

Best practices in chlamydia (CT) and gonorrhea (GC) screening in a changing healthcare environment:

Lessons from the Infertility Prevention Project (IPP)

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Cardea Services

APHA Conference

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Presenter Disclosures

Sarah Goldenkranz Salomon

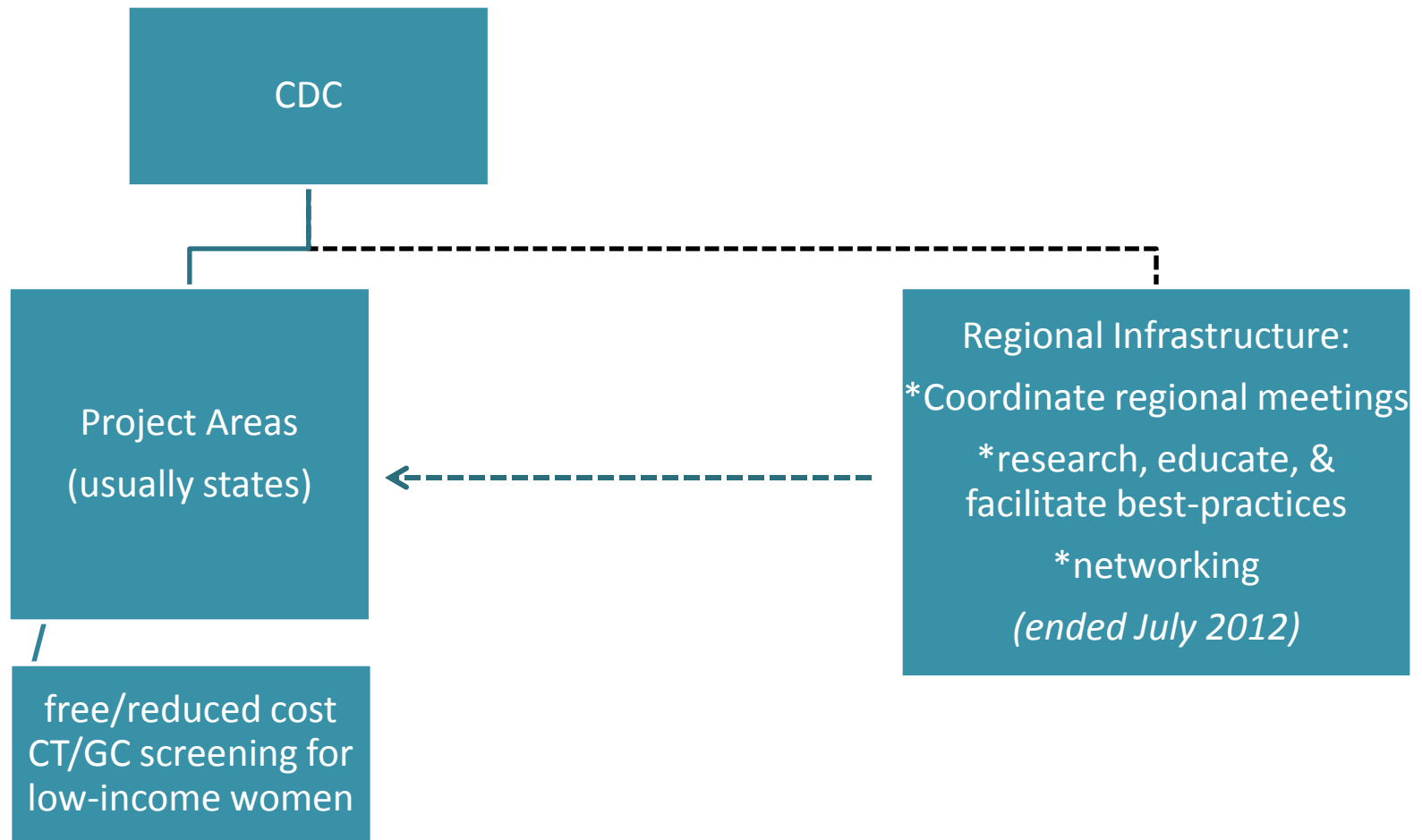
The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

NONE

Learning Objectives

- Describe 5 innovations to improve case-detection and cost-effectiveness of chlamydia (CT) and gonorrhea (GC) screening
- Provide links to useful resources from the Infertility Prevention Project

Infertility Prevention Project





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Our Mission

Improve organizations' abilities to deliver accessible, high quality, culturally proficient, and compassionate services to their clients.

TRAINING

ORGANIZATIONAL
DEVELOPMENT

EVALUATION
AND RESEARCH

- Infrastructure for Region VI, IX, and X IPP
- Now STDRHPTTAC - provide training/technical assistance for billing and program improvement data analysis

Why screen for Chlamydia (CT) and Gonorrhea (GC)?

- Usually asymptomatic
- Can lead to pelvic inflammatory disease (PID), chronic pelvic pain, infertility, and ectopic pregnancy
- Most common STD, especially among young women

Screening for Chlamydia (CT) and Gonorrhea (GC)

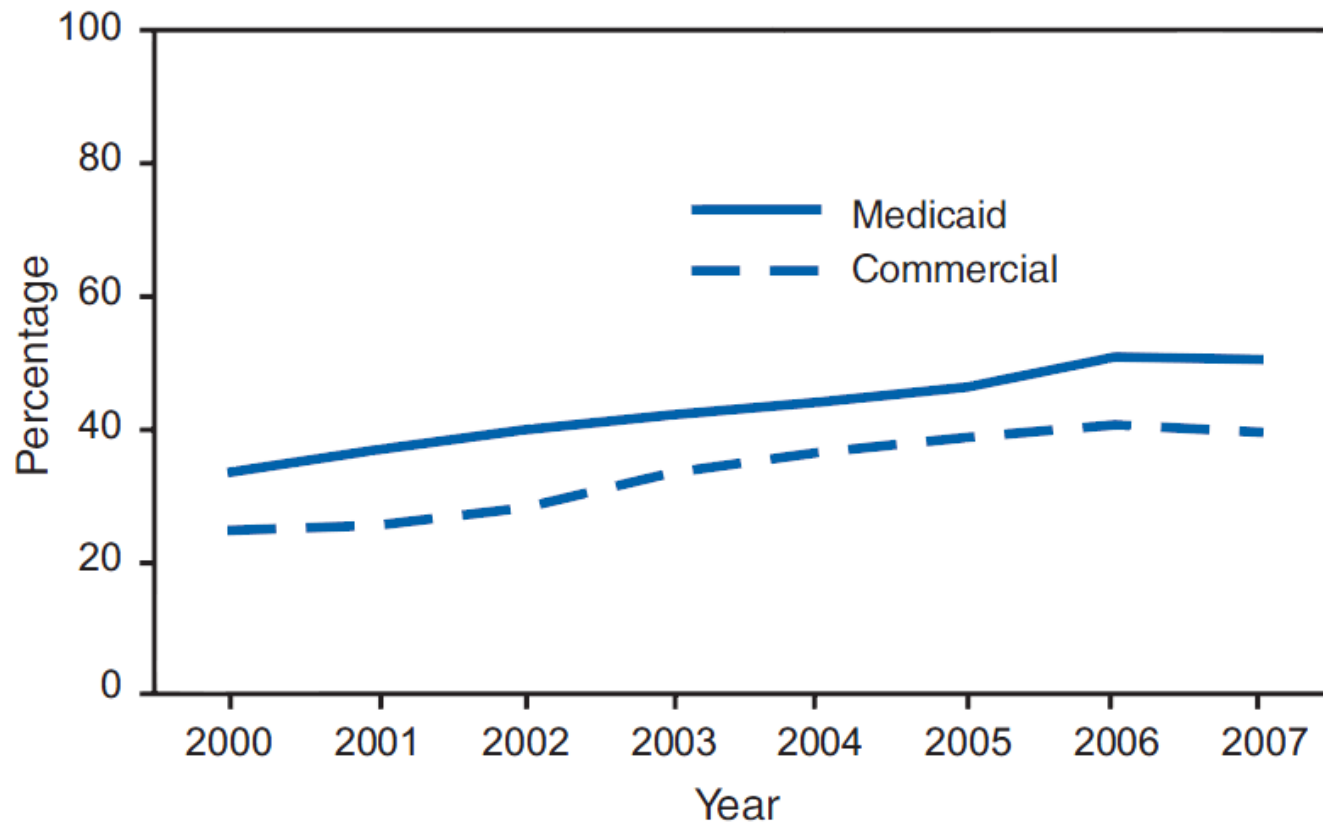
- Thus, annual chlamydia (CT) screening is recommended by CDC, ACOG, USPSTF
 - for *all* women under age 25
 - Older women & men based on risk

- USPSTF “A”-rating

Sources: Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2010. MMWR Rec Rep 2010; 59(RR-12):1-110.

<http://www.uspreventiveservicestaskforce.org/uspstf/uspschlm.htm>

FIGURE. Percentage of sexually active female enrollees aged 16–25 years* who were screened for *Chlamydia trachomatis* infection, by health plan type and year — Healthcare Effectiveness Data and Information Set, United States, 2000–2007



* 16–26 years during 2000–2002.

Efforts to Improve CT Screening

- ✓ Identify priority groups for screening and treatment
- ✓ Provider and patient education
- ✓ Update clinical protocols and tools
- ✓ Promote new technologies
- ✓ Increase efficiency - do more with less

5 Impactful Innovations

- 1) Screen adolescent women
- 2) Self-collected specimens
- 3) Expedited Partner Therapy
- 4) Re-testing
- 5) Pooling Samples

A large, ornate brick building with a crowd of people in purple shirts gathered in front. The building features a prominent corner bay window with decorative stonework and a series of arched doorways at the ground level. The crowd consists of many young people, some wearing purple t-shirts, and a few adults. A brass instrument, possibly a tuba, is visible in the crowd. The scene is set outdoors on a clear day.

INNOVATION 1

SCREEN ADOLESCENT WOMEN

Adolescent Screening Background

- Over-screening of women over age 25 is a widely recognized problem
- Insufficient resources to screen all women under age 25
- Little focus on prioritizing available resources among women under age 25

CT Risk by Age

Age Group	Region X	Region V	National
15-19	8.2%	11.1%	10.2%
20-24	5.9%	7.5%	6.9%
25+	3.7%	3.8%	3.4%

Current adolescent screening coverage

40%

48%

33%

Source: Goldenkranz S, Rabins C, Torrone E. *Chlamydia (CT) Screening in Family Planning: Maximizing Screening Yield Using Existing Testing Resources*, 2012 National STD Prevention Conference, March 2012

Innovation Proposed

- Allocate screening resources by age/risk
- Resources are sufficient to screen all adolescents plus some older women
 - *Screen all adolescents*
 - *Use remaining tests to screen age 20-25*
 - *Diagnostic testing only for women >26*

Resulting *hypothetical* increase in screening yield

	Region X	Region V	National
Adolescent screening coverage	100%	100%	100%
Screening coverage age 20-25	18%	26%	32%
# additional cases hypothetically detected by shifting resources	1,257	4,068	43,032
% increase in cases detected	28%	35%	33%

Source: Goldenkranz S, Rabins C, Torrone E. *Chlamydia (CT) Screening in Family Planning: Maximizing Screening Yield Using Existing Testing Resources*, 2012 National STD Prevention Conference, March 2012

Adolescent Screening Summary

WHAT?

- If resources do not allow 100% screening of all females under age 25, prioritize test resources for adolescents

WHY?

- Resource limitations preclude screening 100% of women under age 25
- Adolescents are at higher risk for CT than young adults

HOW?

- Utilize local programmatic data to make allocation decisions based on historic client volume, screening, and positivity

LESSONS LEARNED

- *Not yet implemented*

Resources



Interactive worksheet for test allocation decisions

contact sarah@cardeaservices.org

- MS Excel-based
- Shows estimated increase in screening yield by prioritizing teens
- Can ‘reserve’ tests for risk-based screening, etc.
- Produced by Cardea October 2012
- Will be posted to Cardea website

Interactive Resource Allocation Worksheet for Chlamydia Screening

Region/Agency/Clinic: Sample Clinic
 Year: 2012

STEP 1: Use data from the most recent year available to fill in the boxes below:

Females	# of female			Calculated CT "positivity"
	clients	# tested for CT	# positive for CT	
Age 10-19	100	50	4	8.0%
Age 20-24	200	150	8	5.3%
Age 25+	100	50	2	4.0%
Total	400	250	14	5.6%

STEP 2: Estimate client totals and tests available for the coming year by filling in the boxes below:
 if no changes expected, estimate based on last year

	# of clients
Age 10-19	100
Age 20-24	200
Age 25+	100
Total	400

Enter the number of CT tests available for the coming year: 250

STEP 3: Enter the number of tests you need to reserve for re-testing and diagnostic testing:

NOTE: Tests can be reserved for re-testing and diagnostic testing of older females with symptoms or clinical signs. It is important to be realistic in estimating the number of patients that meet diagnostic testing criteria. See appendix A for a discussion of considerations for reserving tests.

Number of CT tests you need to reserve for re-testing and patients meeting diagnostic testing criteria: 25
 Number of CT tests remaining 225

Females	# of female clients	# you should test for CT	Estimated CT "positivity"	Estimated # positive for CT
Age 10-19	100	100	8.0%	8
Age 20-24	200	125	5.3%	7
Age 25+	100	0	4.0%	0
Reserved	-	25	13.0%	3
Total	400	250	7.2%	18

Additional cases detected last year to this year:	4
% increase in cases detected:	28.0%

INNOVATION 2

SELF-COLLECTED SPECIMENS



Specimen Source Options

- Endocervical
- Urethral
- Urine (patient-obtained)
- Vaginal swab (patient- or clinician-obtained)
- Other sites
 - conjunctival, rectal, pharyngeal



Advantages of Self-Obtained Vaginal Swabs (SOV)

- Highest sensitivity/specificity – better than urine
- Highly acceptable to women
- Avoids pelvic examination
 - Efficient & improves outreach to underserved populations



Washington State IPP Innovations

2007

1st Q 2008 SOV data monitoring begins

2008

CSPS grant objective for 2009: “make vaginal swabs specimen of choice”.

2009-2010 Mailings to clinics (research articles and materials developed by regional IPP)

2009

Late 2009-2010 Follow up with slow adopters

2010 Modified CSPS grant objective to replacing urine with SOV

2010

Jan 2010 Region X vaginal swab webinar w/ Dr. Jeanne Marrasso

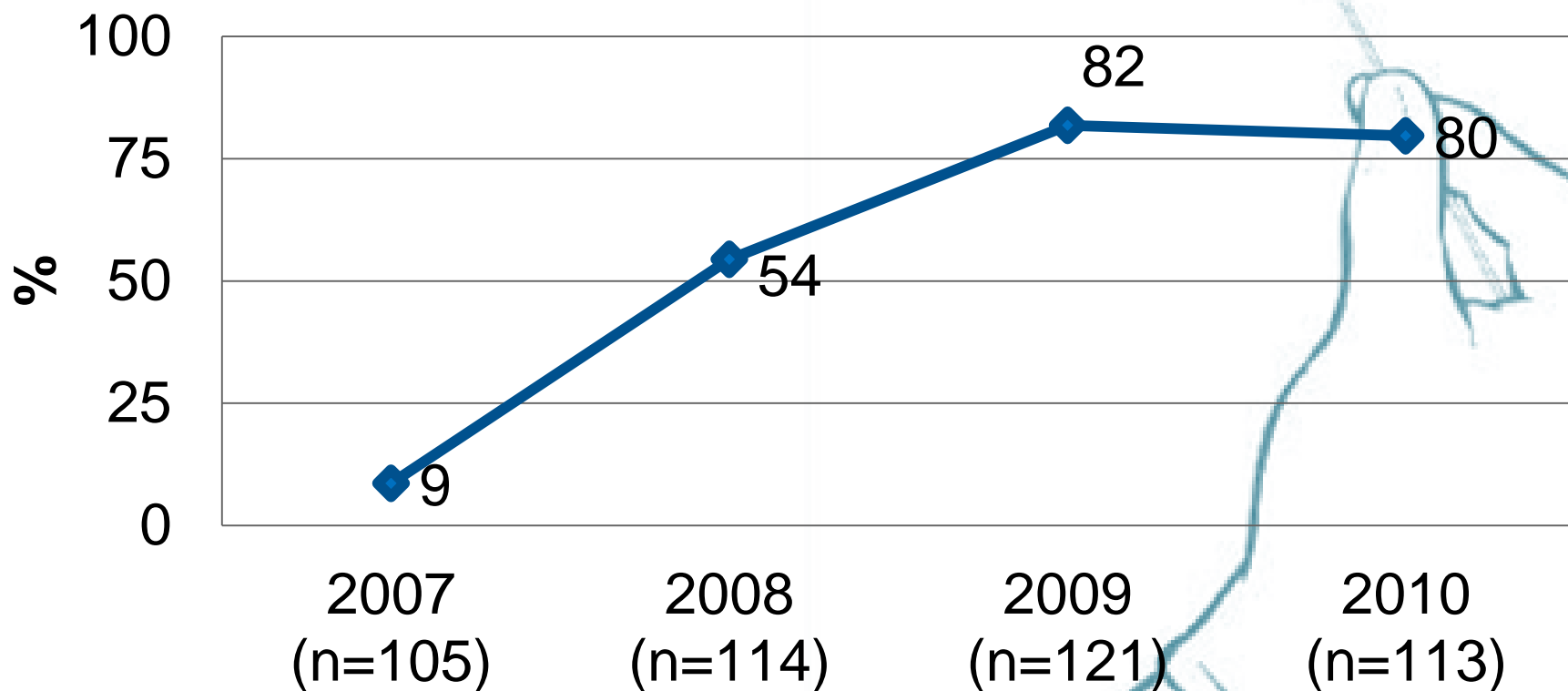
Dec 2010 WA State IPP webinar featured vaginal swabs

2011

2011 Spokane and UW labs validate SOV for use outside the clinic

2011 Region X IPP vaginal swab toolkit made available online

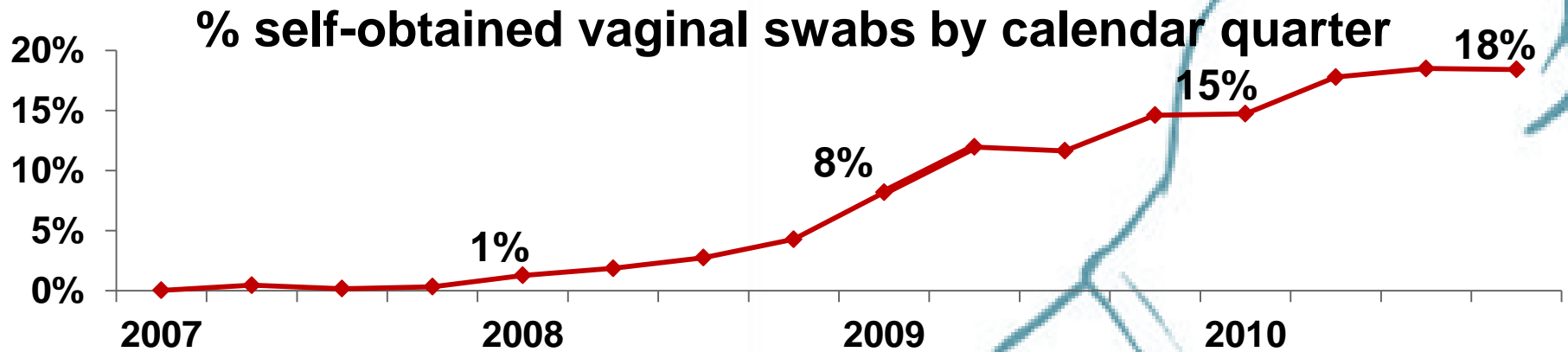
Results: % of clinics using SOV



P < .001

SOV use by clients

Year	# of CT/GC tests (females)	# SOV	Percentage
2007	48,223	123	0.3%
2008	51,306	1290	2.6%
2009	54,055	5984	12.4%
2010	44,292	7,645	17.0%



Predictors of SOV use, given availability in clinic (2010)

Multivariate Logistic Regression

Covariates: Age, Clinic Type, Race/Ethnicity, CT Symptoms, Pregnant
(n= 36,710 visits to 90 clinics)

Characteristic	% SOV	AOR	95% CI
Age			
10-19	28.9	2.54	(2.28, 2.82)
20-24	17.0	1.70	(1.52, 1.88)
25-29	10.6	1.10	(0.97, 1.25)
30+	9.0	REF	
Clinic Type			
FP/RH	18.3	REF	
STD	18.9	0.89	(0.69, 1.15)
College Health	15.2	0.50	(0.41, 0.61)
Adolescent school-based	61.4	5.21	(4.57, 5.92)
Community Health	5.9	0.52	(0.43, 0.62)
Other	9.8	0.58	(0.48, 0.7)

IPP vaginal swab tools



http://cardeaservices.org/projects/ipp_X.html

- Laminated patient instruction placards
- Vaginal swabs toolkit for clinicians

- Vaginal swabs toolkit contents
 - Sexual risk assessment – the 5 Ps
 - Selective screening criteria
 - Advantages/disadvantages table
 - COV & SOV Tip sheets
 - FAQs
 - Positive follow up record
 - Bibliography



Directions for vaginal swab collection (for patients)

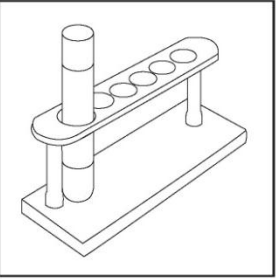


Figure 1

1

Open the vaginal swab collection kit.

2

Remove tube from package and place in test tube rack as shown in **Figure 1**. If there is no test tube rack, please check with clinic staff.

Remove cap from test tube without touching the inside of the cap or tube. If cap is dropped please notify clinic staff.

3

Remove swab package from collection kit.

4

Open the swab package as shown in **Figure 2**.

5

Remove the swab; do not touch the soft tip or lay the swab down.

6

Hold the swab as shown in **Figure 3**.

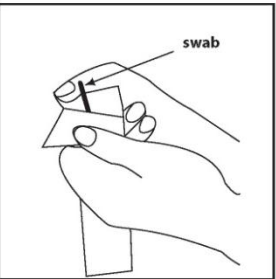


Figure 2

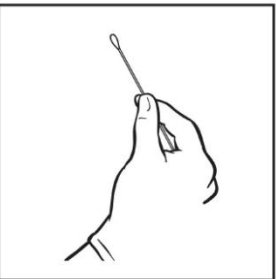


Figure 3

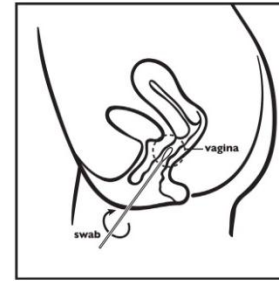


Figure 4

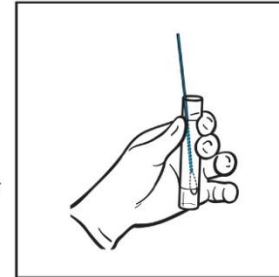


Figure 5

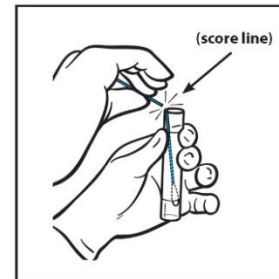


Figure 6

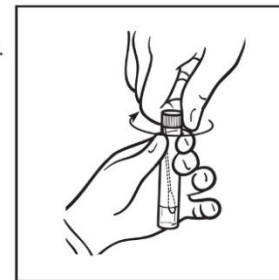


Figure 7

7

Insert the swab into your vagina about two inches as shown in **Figure 4**.

8

Gently rotate the swab for 10 to 30 seconds in your vagina.

9

Withdraw the swab without touching the skin.

10

Place the swab into the test tube so that the tip of the swab is visible below the tube label as shown in **Figure 5**.

11

Break the swab shaft against the side of the tube as shown in **Figure 6**; use care to avoid splashing the contents of the tube. If tube is dropped, contents spilled, or if the swab flips out of the tube, please notify clinic staff.

12

Re-cap the tube tightly as shown in **Figure 7**.

NOTE: If you have any questions about this procedure, please ask your clinic staff.

Please turn page over

Self-Collected Specimens Summary

WHAT?

- Vaginal and urine-based specimen collection for CT/GC testing

WHY?

- Screening efficiency – does not require physical exam
- Best sensitivity and specificity (vaginal swabs)

HOW?

- Educate & train clinicians; change clinical protocols and lab processing

LESSONS LEARNED

- CT/GC screening protocols need to be updated from 'screen at annual exam' to 'screen at first visit of the year'
- Best way to test young women



INNOVATION 3

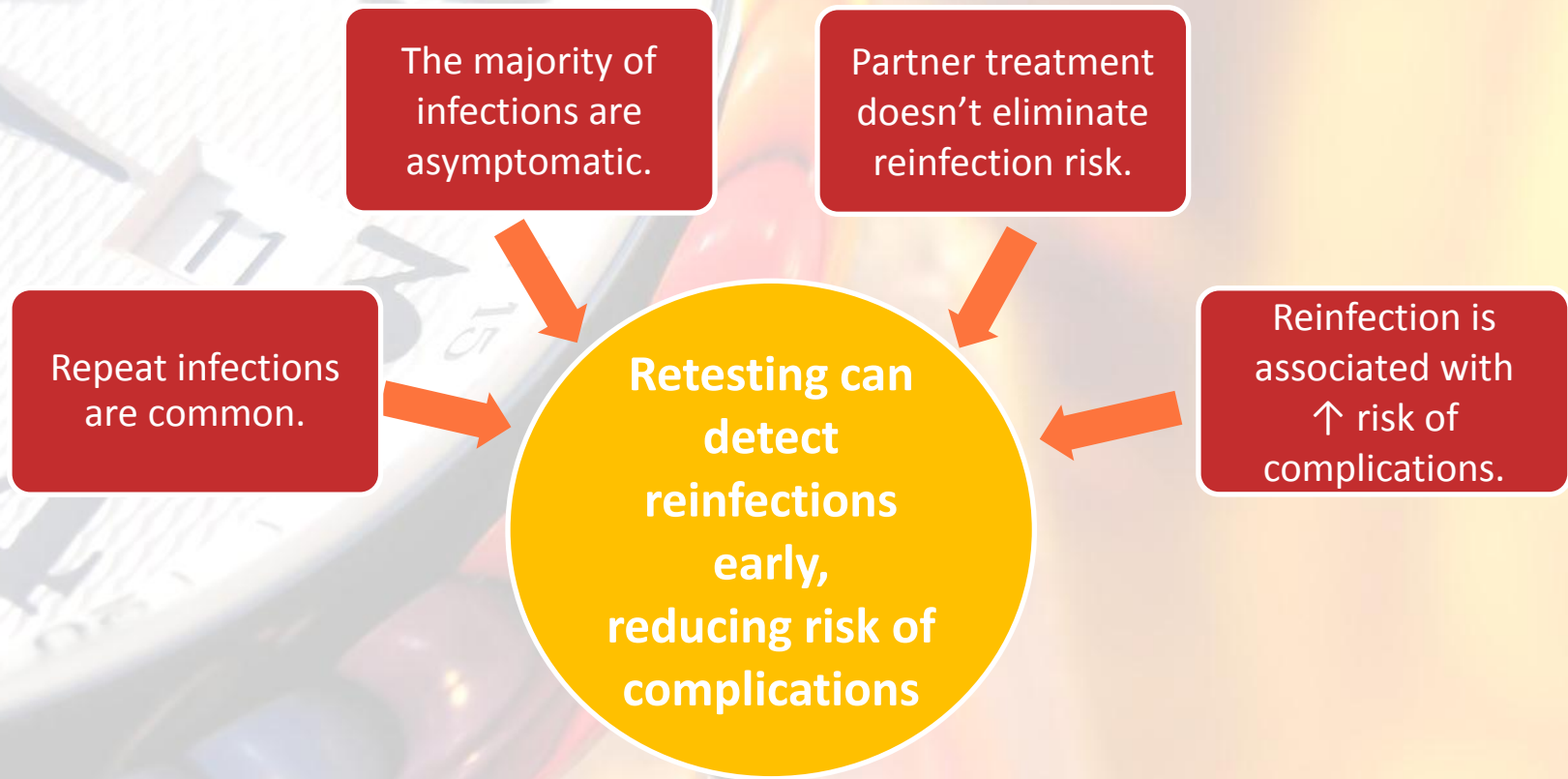
RETESTING



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Why Is Retesting a Priority?





Chlamydia and/or Gonorrhea -infected women and men should be retested approximately 3 months after treatment.

If retesting at 3 months is not possible, clinicians should retest whenever persons next present for medical care in the 12 months following initial treatment.

Related Studies

- *A Closer Look: Barriers and Opportunities to Improve Chlamydia Retesting Rates* by Goldenkranz and Fine
 - 61% of patients did not return
 - 38% of returned patients not retested by clinics = “missed opportunities”
 - Overall, 76% were not retested
- *Missed Opportunities for Chlamydia Retesting at Limited Service Visits in California FP Clinics* by Howard et al
 - 38% of patients did not return
 - 31% of returned patients not retested by clinics
 - Overall, 57% were not retested

Related Studies

- *Retesting for Repeat Chlamydial Infection: Family Planning Provider Knowledge, Attitudes, and Practices* by Park et al
 - “Retesting is difficult because patients will not return” = 73%
 - “Strategies to improve retesting are too difficult to implement” = 50%
- *Interventions to Increase Rescreening for Repeat Chlamydial Infection* by Guy et al
 - Mailed screening kits and phone reminder systems
- *Use of Home-Obtained Vaginal Swabs to Facilitate Rescreening for Chlamydia trachomatis Infections* by Xu et al
 - significant increases in rescreening rates compared with clinic-based rescreening

What are *feasible* and *effective* Interventions that can be introduced now?

Organization-Level:

Lack of policies prioritizing retesting services

Patient-Level:

Patients not understanding importance of retesting

Interventions targeted to various levels may be needed to address specific barriers to retesting

Patient-Level:

Patients not returning to clinic

Clinic-Level:

Missed opportunities for retesting returning patients

Retesting Summary

WHAT?

- Re-test males and females positive for CT

WHY?

- Individuals with prior CT+ are at increased risk of being infected again and adverse outcomes (ectopic pregnancy, PID)

HOW?

- Ideal window: 1-6 months after initial diagnosis
- Patient counseling; Reminder calls/texts; EHR prompts

LESSONS LEARNED

- QI efforts should target both client return rates and provider “Missed Opportunities”



Retesting Resources



Webinar – July 2012 *Evidence-Based Interventions for Increasing Chlamydia and Gonorrhea Retesting Rates*

Recording and slides available at:

http://cardeaservices.org/training/webinars/web_ebi.html

- **Holly Howard, MPH**
 - Chief, Program Development and Evaluation Section; California Department of Public Health, STD Control Branch
- **Wendy Nakatsukasa-Ono, MPH**
 - Program Director, Cardea Services



In Touch

www.InTOUCH4Health.org

- Clinical practice guidelines, resources for patients and providers
- Created by California DOH STD Control Branch with funding from the Office of Population Affairs

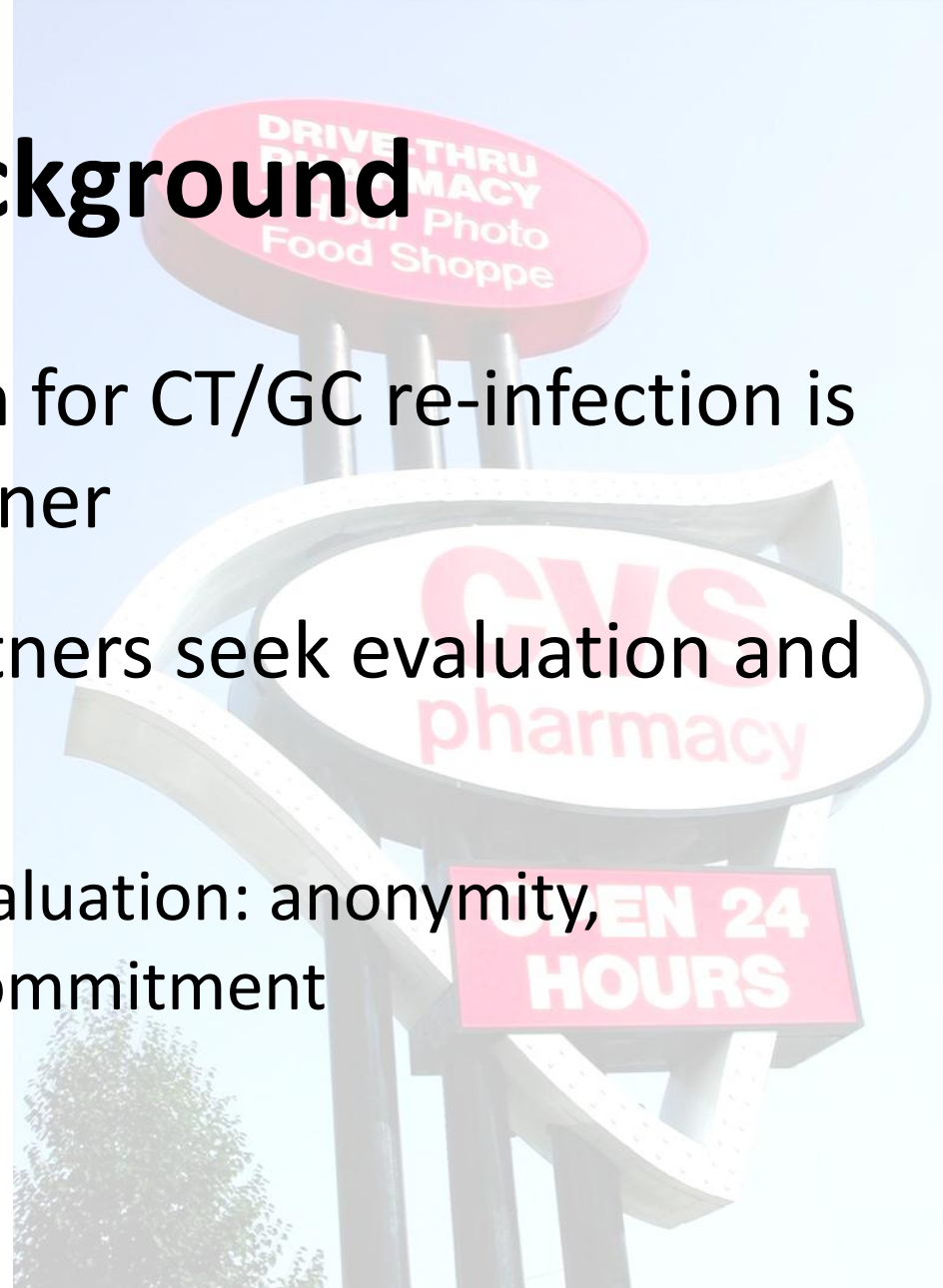
INNOVATION 4

EXPEDITED PARTNER THERAPY



EPT Background

- Most common reason for CT/GC re-infection is an untreated sex partner
- Only 29%-59% of partners seek evaluation and treatment
 - Barriers to seeking evaluation: anonymity, unwillingness, time commitment

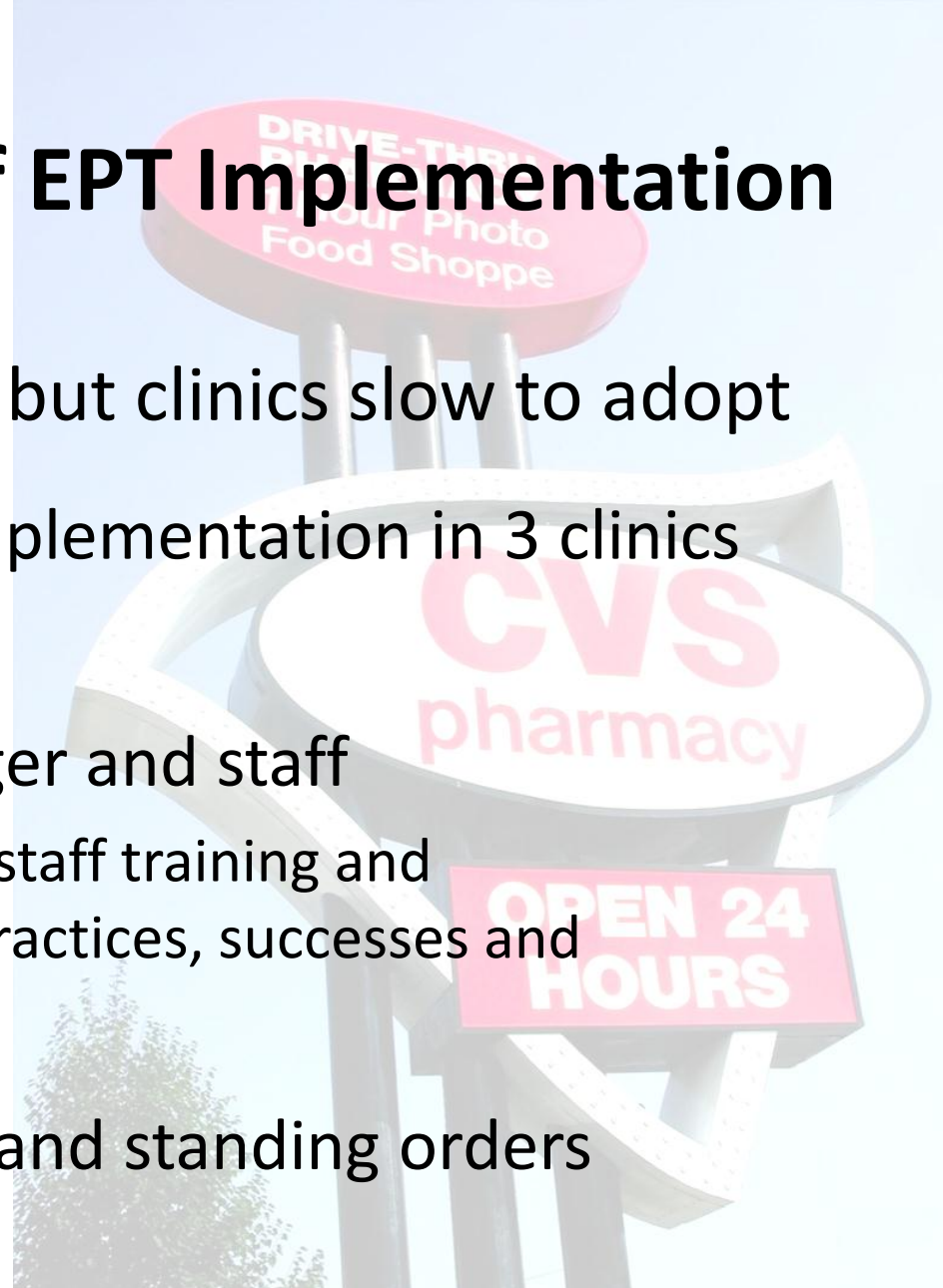


EPT Background

- Definition: *Providing medications or a script to the patient to take to his/her partners without a provider examining the partner*
 - Expedited Partner Therapy (EPT)
 - Patient-Delivered Partner Therapy (PDPT)
- Prevents re-infection and further transmission
- Now legal in 32 states; potentially allowable in 11

Qualitative Study of EPT Implementation

- EPT now legal in Texas, but clinics slow to adopt
- Small study evaluated implementation in 3 clinics pioneering EPT
- Interviewed clinic manager and staff
 - EPT protocol development, staff training and implementation, provider practices, successes and challenges
- Examined EPT protocols and standing orders

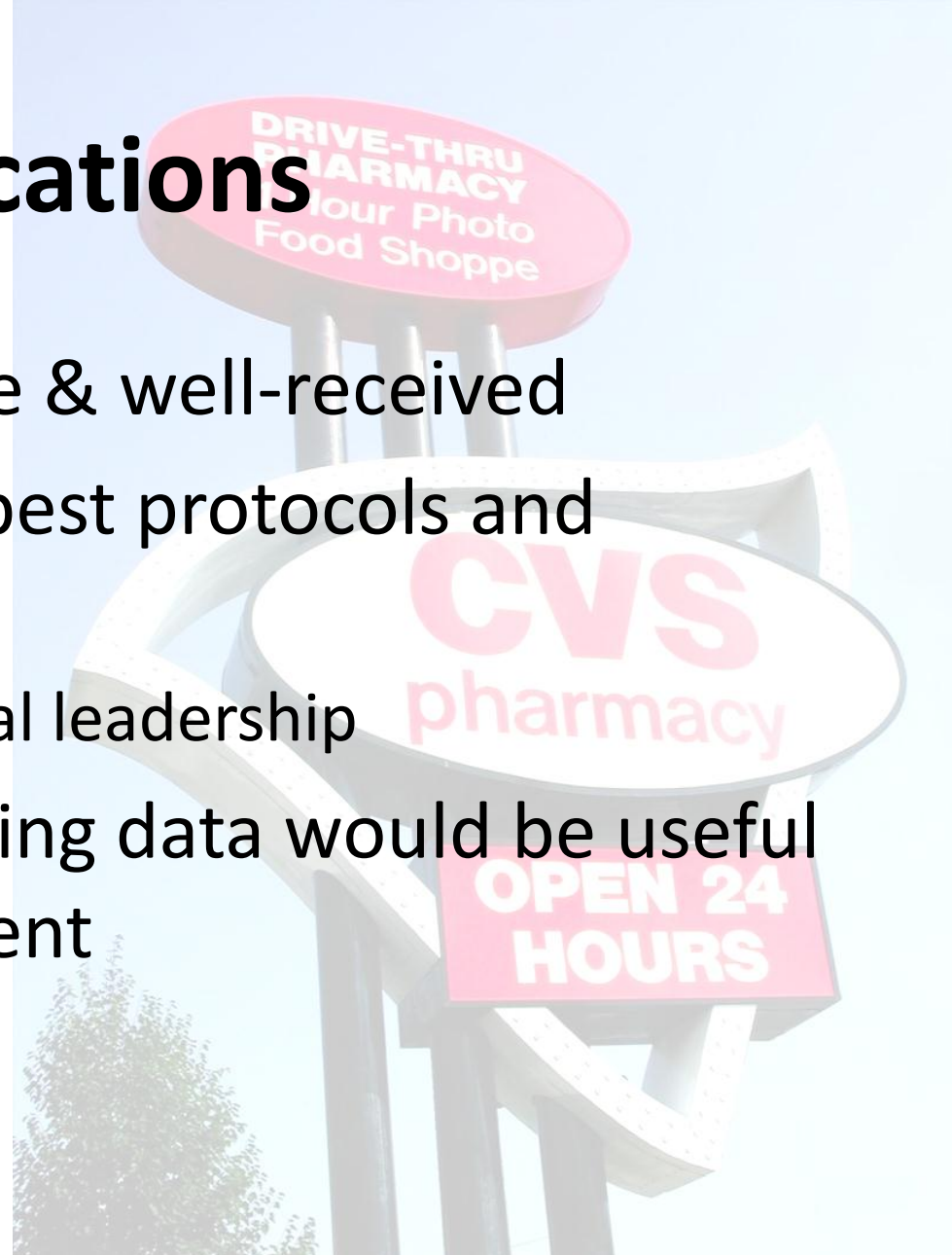


Qualitative Study of EPT Implementation: Results

- ✓ **Implementation was smooth (3/3)**
 - Staff generally supportive; positive response
 - Provided meds prior to official adoption of EPT (2/3)
- ✓ **Protocols & practice vary substantially**
 - Counsel patients & provide written info (3/3)
 - Large variation in eligibility criteria & provider decision-making process
 - CT, GC (3/3)... and Trich? (1/3)
 - Protocol ≠ practice (1/1)
- ✓ **Data is poorly collected & never reviewed**

Implications

- EPT in Texas is feasible & well-received
- No consensus about best protocols and practices
 - Reflects state & federal leadership
- Collecting and reviewing data would be useful for quality improvement



New July 2012 New Resistant GC Response Plan

“State and local health departments and CDC should continue to evaluate the role and advisability of expedited partner therapy (EPT) after the emergence of Ceph-R NG... decision-making may be based upon regional GISP data.”

“**Exposed sex partners** should be informed that dual therapy with ceftriaxone and either azithromycin or doxycycline is the most effective treatment for gonorrhea, and **should be strongly advised to present to a clinic** for dual treatment that includes ceftriaxone. However, for heterosexual patients with gonorrhea whose partners are unlikely to seek evaluation and treatment, EPT using cefixime and either azithromycin or doxycycline can be considered. This approach should always be accompanied by efforts to encourage partners to seek clinical evaluation and to educate partners about the need for test of cure if a cefixime-based regimen is used.”

Test of cure is needed if a cefixime-based regimen is used

Expedited Partner Therapy Summary

WHAT?

- Treatment provided to sex partners of CT/GC+ patients (no clinic visit required)

WHY?

- Prevention of re-infection and transmission when it is difficult to get partners into clinic

HOW?

- Medication or script provided to index patient upon diagnosis to take to partners (depending on state law)

LESSONS LEARNED

- Substantial variation in protocols and practice
- Resistant GC?

EPT Resources



Centers for Disease Control and Prevention

<http://www.cdc.gov/std/ept/default.htm>

Variety of resources including:

- Guidelines
- Legal Status of EPT by Jurisdiction
- Legal/Policy Toolkit for Adoption and Implementation of Expedited Partner Therapy



New July 2012 New Resistant GC Response Plan

<http://www.cdc.gov/std/treatment/Ceph-R-ResponsePlanJuly30-2012.pdf>

Addresses EPT in context of resistant GC



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EPT Resources



Texas Department of State Health Services

<http://www.dshs.state.tx.us/Layouts/ContentPage.aspx?PageID=34561&id=5374&terms=expedited+partner+therapy>

Variety of Provider tools and fact sheets for patients and partners (English and Spanish):

- Treatment Fact Sheet for Sex Partners of Persons with Chlamydia
- Patient-Delivered Partner Therapy Log
- Model Partner Fact Sheet for Chlamydia Trachomatis



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INNOVATION 5

POOLING SAMPLES



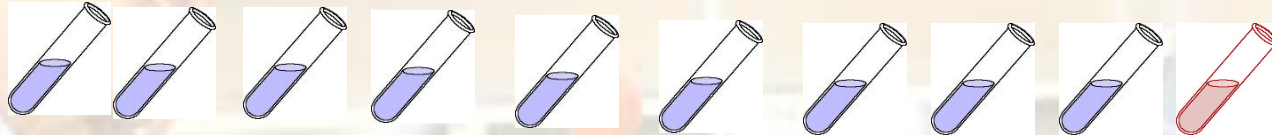
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Pooling Background

- NAAT tests are most sensitive and specific, but expensive
- Pooling saves lab reagents and time
- Pooling is combining samples from multiple patients for processing

What is Pooling?

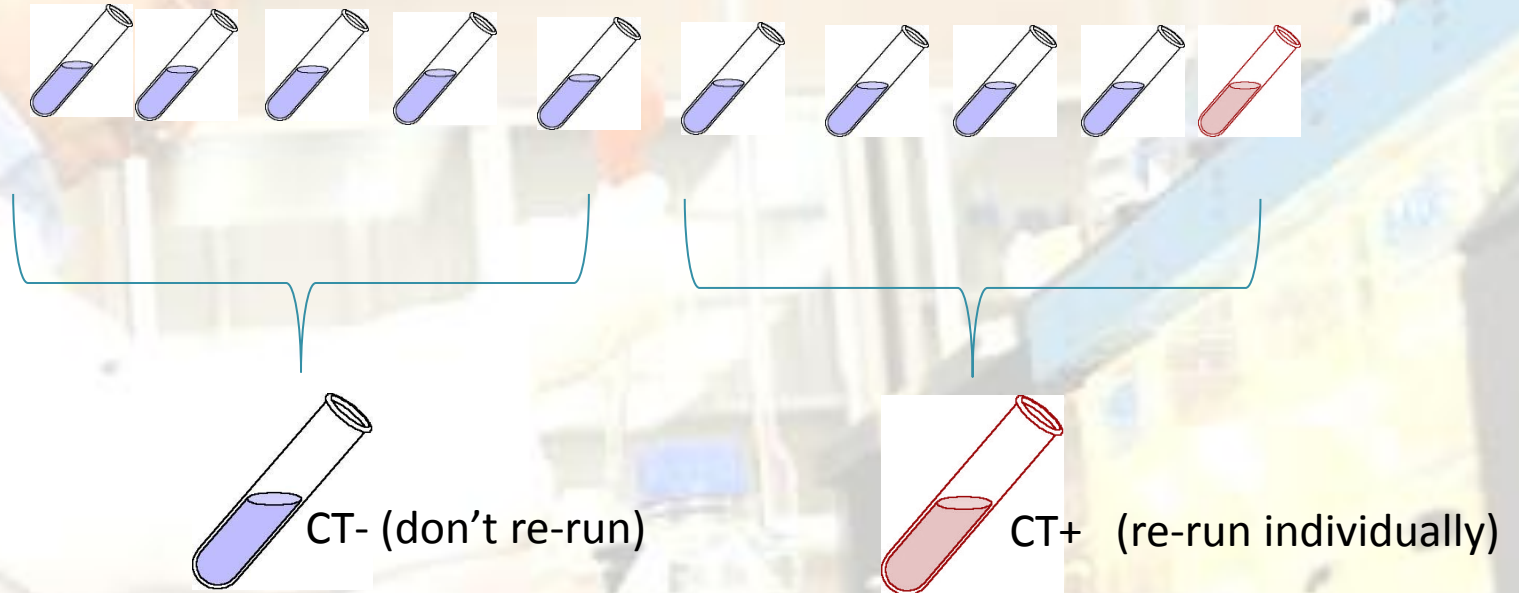


10% positivity = 1 in 10 samples are positive

10 samples = 10 tests

Ratio: 10 tests per 1 positive result

What is Pooling?



Ratio: 7 tests per 1 positive result

✓ More efficient

Pooling Background

- Efficiency and accuracy are affected by:
 - positivity
 - pool size
 - distribution of positive specimens within pools
- Maximum pool size recommended – 5

Potential for Significant Savings

Currie et. Al. 2004 - Pooling resulted in cost savings without significant loss of accuracy

- 4.5% CT+; pooling 5 specimens
- 60% reduction in the number of tests performed
- 39% reduction in total costs
 - 43% reduction in the quantity of reagents used
 - 55% reduction in the costs of other consumables
 - 26% reduction in technologist's time

Positivity varies within populations

Idaho Public Health lab study, 2012

- Pooling most efficient for low positivity populations
- Reason for visit indicated on lab slip
 - “Exposed to CT/GC” and “Rescreening for CT or CG” have high positivity
- Moved from standard pooling to a stratified pool design:
 - Run ‘exposed’ and ‘rescreen’ samples separately
 - pool all other samples

Idaho Results

- % of samples requiring repeat testing (positive) decreased from 31.9% to 22.7%
 - 9.2% reduction in total number of tests
- Stratified pool design saved >\$2K/month in lab direct costs

“little impact on personnel resources... an easy and advantageous strategy”

Pooling Summary

WHAT?

- Combining and running multiple specimens together during lab processing

WHY?

- Extremely cost-saving in low-prevalence populations (<9% positivity)

HOW?

- Combine several specimen into single test tube
- If positive result, re-run samples individually

LESSONS LEARNED

- *Specimen pooling can be optimized based on positivity data*

Pooling Resources



Laboratory Diagnostic Testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

<http://www.aphl.org/aphlprograms/infectious/std/documents/ctgclabguidelinesmeetingreport.pdf>

Expert Consultation Meeting Summary Report 2009

- Describes pooling and other recommended lab procedures for CT/GC testing



Association for Public Health Laboratories

<http://www.aphl.org>

Conclusions

Free resources are available from Cardea and the Centers for Disease Control Division of STD Prevention

5 cost-effective innovations to improve case detection

- Screen adolescent women
- Self-collected specimens
- Expedited Partner Therapy
- Re-testing
- Pooling Samples

Thank You

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