

STI Clinic + Public Health Perspective

A microscopic image of a cell, likely a ciliated epithelial cell, showing a large, rounded nucleus and numerous fine, hair-like cilia extending from the cell surface. The image is rendered in shades of blue and white, giving it a scientific and clinical appearance.

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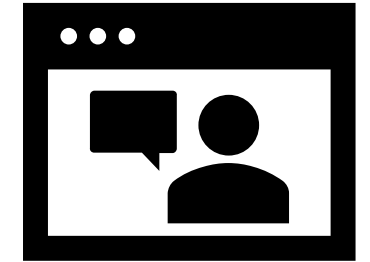
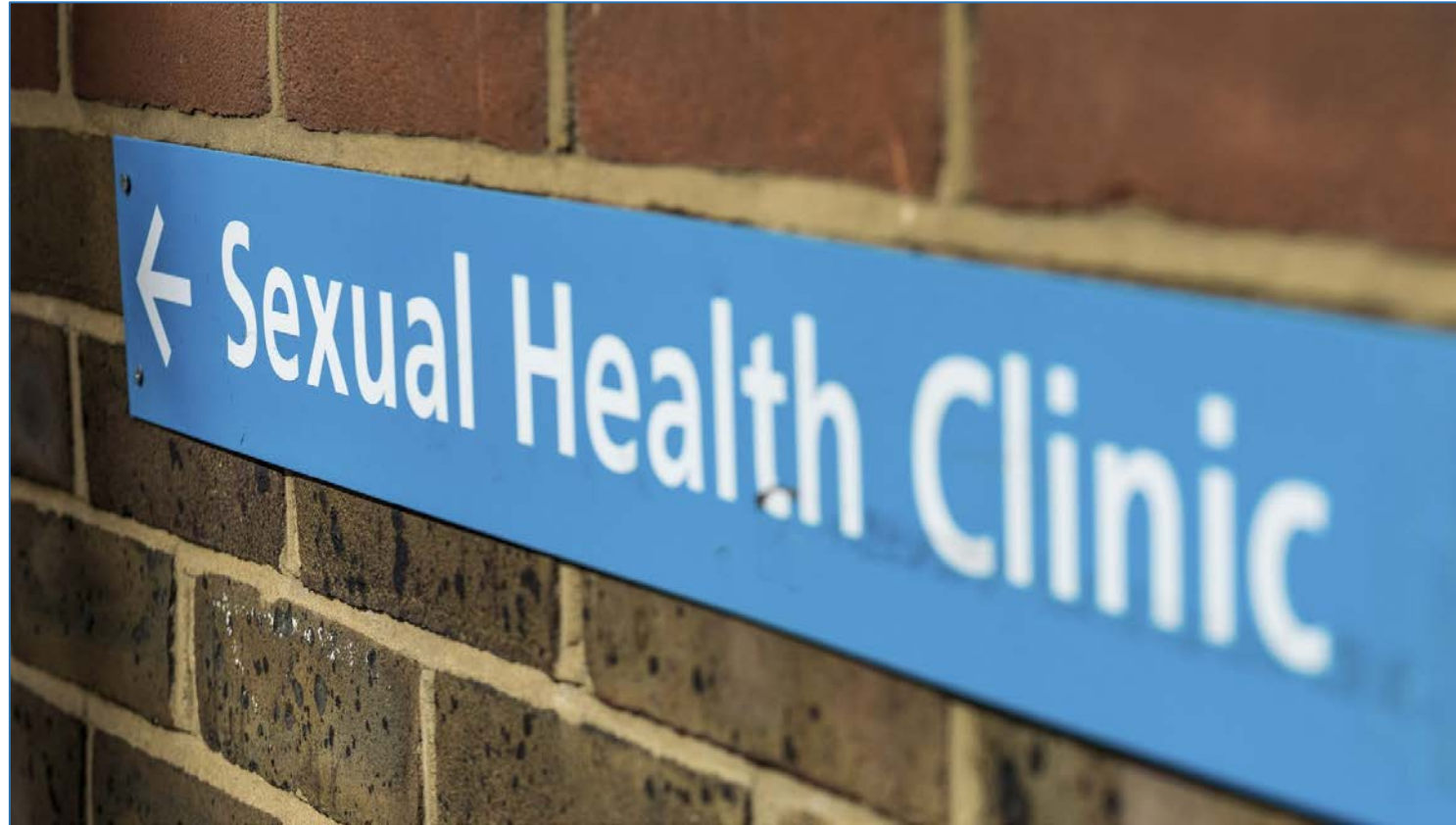
Wake Forest University

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Express Visits



Telehealth



PrEP/ PEP services



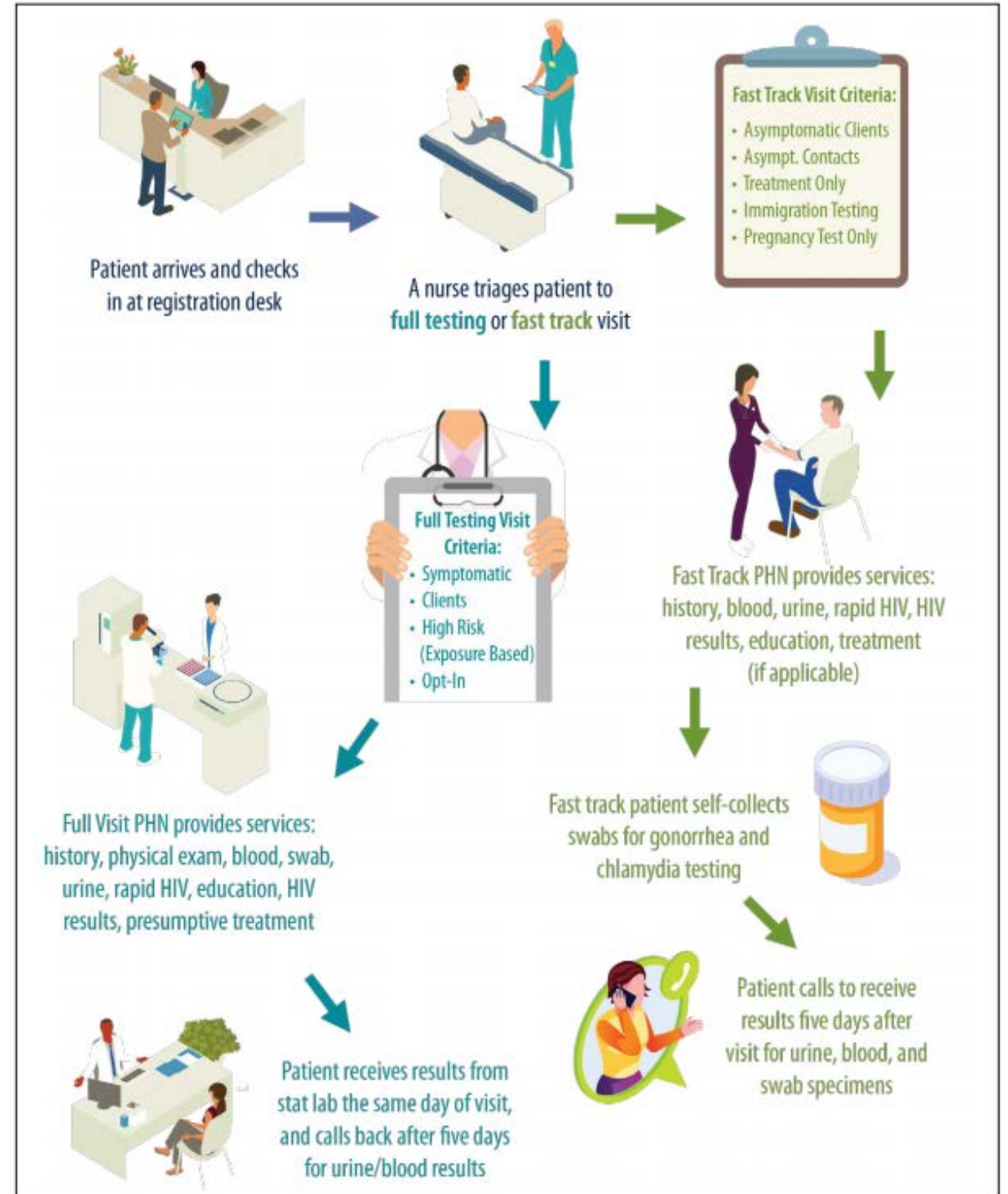
What are express visits?

- Triage based STI testing without a full clinical examination.
- There is no one-size-fits all approach so variable patient flows exist.

Are Express Visits for STI care a (missed) opportunity for clinical trial recruitment?

- Increasing use in clinics
- Percentage of visits varies
- Lack of gram stain
- No treatment at visit
- Opportunity to give info
- Limited staff contact

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>



Traditional STI clinics service assessment

Between February and November 2020, many clinics adopted telemedicine services. Many fewer adopted offsite HIV and STD testing

Number of clinics that reported providing each service in the two time periods

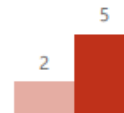
STD express visits
Feb vs. Nov 2020



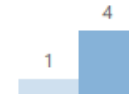
Telemedicine services
Feb vs. Nov 2020



HIV offsite self-testing services
Feb vs. Nov 2020



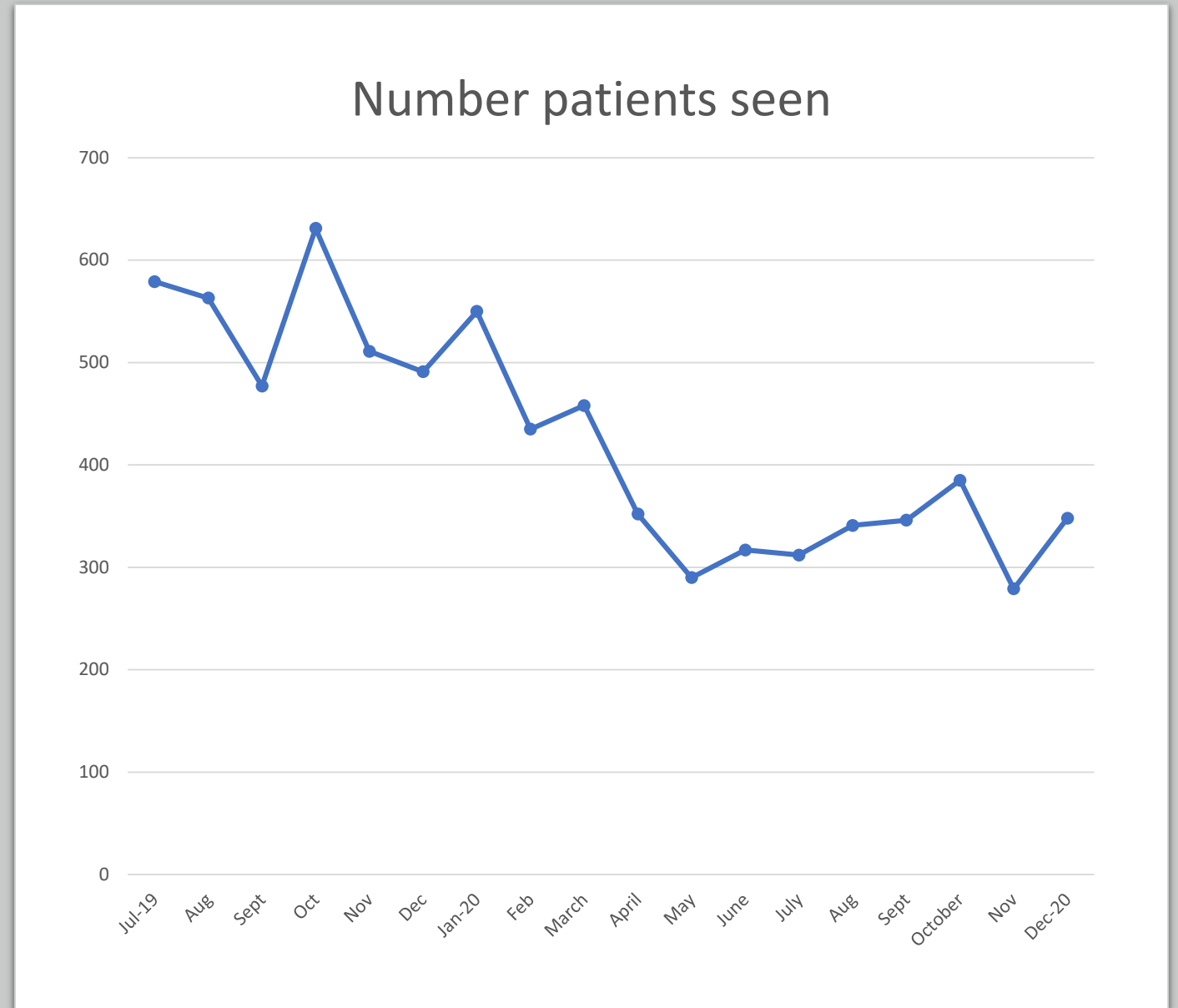
STD offsite self-collection services
Feb vs. Nov 2020



Current environment: Visits over time, 2019- 2020 (St. Louis County)

- Before COVID: 521 pts a month
- After COVID: 330 pts a month

 37%



Added challenges

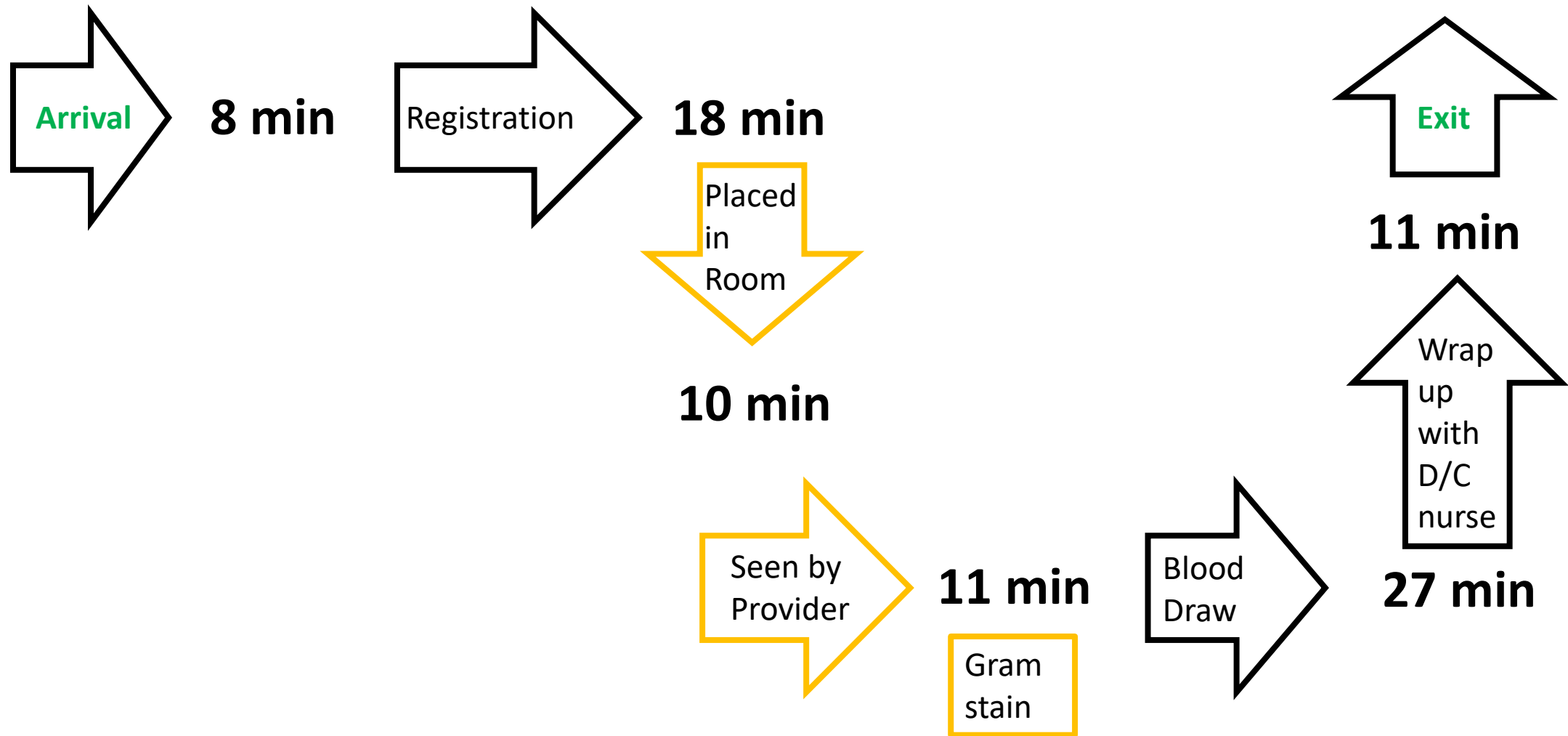
- Space
- PPE supply and how much longer this may be needed
- Drug and testing kit shortages
- Staff exhaustion

Case study: St. Louis County Sexual Health clinic

- 280 cases of GC per 100,000
- **50% increase from 2014-2019**
- Clinic staffing is set for high volume of patients with quick turnover.
- Not much wiggle room.



St. Louis County Sexual Health Clinic Patient Flow (Clinician visits)



Case study: St. Louis County Sexual Health Clinic



Success

Enthusiastic interest from patients

Space for project equipment

Studies with one visit are most successful



Challenges

Disruption in patient flow

Clinic culture

Follow up at offsite research center: transportation

Priority populations and trauma

Case Study: Wake Forest STI Trials Unit, Guilford County Health Department

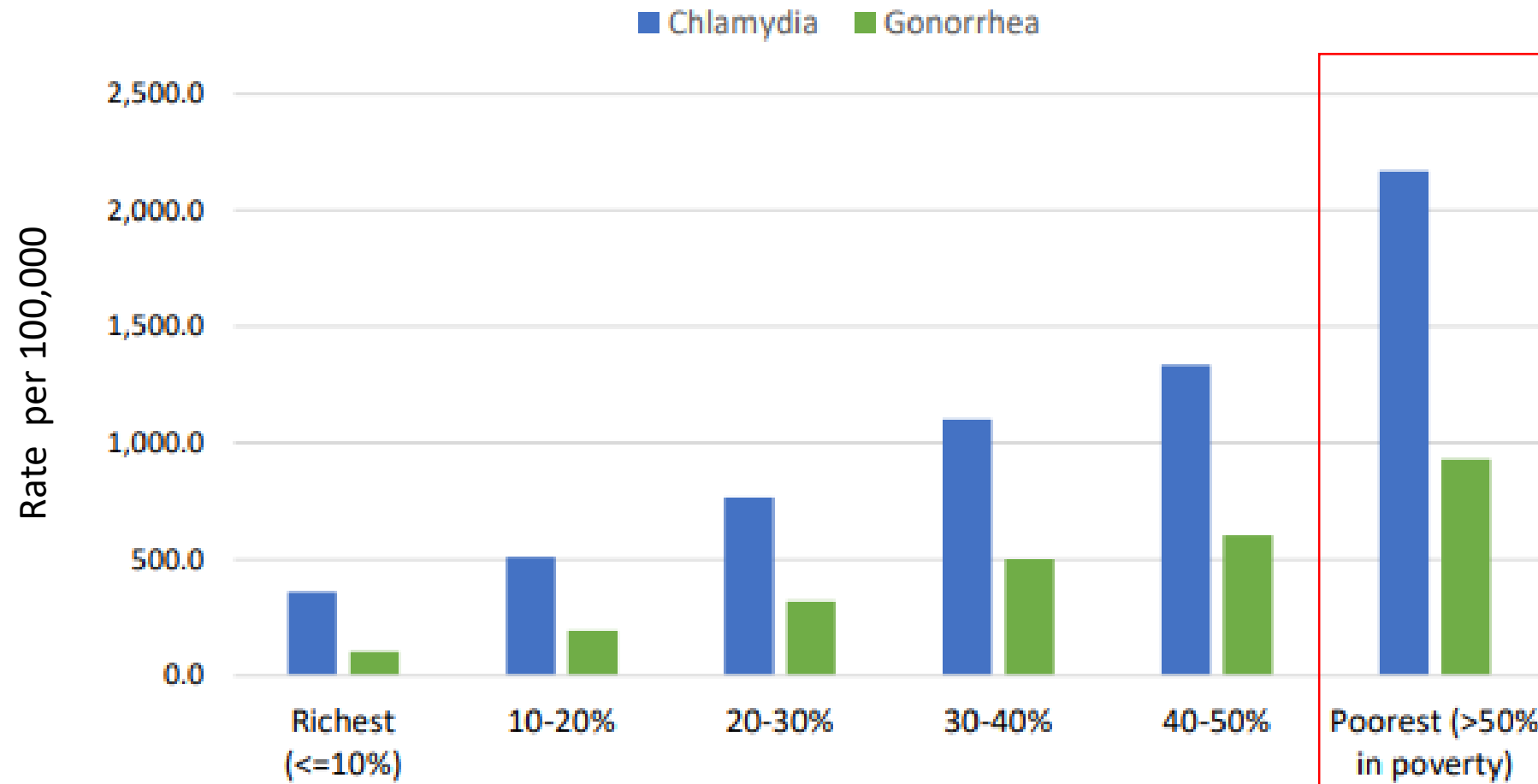
Location:

- Guilford County NC in the Piedmont Triad
- Proximity to several large medical centers
- High STI morbidity
- High volume clinic

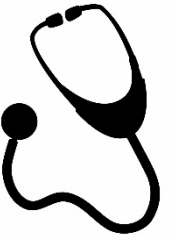


Image source: USGS

People Newly Diagnosed with Chlamydia, and Gonorrhea, in NC by Poverty Indicator, 2019



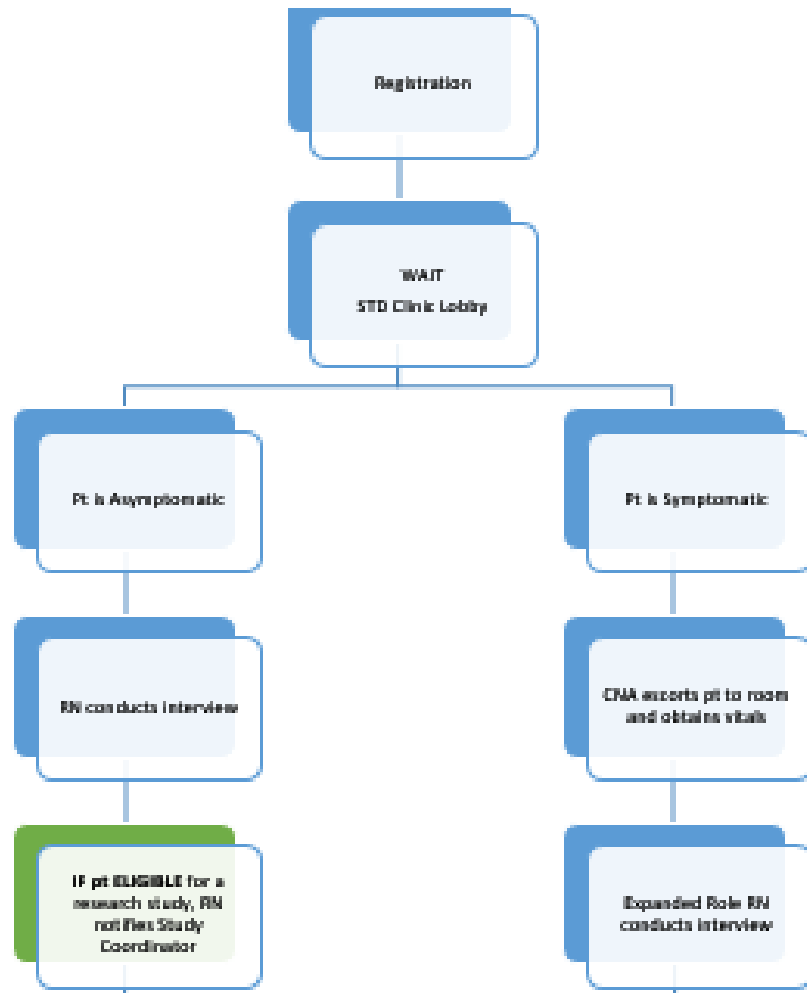
Case Study: Wake Forest STI Trials Unit, Guilford County Health Department



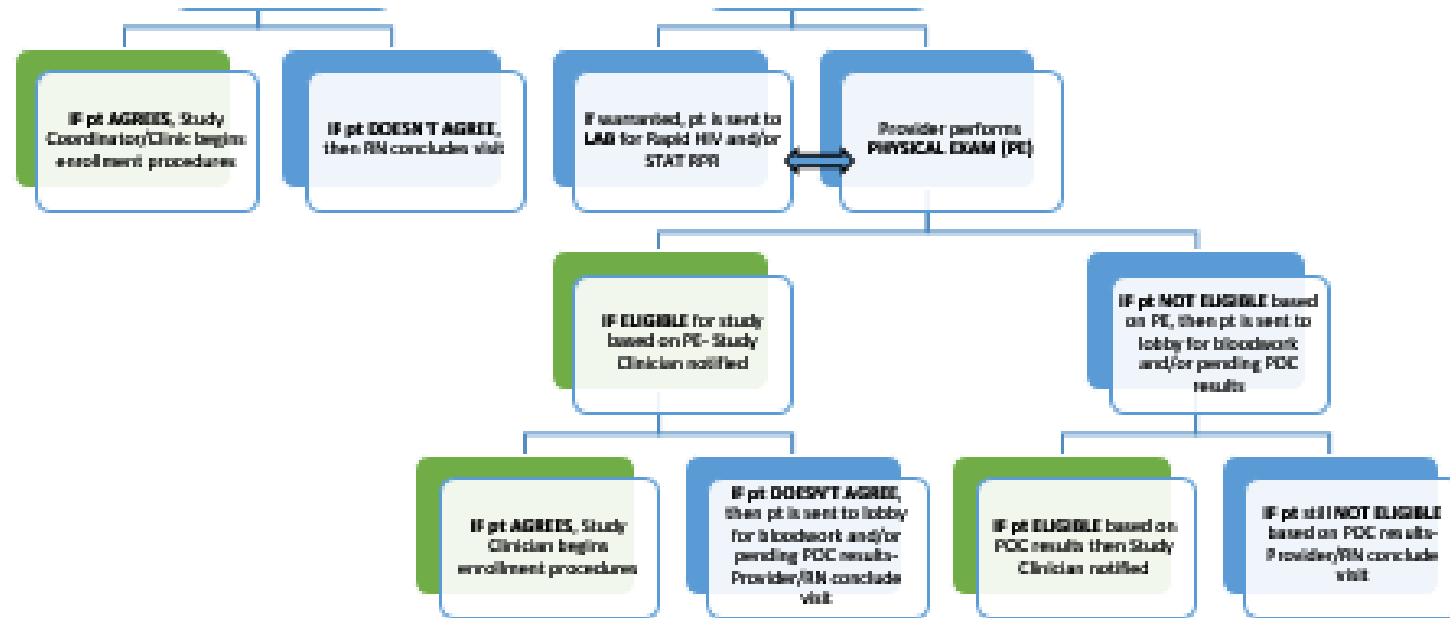
- **Health Department Clinic Staffing:** Health Educators, CNAs, Enhance Role Nurses, Advance Practitioners, Medical Director, Medical Consultants
- **Research Site Capacity:** point of care testing (wet prep, gram stain, culture), onsite nucleic acid amplification testing, gonorrhea (GC) culture, GC antimicrobial susceptibility testing, treatment, language services.
- **STI study staffing:** Advance practitioner, Physician, Laboratory Technician, Epidemiologist, Disease Investigator
- **STI studies:** treatment, STI diagnostics, surveillance, social/behavioral, partner services

Time Course to Enrollment Pre COVID-19

VISIT PART 1



VISIT PART 2



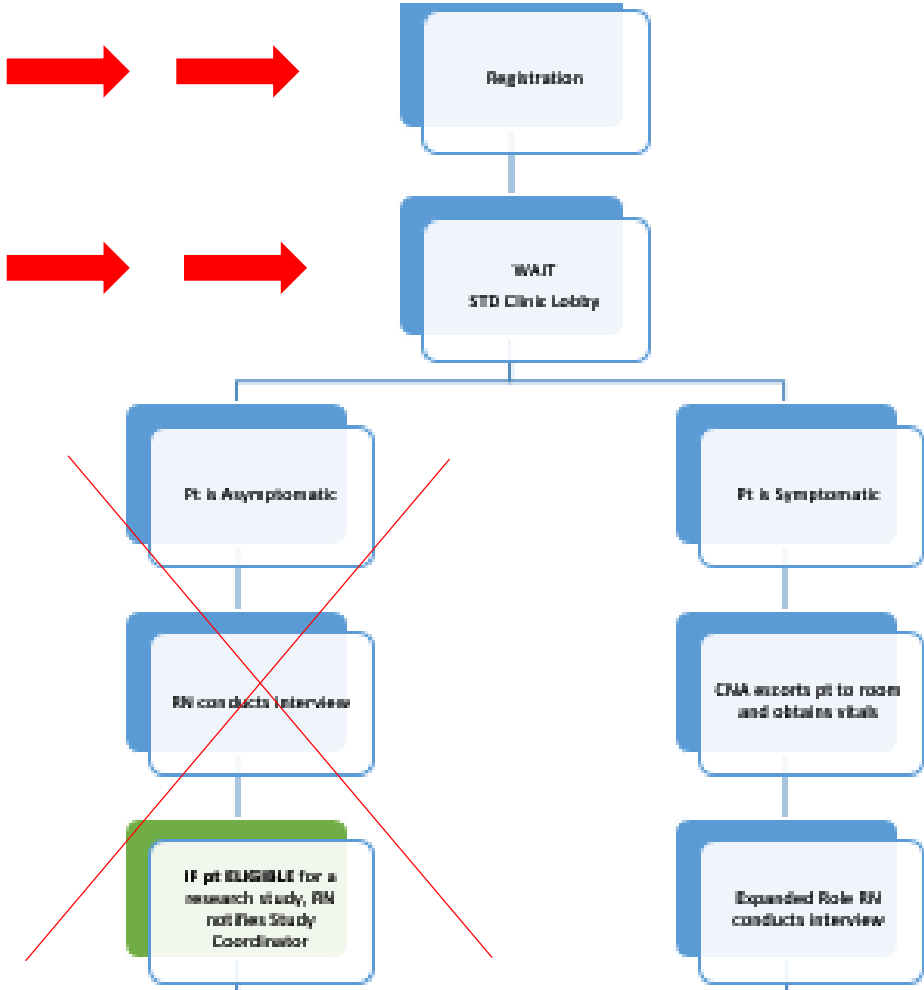
Site Challenges



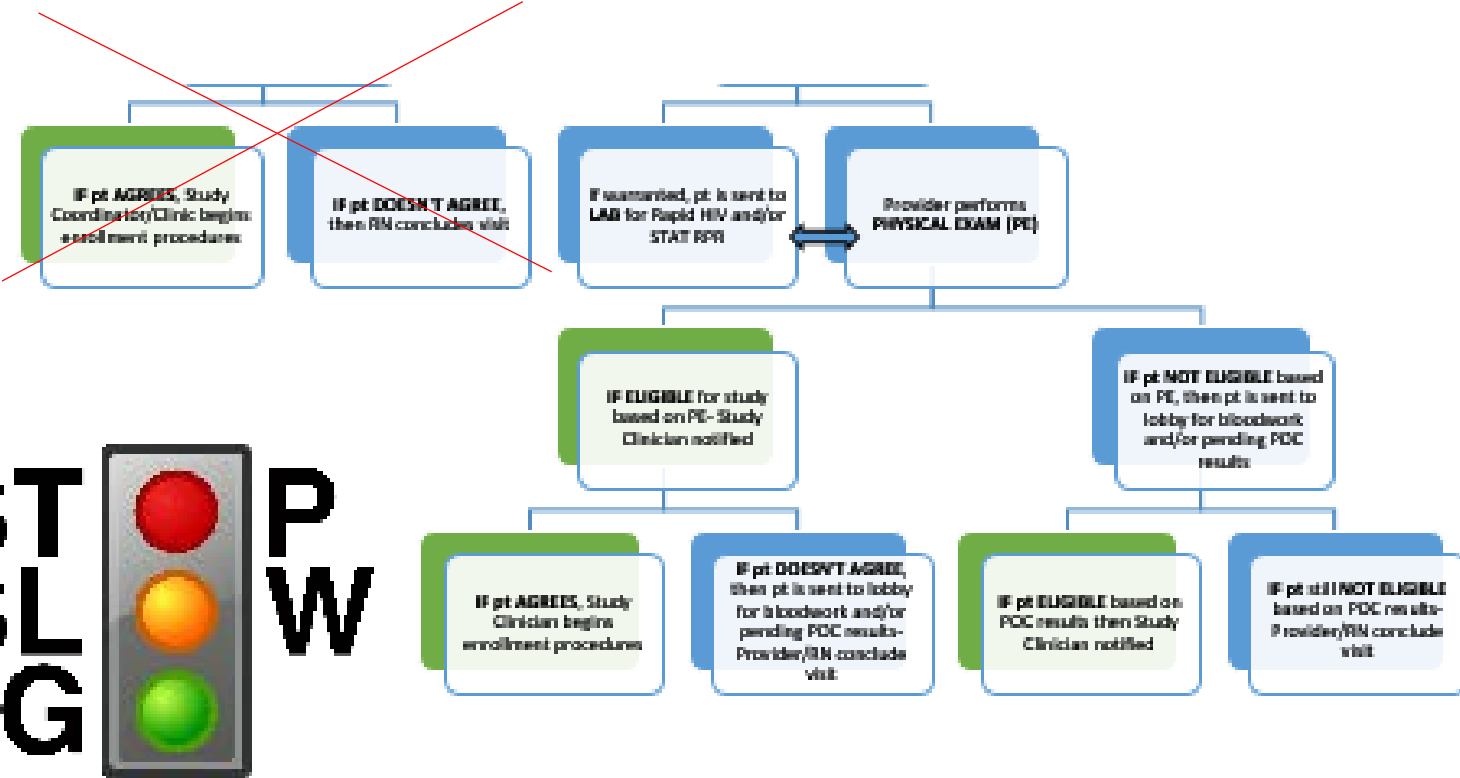
- Understanding the role of clinical trials
- Transportation
- Availability of clinic appointments
- Stigma around clinical research studies in African Americans, Latinx, Gender minorities
- Clinic hours during regular work hours with no weekend options
Time/length of visit depending on the study

Time Course to Enrollment During COVID-19 Pandemic

VISIT PART 1



VISIT PART 2

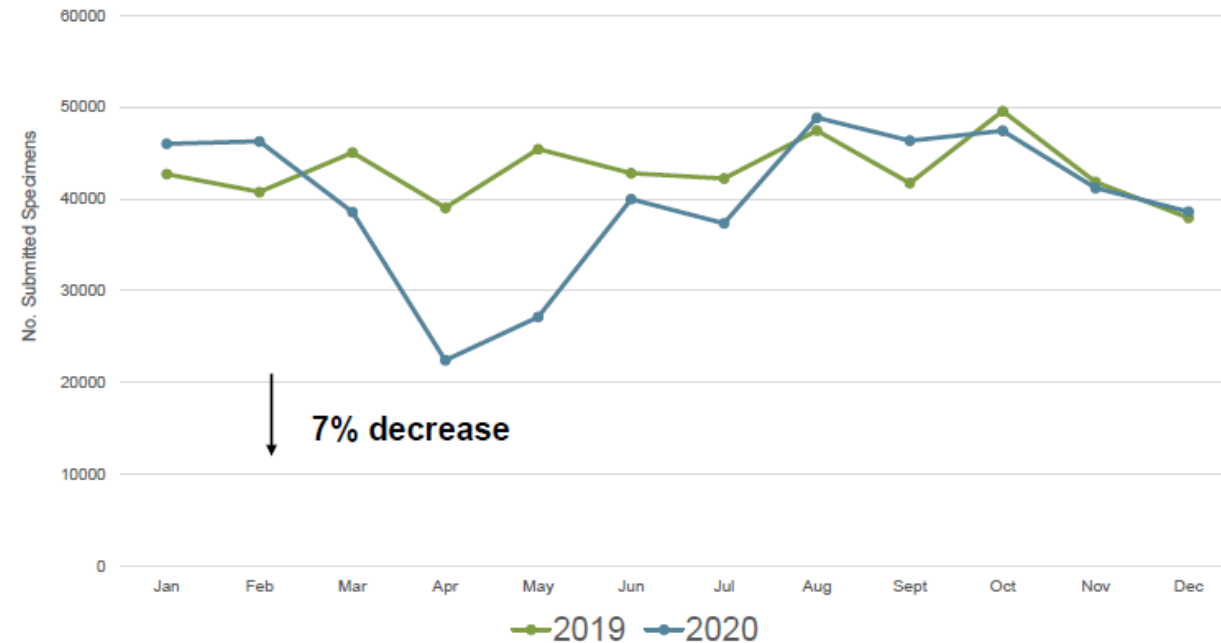


Site Challenges: Limited STD Services

Local Health Department STD Services Assessment

Category	CY 2019	CY 2020	% Decrease from 2019 to 2020
Total visits (all providers)	124,763	83,892	33
Total Male Visits (all providers)	52,183	36,217	31
Total Female Visits (all providers)	72,489	47,606	34
Total Transgender Visits (all providers)	91	69	24
Total visits (ERRNs)	37,436	21,615	42
Total Male Visits (ERRNs)	15,217	8,912	41
Total Female Visits (ERRNs)	22,137	12,678	43
Total Transgender Visits (ERRNs)	82	25	70

LabCorp Gonorrhea Lab Tests



*Testing submission data provided by LabCorp, State Reporting Program, National Office of Quality.

Site Challenges: COVID-19 Pandemic

- **TRANSPORTATION**
- **LIMITED** availability of clinic appointments
- Stigma around Clinical Research studies on African Americans, Latinx, Gender minorities
- **LIMITED** Clinic hours are during regular work hours and patient's find hard time making subsequent visits
- **INCREASED** Time/length of visit
- Understanding the role of Clinical Trials
- **SHORTAGES** PPE
- **SHORTAGES** Testing supplies NAATs and GC culture plates
- **FEAR** of having to come back to the clinic for frequent visits



Site Successes



- Research staff integration in site activities demonstrating strong commitment
- Relationships with academic partners
- Diverse research workforce reflecting the populations served
- Investment in workforce development
- Team effort in meeting research deliverables

Engage a Site Champion



Table 1. Different Types of Champions Described Across Studies.

Topic-related	Specific job position	Broader organizational role
Hand-washing champion	Nurse champion	Clinical champion
Health goals champion	Physician champion	Onsite champion
Immunization champion	Champion teacher	Organizational change champion
Guideline champion		Administrative champion
Skin champion		Managerial champion
Environmental champion		Facility champion
Project champion		Internal champion
Protocol champion		Practice champion
Quality champion		Executive champion
Innovation champion		Technical champion
Change champion		User champion
Program champion		Academic champion
Research champion		Team champion
Practice-based research champion		Unit champion
Patient safety champion		Business champion
Idea champion		Frontline champion
Dementia champion		
Fall champion		

- Works within the intended organization or directly related to it
- Interested and committed to furthering the interest of your project
- Enthusiastic and personable to help motivate others to participate

Workforce and Research Site Development



Staffing

- Mentorship
- Funding/effort
- Training
- Contract support
- Regulatory support

Resources

- Equipment
- Supplies
- Incentives
- Language services
- Technology enhancements

Consider a long-term commitment to support current and future research



Who do you invite to the table?

- Community members Representatives from local service and health-focused organizations, e.g., public health departments (local and state levels)
- Other community organizations, including those serving marginalized populations
- Clinic providers
- Staff Scientists from U.S. federal agencies
- Researchers from universities

Stepping up to Community Engaged Research

- Development of a network of persons with similar areas of interest or concern
- Establishment, maintenance, and commitment of a community-academic partnership
- TRUST
- Identification of health priorities
- Consensus



Characteristics and Strategies of Successful Community Engagement

- Knowledge of and commitment to authentic community engagement
- Commitment to understanding and addressing social determinants of health and how they relate to STDs
- Partner flexibility
- Talented and trusted leadership
- Participation of partners representing diverse sectors
- Collaborative establishment of a vision and mission
- Sharing power
- Open communication
- Shared decision making
- Embracing and working through conflict
- Identifying and leveraging talents, strengths, and resources
- Building a shared history of success



Selection of Collaborating Research Sites

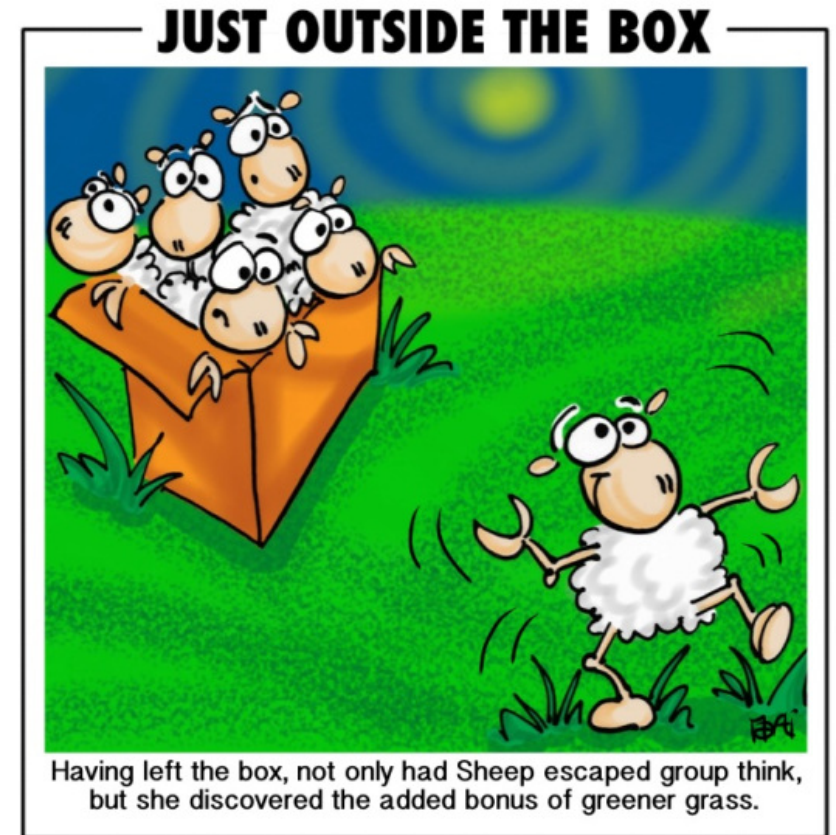
Disease	Non-STD Clinic			STD Clinic			Total		
	Male	Female	Total*	Male	Female	Total*	Male†	Female†	Total†
Chlamydia	488,821	934,566	1,426,509	55,149	45,185	100,453	644,337	1,160,470	1,808,703
Gonorrhea	273,188	200,317	474,679	37,756	15,056	52,875	361,586	253,359	616,392
Primary Syphilis	9,263	1,615	10,900	2,402	238	2,641	12,899	2,073	15,003
Secondary Syphilis	14,216	3,500	17,761	3,627	553	4,188	19,503	4,420	23,989
Early Non-Primary Non-Secondary Syphilis	26,652	5,636	32,378	4,640	864	5,519	34,427	7,081	41,655
Syphilis, Unknown Duration or Late	22,878	10,918	33,967	2,850	946	3,807	32,411	14,598	47,296
Chancroid	2	2	4	0	0	0	6	2	8

* Total includes cases reported with unknown sex.

† Total includes cases reported with unknown reporting source.

Selection of Collaborating Sites: outside the box

- Federally Qualified Health Centers
- Community groups and organizations
- Student health
- Family planning organizations
- Private practice groups
- Urgent care facilities
- Emergency departments



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Take Home Points

- STI clinics are evolving environments
- Innovative clinic models and enhanced services may boost recruitment for research
- Multiple variables account for research site success
- Diversity matters
- We all need a champion
- Invest in the LONG-TERM success of the study site
- Consider an outside the box approach to site selection
- Unflagging and authentic community engagement