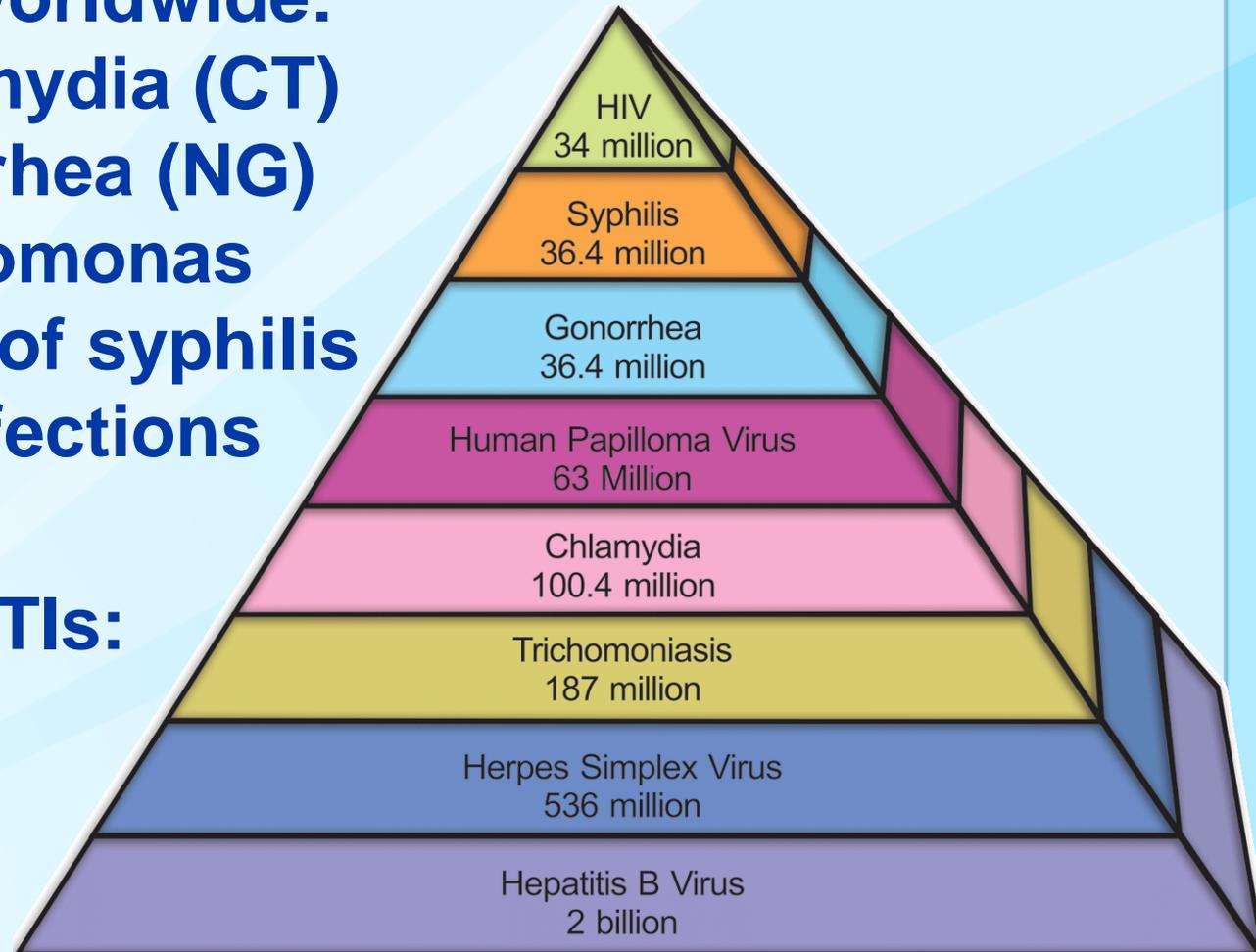
- >110 M prevalent STIs ,U.S. 2008; >20% in 15-24 yr
- 19.7 M incident STIs in U.S. 2008; 50% in 15-24 yr
- PID, ectopic pregnancy, infertility, Cervical CA
- HIV transmission and acquisition facilitation
- Health care cost: – \$15.6 billion (\$11.0-\$20.6 B)
 - CT: \$516.7 M; NG \$162.1 M
 - HBV \$50.7 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**

Background: World Estimates

•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



STD Statistics and Health Inequities

- 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.



Department of Medicine

Center for POC Tests for STDs

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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

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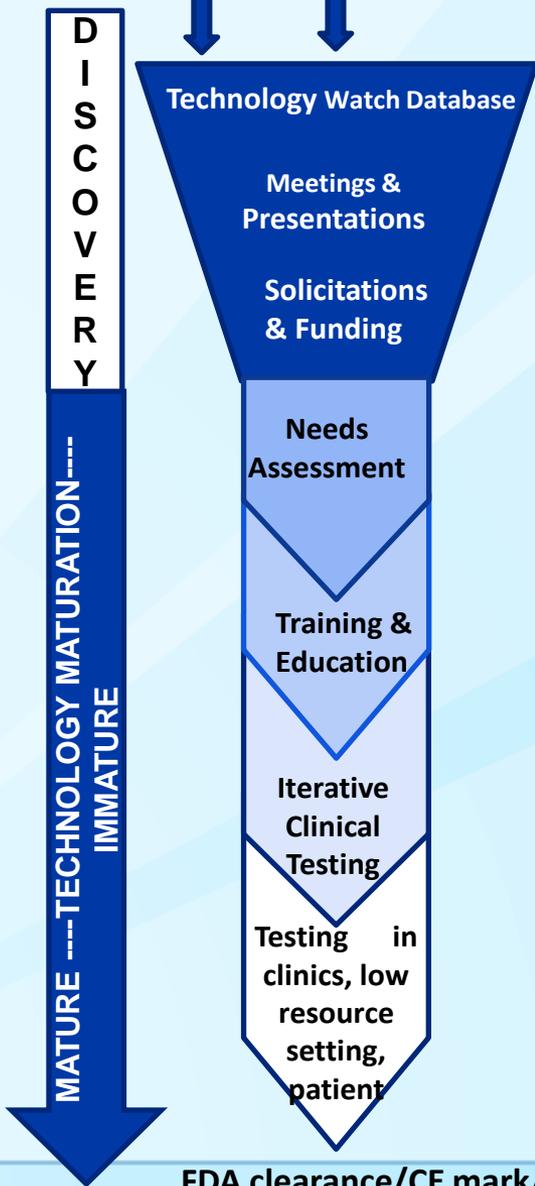
Specific Aims: POC for STDs

- 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 feed back 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



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

www.iwantthekit.org Component

- STD testing outside the Clinic via **Internet Recruitment-**
- We have successfully translated our internet

The screenshot shows the homepage of the 'I Want The Kit' (IWTK) website. At the top, there is a 'LOGIN' button. Below it, the main header reads 'IWTK I WANT THE KIT'. A navigation menu includes 'ABOUT IWTK', 'WHAT IS AN STI?', 'TESTING', 'RESOURCES', and 'RISK QUIZ'. The main content area features three large orange buttons: 'GET THE STI KIT!', 'FREE HIV STUDY!', and 'ENTER MY RESULTS!'. Below these buttons, a text line states: 'Residents of Maryland, Washington DC, and Alaska can order and receive test kits. These kits let you collect your own samples in the comfort and privacy of your home.' A smaller text line below that says: 'If you are interested but not eligible, [register here](#) and we will contact you if a study becomes available.' A row of six small images shows diverse people in various settings. Below the images, the 'INSTRUCTIONS' section is visible, starting with: 'Residents of Maryland, Washington DC, and Alaska can order and receive a test kit. Do NOT order a test kit to give to your sex partner(s). They must create an account and order their own test kit.' At the bottom, there are three white buttons labeled 'VAGINAL', 'PENILE', and 'RECTAL'.

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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.**

Emergency Department- Component

- 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 PearIDX, TPG Biotech, Boston Microfluidics, Strategic Health Adventures/Biolnsight 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, AI 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/Biolnsight, tpg.com, Alere, Wako, Luminostics, Click Diagnostics
- 2015-6: Companies we have sent clinical samples or DNA to: AI 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

<http://hopkinsmedicine.org/medicine/std>



Questions?



cgaydos@jhmi.edu
855 N Wolfe St
530 Rangos Bldg.
Baltimore, MD 21205
PH 410-614-0932
FAX 410-614-9775

Acknowledgements

- Mary Jett-Goheen
- Joany Jackman
- Anne Rompalo
- Yu-Hsaing Hsieh
- Richard Rothman
- Chris Geddes
- Yuka Manabe
- Jeff Wang
- Mathilda Barnes
- Justin Hardick



• Jeff Holden, Laura Dize, Barbara Silver, Brianna Kyburz, Johan Melendez, DJ Shin, Perry Barnes

STD Related Papers in 2015-16

- 1. Kuder M, Jett-Goheen M, Dize L, Barnes M, Gaydos CA. Evaluation of a New Website Design and Risk Scores for iwantthekit for Chlamydia, Gonorrhea, and Trichomonas Screening. Sex Transm Dis 42:243-245, 2015. PMID: PMC4396654.**
- 2. Hess EA, Widdice LE, Patterson-Rose SA, St. Cyr S, Dize L, Gaydos CA. Feasibility and acceptability of point-of-care testing for sexually transmissible infections among men and women in mobile van settings. Sexual Health. 12:71-72, 2015. PMID: PMC4476952.**
- 3. Dize L, Gaydos CA, Quinn TC, West SK. Stability of *Chlamydia trachomatis* on storage of dry swabs for accurate detection by nucleic acid amplifications tests. J Clin Microbiol. 53: 1046-1047, 2015. PMID: PMC4390667**
- 4. Hsieh Y-H, Holtgrave DR, Peterson S, Gaydos CA, Rothman RE. Novel Emergency Department Registration Kiosk for HIV Screening Is Cost-Effective. AIDS Care 28:483-386, 2016.**

STD Related Papers in 2015-16

- 5.** Habel MA, Scheinmann R, Verdesoto E, Gaydos C, Bertisch M, Chaisson MA. Exploring Pharmacy and Home-based STI testing. *Sexual Health*, 12:472-479, 2015. NIHMS766691
- 6.** Cunha CB, Friedman RK, de Boni RB, Gaydos C, Guimarães MRC, Siqueira BH, Cardoso SW, Chicaybam L, Coutinho JR, Yanavich C, Veloso VG, Grinsztejn B. *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and syphilis among men who have sex with men in Brazil. *BMC Public Health*, 15:686, 2015. PMCID: PMC4509695.
- 7.** Lowndes CM, Sherrard-Smith E, Dangerfield C, Choi YH, Green N, Jit M, Marshall RD, Mercer C, Harding-Esch E, Nardone A, Howell-Jones R, Bason J, Johnson OA, Price CP, Gaydos CA, Sadiq ST, White PJ. Point-of-care testing versus standard practice for chlamydia: a new approach to assessing the public health effect of rapid testing and treatment at local level. *The Lancet* 11/2014; 384(S2):S47.

STD Related Papers in 2015-16

- 8.** Gaydos CA, Jett-Goheen M, Barnes M, Dize L, Barnes P, Hsieh Y-H, Use of a risk quiz to predict infection for sexually transmitted infections: a retrospective analysis of acceptability and positivity. *Sex Transmit Infect.* 92:44-48, 2016. Published 18 August 2015, doi:10.1136/sextrans-2015-052058. PMID: PMC4724223.
- 9.** Meites E, Gaydos CA, Hobbs MM, Kissinger P, Nyirjesy P, Schwebke JR, Secor WE, Sobel JD, Workowski KA. Review: Evidence-based Care of Symptomatic Trichomoniasis and Asymptomatic *Trichomonas vaginalis* Infections. *Clin Infect Dis* 61 (suppl 8): S837-S848, 2015. PMID: PMC4657597.
- 10.** Postenriedera NR, Reed JL, Hesse E, Kahn JA, Ding L, Gaydos CA, Rompalo A, Widdice LE. Rapid Antigen Testing for Trichomoniasis in an Emergency Department, Pediatrics (in press). NIHMSID #766692.

STD Related Papers in 2015-16

- 11.** Bachmann LH, Manhart LE, Matin DH, Seña AC, Dimitrakoff J, Jensen JS, Gaydos CA. Advances in the Understanding and Treatment of Male Urethritis, *Clin Infect Dis* 61 (suppl 8): S763-S769, 2015. (CID submits PMC).
- 12.** Butz A, Gaydos C, Chung S-E, Johns B, Huetner S, Trent M. Advances in the Understanding and Treatment of Male Urethritis. *Clin Pediatrics*. (in press).
- 13.** Gronowski AM, Adams A, Ball C, Gaydos CA, Klepser M. Pharmacists in the laboratory space: Friends or foes? *Clin Chem* DOI:2016.1373/clinchem.2015.247445. NIHMS #766693.
- 14.** Quinn TC, Gaydos CA. Treatment for Chlamydia Infection — Doxycycline versus Azithromycin. Editorial, *New Eng J Med*. 373:2573-2574, 2015.

STD Related Papers in 2015-16

15. Chan K, Wong P-Y, Yu P, Hardick J, Wong K-Y, Wilson SA, Wu T, Hui Z, Gaydos C, Wong SS. A Rapid and Low-Cost PCR Thermal Cycler for Infectious Disease Diagnostics. PLoS ONE 11(2): e0149150. doi:10.1371/journal.pone.0149150. PMCID PMC4752298.

16. Gaydos C, Hobbs M, Marrazzo J, Schwebke J, Coleman JS, Masek B, Dize L, Jang D, Li J, Chernesky M. Rapid Diagnosis of *Trichomonas vaginalis* by Testing Vaginal Swabs in an Isothermal Helicase-Dependent AmpliVue™ Assay. Sex Transm Dis (in press). NIHMS766259.

OP ED

Klapperich C, Gaydos C, Parrish J. Commentary: Despite Doubts Raised On Theranos, Great Need For Quick Diagnoses. wbur's Common Health Reform and Reality. <http://commonhealth.wbur.org/2015/10/theranos-quick-diagnoses>. Oct 19, 2015.

Posters and Invited Oral Presentations: 31

POC Pipeline to Success

