

Region VIII IPP Strategic Plan
Implementation Plan
Lab Services Workgroup

2005-2008 Regional Plan Priorities

Goal 1: Assure availability of lower cost and quality lab technologies.

Objectives/Outcomes 1: By May 2006, the Lab Services workgroup will consider implications of pooling NAAT specimens (limitations and benefits).

Comments:

The Colorado State Lab volunteered as the regional study site to determine cost effectiveness and feasibility of pooling.

The study attempted to determine the following in relation to implementing pooling:

- Determine flow
- Pro/cons with pooling
- Savings realized

The lab started pooling in November 2007. Findings from the pilot were:

- Stopped pooling-mainly due to limitations of the computer system
- Pooling does save money for reagents but there are increases in technician time, stress and turn-around-time
- Pooling doesn't have an impact on obtaining accurate results or reproducibility.

*Good read, RLUs are as expected

*300 RLUs on primary sample might dilute results. Assessment planned to determine what the incidence of dilution might be.

The report of the pooling feasibility study is the final activity for this objective. The intent of the report is to communicate uses and limitations of pooling in the laboratory. The report will address

- A national perspective of pooling—what other regions are doing and
- Regional implications and how to address them
- Advantages/disadvantages (costs, equipment needs)

Activities	Who	By When	Status
1.1a – CO Lab representative will draft a report of the pilot study and share with Lab W/g for comments.	CO Lab representative-Lab W/G	1/20/09	
1.1b – Lab W/g will review draft report and provide comments back to CO by 1/30/09	Lab W/g	1/30/09	

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1.1c – Final report will be shared with w/g by 2/2/09, prior to the next w/g call.	CO Lab representative	2/2/09	
1.1d – Final report will be approved on the next w/g call, 2/4/09.	Lab W/g	2/4/09	
1.1e – The report will be distributed and presented at either the Spring or Fall 09 RAC meeting.	Lab W/g-CO Lab Representative	TBD	
1.1f - Suggested strategies will be incorporated into Project Area activities when possible.	Project Area Partners	On-going	

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Goal 2: Promote the use of high quality diagnostic testing for Chlamydia and Gonorrhea through innovations in lab testing.

Objectives/Outcomes 2: By May 2007, develop Regional Capacity to Test Alternate Site Specimens

Comments:

A recent goal of the Region VIII Infertility Prevention Project (IPP) was to validate the use of the GenProbe APTIMA Combo 2 assay for the detection of *C. trachomatis* and *N. gonorrhoeae* from rectal and pharyngeal specimens. This accomplishment represents both multi-state lab collaboration as well as collaboration between lab and program. The need for alternate site specimen testing was first brought to the Committee by a Family Planning partner. At that time, no labs in Region VIII had the capacity to provide pharyngeal or rectal testing and it was difficult for each lab to perform verification since volumes were quite low. Due to these barriers, the Utah Public Health Laboratories (UPHL) agreed to act as the regional lab to process alternate site specimens.

Progress on this goal was initiated by determining the potential alternate sites testing need; the lab w/g surveyed clinics about how many rectal, pharyngeal, and vaginal CT/GC tests they would order each month.

- Survey question: If an alternate site (rectal or pharyngeal) test were available for CT/GC, do you perceive a need for it in your clinic?
- Survey results summarized and sent to JSI to summarize by state
- Determine potential alternate sites testing need
 - Wyoming: half of clinics perceive a need
 - Colorado: varies, some perceived need
 - North Dakota: probably wasn't much of a need
 - Oral: maybe 5 a month
 - Maybe 2-3 alternate site collections a month
 - Conclusion: 30-50 per month

The UT Lab representative wrote a report summarizing the results with the intent that the STD and FP partners could share with the clinics as a way to promote the regional capacity to test these alternate site specimens with Aptima. The report was also submitted to the monthly CDC/STD Program Newsletter, The Thursday Report.

UT will continue to be the laboratory for this region because volumes are quite low.

Lab workgroup will write-up information to promote the ability to test pharyngeal and rectal specimens for CT and GC in order to get

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the word out about this service.

- The following activities were identified in the 2005-2008 plan but were tabled at the time. Are they pertinent now or are they not applicable:

Write a letter to CDC about rectal validation pushing along validation protocol-- Will wait to write until after we know plans for guidelines

Write a letter to Dr. Douglas about guidelines- Include need for alternative site validation and Check with John Papp to see if this is the correct way to approach

- John is developing a protocol that will meet with CLIA requirements, and is assembling a panel of specimens that can be used for validation.
- It is becoming more difficult to validate off label used due to CLIA regulations
- Letter to CDC was not written

After the National CT Laboratory Committee met, it didn't look like that was the way to go. Instead, we could work directly, with a laboratory that has already validated the rectal and throat specimens for CT and GC (such as Sally Liska's lab in San Francisco). STD Steering committee of APHL (which reports to Infectious Disease Committee of APHL) discussed a proposal from San Francisco that contained guidance for validating the off label use of NAATs. It was decided to poll the other IPP regions to see if they have discussed our Region VIII approach; a regional response to getting one laboratory validated for these specimens, so that all the states in that region could send specimens to that one laboratory for testing.

Activities	Who	By When	Status
2.1a – Lab workgroup will write-up information to promote the ability to test pharyngeal and rectal specimens for CT and GC in order to get the word out about this service.	Lab W/g	1/9/09	MT Lab shared 2 documents with the rest of the w/g: protocol and collection instructions.
2.1b – Each lab representative will tailor the information from MT for their program area	Lab W/g	1/23/09	
2.1c – Notify Family Planning & STD partners re: alt. spec. testing referral by sending the protocol, instruction and validation study.	Lab W/g	1/30/09	
2.1d – Lab W/g will continue promote the alternate site specimen testing ability with their partners.	Lab W/g	On-going	

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2005-2008 Regional Plan Priorities

Goal 3: Promote the use of high quality diagnostic testing for Chlamydia and Gonorrhea through innovations in lab testing.

Objectives/Outcomes 3: By June 2008, determine how long residual RNA is detected, after antibiotic treatment, for a positive *Chlamydia trachomatis* infection when testing with amplified technology using the APTIMA Combo 2 Assay

Comments:

The special project was submitted as a collaborative project with JSI Research & Training Institute-Denver and Wyoming Public Health Laboratory as Lead Research Entity. The initial timeline for the project was planned for September 1, 2007 to June 30, 2008. However, the lead research entity has met several barriers which have impacted their ability to implement the project. Please see the original proposal below as well as a description of barriers and solutions at the end of the report.

The study attempts to determine how long residual RNA is detected, after antibiotic treatment, for a positive *Chlamydia trachomatis* infection when testing with amplified technology using the APTIMA Combo 2 Assay. Previous CDC recommendations, based on older testing technology, suggest waiting for at least 3 weeks before follow-up testing. With newer amplified technology, residual RNA from nonviable organisms may still be detected after 3 weeks, which could be mistaken as treatment failure.

DESCRIPTION: Current CDC Guidelines (U.S. Centers for Disease Control & Prevention) suggest an interval of at least 3 weeks before follow-up testing after a positive *Chlamydia trachomatis* infection has been treated¹. Previous studies to monitor persistence of chlamydial RNA/DNA after therapy were done with earlier amplification assays²³. With newer amplified technology, minute amounts of nonviable organisms may be detected longer than 3 weeks post treatment. In some instances the residual RNA/DNA may be mistaken as treatment failure. This study proposes following 50 CT positive female patients by testing sequential urine specimens for 6 weeks and/or until 2 consecutive urine specimens test negative for CT.

EXPECTED RESULTS: It is expected that the amplification technology used in the APTIMA Combo 2 assay will find residual chlamydial RNA in samples longer than 3 weeks after antibiotic treatment.

PROGRAM IMPLICATIONS: Determining how long residual *Chlamydia trachomatis* RNA from nonviable organisms can be detected after antibiotic treatment has large implications. Misinterpretation of positive results post treatment may lead to additional unnecessary treatment, which in turn could lead to resistant bacteria. Current CDC Guidelines suggest an interval of at least 3 weeks before follow-up testing after infection. The study may implicate a revision of the guidelines is necessary, suggesting a longer interval before retesting. Additionally, participants may benefit directly from the study; 1) If the required criteria are met and the time frame is completed, a monetary benefit in the form of a Visa card will be presented; 2) If the sequential urine specimens show treatment failure, alternate treatment may be necessary, which would have gone undetected without the study results; [Question about program implications item 2: It says that it might

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be able to identify treatment failure. How would that work, since there is no culturing involved? How would we know that it was treatment failure and the organism was still viable?]

3) Clinician involvement, when assuring sexual diary entries are complete, may result in opportunities to increase patient awareness concerning safe sexual practices.

Barriers Encountered:

The study has been given IRB approval through the WDH Institutional Review Board, but some obstacles have surfaced.

- This study is covered by “special study funding” but is behind schedule (originally targeted for 6/30/08 completion), so there is now a September 08 start date to coincide with college students returning back to campuses.

- In general, there has been a limited number of sites that have signed on to participate, so perhaps the study could be opened up to others states in an effort to increase study numbers. However, the lead research entity, Wyoming Public Health Laboratory, has identified two sites which have begun to enroll participants. Additionally, Montana, Colorado and South Dakota have expressed an interest in trying to have at least one site participate. These individual states should also try to identify one or two potential sites and notify JSI with this identification.

- Since some states (i.e., Montana and South Dakota) do not have their own IRB, JSI will research whether a blanket IRB approval could be granted through JSI.

- The goal is to have at least 75 women enrolled, expecting 50 to complete the 6 week program.

- The revised timeframe is Sept 1, 2008 to March 31, 2009. This allows for enrollment from Sept 1 to Dec 31 2008. Analysis and reporting Jan 1 to March 31, 2009.

- JSI requested an extension on the project period with CDC.

Indicators of success:

- Enrolling 75 females with at least 50 completing the 6-8 week study period.

At the time of the Jan Lab w/g call, WY had only enrolled 1 participant from one site with an initial positive but no other positive specimens since.

How many sites from WY are participating?

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Activities	Who	By When	Status
3.1a – Add more sites and turn into a regional study	RAC	1/30/09	Claudia presented the study to the RAC at the Nov 08 meeting. UT and MT expressed an interest in having a site participate.
3.1b – Sending packets of info to states	WY lab representative/JSI	12/1/09	Information was sent to MT and UT.
3.1c – Confirm with UT FP: potential recruiter for enrollees before opening the study up to additional states	Wy Lab representative	1/14/09	
3.1d – Obtain confirmation of participation from UT FP clinic	WY Lab and UT FP representatives	1/23/09	
3.1e – JSI to draft clinician form mirrors sexual diary questions.	JSI	1/16/09	Completed. Forms were sent to Lab w/g for review and comments.
3.1f – Wy lab representative to draft an IRB amendment for utilization of clinical sexual history forms and adding sites.	WY lab representative	1/30/09	

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2009-2011 Regional Plan Priorities

Region VIII Goal and National IPP Priority Area 1: Promote the use of high quality diagnostic tests for Chlamydia and Gonorrhea at the most competitive price.

Objectives/Outcomes 1: By December 1, 2009, collaborate with Gen Probe, CDC and NLC consultant to negotiate “regional” public health pricing for Chlamydia and gonorrhea laboratory tests in Region VIII.

Comments:

Relates to Region VIII Priority Area 3: Assure availability of lower cost and quality lab technologies.

- NCLC, Rick Steece, contacted Charlotte Kent at CDC to see if CDC was pursuing national pricing; they are not pursuing national pricing.
- All of the labs which are using GP Aptima kits are not interested in doing standing orders with GP.
- Overall Region VIII labs get a good price with GP and there haven't been any price changes in a while. However, if any of our states decided to test with the new Abbott product, we could lose our regional GenProbe pricing, which could result in a price increase. If all the states continued to use GenProbe, the pricing decrease with competition. The Abbott product is FDA cleared but not for all specimen types.

The w/g would like to review current pricing across the region. JSI and NCLC will draft a format in which to collect the information (modeled on the Azithromycin price sheet that CDC does every 2 years). Once the baseline pricing is collected, the w/g will update it on a regular basis as well as invite the other regions to contribute their pricing information.

Indicators of success:

Complete review of regional pricing (for accuracy)

Gathering national pricing

Once baseline information has been collected, a bi-annual review should be conducted (unless a specific state changes technology)

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Activities	Who	By When	Status
1.1a - Determine status of each lab and contract deadlines	Infrastructure Lab W/g		
1.1b - Work with Gen Probe Public Health representative and NCLC consultant to determine possible price and volume options available as a region	Infrastructure Lab W/g		
1.1c - Depending on results, negotiate regional pricing	Infrastructure Lab W/g		

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2009-2011 Regional Plan Priorities

Region VIII Goal and National IPP Priority Area 1: Promote the use of high quality diagnostic tests for Chlamydia and Gonorrhea through innovations in lab testing.

Objectives/Outcomes 2: By December 1, 2009, disseminate the results of the study to determine how long RNA is detected after antibiotic treatment for a positive Chlamydia trachomatis (CT) infection when testing with amplified technology using APTIMA Combo 2 Assay.

Comments:

Relates to Region VIII Priority Area 10: Establish baseline reinfection rates.

JSI will try to identify a MPH student to help write rough draft and data compilation.

The following activities will help support the achievement of this strategic action:

- The Infrastructure staff, in collaboration with the Wyoming Public Health Lab, will write up the final results of the study.
- The Infrastructure staff will facilitate consideration of findings and presentation among advisory committee for future implications and action in relation to rescreening practices.
- The Infrastructure staff will disseminate the study findings to other regional Infertility Prevention Projects.

Activities	Who	By When	Status

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2009-2011 Regional Plan Priorities

Region VIII Goal and National IPP Priority Area 1: Promote the use of high quality diagnostic tests for Chlamydia and Gonorrhea through innovations in lab testing.

Objectives/Outcomes 3: Explore how the use of fast express (mucoytic agent) can facilitate repeat testing.

Comments:

Relates to Region VIII Priority Area 10: Establish baseline reinfection rates.

The anticipated impact of this objective and activities will be to confirm that by using FastExpress in an off-label way does not affect results. Additionally by reducing the number of tests that are repeated to improve PPV can result in cost savings to programs, allowing more screenings to be performed.

Activities	Who	By When	Status
Develop and distribute 6 verification panels (positives and negatives) for each of the Region VIII state PH Labs.	Mt Lab Representative	03/01/09	