

Regional Plan for Region VIII Infertility Prevention Project

2009-2011

This document comprises the regional plan for the Region VIII Infertility Prevention Project. It reviews its strengths, weaknesses, threats and opportunities; presents a series of fundamental statements relating to the Region VIII Infertility Prevention Project's vision, mission, values and objectives; and sets out Region VIII Infertility Prevention Project's proposed strategies, goals and action programs.

Introduction

The DHHS Region VIII Infertility Prevention Project (IPP) aims to control Chlamydia and gonorrhea through the collaborative efforts of Sexually Transmitted Disease (STD), Family Planning (FP) and Laboratory Services providers throughout Region VIII. Region VIII is composed of six states (Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming). The STD and FP programs in Region VIII provide approximately 150,000 Chlamydia tests each year. The first full year of service began in 1994.

The project works to promote innovative, high quality and cost-effective approaches in the prevention of STD-related infertility, especially in adolescent girls and young adult women. Prevention approaches are designed to link surveillance, clinical, laboratory, behavioral and epidemiologic activities to prevent transmission of STDs that result in PID, infertility, and ectopic pregnancy.

The committee acts in an advisory capacity in the implementation of the goals and objectives of the CDC National IPP on the regional and project area level. Advisory Committee meetings are structured to enhance project area efforts in realizing national, regional and local IPP goals and objectives in the prevention of STD-related infertility. It is the ultimate goal of the regional process to inform, support and enhance STD-related practices across many disciplines and settings through the promotion and exploration of evidence and science-based programming.

Report Format

This report is divided into four sections. The first section of the report provides a brief description of the program. This section also includes a discussion of regional screening criteria. The second section includes the 2009-2011 Region VIII IPP Regional Plan. The Plan includes objectives and activities for the regional project that respond to National IPP Priority Areas and are organized by IPP Core Components as outlined the CSPS Application. Section three provides an update of progress made on 2005-2008 Regional

Plan objectives and activities; and section four provides a brief description of the Regional Protocols and Guidelines and summarizes how they are monitored.

Section 1: Program Description

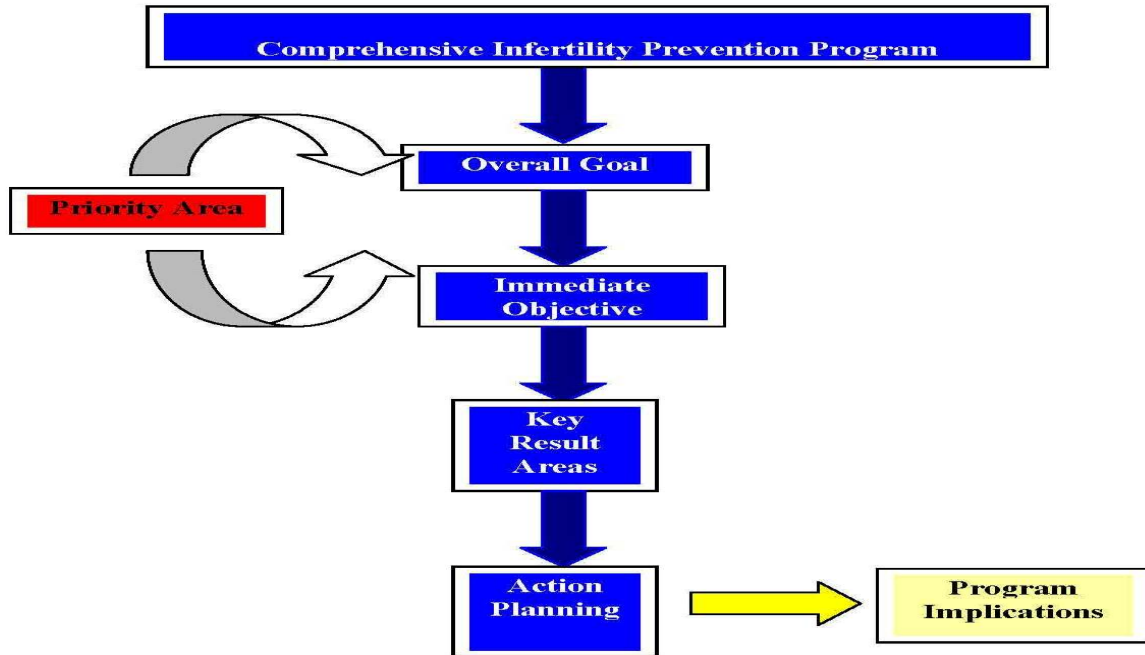
Purpose of the Region VIII Chlamydia Project

The purpose of the Region VIII Infertility Prevention Project (Regional Project) is to reduce the prevalence of Chlamydia infections in populations at risk of acquiring sexually transmitted infections through the collaborative efforts of sexually transmitted disease (STD), family planning (FP) providers and laboratories throughout Region VIII. Region VIII is composed of six states: Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming. Reducing prevalence will result in decreasing the morbidity associated with the complications of Chlamydia infection. These complications include pelvic inflammatory disease, ectopic pregnancy, chronic pelvic pain, epididymitis, and involuntary infertility, particularly in women.

Purpose of the Regional Plan

The Region VIII Chlamydia Project Advisory Committee and JSI have fully adopted the new approach to Regional Plan which serves as a mechanism to assist diverse programs create similar goals and objectives; provides a work plan for regional committee work; and provides a mechanism to assure accountability. Creating a long-range vision of the Regional Infertility Prevention Project and helping create a more comprehensive approach to Chlamydia screening, treatment and prevention within the Region are goals that the RAC wishes to accomplish.

Since 2003, the Region VIII Advisory Committee (RAC), facilitated by the infrastructure staff, initiated a comprehensive planning process. This process provides a systematic approach for addressing emerging challenges and for achieving the implementation of a strategic and operational work plan. Please see the schematic representation (below) of the strategic planning framework which the Region VIII RAC has fully adopted as the approach to assist diverse programs create similar goals and objectives. It provides a work plan for regional committee work and a mechanism to assure accountability. Creating a long-range vision of the Regional Infertility Prevention Project and helping create a more comprehensive approach to Chlamydia screening, treatment, and prevention within the Region are goals that the RAC wishes to accomplish.



The framework includes the following elements:

- A clearly stated **vision**;
- The **overall goal** of the project;
- The **immediate objectives** of the project;
- The **key result areas** on which the project intends to focus; and
- The **program implications**.

The program implications provide a common understanding of the gaps between where the project is and where it needs to be to achieve its goals and objectives and of the forces that are likely to help and hinder it. JSI and the RAC firmly believe that all these elements need to be in alignment; this means that they should complement one another. As a result of the alignment, the regional plan reflects upon and shape Region VIII's unique environment and influence all areas of implementation.

As a regional IPP infrastructure partner, JSI/Denver works to ensure that regional project goals are realized and expanded. The project staff provide technical assistance to individual project areas and are primarily responsible for:

- Coordination and promotion of cooperation and innovation among the project areas;
- Quality assurance and maintenance of a regional prevalence monitoring system;
- Data analysis and reporting activities;
- Promotion of project activities nationally; and
- Promotion for cost-effective screening and treatment activities.

Overview of the Region VIII Infertility Prevention Project

◆ Screening and Service Gaps

In accordance with the regional screening criteria, all women 25 years of age and under are being screened for Chlamydia. All other women are screened based on clinical signs or risk history. Every state has also initiated a certain level of male screening activities and projects. However, in order to ensure appropriate allocation of limited screening resources targeting high risk populations, grantees must describe Chlamydia tests performed in prevalence monitoring sites during 2007, among women < 25 years of age and among women ≥ 25 years of age. In addition to reviewing the number of tests and positivity among those women tested, the Region VIII IPP believes that before moving funds from a site with positivity below the 3% threshold, a site should reach at least an 80% screening coverage as well as having maintained a 3% or below positivity for two years.

The screening coverage is a regional measure of effectiveness. It is an estimate of Chlamydia screening coverage among sexually-active women attending family planning clinics, stratified by standard age groups. The table below reports an estimate of Chlamydia screening coverage among sexually-active women attending family planning clinics, stratified by standard age groups.

Chlamydia Screening Coverage
CY 2005-2007

	Age Group	# women screened	# women eligible	Estimated Screening Coverage (%)
CY 2005	15-19	17,446	43,578	40%
	20-24	20,155	52,089	37%
	>24	13,394*	52,218**	26%
	TOTAL	50,995	147,885	34.5%
CY 2006	15-19	18,699	46,750	41%
	20-24	20,807	52,899	39%
	>24	13,997*	51,088**	27%
	TOTAL	53,503	150,737	35.5%
CY 2007	15-19	15,221	37,708	40%
	20-24	18,274	37,161	49%
	>24	11,826	51,382	23%
	TOTAL	45,321	126,251	35.8%

*Agegroup is 25 and over

**Age groups are 25-29, 30-34, 35-39, 40-44, Over 44

Source: Family Planning Annual Report

In 2007, private providers, who submitted data to the Region VIII IPP database reported screening coverage was 26%, with the range being 12%-35%.

Additionally, the Region VIII IPP monitors the number of screening test utilized. It is an estimate of the number of women screened for chlamydia, stratified by age, among clients attending Family Planning Clinics.

The table reports a proportion of Chlamydia screening tests performed among women <25 years of age and \geq 25 years of age.

Chlamydia Screening Test Utilization
CY 2005-2007

	Age Group	# by age, group female tests utilized	Proportion of female tests utilized, by age
CY 2005	15-19	15,348	33%
	20-24	19,315	41%
	25-29	6,385	14%
	> 29	5,518	12%
	TOTAL	46,965	NA
CY 2006	15-19	10,104	27%
	20-24	17,208	45%
	25-29	6,084	16%
	> 29	4,460	12%
	TOTAL	37,856	NA
CY 2007	15-19	15,439	31%
	20-24	20,287	41%
	25-29	7,157	15%
	> 29	5,883	12%
	TOTAL	48,766	NA

The Region VIII IPP, in collaboration with the Steering Committee and Data Workgroup, will develop regional guidance and funding allocation formula in order to increase screening coverage in identified and prioritized high risk populations. This will be accomplished through the following activities:

- Conduct a regional assessment of the current screening criteria to ascertain if they vary by state.
- Conduct an analysis of the proportion of women being screened using current criteria and proportion of infections being identified by these criteria.
- Pilot formula using the previous year's data and present findings at the fall 2009 meeting.
- The pilot will result in the distribution of best practice guidelines for funding allocations based on a 3% positivity threshold which is maintained for two years, while also reaching at least an 80% screening coverage rate in our targeted high-risk populations.

♦ *Provider Selection and Screening Criteria*

As a region, providers who are able to provide services to targeted populations are selected to participate in the project. Providers are principally selected because they have access to high-risk and geographically diverse populations. Furthermore, expansion and outreach have brought on providers usually found in non-traditional settings. Providers include local/county health departments, community health centers, college

student health, correctional facilities, Title X Family Planning clinics, STD clinics, correctional facilities, counseling centers, non-Title X Family Planning clinics, private providers, school-based clinics, street outreach and other public agencies.

Five out of six states follow the screening criteria written in the Region VIII IPP Service Protocols and Program Guidelines. The screening criteria is a selective one, where all women less than 25 years are screened and women 25 and above are screened when there is a reason such as clinical signs or risk history. A handful of clinics also use the HEDIS criteria, which routinely screens women between the ages of 15 and 25.

◆ *Other Providers*

Other providers in the project who may be involved in data collection include Indian Health Services (IHS). Providers who may not be involved in data collection include those in non-traditional settings such as juvenile detention centers, substance abuse clinics, and other types of outreach sites that have access to high-risk adolescents.

◆ *Patient/Partner Educational Activities and Efforts*

As a minimum, all states follow the patient/partner notification guidelines as stated in the Region VIII IPP Service Protocols and Program Guidelines. In many states, such as Wyoming, sites are committed under their contract to apply the protocols and guidelines. It is understood that there is a hierarchy of possible treatment procedures for partners, in the order of preference: (1) test and counsel the partner in the clinic, and arrange for appropriate treatment; (2) counsel the partner in the clinic and arrange for appropriate treatment; (3) counsel the partner by telephone and arrange for appropriate treatment; (4) send the partner medication home with the client with specific written instructions; or (5) refer partner to another facility for treatment. The guidelines also highlight that no person with Chlamydia can be considered adequately treated until his or her sex partner(s) is also treated. Prevention of re-infection is critical to the reducing the serious long-term consequences of Chlamydia.

Activities and efforts can be clearly seen as states are applying these guidelines and protocols. In Colorado, for instance, “Chlamydia positive clients are counseled about the importance of notifying and referring their partner(s) for exam and treatment. They are also given the option of partner-delivered treatment, in accordance with Region VIII IPP Service Protocols. Chlamydia positive patients who desire partner notification services are referred to STD program-funded Disease Intervention Specialists.”

Efforts to assure that Patient/Partner educational materials are culturally, linguistically, and developmentally appropriate have not been assessed region-wide. Nevertheless, states such as Montana have completed this objective as well as continued the initiative of developing and distributing “age-specific, culturally sensitive education materials that include information on the availability of affordable screening and treatment services throughout Montana.” The resulting bookmark-style pamphlet was collaboration between public health nurses and health educators from each of Montana’s seven Indian reservations and a focus group consisting of youth from two Indian communities to provide input concerning effectiveness, appropriateness and cultural sensitivity contained in the education materials. Because Region VIII is home to a diversity of populations,

states are expected to provide materials that are culturally, linguistically, and developmentally appropriate so as to facilitate service delivery.

External Environment

Strengths, Weaknesses, Threats & Opportunities

This strategic plan addresses the following key strengths, weaknesses, threats and opportunities which apply to Region VIII Infertility Prevention Project now and in the foreseeable future:

Strengths:

- The level of collaboration across the program areas
- The work of Region VIII and this committee in particular is widely recognized nationwide

Weaknesses:

- Attendance and participation in the RAC due to travel restrictions and program area staff changes
- Some program areas do not have state STD funding
- Data issues Delays in receiving data from providers; and delays in regional reporting of data to RAC

Threats:

- Political climate nationally and with some individual states
- The current level of funding
- Continued flat funding.

Opportunities:

- The development of collaborative relationships
- The development of a communication plan
- The Region VIII IPP will strengthen program efforts through improved collaboration with current regional partners and new partners.

Vision

The vision of the Region VIII Infertility Prevention Project is:

dedicated to the prevention of infertility caused by sexually transmitted diseases, particularly Chlamydia and gonorrhea.

Mission Statement

The central purpose and role of the Region VIII Infertility Prevention Project is defined as:

The mission of the Region VIII Chlamydia Project is to assess and reduce the prevalence of Chlamydia and associated complications in family planning and STD clinic populations, and other community-based provider populations through a program of outreach, education, screening, treatment, and follow-up.

Project Values and Standards

The values and standards governing the Region VIII Infertility Prevention Project's development will include the following:

In order to meet unmet and growing needs of the prevention and control of STD-related infertility, JSI, as the Region VIII coordinating agency, will take a systematic approach to the continued implementation of the Region VIII IPP program structure. The JSI/Denver team, working with the Region VIII IPP program areas and CDC, will strive to be innovative in delivering high-quality services at low cost to the largest number of people. As we work toward strengthening local, state, and regional responses to STD and reproductive health challenges, JSI is committed to:

- Active participation of project beneficiaries in all activities
- Internal and external partnerships and collaborations
- Adopting a multi-sectoral approach to address the social and cultural factors that increase individual and community vulnerability, and
- Capacity-building to create or enhance sustainability.

Further, our efforts to build accessible, appropriate, effective, and efficient STD and reproductive service delivery programs in collaboration with partners will incorporate the following standards:

- **Appropriate Constellation of Services**—The cornerstone of an effective STD prevention and related services program is an appropriate mix of services from the public and private sectors, including community-based organizations (CBOs). It is this tailored constellation of integrated services that can be responsive to both physical and sociocultural environments. The range of offerings must address the rural-urban differential, gender, racial and economic inequity, and the needs of special populations such as adolescents, women, and other vulnerable groups. Community-based outreach programs complement clinic-based programs and bring services closer to community members. Social marketing of health products and services is also important to increase access to services.
- **Quality of Care**—To achieve high-quality services, two key dimensions of quality must be addressed: quality of fact and quality of perception. Quality of fact may involve upgrading provider skills and knowledge, implementing service standards and protocols, introducing a facilitative supervisory system and disseminating best practices. Underscoring all of this is a focus on client-oriented services, with providers trained to deal with equity issues around gender, economic status, residence, occupation, race, ethnicity, culture and language.
- **Equity**—Easy access to prevention and related services for people of all income groups, races, religions, genders, sexual orientation identities, and locations of residence can create equal opportunity for equal needs.

- **Efficiency**—Efficiency in the delivery of prevention and related services can be achieved by reducing cost without compromising access and quality through maximizing resource utilization, utilizing appropriate technologies, and improving staff capabilities. Improving efficiency may require institutional integration, which can be done without sacrificing the achievements made by some vertical programs.
- **Capacity Building**—The Region VIII IPP’s approach to service delivery management centers around building institutions from within. Specific activities include: increasing management capabilities through the introduction of management tools; training managers and clinical staff to use data for decision-making; and improving the capacity of programs in planning, management, and quality improvements.
- **Evaluation**—Service delivery programs must be evaluated periodically to identify achievements and gaps at the local, state, and regional levels. The participation of service providers and managers, with input from the community and clients, are critical. Issues of concern may be addressed through training, orientation, and policy intervention. Addressing some identified issues may require additional resources.

Section 2: 2009-2011 Region VIII Region Plan

The Regional Plan is a tool for focusing regional efforts and communicating national priorities. It serves as a guide for work to be accomplished at the regional level and as a template for project areas in the development and maintenance of their local infertility prevention programs.

The following pages outline objectives and activities for the 2009-2011 Regional Plan. The Plan is organized by IPP Core Components and addresses the National IPP Priority Areas as described below.

1. IPP Core Component: CLINICAL SERVICES

National IPP Priority Area: Target/expand Chlamydia screening to young sexually active women and men at risk for infection in public and private settings.

- Services should be expanded to sites that serve populations with known or expected high positivity. Sites can include traditional and non-traditional settings where young women and men access reproductive health care services. Examples of traditional settings might include Indian Health Service, migrant and community health centers, adolescent clinics, and school-based facilities. Non-traditional sites may include detention centers and homeless shelters.

National IPP Priority Area: Improve appropriate and timely treatment for persons diagnosed with chlamydial infection and their partners.

- Objectives should assure that adequate systems are in place to routinely monitor treatment timeliness and adequacy.

2. IPP Core Component: DATA

National IPP Priority Area: Incorporate analysis of regional prevalence monitoring data

for regional and local data-directed program planning.

- Data should help target Chlamydia screening activities to assure that resources are being used in the most cost effective way and that adequate screening coverage is occurring for the highest risk populations of women.

3. IPP Core Component: LABORATORY

National IPP Priority Area: Promote the use of high quality diagnostic tests for Chlamydia.

4. IPP Core Component: TRAINING AND PROGRAM MANAGEMENT

National IPP Priority Area: Increase adoption of “best practice” prevention strategies to reduce efficiency of Chlamydia transmission.

- As new information is provided in this area, regional projects should address how to adopt best practice prevention strategies. Currently, several recent guidelines from CDC may assist this process including the *2006 STD Treatment Guidelines* and *2006 Expedited Partner Therapy in the Management of Sexually Transmitted Diseases: Review and Guidance*.

Overall Region VIII IPP Goals

The Region VIII IPP’s goal is to support health care professionals in preventing STD-related infertility by promoting science and evidenced-based standards in the planning, implementation, and maintenance of targeted Chlamydia and gonorrhea screening programs throughout Region.

The following key targets will be achieved by the Region VIII Infertility Prevention Project over the next three years:

- Maintain a regional data collection system;
- Evaluate and update regional screening criteria;
- Expand services to facilities that reach high risk populations;
- Improve services, such as screening, treatment, and follow-up; and
- Reduce test, treatment, and laboratory costs.

Region VIII IPP Priority Areas

Because STD and reproductive health programs exist in highly diverse, complex, and dynamic social health settings, the Region VIII IPP identified three primary components that are critical in order to implement a comprehensive program. These components are clinical services, lab services and data-informed programs. Each of these components has related priority areas. In support of CDC DSTDP’s priority related to Chlamydia and gonorrhea prevention, “Prevention of STD-related Infertility and other complications of PID by screening and treating at-risk persons, primarily women <26 years of age, and by working to reduce racial/ethnic disparities in gonorrhea and Chlamydia”, the RAC identified the following priority areas:

1. Determine and monitor screening coverage in Family Planning clinics conducting screening through the IPP.
2. Determine appropriate funding allocations for screening identified populations.
3. Assure availability of lower cost and quality lab technologies.
4. Ensure that Region VIII IPP Guidelines support best practices for the provision of partner services and primary prevention of CT/GC.
5. Target/expand Chlamydia screening to young sexually active women and men at risk for infection.
6. Adherence to screening criteria which includes that all women under 25 are screened; that all women over 25 are screened if they have a specific risk history or specific clinical symptoms, and establish a regional compliance rate.
7. Continue to support the collaboration between the Region VIII IPP and I.H.S. Stop Chlamydia Project.
8. Disseminate an evaluation of a standardized tool used to gather data regarding Chlamydia and gonorrhea health care delivery systems to AI/AN populations, as well as surveillance practices among AI/AN populations.
9. Disseminate a regional epidemiologic profile of pregnancy-testing only clients seen in prevalence monitoring clinics.
10. Establish baseline reinfection rates.
11. Define case-mix of screening population and establish a regional screening coverage goal.
12. Develop an IPP Health Communications Plan targeted towards providers, thereby increasing member knowledge and awareness of “Communications” best practices.
13. Assess and assure that adequate systems are in place to routinely monitor treatment timeliness and adequacy.
14. Promote the use of high quality diagnostic testing for Chlamydia and Gonorrhea through innovations in lab testing.

Region VIII Objectives:

IPP Core Component: CLINICAL SERVICES

Region VIII Goal & National IPP Priority Area: Improve appropriate and timely treatment for persons diagnosed with chlamydial infection and their partners.

Relates to Region VIII Priority Area 13.

Objective 1: Conduct a regional assessment to establish baseline information regarding time elapsed between diagnosis and treatment.

- Discussion: This will ensure that the entire region is tracking the same information and will reinforce the goal of uniformity. Once criteria have been established, Region VIII will move forward by determining how they may be improved (e.g. length of treatment).

Objective 2: Disseminate the results of a treatment verification best practices survey aimed at collecting best practices on treatment verification used throughout Region VIII.

- Discussion: The following activities will help support the achievement of this strategic action:
- Clinical Services workgroup members will develop a treatment verification best practices survey in collaboration with Infrastructure staff.
 - Infrastructure staff will disseminate the survey and facilitate the collection of results.
 - Infrastructure staff will analyze results of treatment verification survey and develop a draft report to be shared and finalized in collaboration with the Clinical Services workgroup.
 - Infrastructure staff will create a data flow blueprint from various databases and how these data result in the CSPS/IPP performance measure reporting.

Region VIII Goal & National IPP Priority Area: Target/expand Chlamydia screening to young sexually active women and men at risk for infection in public and private settings.

Relates to Region VIII Priority Areas 7, 8, 9.

Objective 1: Disseminate the results of a standardized assessment used to gather data regarding Chlamydia and gonorrhea health care delivery systems to AI/AN populations, as well as surveillance practices among AI/AN populations.

- Discussion: The following activities will help support the achievement of this strategic action:
- The Infrastructure staff will continue efforts to make contact with and assess current Chlamydia and gonorrhea screening practices and policies in at least one Indian Health Service Office in Region VIII.
 - The Clinical Services workgroup will conduct a Regional Assessment of AI/AN health care delivery systems in the Region through I.H.S., tribal and urban health facilities.
 - Infrastructure staff will conduct analysis of IPP Prevalence Monitoring data as it relates to AI/AN populations.

The outcomes will be to have at least one urban Indian clinic from all Region VIII related-area offices, as well as to have all I.H.S. Service Areas represented, and RAC member, where appropriate, will assist Infrastructure staff to increase data collection among I/T/U facilities in Region VIII.

Objective 2: Disseminate a regional epidemiologic profile of pregnancy-testing only clients seen in prevalence monitoring clinics.

- Discussion: The following activities will help support the achievement of this strategic action:
- The Region VIII RAC will conduct regional assessment of data availability of PTO visits.
 - The Clinical Services and Data Use workgroups will pilot a project impact of

offering Chlamydia screening during non-pelvic (“off-table”) visits in Family Planning, Title X clinics in the region.

- Each state will set a target of at least one site to pilot Chlamydia and gonorrhea screening in PTO clients.
- The Infrastructure staff will conduct data collection and analysis of available data.
- Infrastructure staff will create a PTO epidemiologic profile for submission to CDC and the Region for use in shaping programmatic decisions.

IPP Core Component: DATA

Region VIII Goal & National IPP Priority Area: Incorporate analysis of regional prevalence monitoring data for regional and local data-directed program planning.

Relates to Region VIII Priority Areas 1, 2, 5, 6, 10, 11.

Objective 1: Establish a regional baseline to measure how effective Chlamydia screening is in currently participating screening sites for women as well as current adherence to screening criteria.

Objective 2: Assess current data to determine which variables/elements are useful to the Region for making decisions; streamlining will allow for better data collection and will result in more complete data sets.

Objective 3: Identify trends in the number of Chlamydia screenings performed over time according to age, gender, and population/agency (e.g. family planning, community health center).

- Discussion: Prior to expanding, Region VIII would like to assess its impact on serving its current populations, especially as it relates to screening criteria and uniformity.

Objective 4: Update Region VIII IPP Chlamydia Reinfection Analysis to include through CY 2008.

- Discussion: The following activities will help support the achievement of this strategic action:
 - Data workgroup will share significant changes in trends with advisory committee members at a regional advisory committee meeting through a PP presentation.

Objective 5: Develop a Region VIII IPP specific recommendation for screening males for Chlamydia by conducting an assessment of Chlamydia positivity in males in all Region VIII project areas in new venues.

- Discussion: Utilize the CDC guidelines to develop and include Region VIII guidance on male screening in the revised Region VIII IPP Guidelines document.

Objective 6: Identify what percentage of eligible women are being screened on an annual basis among select sites participating in the Region VIII IPP.

- Discussion: Estimate Chlamydia screening coverage among eligible female patients according to Region VIII IPP minimum screening criteria

IPP Core Component: LABORATORY

Region VIII IPP Goal & National IPP Priority Area: Promote the use of high quality diagnostic tests for Chlamydia.

Relates to Region VIII Priority Area 3.

Objective 1: Collaborate with GenProbe, CDC and APHL to negotiate regional public health pricing for the GC and CT kits.

- Discussion: The following activities will help support the achievement of this strategic action:
 - Determine status of each lab and contract deadlines.

Objective 2: Identify new funding sources or maximize current sources.

- Discussion:
 - Billing Medicaid for lab services—current practices and plans
 - Does this get impacted by specimen collection methods?
 - See Medicaid Rates-Region VIII
 - Consider issues around contracting with private labs

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

Relates to Region VIII Priority Area 14.

Objective 3: 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.

- Discussion: 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.

Objective 4: Explore how the use of fast express (mucoytic agent) can facilitate repeat testing.

- Discussion: The following activities will help support the achievement of this strategic action:
 - Research other project areas that are doing fast express.
 - South Carolina is doing fast express
 - Add fast express to all cervical specimens prior to testing.
 - Continue to do repeat testing on all positives specimens.
 - Perform validation:
 - Run 10+ and 10- before and after fast express
 - Perform an evaluation over the course of three months.

Objective 5: Point of Care Tests

- MT POC Study

Objective 6: Self-collected specimens & Internet-based collected specimens

- Education and training needed for clinicians
- Awareness and capacity building for clinicians and labs

IPP Core Component: TRAINING AND PROGRAM MANAGEMENT

Region VIII Goal & National IPP Priority Area: Increase adoption of “best practice” prevention strategies to reduce efficiency of Chlamydia transmission.

Relates to Region VIII Priority Area 4.

Objective 1: Complete revision of Region VIII Infertility Prevention Project Guidelines.

- Discussion: The following activities will help support the achievement of this strategic action:
 - The Steering Committee will review guidelines and provide final approval.
 - Steering Committee will distribute to RAC and other pertinent partners.
 - Incorporate EPT toolkit in overall IPP guidelines to encourage the use of Expedited Partner Therapy among IPP providers.
 - Infrastructure staff will post revised guidelines to regional website.

Region VIII Goal: Encourage effective use of limited IPP resources by diagnosing and treating the maximum number of Chlamydia infections.

Relates to Region VIII Priority Area 2, 11.

Objective 1: Increase estimated screening coverage among females 15-19 years old and 20-24 years old by 5% within each Title X Grantee.

Objective 2: Decrease routine CT and GC screening by 20% in women >25 years of age in FP clinics where the prevalence of CT is less than 3%.

The Region VIII IPP, in collaboration with the Steering Committee and Data Workgroup, will develop regional guidance and funding allocation formula in order to increase screening coverage in identified and prioritized high risk populations. This will be accomplished through the following activities:

- Conduct a regional assessment of the current screening criteria to ascertain if they vary by state.
- Conduct an analysis of the proportion of women being screened using current criteria and proportion of infections being identified by these criteria.
- Pilot formula using the previous year's data and present findings at the fall 2009 meeting.
- The pilot will result in the distribution of best practice guidelines for funding allocations based on a 3% positivity threshold which is maintained for two years, while also reaching at least an 80% screening coverage rate in our targeted high-risk populations.

Region VIII Goal & National IPP Priority Area: Target/expand Chlamydia screening to young sexually active women and men at risk for infection in public and private settings.

Relates to Region VIII Priority Areas 12.

Objective 1: Facilitate consideration of findings and presentation among advisory committee for future action. develop an IPP Health Communications Plan targeted towards providers, thereby increasing member knowledge and awareness of "Communications" best practices.

- Discussion: The following activities will help support the achievement of this strategic action:
 - Infrastructure staff will provide a review of existing communication tools and strategies for outreach to various target populations (patients and providers).
 - Infrastructure staff will invite speakers to present on "Communications" best practices.
 - At the November 2008 Region VIII IPP advisory committee meeting, facilitate opportunities for project area partners to meet to discuss the development of a communication plan.

- Steering Committee will lead the RAC in the development of a comprehensive communications strategy, including public and private sector focus, and integrating new and existing tools (Web site, clinician cards, and e-learning tools).
 - Determining how to best frame messages to the private sector.
 - Developing a communication plan (to providers/clinicians, medical journals, etc.).
 - Evaluating screening rates using the HEDIS dataset pre/post communication campaign.
- Infrastructure staff will lead the effort to evaluate the effectiveness of a communication plan directed toward private providers to increase Chlamydia screening among private providers in Region VIII.

Region VIII Goal: The Region VIII IPP RAC will strengthen program efforts through improved collaboration with current regional partners and new partners.
No associated Region VIII Priority Area.

The Steering Committee will develop concrete ideas on how to build on partnerships with certain entities including higher education institutions, social networking systems, corporate alliances, medical professionals, managed care administrators, family planning/STD clinics and pharmaceutical companies.

The Infrastructure staff will ensure that regional materials include the latest guidance on CT/GC screening and treatment.

Priority Area Action Plans

Once these are completed by the workgroups, the action plan form tables will be put here: these will include timeframes, responsible entity, additional resources, implications/questions for consideration and products to be developed]

Priority Action Plan Form: 2009-2011 Regional Plan Priorities

Region VIII Goal & National IPP Priority Area:

Activity:

What is the impact of this priority?

How does this priority support regional success:

How does this priority support my program's success:

Person responsible for ensuring priority's implementation and completion:

Other individuals necessary for priority implementation and completion:

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What is the timeframe for the priority?

What is the target completion date?

What are the action steps for implementing the priority?

Indicators of success:

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Section 3: Status of Current Regional Plan (2005-2008)

SUMMARY OF STRATEGIC PLAN GOALS 2005-2008

Following are the resulting goals from the Strategic Planning process which took place at the May 2005 RAC meeting. Workgroups are currently completing the activities and tasks associated with each goal.

Priority Area: Partner Services

GOAL: Implement feasible, effective, and appropriate practices for partner management.

Objective 1: Develop and implement plans to encourage the use of Expedited Partner Therapy among IPP providers.

The workgroup has informally surveyed agencies in their respective states regarding Expedited Partner Therapy (EPT) practices. The group has also collected regulations and rules around EPT practices. These activities will be assembled into a resource guide to be available to agencies considering using EPT as one of their strategies used to manage partners. This guide will be a Region VIII-specific supplement to the work currently being done at the national level. To support decision-making and implementation among policymakers and health care providers within a six-state area, the Region VIII Infertility Prevention Project (IPP) developed an EPT toolkit to address provider concerns and questions regarding EPT practice.

An EPT toolkit was designed to address participant concerns and was developed for distribution to IPP participating sites and other providers in Region VIII. This toolkit will be used as a clearinghouse of resources developed for states in various stages of considering EPT as an effective strategy for partner management.

The toolkit development was presented as a poster presentation at the 2008 National STD Prevention Conference.

Priority Area: Treatment Verification

GOAL: Improve appropriate and timely treatment for persons diagnosed with Ct infection

The workgroup has also agreed to review the Performance Measures Data once it has been collected and released by CDC in order to determine whether Region VIII should develop its own set of standards.

Priority Area: LAB SERVICES

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

Objective 1: By Nov 05, the Regional Labs will have explored better regional lab pricing with GenProbe

Already have the best price w/GenProbe—pricing has been level for past 5 years. When new tests come to market, which increases competition, this will be revisited. Penny also

suggested a national perspective for this too. Rick said that until there is more competition, costs are not likely to go down. The majority of Region 8 labs are using GenProbe which provides a volume pricing advantage over other regions. There is also early talk about taking a national pricing approach (as Rick heard from Charlotte Kent at the National STD Conference in March), so there may be activities going on around this soon.

Objective 2: By May 2006, ad hoc workgroup will consider implications of pooling NAAT specimens (limitations and benefits).

The pilot pooling study was completed in November 2007 by the Colorado State Lab. The CO State Lab RAC representative will write report on advantages/disadvantages (costs, equipment needs); this doc will be the final product for this priority. Good for other 2 groups to understand this as well. Timeframe: June 1, 2008. It will be distributed to the full RAC. Penny suggested also including info about what other regions are doing: a national perspective.

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

Objective 3: By March 2008, determine the reproducibility of a repeat test performed on the same specimen

All state public health laboratories in the CDC Region VIII Infertility Prevention Project (CO, MT, ND, SD, UT and WY) perform Chlamydia and gonorrhea screening with the Gen-Probe APTIMA Combo2 assay. To improve the positive predictive value (PPV) of the assay, each state uses state-specific criteria for repeating an initial equivocal or positive test on the same specimen. The Lab Services workgroup conducted a retrospective study to determine the reproducibility of a repeat test performed on the same specimen. The study found that when the initial RLU is greater than 600, the Gen-Probe APTIMA assay reliably repeats as positive, regardless of specimen source or gender. These results in reducing the number of tests that are repeated to improve PPV can result in cost savings to programs, allowing more screenings to be performed.

This study was presented as a poster presentation at the 2008 National STD Prevention Conference.

Objective 4: By May 2007, develop Regional Capacity to Test Alternate Site 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 State Lab agreed to act as the regional lab to process alternate site specimens.

The Lab workgroup established a regional lab for alternate specimen source NAAT testing for Chlamydia and gonorrhea. Region VIII Lab representatives worked closely

with the National Laboratory Consultant and John Papp at CDC to review and implement protocols for assay verification. This regional collaboration was reported in the May issue of the Program and Training Branch (PTB) Thursday Report Monthly Highlights from the STD Programs.

Objective 5: By June 2008, determine the persistence of residual Chlamydia trachomatis RNA after treatment as detected by APTIMA Combo 2 Assay.

The proposed study of “Persistence of Residual Chlamydia trachomatis RNA after Treatment as Detected by APTIMA Combo 2 Assay” 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. The revised timeline for the project is expected to continue through June 30, 2009.

Priority Area: EFFECTIVE USE OF RESOURCES

GOAL: Increase screening coverage in an identified and prioritized high risk group.

Objective 1: By 10/1/05 each state’s IPP representatives will meet to identify high risk populations included in the IPP project

Objective 2:

By 12/31/05, determine appropriate allocations for screening identified populations

Effective Use of Resources Workgroup - Prioritizing ways in which data can be effectively utilized are at the forefront of the Project’s agenda. Data activities continued as the Committee pursued the priority area “Effective Use of Resources” as part of the regional plan. Following are some of the priorities that were identified in the data analysis plan:

- **Number 1 Priority: Screening Criteria Adherence Analysis**
Status of priority 1 analysis:
Initial descriptive analysis presented at the April 2006 RAC meeting.
Second analysis presented at the November 2006 RAC meeting.
- **Number 2 Priority: Male Positivity Analysis**
Status of priority 2 analysis:
Initial descriptive analysis presented at the April 2006 RAC meeting.
- **Number 3 Priority: Calculate re-infection rates**
Status of priority 3 analysis:
Initial analysis presented at the November 2006 RAC meeting

A significant activity of the Data/Effective Use of Resources workgroup involved reviewing the quality of the data to ensure that appropriate data is being collected in a timely manner. The workgroup has reviewed each data element to confirm definition and assess completeness and usefulness of the current variables. It was decided that in order to capture the information required to drive programmatic decisions, the variables needed

to be updated. During this regional plan period, the group finished the review of the agency type code variable; the assessment was comprised of confirming the definition of the codes which make up the agency-type code variable as well as condensing codes. The following points were applied in the assessment:

- Think about grouping agencies to identify unique populations, interventions or geography.
- Agency type codes should help by following populations not funding.

Additional proposed changes are as follows:

➤ Exam Reason – Code indicating a patient’s reason for getting exam
 More than one option can be marked. The exam reason field is populated by what is marked on the lab form in the clinic; the clinician should ask the patient about their reason for having an exam in order to complete this section of the lab form.

Current Field/Variables

Reason for Exam:
 Symptomatic
 Routine Exam
 Exposed to CT
 Exposed to GC
 Exposed to Other STD

Proposed Field/Variables

Reason for Visit:
 Symptomatic
 Exposed to STD in past 60 days
 IUD Insertion
 Patient Request
 Pregnancy Test Only Visit
 Client Meets Screening Criteria
 Positive Ct – 3-month rescreen

Definitions of each variable choice:

Symptomatic
 History of discharge, bleeding with intercourse, lower pelvic pain (females)
 Burning with urination (males)

Exposed to STD in past 60 days (includes past exposure to Ct, GC and any other STDs)
 The 60 day timeframe is to have alignment with risk history timeframe.

Client Meets Screening Criteria (routine exam becomes meeting screening criteria)
 Age and/or Risk History/Clinical Signs; assumption is that the form filler knows what the criteria are for their site.

IUD Insertion

Per Title X protocols, women getting an IUD insertion receives a Ct/GC test.

➤ Risk History – Code indicating patient’s risk history
 More than one option can be marked with the exception of No Risk History. If No Risk History is marked then no other option can be chosen.
 The risk history field is populated by what is marked on the lab form in the clinic; the clinician should ask the patient about their risk history in order to complete this section of the lab form.

Current Field/Variables

Risk History:
More than 1 Partner in Past 90 days
New Partner in Past 90 Days
Positive for Ct in Past 12 months
No risk history

Proposed Field/Variables

Risk History:
More than 1 Partner in Past 60 days
New Partner in Past 60 Days
Positive for Ct in Past 12 months [keep]
No risk history

➤ Race – Code corresponding to the race of the patient

Will use FPAR definitions

The race field is populated by what is marked on the lab form in the clinic.

Instructions on form should read:

Mark one or more

Current Field/Variables

Race:
Other
White
Black
Native American
Asian

Proposed Field/Variables

Race:
White
Black or African American
American Indian or Alaska Native
Asian
Native Hawaiian or Other Pacific Islander

- The method for respondents to report more than one race should take the form of *multiple responses* to a single question and *not* a single “multiracial” category.
- The lab form will have each the five choices listed with the client marking all that apply.

AMERICAN INDIAN OR ALASKA NATIVE – A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.

ASIAN – A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

BLACK OR AFRICAN AMERICAN – A person having origins in any of the black racial groups of Africa.

NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER – A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

WHITE – A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Source – Code corresponding to the source of the specimen.

This field is populated by what is marked on the lab form in the clinic.

Current Field/Variables

Other
 Cervical
 Urethral
 Vaginal
 Urine

Proposed Field/Variables

Cervical
 Urethral
 Vaginal
 Urine
 Rectal
 Pharyngeal

Other is being dropped

Adding rectal and pharyngeal

Plan and Timeframe for Implementing Changes

- The proposed changes were be vetted through the Lab Services workgroup (August 6, 2008) and the Clinical Services workgroup (August 26, 2008) for feedback. The goal is to begin implementing new forms by July, 2009. In the interim, deadlines will be set for the time period in which old and few forms will overlap.

Another significant data activity involves reviewing the quality of the data to ensure that appropriate data is being collected in a timely manner. During this budget period, the group finished the review of the agency type code variable; the assessment was comprised of confirming the definition of the codes which make up the agency-type code variable as well as condensing codes.

➤ Agency type code: Code specifying agency type

The assessment was comprised of confirming the definition of the codes which make up the agency-type code variable as well as condensing codes. The following points were applied in the assessment:

- Think about grouping agencies to identify unique populations, interventions or geography.
- Agency type codes should help by following populations not funding.

This variable is not collected by the clinic via the lab form. The coding for this field is populated once the data is imported into the regional database. The codes are generated from the Clinic Reference File and are determined by FP, Lab and/or Lab program representatives.

Updated Clinic Reference File to reflect new agency type codes for: CO, ND, UT, WY

How labs will be notified of agency type code changes:

1. Share the attached agency type code definition table with partners (particularly) lab so that everyone is aware of the new agency type codes.
2. Share the update excel files which reflect the changes in how current agencies are coded as well as any agencies that are no longer submitting data. CO, ND, UT, WY have updated files. They are uploaded to project spaces.
3. Otherwise for current agencies, there is no need for the programs to do anything. I will make the changes in the regional database.

From this point forward, when a new agency is added, the following process will be followed per the July 07 workgroup call notes:

As new sites are added, JSI will contact the program representatives (FP and STD) and copy the Lab representative to confirm the addition of the new site: site name, agency id, date the site started submitting data and how the site should be coded in terms of type of agency.

JSI Chlamydia Project Evaluation Plan
Updated March 2007
Updated Priority Analysis

Purpose of collecting the IPP data:

- ❖ To evaluate progress toward the project's goal of reducing Chlamydia prevalence
- ❖ To evaluate screening criteria for Chlamydia on an ongoing basis
- ❖ To assess epidemiology of Chlamydia in the project population

When considering additional analyses, keep the following 'principle' in mind:

What questions are we trying to answer?

Will we change the way we are planning the program or services such as targeting populations differently based on the answers to the questions or analysis?

Number 1 Priority: Screening Criteria Adherence Analysis

- **This is one of the infrastructures PM that Region is required to address.**

Status of priority 1 analysis:

Initial descriptive analysis presented at the April 2006 RAC meeting.

Second analysis presented at the November 2006 RAC meeting:

Follow-ups or questions from presentation:

1. Need to collect screening criteria by state.
2. Calculate the Chlamydia positivity in women under 25 who meet screening criteria; women over 25 who meet screening criteria and women who do not meet screening criteria and plot by age in years for each state and the region. –

Completed-

3. Frequencies of missing data for clinical signs and risk history by clinic in women over 25 who meet do not meet screening criteria for each state. --**Completed**
4. Develop a report template for JSI to give to the CDC for screening adherence reports. Will include the three screening groups in #1 and have the total N tested; the total N positive and the % of Chlamydia positivity by clinic for each state and the region.
5. Trend analysis of women in FP title X clinics who met and do not meet screening criteria for 2000-2006 by state and region.

- **Have we completed this analysis?--Any next steps for this analysis?**

Suggestions for additional variables to enhance our ability to assess meeting screening criteria were to add the following:

Reason for exam:
Positive partner
IUD insertion
Pregnancy test visit
Patient request

Need to set target date for adding the above variables. Data W/G members will need to discuss a reasonable goal for updating lab forms.

Number 2 Priority: Male Positivity Analysis

Status of priority 2 analysis:

Initial descriptive analysis presented at the April 2006 RAC meeting.

Follow-ups or questions from presentation:

1. Trend analysis for male positivity

- **Have we completed this analysis?--Any next steps for this analysis?**

Suggestion for adding variables to assist in program planning for male screening:

Examples: break up males that come in as partner vs. those that come in for another reason. This can assist in determining what is partner testing and screening.

Need to set target date for adding the above variables. Data W/G members will need to discuss a reasonable goal for updating lab forms.

Number 3 Priority: Calculate re-infection rates

Status of priority 3 analysis:

Initial analysis presented at the November 2006 RAC meeting:

Follow-ups or questions from presentation:

1. Breakdown reinfection percent by demographics, clinic type, age group, exam reason, risk history, and clinical signs as well as by 3 month intervals
2. Collected several articles for suggested references to compare methodologies. Currently reviewing articles.

- **Have we completed this analysis?--Any next steps for this analysis?**

Confirm methodology—redo initial analysis if needed based on lit review.

Start monitoring reinfection analysis since we've established baseline. Particularly in the programs which are establishing EPT such as WY.

Number 4 Priority: Screening coverage analysis—determines if coverage to targeted population has increased. What is the proportion of the sexually active women in clinic population that are being screened for Chlamydia?

- **This is one of the infrastructure PM that Region is required to address.**

Status of priority 4 analysis: Put on hold while CDC is determining definitions.

Section 4: Regional Protocols and Guidelines

I. DATA FORMS – Guidelines indicate that data received are used to evaluate the project by monitoring trends in Chlamydia positivity rates among participating clinic populations as well as assessing the screening criteria used and characterizing the population tested. If patient name or date of birth are missing from the data form, the data form is not entered in the Chlamydia Project database. Patient names are not stored since they are converted to an alphanumeric Soundex code in the database. Complete data on each tested person are most important for the project to be most useful and interpretable. Quality assurance for Chlamydia Screening and Treatment are conducted through audits, which are considered the more efficient approach to documenting compliance with the regional guidelines. Medical records are selected in a systematic way.

II. SCREENING AND TREATMENT – **The** Regional Guidelines for selective criteria were developed using published studies, data from Region VIII Title X Family Planning clinics, and from CDC screening criteria. The region has a set of minimum screening criteria that can be augmented by individual states and programs, based on their data and programmatic considerations.

The regional set of minimum Chlamydia screening criteria are given below. As indicated, these are minimum criteria; individual states and programs may do more based on their data and programmatic considerations. Annual screening of all sexually active women aged ≤ 25 years is recommended, as is screening of older women with risk factors (e.g., those who have a new sex partner or multiple sex partners).

1. All sexually active women under age 25
2. Women age 25 and older with one or more of the following:
 - (a) New sex partner in the last 60 days.
 - (b) Multiple sex partners in the last 60 days.
 - (c) MPC
 - (d) Cervical friability
 - (d) PID
 - (e) Positive for Chlamydia in the last 12 months

Gonorrhea:

Region VIII does not have a regional screening criteria for gonorrhea; however, all programs in the region (with the exception of Denver Public Health, Lab 2 and Denver Community Health Centers (Lab 7), use the GenProbe Aptima dual test. As a result, most specimens submitted through the IPP screening for Chlamydia testing also get tested for gonorrhea.

B. Physical Examination

Guidelines emphasize that definitive diagnosis of Chlamydia trachomatis infection can only be made by using one of several available laboratory tests.

Females: Physical examination findings can include cervicitis, PID, urethritis and Fitz-Hugh-Curtis Syndrome (Perihepatitis).

Males: Physical examination findings can include urethritis, epididymitis, proctitis and Reiter's Syndrome.

C. Chlamydia Specimen Collection

Guidelines discuss the sensitivity of Chlamydia tests and how the greater the number of cells collected, the more likely a Chlamydia infection, if present, will be detected.

Protocols enumerate devices that are available for specimen collection:

Valid Chlamydia Test Types	Valid Gonorrhea Test Types
Transcription Mediated Amplification (TMA); Gen-Probe Aptima Combo 2 CT/GC	Transcription Mediated Amplification (TMA); Gen-Probe Aptima Combo 2 CT/GC
Strand Displacement Assay (SDA); Becton Dickinson; BDProbeTec CT/GC	Strand Displacement Assay (SDA); Becton Dickinson; BDProbeTec CT/GC
Polymerase Chain Reaction (PCR); Roche; Amplicor CT/GC	Polymerase Chain Reaction (PCR); Roche; Amplicor CT/GC
Transcription Mediated Amplification (TMA); Gen-Probe; Aptima CT Assay	Transcription Mediated Amplification (TMA); Gen-Probe; Aptima GC Assay
Nucleic Acid Hybridization; Gen-Probe; PACE 2 CT	Nucleic Acid Hybridization; Gen-Probe; PACE 2 GC
Nucleic Acid Hybridization; Gen-Probe; PACE 2C CT/GC	Nucleic Acid Hybridization; Gen-Probe; PACE 2C CT/GC
Signal Amplification; Digene; Hybrid Capture 2 CT/GC DNA Test	Signal Amplification; Digene; Hybrid Capture 2 CT/GC DNA Test
Enzyme Immunoassay (EIA)	Culture
Direct Florescent Assay (DFA)	
Culture	

Lab	Common Test Type Name	Manufacturer/Test Brand Name
Colorado State (lab 1)	GP Aptima	Transcription Mediated Amplification (TMA); GenProbe Aptima Combo 2 CT/GC
Denver Public Health (lab 2)	ProbeTec	Strand Displacement Assay (SDA); Becton Dickinson; BDProbeTec CT/GC
El Paso County (lab 3)	GP Aptima	Transcription Mediated Amplification (TMA); GenProbe Aptima Combo 2 CT/GC
Weld County (lab 5)	GP Aptima	Transcription Mediated Amplification (TMA); GenProbe Aptima Combo 2 CT/GC
Mesa County (lab 6)	GP Aptima	Transcription Mediated Amplification (TMA); GenProbe Aptima Combo 2 CT/GC
Denver Health & Hospitals (lab 7)	PCR	Polymerase Chain Reaction (PCR); Roche Amplicor CT/GC
Montana State (lab 9)	GP Aptima	Transcription Mediated Amplification (TMA); GenProbe Aptima Combo 2 CT/GC
North Dakota State (lab 13)	GP Aptima	Transcription Mediated Amplification (TMA); GenProbe Aptima Combo 2 CT/GC
South Dakota State (lab 11)	GP Aptima	Transcription Mediated Amplification (TMA); GenProbe Aptima Combo 2 CT/GC
Utah State (lab 10)	GP Aptima	Transcription Mediated Amplification (TMA); GenProbe Aptima Combo 2 CT/GC
Wyoming (lab 12)	GP Aptima	Transcription Mediated Amplification (TMA); GenProbe Aptima Combo 2 CT/GC

D. Follow-up of Chlamydia Test Results

The Guidelines for follow-up on test results revolve around:

- (a) Facilitating Follow-up
- (b) Positive Test Results
- (c) Negative Results
- (d) Borderline Results

E. Chlamydia Treatment

Guidelines address presumptive treatment for clients including:

- (a) Presumptive Treatment Criteria for Females
- (b) Presumptive Treatment Criteria for Males
- (c) Treatment of Choice
- (d) Treatment Options for Pregnant Women

F. PID Treatment Options

Guidelines define the symptoms of Pelvic Inflammatory Disease (PID) and treatment options available for Outpatient treatment only (with limited evidence from clinical trials supporting their use). Management of Sex Partners is also addressed.

G. Test of Cure

Guidelines explain the lessened need for retesting a patient after completing treatment with doxycycline or azithromycin unless symptoms persist or reinfection is suspected, since these therapies are highly efficacious. A test of cure may be considered 3 weeks after completion of treatment with erythromycin.

III. PARTNER MANAGEMENT – Regional Guidelines detail the importance of partner treatment once a client has tested positive for an infection associated with *Chlamydia trachomatis* and appropriate therapy has been initiated. It is understood that there is a hierarchy of possible treatment procedures for partners. Adherence to the most current CDC guidelines for the management of the sex partners of individuals with Chlamydia, as stated in their Guidelines for Treatment of Sexually Transmitted Disease, is reinforced. Abstinence from sex until both partners are cured is also highlighted.

Males: Protocols for the evaluation and treatment of male sex partners are addressed, paralleling the recommendations for females.

Females: Guidelines strongly encourage that clinical and laboratory examinations be done as indicated, in female sex partners.

IV. EDUCATION AND COUNSELING – The Education and Counseling Protocols are used as guidelines for clinics to develop counseling protocols that are appropriate to their particular agency's needs, services, and resources. Clinics participating in the Region VIII Chlamydia Project are to provide Chlamydia-specific information, education, counseling and referral services based on the client's needs. Information should be provided in verbal communication with the client, as well as reinforced and supplemented with written client education materials. Information and materials include:

- (a) General STD overview and how to avoid STD infection(s)
- (b) Basic Chlamydia information for all clients receiving tests
- (c) Education/Counseling for Chlamydia-positive clients and their sex partner(s)
- (d) Patient Referral
- (e) Prevention of Additional Exposure

V. LAB TESTING AND TESTING TECHNOLOGIES – Regional Guidelines emphasize a variety of diagnostic assays acceptable for Chlamydia screening and recommended by CDC. Recommended tests include:

- (a) amplification assays (ligase chain reaction (LCR), polymerase chain reaction (PCR), and transcription mediated amplification (TMA)
- (b) direct detection assays that use fluorescent monoclonal antibodies (DFA).
- (c) enzyme immunoassays (EIA), nucleic acid hybridization assays (e.g., Gen-Probe)
- (d) Culture, generally reserved for medical-legal cases.

Criteria for Laboratory participation and for unsatisfactory specimens, as well as recommendations for supplemental and/or confirmatory testing, are listed as part of the Regional Guidelines for Laboratory Testing.

In sexual assault and abuse cases, clinics are expected to follow Regional Guidelines, which emulate CDC's guidelines. Interpretation of laboratory results is available in an easy-to-read table format.

MONITORING OF REGIONAL PROTOCOLS AND GUIDELINES - Although every state complies with the Region VIII Protocols and Guidelines, each state is responsible for monitoring the use of the protocols and guidelines. Monitoring is done during quality assurance/site reviews. Site reviews are conducted as part of the ongoing quality assurance of the STD and Family Planning Programs.