Implementing Self-screening for Extragenital Chlamydia & Gonorrhea In Low-resource U.S. Settings

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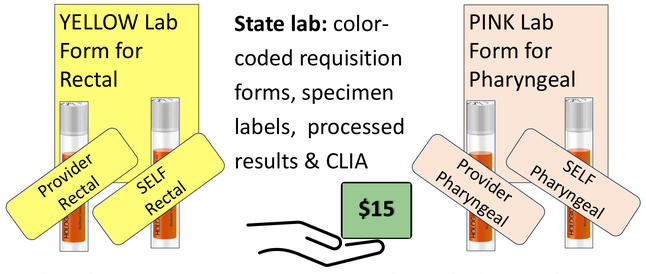
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BACKGROUND

- In 2021, the CDC expanded recommendations for rectal & pharyngeal screening for chlamydia & gonorrhea:
  - Sexual & gender minorities male-at-birth
  - Patients < 25-years-old female-at-birth
- Offering self-collection improves extragenital testing uptake but extragenital assays lack FDA-approval for self-collection
- Michigan state lab, Detroit STD Clinic, & UM conducted a validation study to implement extragenital self-collection via a Clinical Laboratory Improvement Amendment (CLIA)

METHODS

- Clinicians (1 MD & 4 NPs) invited patients ≥14 years from July-Sept 2024
- Patients were given verbal & visual collection instructions
- State lab processed using Aptima Panther Combo 2, repeating tests to adjudicate discrepancies
- Comparability assessed by Cohen's kappa & McNemar tests
- Thematic analysis of transcripts using Consolidated Framework for Implementation Research (CFIR):
  - Clinic staff focus group (N=4)
  - Lab key informant interview (N=1)



State lab: color-coded requisition forms, specimen labels, processed results & CLIA

University: incentives, IRB (not regulated) & analysis

Clinic: invited patients, collected & shipped

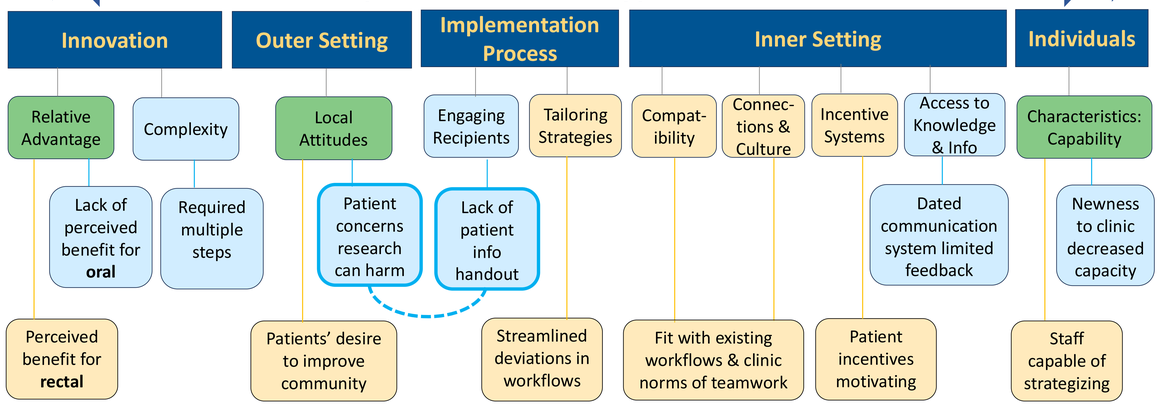
PATIENT CHARACTERISTICS

Demographics (*p<0.05)	Sample (N=320)	Clinic Tests 2024
Male sex at birth*	**95.0%**	81.4%
Race/ethnicity*		
Black, non-Hispanic	**67.7%**	79.7%
White, non-Hispanic	**19.1%**	14.8%
Largest age group 30-39 yrs	**37.2%**	37.8%

Abbreviations: CDC= Centers for Disease Control & Prevention; FDA= Food & Drug Administration; UM= University of Michigan; MD= Medical Doctor; NP= Nurse Practitioner; IRB= Institutional Review Board.

The state health lab, clinic & university collaboration strategically validated 320 self-collected extragenital STI specimens from 1 clinic, launching self-sampling at 198 other low-resource clinics.

Clinic Staff Focus Group Themes & Quotes Mapped onto CFIR Domains & Constructs



Innovation	Outer Setting	Implementation Process	Inner Setting	Individuals
Relative Advantage	**Local Attitudes**	**Tailoring Strategies**	**Relational Connections & Culture**	**Capability**
"Oh, there are some people that would not swab if they couldn't do it themselves...mostly with rectal."	*"That was motivation for a lot of people, you know, wanting people in their community to benefit from this."*	*"I think having everything provided to us up front, like the color-coded sheets, the stickers, that definitely helped to streamline our processes, and we put the stickers in the rooms next to the swabs."*	*"In our clinic space, we know that the work of one person impacts the work of the next and like, we have to move in a systematic manner.... So I think that was a bit of a motivation, just of our natural clinic working styles with one another."*	*"I'm pretty meticulous...so I make stations for everything so that they know where to drop it off. I would designate an area where you can clearly see."*
Complexity	**Local Attitudes**	**Engaging Recipients**	**Access to Knowledge & Info**	**Capability**
"Having to pull out, like, the two, you know, four different swabs, okay, make sure each one's labeled correctly, it's lined up with the patient sticker.... I was just saying to patients, I'm like, 'Yeah, it's sticker, sticker galore!'"	*"Recognizing sadly, like mistrust... in the communities with research and like, "Where is my information going and why?" You know... that was some of the reasons for hesitation with patients."*	*"So once we kind of reassured them with that, that nothing would change with their HIPAA and all of that, they usually were pretty agreeable. We did have to tell them a lot, though. Sometimes it took a little bit. So I like [colleague]'s suggestion about [a] handout that just really lays it out."*	*"We usually get a fax from the state if there is, in general, if there's an issue... like, 'Resolve the [results] discrepancy.' But nothing about spilled packages... or anything of that sort."* *"So I have no way of knowing if something had spilled or if I had overlooked something."*	*"That was my [learning] curve. ..I'm just coming from a [different clinic] system.... The reasons that I didn't do [recruitment], full transparency, was when it was really busy, especially, you know, because I sometimes was like running behind."*

RESULTS

Feasibility & Acceptability

- **< 2 months to complete** specimen collection
- **84.4% participation** for patient specimens (320/379)
  - Rectal 83.1% (138/166); pharyngeal 85.4% (182/213)
  - 293 patients: 92% x1, 8% x2 visits = 320 specimens

Fidelity

- **95%** paired specimens included in comparison
  - Excluded 9 early retests, 6 wrong devices, 1 insufficient sample

Clinical

- **> 96.9% self & provider agreement**, 12 discrepancies**

Self Results	Provider +	Provider –	Kappa, P-value
	Rectal Gonorrhea		0.59, p=0.08
self +	3	**4**	
self –	0	122	
	Rectal Chlamydia		0.66, p=0.29
self +	2	**2**	
self –	0	125	
	Pharyngeal Gonorrhea		0.84, p=0.77
self +	9	**2**	
self –	**1**	163	
	Pharyngeal Chlamydia		1.00, p=1.00
self +	1	0	
self –	0	174	

**3 discrepancies indeterminate vs – : 2 provider vs self, 1 self vs provider. All "–" in table.

- State CLIA enabled self-collection at affiliated clinics in **Jan 2026**

CONCLUSIONS

- **Self-collected & clinician results were comparable.**
  - Self swabs detected more rectal infections.
  - Per focus group: patients comfortable self-collecting "deep."
- **Clearly labeling** different specimens streamlined implementation.
- **Lack of patient handout** (though not IRB-required) **exacerbated research mistrust** in community.
- **Teamwork & perceived clinical benefit** facilitated success.
- **Strategic collaboration can enable extragenital self-testing** to help increase STI testing/treatment, even absent federal support.

PLAIN LANGUAGE SUMMARY

A public health lab, clinic & university teamed up to initiate self-testing for rectal & oral STIs at hundreds of clinics.

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