STI Diagnostics & Screening Applications to Practice

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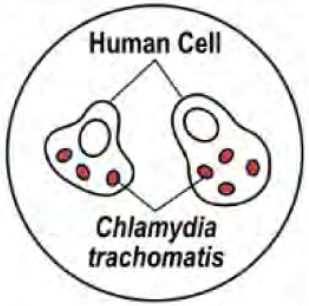
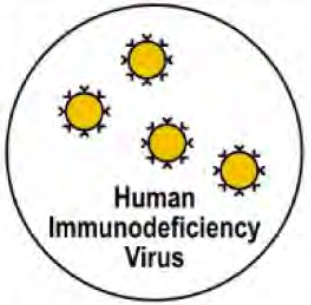
STI Screening: asymptomatic detection

- Who
  - Pregnant women, Women <25, MSM, HIV infection and populations on PrEP
- What STIs does the CDC recommended screening for
  - Chlamydia, gonorrhea (swabs)
  - HIV, Hepatitis C, and syphilis (blood)
- Why
  - To decreased adverse health outcomes: PID, chronic pain, and infertility
  - Decrease pregnancy related outcomes: premature delivery, congenital infection
  - Decrease acquisition of other STIs e.g. HIV
- How good are we doing at this?
  - Hard to estimate as we just have numbers of positive tests, not screenings
  - We know from the COVID-19 pandemic that STI clinics were closed, many were not testing or treating STI's during that time

1. National Coalition of STD Directors. 2020. *COVID-19 & the state of the STD field.* National Coalition of STD Directors, Washington, DC. https://www.ncsddc.org/wp-content/uploads/2020/05/STD-Field.Survey-Report.Final_.5.13.20.pdf.
2. Nagendra, G, et al. The potential impact of availability of sexual health serices during the covid-19 pandemic. STDs. 2020.

Global Impact of STIs

Disease	Chlamydia	Gonorrhea	Trichomoniasis	Syphilis	HIV
Causative Agent	 Bacterium	 Bacterium	 Protozoan	 Bacterium	 Virus
Global Incidences, 2020	128 Million	82 Million	156 Million	7.1 Million	1.5 Million
Global Prevalences, 2020	128 Million	29 Million	105 Million	22.3 Million	37.7 Million
Standard Diagnostic Method	Commercial Benchtop NAAT	Commercial Benchtop NAAT	Commercial Benchtop NAAT	Commercial Serological Test	Commercial Serological Test & Benchtop NAAT
Notable Challenge		Antimicrobial Resistance		Active Infection	Viral Load Quantification

Hsieh, et al. 2023 Lab Chip; Bridging the Gap between development of POC NAAT and patient care for STIs. 22 (3): 476.

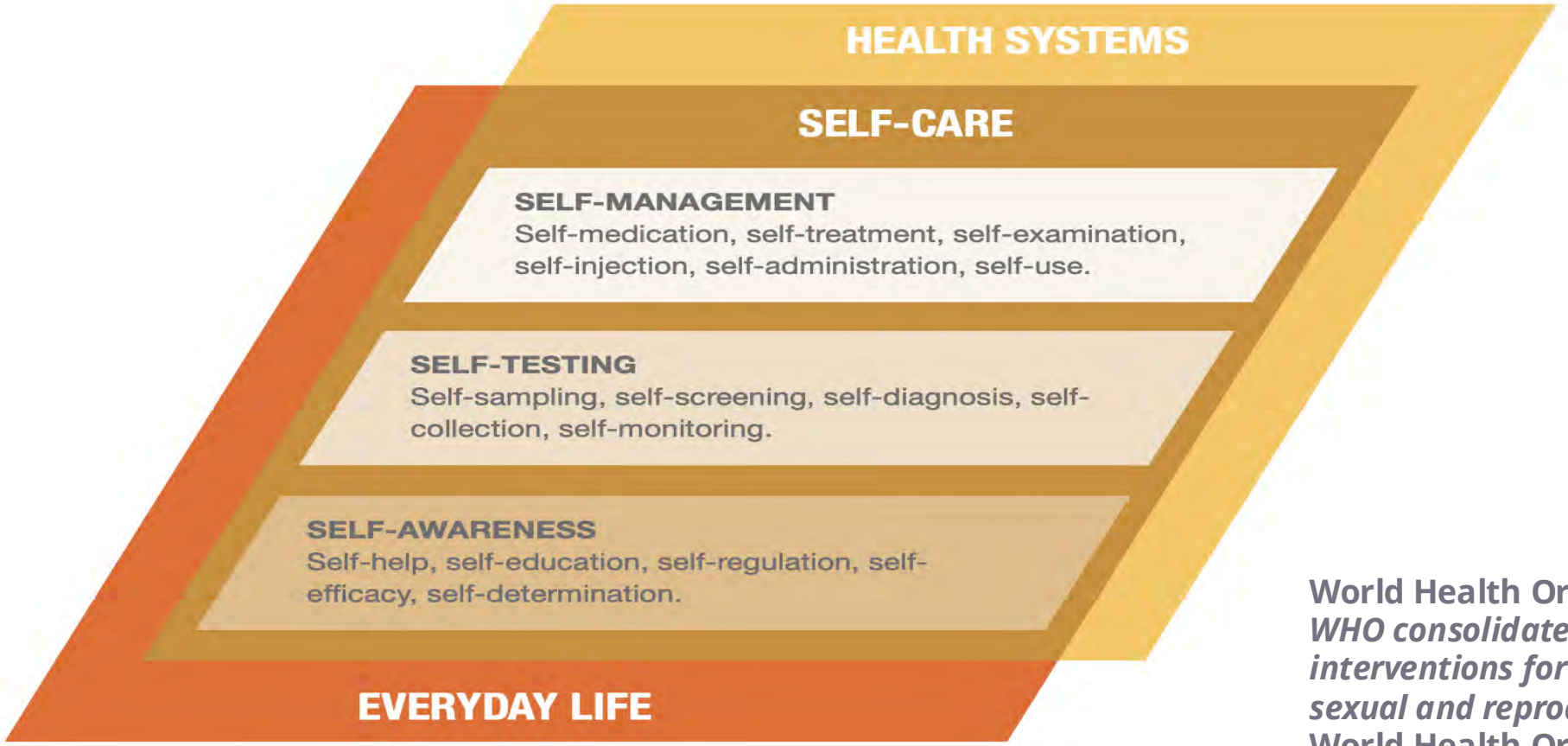
STI Testing What's New?

- Testing in non-traditional setting e.g. medical supervised van, health fair etc.
- "Home Testing" per the FDA is
  - Self-testing or self-collection without direct medical supervision
- Rapid Testing or Near point of care (POC) testing
  - Collection performed by patient and/or provider and testing at the clinic site and performance of test by non-laboratory personnel

Kersh EN, Shukla M, Raphael BH, Habel M, Park I.2021.At-Home Specimen Self-Collection and Self-Testing for Sexually Transmitted Infection Screening Demand Accelerated by the COVID-19 Pandemic: a Review of Laboratory Implementation Issues. J Clin Microbiol59:10.1128/jcm.02646-20.https://doi.org/10.1128/jcm.02646-20

WHO Report on Self-Care

FIGURE 1: SELF-CARE IN THE CONTEXT OF INTERVENTIONS LINKED TO HEALTH SYSTEMS



World Health Organization. 2019.
WHO consolidated guideline on self-care interventions for health:
sexual and reproductive health and rights.
World Health Organization,
Geneva, Switzerland.

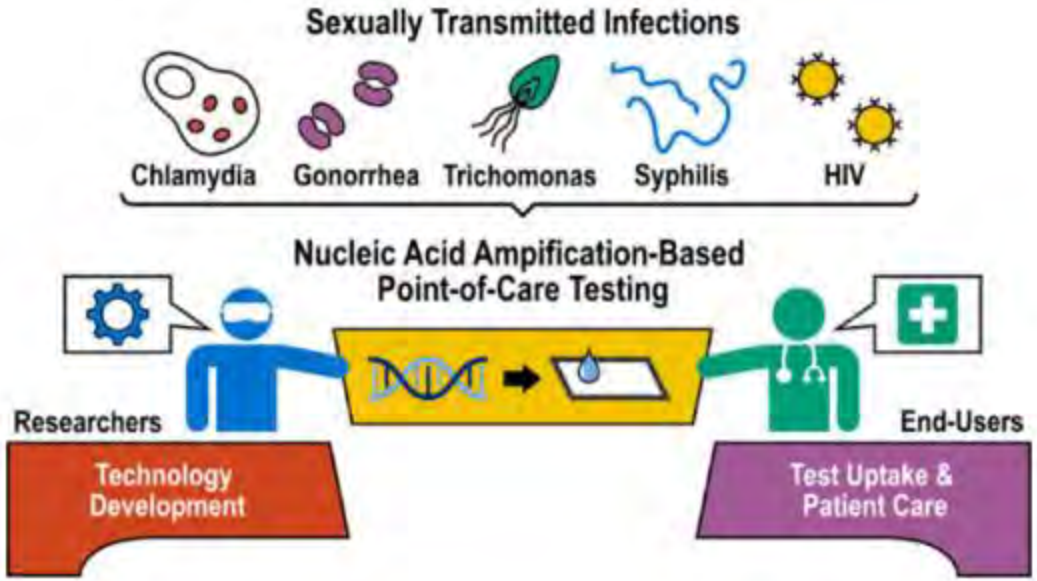
Source: adapted from Narasimhan M, Allotey P, Hardon A. Self-care interventions to advance health and well-being: a conceptual framework to inform normative guidance. BMJ. 2019;365:l688. doi:10.1136/bmj.l688.

What should a Rapid or POC test look like?

	Criterion	Description
A	Affordable	Tests are affordable to the health system and individuals using the test
S	Sensitive	To avoid false negatives
S	Specific	To avoid false positives
U	User-friendly	Simple to perform, with minimal steps and requiring minimal training
R	Rapid and robust	Rapid to enable same-visit treatment Robust to withstand diverse transportation and storage conditions without refrigeration
E	Equipment-free	Does not require additional equipment for collection or for processing
D	Delivered to end users	Accessible to end users

WHO Assured Criteria

Rules, Regulations, and Innovation in Testing



Hsieh, et al. 2023 Lab Chip; 22 (3): 476.

Vocabulary: Regulatory Terms

Regulatory Term	Definition
FDA cleared	Developed and approved by FDA for use in the US with specific instructions on specimens and collection of specimens
CLIA regulated	Clinical laboratory testing is governed by the CLIA and involves activities such as documentation of staff training and proficiency
CLIA waived	A test that can be performed by non-laboratorian, simple to perform, and low risk of error- good for self-testing but may not be able to be done at home.
Lab developed test	Lab developed test, not FDA clearance but meets standards set by lab director according to CLIA regulations

Adapted from I Park, J Clin Micro, 2021

Vocabulary: Testing and Collection Setting

Testing/Collection	Definition
POC and/or Rapid Test	Test performed rapidly at a medical provider facility usually in the laboratory, while the patient waits; some rapid tests can be performed as POC, so it doesn't have to go to the lab, but may not be able to perform it outside medical provider facilities
Provider instructed specimen self collection kit	Kit sold to patients with package insert that specifies that the provider instructed them on collection and that they will submit it to a laboratory. These are FDA cleared and are available for GC/CT NAATS
Self-test	Test is over the counter, patient performs the test. Problem: results are not reported.

Adapted from I Park. J Clin Micro. 2021

Issues with POC Testing

- Issue: May not be as sensitive as traditional testing
- Benefit: Quick results allow for treatment and possibly decreased transmission to partners
- Limitation: Most are performed in a clinical setting, thus home collection must be sent to the lab, this requires approves

Clinic vs Home Testing and Implementation?

Testing methods

- Rapid Clinic testing (GC/CT/Trich/HIV)
  (Provider and/ or patient collected samples)
  - Point of Care: <30 minutes
  - Laboratory testing: 3 hours
- Home collection: self-collection
  - Point of care testing: only HIV
  - Laboratory testing (provider instructed, patient collected)

Implementation

- Patient directed
- Provider directed
- Telehealth
- In- clinic
- Pharmacy
- Emergency departments or urgent care

STI Testing Platforms

Platform	(A)  GeneXpert	(B)  SAMBA II	(C)  *io*	(D)  Sexual Health Test	(E)  Solana
Company	Cepheid	DRW	binx health	Visby Medical	Quidel
Assay	CT, CT/NG, TV, HIV	HIV	CT, CT/NG	CT/NG/TV	TV
Turnaround Time	< 120 min[54] < 63 min[55]	< 120 min	30 min	30 min	< 40 min
Sample Type	Vaginal Swab[54,55] Endocervical Swab[54,55] Urine[54,55] Blood[56] Dried Blood Spot[56]	Blood[59]	Vaginal Swab[61,62] Urine (Male)[62]	Vaginal Swab[64]	Vaginal Swab[66] Urine[66]
Sensitivity	Female: 97.4 – 98.7% (CT)[54] 95.6 – 100% (NG)[54] 99.5 – 100% (TV)[55] Male: 97.5% (CT)[54] 98.0% (NG)[54] 97.2% (TV)[55]	97.3%[59]	96.1% (CT)[61] Female: 96.1% (CT)[62] 100% (NG)[62] Male: 92.5% (CT)[62] 97.3% (NG)[62]	97.6% (CT)[64] 97.2% (NG)[64] 99.2% (TV)[64]	Swab, Asymptomatic: 100%[66] Swab, Symptomatic: 98.6%[66] Urine, Asymptomatic: 98.0%[66] Urine, Symptomatic: 92.9%[66]
Approval	FDA & CE	CE	FDA & CE	FDA	FDA & CE

Rapid and/or Point of Care testing: Implementation in clinic setting

Rapid vs Point of Care (POC) Testing Available

TABLE 2 Landscape of STI tests with relevance for future home testing pending further development

	Description	
Test parameter	**GC/CT**	**Syphilis**
CDC-recommended main diagnostic or screening test	GC/CT NAAT from urine (men) and vaginal swabs (women)	Sequential treponemal or nontreponemal antibody detection in blood
Is a self-test[a] currently available in the U.S.?	No	No
Existing CLIA-waived tests	Binx io NAAT; 30 min (as of March 2021); near-patient test with instrument need Visby Medical Sexual Health Test NAAT; 30 min (as of August 2021), uses portable, handheld, disposable device, accepts vaginal swabs	Syphilis Health Check, a rapid qualitative test for detection of antibodies to *T. pallidum*; 10–15 min; visual reading of results
Existing POC or rapid tests without a CLIA waiver[b]	Cepheid GeneXpert NAAT; 90 min; near-patient test with instrument need	Chembio HIV-syphilis (treponemal antibody), a rapid qualitative multiplex test for the detection of antibodies to HIV/*T. pallidum*; 15–25 min; reader and test device holder assembly are required for reading results

[a]"Self-test" refers to a test that an individual can use to obtain, perform, eceive results without shipping a specimen back to the laboratory and waiting for results.
[b]The GeneXpert technology has been adapted to a CLIA-waived "Xpres rument; however, to our knowledge, this is currently not available for GC/CT testing. Criteria used here are a turnaround time of 90 min or less and up to moderate lexity.

Cepheid: 2019 cleared for extra genital specimens

Implementation of STI Testing

Express Visits

Telehealth

Credit: H Reno

PrEP/ PEP services

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Express visits

What does it mean?

- Triage based STI testing without full clinical examination
- Adopt patient flow strategies to fit your clinic
- Staffing models to allow providers to operate at the top of their licenses
- Patient –self collection
- Technology and automation

How do I do this?

- Automated check in (CASI system)
- If asymptomatic, self-collection, non provider visit
- Patient waits for results and gets education on prevention
- Rapid tests reported directly to patient
- Treatment available on site
- Referrals for partner testing and therapy or EPT (edited patient therapy)

NACCHO (2021). *Implementing Express STI Services: Considerations and Lessons Learned*. National Association of County and City Health Officials: STI Express Initiative. https://www.naccho.org/uploads/downloadable-resources/Implementing-Express-STI-Services-Guide.pdf

Barriers and Facilitators to Express STI Visits

- Lab, Testing and Space
  - Location (onsite vs offsite); # bathrooms
  - Capacity of lab and waiting room
  - Availability of POC testing
- EMR
  - Intake, forms, orders, labs and results
  - https://www.naccho.org/uploads/downloadable-resources/Programs/Community-Health/STI-Express-Initiative/New-York-STI-Express-Triage-Card-English.pdf
- Staffing
  - Nursing, MA and expanding scope of work
- Billing
  - Grant vs insurance, vs state, 340B pharmacy programs
  - Express billing fact sheet: ://www.naccho.org/uploads/downloadable-resources/Programs/Community-Health/STI-Express-Initiative/Primer_Billing-for-STI-Express-Services_2020.pdf

EXTRAGENITAL TESTING

Nurse/MA-Led Model of Care

Patient checks in

Patient completes screener* (alone or guided)

Nurse/MA reviews screener

Nurse/MA and patient discuss what EGT is and how it's done

Patient Sample Collection

Patient completes swabs; hands to Provider

or

Provider completes swabs

Provider Sample Collection

Provider and patient determine next steps

- PrEP referral
- Benefits navigation
- Partner services
- Mental health referral
- Pregnancy prevention (if applicable)
- Follow-up appointment

This figure depicts one model of EGT that relies more on nursing and MA staff; patient may have a choice between self-collection of three-site testing or provider collection

* Refer to our Sample Screeners in our Toolkit

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EXTRAGENITAL TESTING

Provider-Led Model of Care

Patient checks in

Patient completes screener*

Providers reviews screener

Provider and patient discuss testing rationale and privacy

Patient Sample Collection

Patient completes swabs; hands to Provider

or

Provider completes swabs

Provider Sample Collection

Provider and patient determine next steps

- PrEP referral
- Benefits navigation
- Partner services
- Mental health referral
- Pregnancy prevention (if applicable)
- Follow-up appointment

This figure depicts one model where the provider is the one to introduce EGT; patient may have a choice between self-collection of three-site testing or provider collection

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EXTRAGENITAL TESTING

Before You Get Started

There are important steps to take before you can start offering extragenital (EG) testing. Below are a few tips to get you started.

LAB

- Check with your lab about its capacity and capabilities for three-site testing: can it receive oral and rectal swabs?
- Check how your lab runs tests (e.g., does urine go in cups or tubes?) and ensure you have the necessary supplies.
- Only urine and vaginal samples are FDA cleared for self-collection in a clinic setting. If self-collection of oral and rectal samples is of interest, check with your clinic's lab about validation requirements.

CLINIC

- Consider making patient education posters available in relevant languages
  - ☐ option one
  - ☐ option two
- Make sure that all needed supplies are in the exam room and not expired!
- Make sure staff are trained in taking a comprehensive sexual history and are comfortable asking patients about their sexual practices.
- Establish a workflow for clarity and efficiency.
  - Who will be labeling swabs and when?
  - Will patients be asked screening questions or given self-administered screeners?
  - Where will collections be completed?
  - How will patients be informed of their results?

There are more resources in our Toolkit to help you with this process. You can reach out to the NYC STI/HIV Prevention Training Center for more personalized support at

nycptc@cumc.columbia.edu

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EGT T Started

EXTRAGENITAL TESTING

Standing Orders for Extragenital STI Testing

What are standing orders?

Non-patient specific standing orders allow non-physicians, like nurses, to sign off on tests—in this case, sexually transmitted infection screening. "Standing orders . . . allow for an expanded scope of practice for nurses, MAs, and health educators." —Source, NACCHO

"Non-Patient Specific Standing Orders are written instructions, orders, rules, regulations, or procedures prepared by a physician and designed for a patient population with specific preventative care or screening needs. Standing Orders are distinct from specific orders written for a particular patient." —Source, CHCANYS

"Standing orders are the signed instructions of a licensed physician which outline the medical assessment, appropriate testing, and treatment that a clinician may perform or deliver on behalf of the physician. In some states, non-physicians are authorized to perform assessments and prescribe medications independently. Standing orders also serve to standardize the clinical care practiced by all clinicians." —Source, CDC

How does my clinic site set up a standing order?

STATE LAWS

State laws differ when it comes to licensing and scopes of work; these need to be reviewed and understood before implementing a standing order.

UNION RULES

Nursing unions and others may have rules around scopes of work that will need to be reviewed before attempting to implement a standing order.

INSTITUTION GUIDELINES

Ensure your institution would allow standing orders before moving forward with developing a standing order for STI screening.

ELECTRONIC MEDICAL RECORDS

Standing orders are often integrated into EMRs. This process will need to be reviewed before moving forward with implementing a standing order for STI screening.

Information about and Examples of Standing Orders

1. Sample standing order for STI screening from Community Health Care Association of New York State (CHCANYS), complying with New York State law
2. Sample standing order for STI screening from North Carolina Department of Health and Human Services, complying with North Carolina state law
3. NACCHO Express Testing Guide—includes information about standing orders

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Why Implement Express Services?

- Improve clinic capacity (Clinic and Patient Satisfaction)
  - Reduce turn-aways
  - More patients seen
  - Staff time is effectively used
  - Test results return more quickly (if rapid testing used)
- Improve Sexual Health Services (Individual and Community Impact)
  - Addressing stigma
  - Increase access to marginalized populations
  - Empowering self- care

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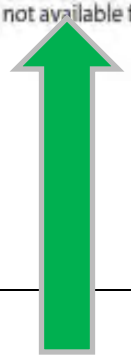
[b]The GeneXpert technology has been adapted to a CLIA-waived "Xpress" instrument; however, to our knowledge, this is currently not available for GC/CT testing. Criteria used here are a turnaround time of 90 min or less and up to moderate complexity.



Syphilis POC vs Lab based testing

	POC	Laboratory
Specimen collection	Whole blood e.g. fingerstick	venipuncture
Time to result	15 minutes	Varies: hrs to weeks
Type of Test	Treponemal Test (doesn't distinguish old or treated infection; remains positive for life)	Non- Treponemal and Treponemal tests (Non Trep allows for tittering and thus helpful for treatment)
Sensitivity/Specificity	Lower (77-100%)	Better (>90-100%) due to combination with Trep specific as non-trep less sensitive

Implementation of Syphilis POC Program

- Staffing: can be done by non-clinical staff
- CLIA requirement: the laboratory in the facility needs to hold a CLIA certificate of waver
- Training of testers: need for certification, training and follow up
- Collaboration with local health department: Need to report tests, coordinate with DOH and follow up
- Reporting recommendations: needs to be reported to the DOH
- Reporting of problems with the test to FDA: mandated reporting of issues with the testing and adverse events

Choosing POC vs Lab for Syphilis

Table 3: Choosing Lab-based Versus POC Tests

Where Lab-Based Tests Are Most Useful	**Where POC tests Are Most Useful**
Individuals with prior history of syphilis should only have lab-based tests Low risk* individual presenting for routine visit	Where identifying syphilis infection is important for same day treatment
Disadvantages of POC Tests	**Advantages of POC Tests**
Results are treponemal only and less accurate than lab-based tests If positive, lab-based tests are needed for patient care and follow-up	Results quicker than lab-based tests Easier to perform Less sample required, easier to collect
Settings for Lab-Based Tests	**Settings to Consider for POC Tests**
Where feasible and accessible Routine screening Hospital inpatient, especially if likely to stay 48 hours or more Maternal testing at delivery prior to newborn discharge (requires lab-based testing)	Correction facilities Emergency departments Substance use treatment programs Syringe service and harm reduction programs Outreach and community-based care events Rural communities Shelters
Populations Most Appropriate for Lab-Based Tests	**Populations Most Appropriate for POC Tests**
Lab-based testing should be used to confirm all positive POC tests results Low risk Populations likely to follow up if results positive Geographic areas where syphilis is not common	Pregnant people not engaged in prenatal care Persons using substances and not engaged in health care Populations with limited access to healthcare Geographic areas where syphilis is spreading rapidly

*Low risk: Based on geographic spread of disease and behavioral factors, including likelihood to follow up

https://www.hhs.gov/sites/default/files/nscss-considerations-for-the-implementation-of-syphilis-poc-tests.pdf

POC TESTING AND RAPID TESTING IN THE REAL WORLD?

WILL IT WORK?

Trials for use of rapid testing protocols: ProSPeRo network

BMJ Open

Standardised protocol for a prospective international multicentre clinical-based evaluation of point-of-care tests for the screening of genital and extragenital chlamydial and gonococcal infections in men who have sex with men and for the screening of genital chlamydial, gonococcal and *Trichomonas vaginalis* infections in at risk women

Maddalena Cordioli,[1,2] Lorenzo Gios ,[1,2] Massimo Mirandola,[1,2] Antonella Zorzi,[1,3] Christopher Barbara,[4] Valeska Padovese,[5] Amina Hancali,[6] Hicham Oumzi,[7] Ranmini Kularatne,[8] Ting-Ting Jiang ,[9] Carlos F Caceres,[10] Silver Vargas,[11] Christian S Alvarez,[12] Elsy Camey,[12] Rosanna W Peeling ,[13,14] Magnus Unemo,[15,16] Ron Ballard,[17] Karel Blondeel ,[18,19] James Kiarie ,[18] Soe Soe Thwin,[20] Igor Toskin,[18] The ProSPeRo Network

To cite: Cordioli M, Gios L, Mirandola M, *et al*

- First multicenter study clinical based evaluation of POC screening men and women
- Real world conditions
- Assess performance of the testing
- Assess patient and provider acceptability e.g. would you wait for test results, are instructions easy to read, how long did testing take, etc.

BMJ Open 2024 published

Near patient testing systems: real world testing

- Multi-site (Malta, Itay, Peru)
- Testing: urine, swabs (3-site) Cepheid GeneXpert
- Testing in the clinic with cepheid and also swabs sent to the lab for testing
- Results:
  - 1702 MSM; 5035 samples
  - GC POCT
    - Urine sens/spec 91% & 99%
    - Rectal sens/spec 89 & 99%
    - Pharynx sens/spec 76% & 99%*
  - CT POCT
    - Urine sens/spec 84% & 99%
    - Rectal sens/spec 78% & 99%
    - Pharynx sens/spec 67% & 99% *

Patient acceptability: 95% willing to wait to get results
22% will wait 2 hrs, 41% 1 hr and 30% up to 30 min.

Provider: indicated it took 10 min
43% said instructions were clear and 36% said excellent

Cordioli, et al. BMC Infectious Diseases 2024. 24:224

Impact of Rapid & Point of Care Testing

Walter, et al. BMJ Open 2023.

- Goal: assess impact of near point of care testing for STIs on testing, diagnosis and treatment
- Setting: 2 sexual health clinics in UK(intervention and control site)
- Outcomes: time to test notification, staff capacity, cost per episode of care, other costs; and rate of GC and CT, and attendance in clinci

Table 2 Summary of population characteristics and outcomes by site, sex and time period based on EPR data

	Intervention site		Control site	
	Pre	Post	Pre	Post
Males				
Total attendances, n	17626	16787	11920	12085
Total episodes of care, n	11445	10628	7946	8021
Total patients, n	9932	9151	6271	6335
Symptomatic attendances, n (%)	7307 (41.5%)	7084 (42.2%)	4735 (39.7%)	4556 (37.7%)
Complex attendances, n (%)	9869 (56.0%)	9259 (55.2)%	4458 (37.4%)	4940 (40.9%)
Ethnic minority attendances, n (%)	2834 (16.1%)	3025 (18.0%)	7244 (60.8%)	7311 (60.5%)
MSM attendances, n(%)	5300 (30.1%)	5418 (32.3%)	2529 (21.2%)	2849 (23.6%)
Mean age, years	30.2	30.8	34.9	35.1
Urethral GC swabs per consultation	0.18	0.11	0.08	0.07
Median time-to-notification	10.90	6.73	4.51	4.95
Examinations per symptomatic attendance	0.76	0.67	0.64	0.60
Follow-up attendances per episode	0.40	0.36	0.50	0.37
Females				
Total attendances	28487	20289	20931	16910
Total episodes of care	18616	13866	13971	11660
Total patients	16779	12794	11799	9902
Symptomatic attendances	6312 (22.2%)	4929 (24.3%)	6860 (32.8%)	5561 (32.9%)
Complex attendances	26022 (91.3%)	18173 (89.6%)	12328 (58.9%)	11221 (66.4%)
Ethnic minority attendances	3979 (14.0%)	3067 (15.1%)	12647 (60.4%)	10107 (59.8%)
Mean age	25.1	25.8	29.8	30.4
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Median time-to-notification (median, IQR)	10.58	3.52	4.90	5.32
[illegible]	0.73	0.70	0.58	0.60
Follow-up attendances per episode	0.36	0.34	0.31	0.23

EPR, electronic patient record; GC, gonorrhoea culture; MSM, men who have sex with men.

Decrease in time to notification and decreased in GC culturing as case was rapidly identified

We have the technology, what if we let the patients test themselves?

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Systematic Review of Self Collection

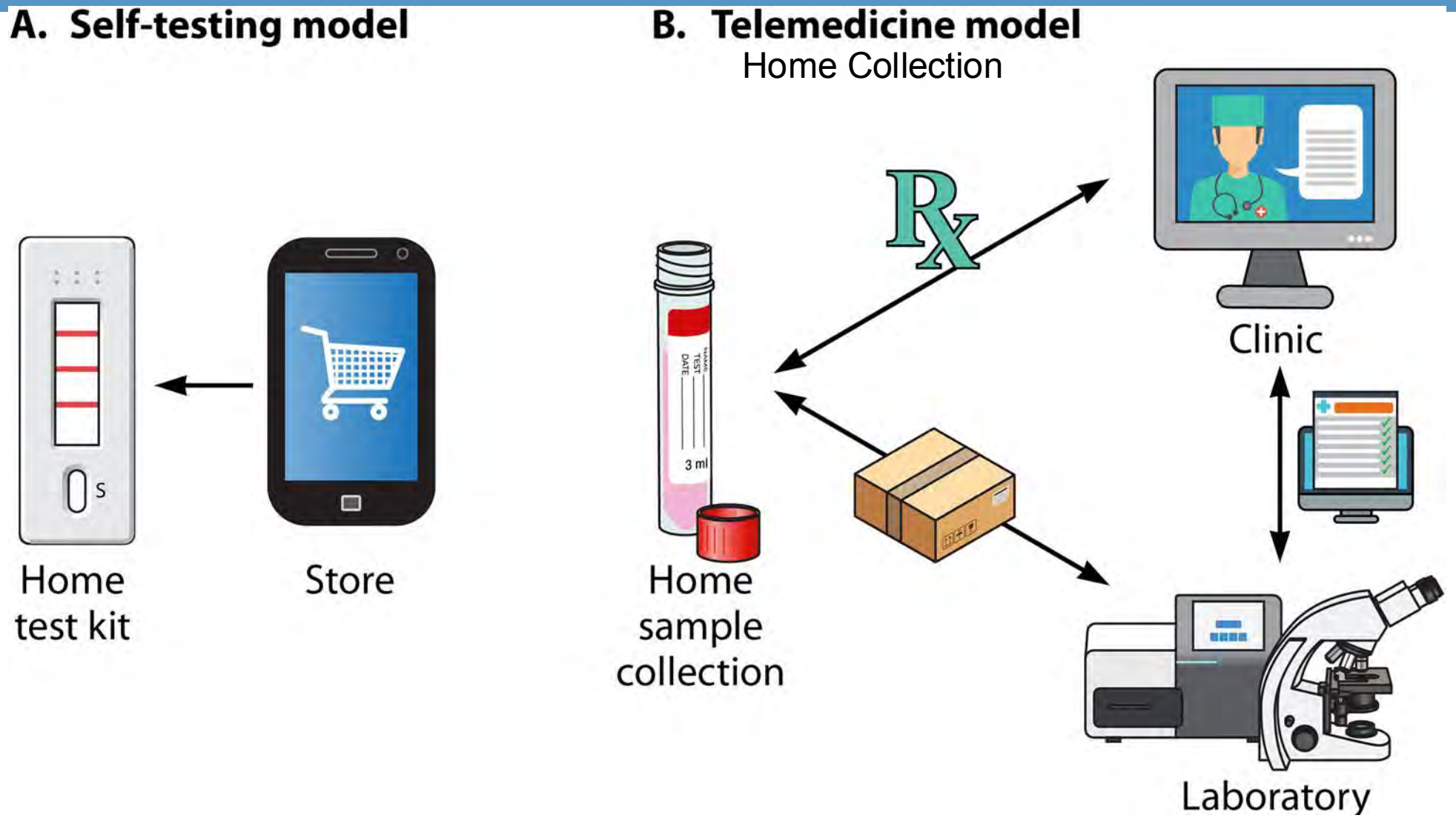
- Method: meta-analysis
  - Peer reviewed studies with self-collection vs provider collected (GC, CT, Syphilis, Trichomonas)
  - Outcomes: Uptake/frequency of STI testing, Social harms: adverse events, positive tests, linkage to care and treatment, and reported sexual behavior
- Results:
  - Eleven studies, including five RCTs and six observational studies
  - 202,745 participants
  - Australia, Denmark and USA
- Impact of Programs offering self-collection:
  - Uptake of STI testing services [RR], 2.941 [{CI}, 1.188 to 7.281])
  - Case finding (RR, 2.166 [95% CI, 1.043 to 4.498])
  - No studies measured frequency of STI testing, social impact or AE, linkage to care or sexual behavior

Ogale Y, BMJ Glob Health 2019;**4**:e001349

IMPLEMENTATION OF HOME TESTING

Please check state permission rules
Not available in NY and Rhode Island

Implementation of Home Testing



Kersh EN, Shukla M, Raphael BH, Habel M, Park I. At-Home Specimen Self-Collection and Self-Testing for Sexually Transmitted Infection Screening Demand Accelerated by the COVID-19 Pandemic: a Review of Laboratory Implementation Issues. J Clin Microbiol. 2021 Oct 19;59(11):e0264620. doi: 10.1128/JCM.02646-20. Epub 2021 Jun 2. PMID: 34076475; PMCID: PMC8525576.

Risks Associated with Self- Collection

- Low specimen return rates
- Issues with follow-up
  - linkage to care
  - Treatment
  - Follow up testing
- Partner notification
- Diminished counseling on risk reduction
- Impact on surveillance data (e.g. the tests do not get reported)

Home Collection and Validation

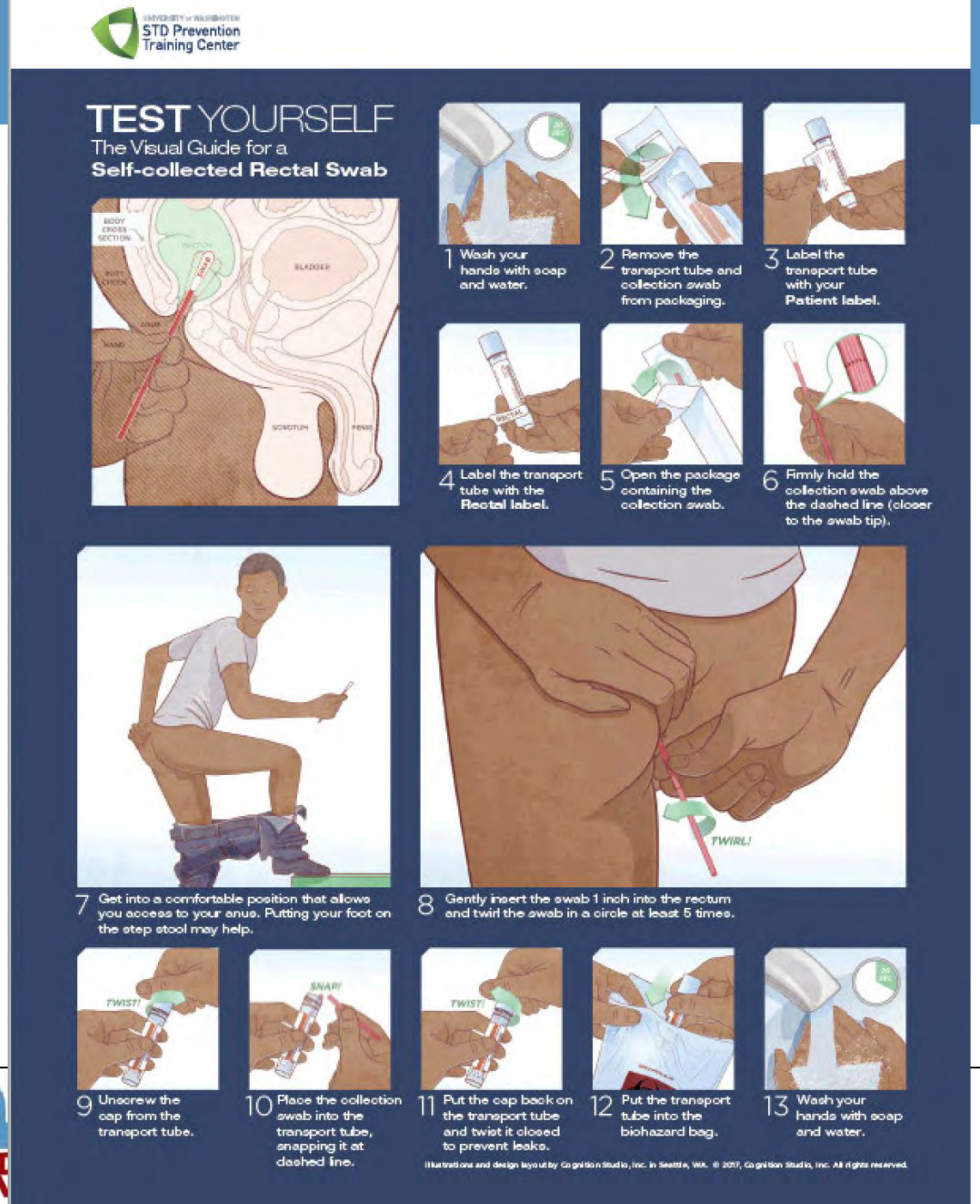
Concerns

- Lack of medical oversight
- Preservation of the specimen integrity due to handling and temperature variation, or delays in getting to the lab

Solutions

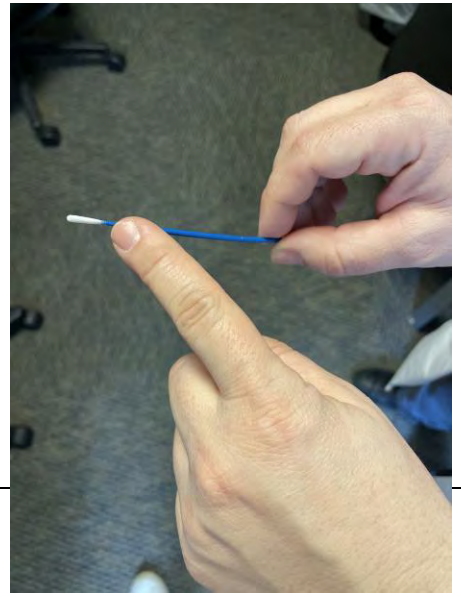
- Available phone contact
- Video instructions
- Posters or inserts in the test kits
- Validation study, but need to enroll home and in-clinic in parallel (not easy)
  - Use of spiked specimens
  - 30 samples needed to validate (minimum of 10 positive and 10 negative)
  - Have non-lab personal set up specimens
  - Use left over specimens

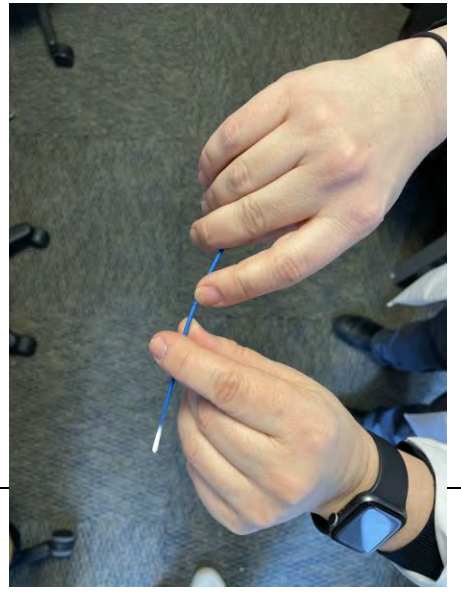
Education on 3 site Self Collection



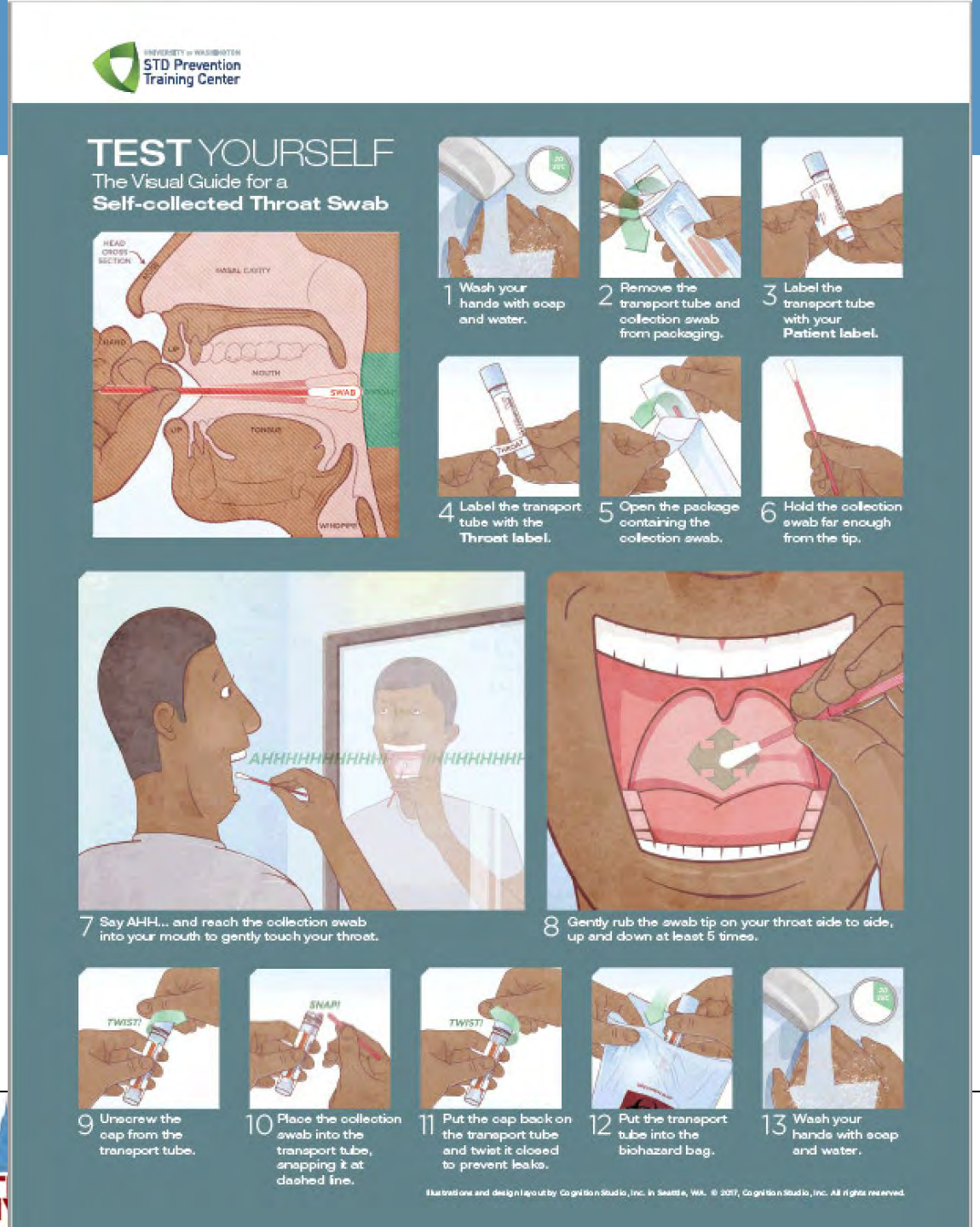
Rectal Swab

- Here is a swab that is going to go in your butt until right about here.
- You are going to twirl it about 5 times
- The swab breaks in the middle and you twist off the top of the tube and put it in the tube





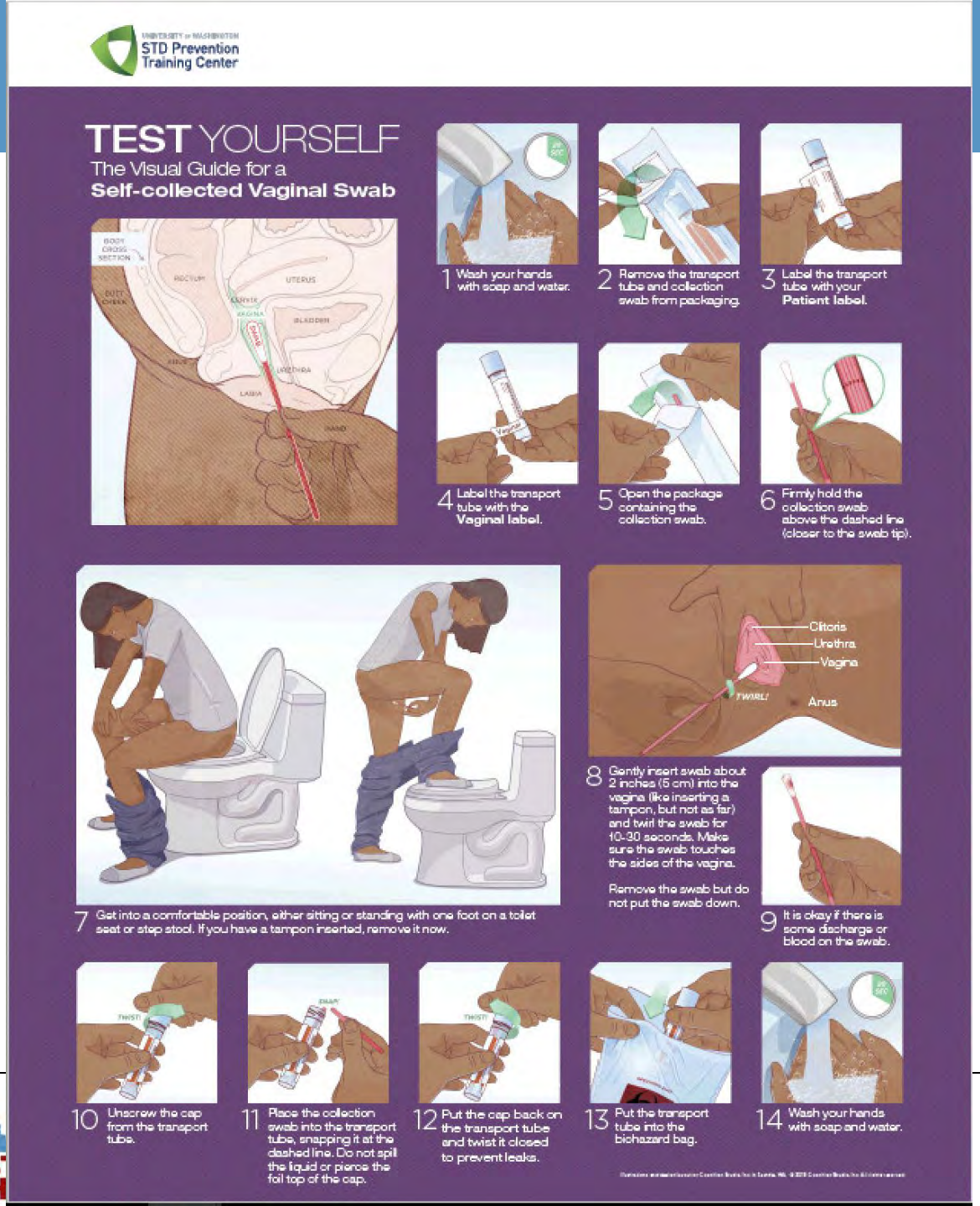
Education on 3 site Self Collection



Pharyngeal/Throat Swab

- In the mirror in the bathroom, use this swab to gently run the tip at the back of your throat from side to side
- Again the swab breaks in the middle and you take off the top and place the swab tip down in the tube

Education on 3 site Self Collection



Vaginal/Urethra/Urine

- Urine collection is pretty self-explanatory
- If a patient is unable to urinate, vaginal swabs or penile meatal swabs are an option

NYC STD PTC: Extragenital Testing Toolkit

COLUMBIA UNIVERSITY IRVING MEDICAL CENTER

Columbia University Mailman School of Public Health

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NYC STI/HIV PREVENTION TRAINING CENTER

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STI Testing & Care

Evidence-based resources for clinical professionals providing STI care

Extragenital Testing Toolkit ^

This extragenital testing toolkit was developed for clinics and healthcare providers interested in exploring or improving extragenital STI testing, also known as three-site testing. These tools were designed to improve provider knowledge, service implementation, clinic flow, and more. They can be used either individually or in combination with each other.

- Before You Get Started
- Population-Based Key Evidence
- Rationale and Evidence by Population Groups
- Models of Care
- Sample Screeners
- Standing Orders for Extragenital Testing
- Complete EGT Toolkit

Extragenital Testing Toolkit en Español v

NEW YORK CITY STD HIV PREVENTION TRAINING CENTER

A Study of at Home Testing

NewYork - Presbyterian Hospital HIV Prevention @Home Program
Patient Demographics (Kits Not Returned vs Kits Returned)
4/1/2020 - 7/8/2020

Demographic Characteristics		Overall N=201	N	Kits Not Returned N=52	N	Kits Returned N = 149	N	p-value▲
Age		30 (26,35)	201	31 (25, 36)º		29 (25, 34)º		0.6
Sex at Birth			201		52		149	0.2
	Male	195 (97%)		49 (94%)		146 (98%)		
	Female	5 (2.5%)		2 (3.8%)		3 (2%)		
	Other	1 (0.5%)		1 (1.9%)		9 (0%)		
Gender			201		52		149	0.4
	Male	194 (97%)		49 (94%)				
	Female	6 (3%)		3 (5.8%)		3 (2%)		
	Other	1 (0.5%)		0 (0%)		1 (0.7%)		
African American		34 (20%)	172	13 (31%)		21 (16%)		0.061
Hispanic		90 (54%)	167	22 (54%)		68 (54%)		>0.9
Length of Time enrolled as a patient in NYP-HPP*		727 (336, 1015)	201	630 (420, 890)º		755 (335, 1030)º		0.14
Orasure Results Documented		108 (54%)	201	9 (17%)	52	99 (66%)	149	**<0.001**
Pre-Visit Paperwork Completed		108 (100%)	108	21 (100%)	52	87 (100%)	149	<0.9
STI Results								**0.004**
	Negative	130 (87%)		N/A		130 (87%)		
	Positive	19 (13%)		N/A		19 (13%)		

ºStatistics presented: median (IQR); n(%)
▲ Statistical tests performed: Wilcoxon rank-sum test; Fisher's exact test; chi-squared test of independence
* NewYork-Presbyterian HIV Prevention Program

- Overall, @Home Testing was well adopted by patients (4/20-7/20)
  - 201 samples sent – 149 (74%) returned results
  - 19 patients with positive STIs (13%)
  - Only 1 insufficient sample
- Limitations
  - No testing for syphilis
  - Long time (15 days) for mail to turn packages around

Carnevale C, Richards P, Cohall R, Choe J, Zitaner J, Hall N, Cohall A, Whittier S, Green DA, Sobieszczyk ME, Gordon P, Zucker J. At-Home Testing for Sexually Transmitted Infections During the COVID-19 Pandemic. Sex Transm Dis. 2021 Jan;48(1):e11-e14..

Benefits of Home Testing or Self Collection

Table One:

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[a] Statistics presented: median (IQR); n(%)

[a] New York-Presbyterian HIV Prevention Program

13% positive STI test

Individual benefits to STI testing

- Privacy
- Confidentiality
- Speed
- Convenience
- Access if the price is affordable

System benefit

- People centered
- Reduce health care costs

Carnevale, et al J. 2021. At-home testing for sexually transmitted infections during the COVID-19 pandemic. *Sex Transm Dis. 2021*

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Benefits of Home Testing (HIV is the model)

- Reduced stigma
- Reaching hard to reach marginalized populations especially Black and Latino MSM
- Reach partners same time

HIV Testing: Why Home Testing is Valuable

PREVENTION RESEARCH

HIV Self-Testing Increases HIV Testing Frequency in High-Risk Men Who Have Sex With Men: A Randomized Controlled Trial

Katz, David A. PhD, MPH[*,†]; Golden, Matthew R. MD, MPH[*,†,‡]; Hughes, James P. PhD[§]; Farquhar, Carey MD, MPH[*,‡,‖]; Stekler, Joanne D. MD, MPH[*,‡]

Author Information

JAIDS Journal of Acquired Immune Deficiency Syndromes 78(5):p 505-512, August 15, 2018. | **DOI:** 10.1097/QAI.0000000000001709

- 230 MSM were randomized to receive Home Tests for free and standard of care (3 month visits with HIV testing)
- The folks who were in the Home Testing Arm tested 1.7 more times in between screening visits than the standard of care folks
- Access to free HIV self-testing increased testing frequency among high-risk men who have sex with men and did not impact sexual behavior or STI acquisition

Home testing challenges

- Results interpretation

- Needs clear instructions on what to do with results
  - E.g. test +/-
  - Who to call, where to go etc

The Home HIV Test said I'm Positive/Negative…
Now what?
It is helpful if the Home Test Kit Has….
Clear instructions on Test Administration
Clear instructions on interpretation of results
Phone numbers to call if assistance is needed
One phone number if results are positive or negative

Changing Landscape of STI Testing

INDIGI iwtk™
I WANT THE KIT
Take Control. Know Your Status.

NEW YORK CITY STD HIV PREVENTION TRAINING CENTER

Internet Program of STI testing, I Want The Kit (IWTK)

Design: Maryland, Baltimore and DC

- The Program: IWTK
  - Online request for the kits (GC, CT, Trich); male and female; 3 site testing
  - Notification by text or email of results and logon to system
  - Referral to treatment center
- Survey to assess user acceptability of IWTK and gauge interest in future directions
  - General demographic data on users
  - Repeat users(33%): asked acceptability questions ease of ordering, past experience, ease of collection, understanding instructions

Results

- Satisfaction:
  - **85% very easy to order**
  - 75% very satisfied with past experience
  - **75% ease of swabbing**
  - **78% very easy to understand collection instructions**
- Testing location preference
  - **62% preferred home testing**
  - 26% no preference
  - 6% preferred health care setting
- Preferred site of self- testing
  - Genital > urine> rectal
- "Hypothetical" POC home test
  - They would pay $23
  - 95% would be interested in it
  - 80% willing to do a finger stick for dried blood spot (syphilis testing)
- Limitations
  - Not generalizable, self selected population

Gaydos, et al. Sex Trans Dis. 2019

Mail-in Kits are Here to Stay!

- Review of commercial, fee-for service, mail in STI testing services advertised on the Web
- Reviewed access in 50 states (only 48 had this testing e.g. not NY or RI)
- Results
  - 20 programs
  - 5 (25%) free to consumers
  - 6 (30%) prefixed kits with ½ offering extragenital testing, 2 did not and 40% did not clarify EG testing
  - 3 (15%) used their own lab
  - 11 (55%) did not provide lab information
  - 1 commercial lab provided services to 5 organizations

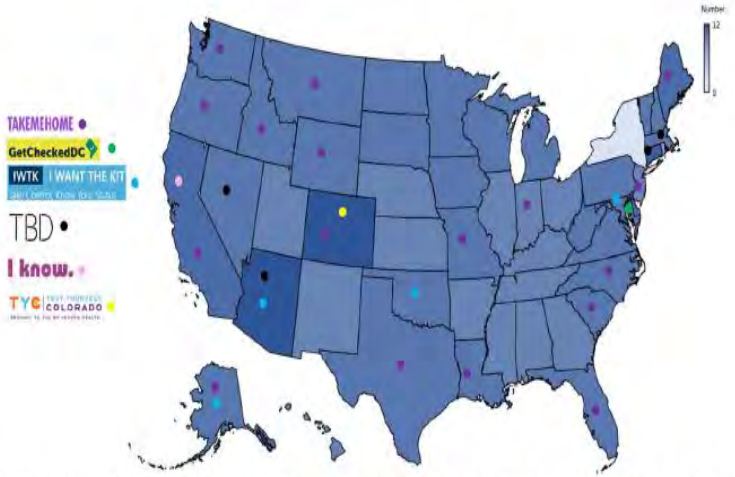

Figure 1. Number of Web site mail-in STI testing services by state. Number of mail-in testing services is denoted by blue shading. The darkness of the blue shading corresponds to increasing numbers of services in a particular state. The services offering no-cost-to-consumer mail-in STI services are denoted by different color dots on the states they service. The citations for the services shown by logo from top to bottom are Refs. [32s,23,26,33s,21] and [34s].

Pontes, Armington, Fink, Gaydos and Manabe. Sex Trams Dis. June 2023

Summary

- Screening for STIs is important, there are new diagnostic tools
- Self- collection can be used at home or in clinic (validation study needed)
- Rapid or near point of care (POC) can be implemented in clinics
- Rapid or POC tests have good sensitivity and benefits of diminished time between testing and test results to the patient and may impact transmission due to rapid treatment
- Implementing new testing strategies may include: Clinic self test, Express testing, Rapid testing , POC testing or Home testing
- Resources:
  - NYC STI HIV Prevention Training Center (STI Testing & Care | Columbia University Mailman School of Public Health)
  - NACHO (2021). *Implementing Express STI Services: Considerations and Lessons Learned*. National Association of County and City Health Officials: STI Express Initiative https://www.naccho.org/uploads/downloadable-resources/Implementing-Express-STI-Services-Guide.pdf