Region I IPP Advisory Board Meeting
June 6 & June 7, 2011

Participants

Connecticut
- Susan Lane
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- Heidi Jenkins

Massachusetts
- Marcy Moyel
- Arthur Kazianis
- Roberta Moss
- Christina Lombardo
- Laura Smock
- Elizabeth Torrant
- Tracy Stiles
- Hillary Johnson
- Brenda Cole
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Maine
- Sarah Elie-Bennett
- Jemelie Bessette
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New Hampshire
- Michelle Ricco
- Lindsay Pierce
- Carol Loring

Rhode Island
- Bob Ireland
- Barbara McNeilly
- Michael Gosciminski

Vermont
- Rebecca Levasseur
- Sherry French
- Daniel Daltry

JSI
- Jennifer Kawatu
- Andee Krasner
- Jaya Mathur
- Marie Kaziunas

A. Welcome & Introductions

B. Dr. Edward Hook: Challenges to IPP: Emerging Gonococcal Antimicrobial Resistance and Skepticism that Screening in its Current Form Can Reduce Chlamydial Morbidity
    a. Emerging gonococcal antimicrobial resistance
        i. Gonorrhea (GC) rates are lower in the US than they have been since they were first recorded
        ii. Since the 1970s, GC rates have declined
        iii. Now STD rates are in a state of equilibrium – as long as we continue control efforts, rates will either stay the same or go down
        iv. The history of GC antimicrobial resistance
            1. In gonococcal infections, antimicrobial resistance is a recurring theme
            2. Pre-1937: Antiseptic irrigation was used
            3. 1937: Sulfonamide therapy was used
            4. 1943: Penicillin therapy was used
            5. 1944: 35% treatment failure with Sulfonamides
            6. 1972: Pencillin regimen increased to 4.8 million units plus Probenecid
            7. 1976: Recognition of PPNG (Africa, Southeast Asia)
            8. 1984: High level chromosomal Penicillin resistance (Durham, NC)
            9. 1985: Recognition of plasmid mediated Tetracycline resistance
            10. 1987: High level Spectinomycin resistance (Korea)
            11. 1989: Decision that Penicillin was no longer an effective therapy for GC
            12. 2002: Concerns about using Quinolone MICs
        v. Gonococcal Isolate Surveillance Project (GISP)
            1. GISP collects gonococcal data on men in various clinics and regional labs across the US
            2. We would like to stay ahead of the curve regarding gonococcal antimicrobial resistance
            3. Data around 2001 showed several important changes
                a. Rates increased a lot more among MSM v. heterosexual men
                b. Recommendations that were developed as a result
                    i. GC infections among people on the west coast should not be treated with quinolones (because of resistance)
                    ii. Treatment guidelines were changed
            4. New 2010 CDC STD treatment guidelines
                a. Quinolones are no longer recommended
                b. Amount of Ceftriaxone was doubled
                c. Drug resistance put an end to the utility of Quinolones and people were worried that Cephalosporine would not be effective
                d. There is a question of how long Cefixime will be recommended – it is an inexpensive oral antibiotic, but it does not get quite the same serum levels as an injection of Ceftriaxone
            5. “Those who cannot remember the past are condemned to repeat it.” (George Santayana)
        vi. Where we are now regarding Cephalosporin susceptibility
            1. People have been concerned about Cephalosporin antibiotics since the late 1990s
            2. It is reasonable to look to Asia as a predictor of what will happen in the US regarding gonococcal antimicrobial resistance

3. Resistance is just a line in the sand – it is an arbitrary number
4. Treatment failures occur more often in hard to treat places (e.g. pharynx and rectum), but genital resistance has been happening as well

vii. Distribution of MICs to Cefixime, 2005-2010
1. .06, .125, .25, .5 MICs are of concern, even though they represent less than 10% of gonoccocal isolates in GISP
2. There is a temporal increase in 2009 and 2010
3. Isolates are going up steadily with time and are more prominent on the west coast of the US compared to other US regions and are more common among MSM than heterosexual men
4. Annual increases of MICs are worrisome
5. GC rates are somewhat lower in the northeast region of the US, though it is still of some concern
6. We can expect to hear some concern of antimicrobial resistance in this region

viii. What about chlamydia (CT)?
1. We do not worry much about chlamydia antimicrobial resistance
2. A randomized clinical trial was conducted as a two-by-two factorial design
3. Patients were randomized to receiving/not receiving Tinidazole, and also received either Doxycycline or Azithromycin
4. We see infected patients coming back regularly and tend to assume that they have been re-infected – rather, they may represent treatment failures
5. The study observed a difference between Doxycycline and Azithromycin (95% v. 77%, respectively), indicating that in this study, Azithromycin appears not to be as effective
6. Dr. Hook would not recommend stopping used Azithromycin to treat CT but there is an increasing concern about resistance to Azithromycin
7. Azithromycin resistance is not out of the question; most bacteria develop resistance at one point or another

b. Skepticism that screening in its current form can reduce chlamydial morbidity (or is IPP working and why are US chlamydial rates increasing)
i. Slides presented were taken out of surveillance reports
ii. Last year CT rates were higher than have ever been reported for any other reportable disease in this country
iii. Some say it is because the new implementation of nucleic acid amplification tests (NAATs) are more sensitive; but NAATs were implemented 10-15 years ago and we are still seeing this trend
iv. Without screening we will certainly miss a lot of infections
v. CT screening is more common in women
1. Women are socialized to think that they need to pay attention to prevention after menses
2. Alternatively, men tend not to have the same mentality toward prevention
vi. 75% of women have only had one partner in the past year, but have high STD rates
vii. As agents of public health, we are facing an uphill battle; many say that those who contract STDs deserve it because they are promiscuous

viii. It is because of the infertility focus that we have sustained funding for prevention and treatment of CT and GC
ix. IPP logic model
    1. Association of CT and GC with PID
    2. Association of tubal factor infertility with PID
    3. Evidence that CT screening reduces PID
x. How often do you measure infertility? How much PID do you see? The arguments…
    1. Association of CT and GC with PID
        a. This association is based on studies done in the 1970s in Europe
        b. In that time, CT rates have increased up and GC rates have decreased
        c. Is this association still the case?
        d. Other etiologic agents of pelvic inflammatory disease
            i. The role of anaerobic bacteria may be playing a more important role
            ii. Mycoplasma genitalium (proposed)
            iii. TB is the greatest contributor to PID in developing countries
            iv. Non-STD pathogens
    2. Association of tubal factor infertility with PID
        a. This association is based on laparoscopic studies done in Scandinavia in 1970s
        b. How do we reconcile that CT rates are increasing but PID rates are decreasing?
        c. Sources of imprecision in PID diagnosis
            i. Non-specificity of clinical PID diagnosis
            ii. There is a decreasing emphasis on hospitalization for PID management
            iii. In the study, when clinicians made a diagnosis of PID, they were wrong 1/3 of the time (rather patients had cysts, inflammatory bowel disease, appendicitis, etc. because these diseases have many of same symptoms)
    3. Evidence that CT screening reduces PID
        a. Skeptics say that the studies were done in high-risk women, i.e. women who had identified risk factors for STDs
        b. One could make an argument that CT screening is appropriate for high-risk women but maybe not <u>all</u> women <u>every</u> year
        c. Occurrence of PID in women following screening
    4. NHANES US chlamydial prevalence, 1999-2008
        a. CT rates have decreased overall, however there are wide and overlapping confidence intervals across years; therefore rates may not be that different from what they were decades ago
xi. Suggested steps to enhance IPP
    1. We need more data, but data is not sufficient
    2. We need to measure PID and infertility, i.e. the outcomes of interest
        a. We can measure these things
        b. Infertility would be pretty easy to measure, e.g. if a woman has unprotected intercourse for at least a year and has not gotten pregnant
        c. Expand screening efforts

i. Only about 40% of Medicaid eligible women who are supposed to have annual CT screening actually get annual CT screening

d. We should consider new metrics to encourage continuous quality improvement
e. We can optimize chlamydia screening
    i. Target those who need screening
    ii. Improve the process of chlamydial screening
    iii. Assure timely treatment

3. Time to treatment following STD screening (JCHD STD Clinic in Jefferson County, Alabama)
    a. Many patients are treated presumptively, but others receive treatment after testing – however, not always
        i. About 20% of positives were not treated within 30 days of screening
4. Chlamydial culture performance in women without other indications for therapy (Hook, JAMA)
    a. 24% had developed clinical PID in the interval between positive diagnosis and returning for care
    b. This study looked at the University of Alabama Birmingham (UAB) ER data
        i. 4.5% of women were screened for CT and not treated in the UAB ER and then came back with PID
    c. Therefore, we need to focus on treating positive patients in a more timely fashion
5. Optimization of time from screening to treatment
    a. Specimen transit time to lab
    b. Turnaround time in the lab (e.g. lab technicians may not associate the tests with patients)
    c. Time to recording of test results
    d. Time to notification of infected persons (e.g. it can take a long time to get contact with a patient)
    e. Mechanisms for facilitating treatment of persons with positive screening tests
6. We must keep in mind that the ultimate goal is not to <u>test</u> people for CT but to <u>treat</u> people with CT

xii. Changing paradigms for urogenital testing
1. Arguments for non-invasive STD testing, e.g. vaginal swab
    a. Faster for patient and less uncomfortable than cervical
    b. Faster for provider and fewer resources (e.g. personnel, specula, exam table)
    c. Testing at sites of opportunity
2. We have done more STD testing in non-health care settings – e.g. school based clinics, incarcerated youth and adults, etc.

c. Question & answer session
i. Can you discuss Azithromycin resistance for GC?
1. It is more of a problem than emerging resistance to Ceftriaxone
2. As of now, using 2 mg of Azithromycin to treat GC in combination is not a problem, but there are reservations

ii. What is the efficacy of vaginal swabs for CT and GC?
    1. Vaginal swabs are always a little better than endocervical swabs and are better than urine for CT and GC testing
    2. Vaginal swabs are the test of choice from a lab perspective and preferred by many women in study by "I want the Kit"
    3. Self-collected vaginal swabs are a better detector than clinician-collected vaginal swabs (because there tends to be more DNA)
        a. One possible explanation is that patients are interested in taking a good specimen, and are therefore perhaps more vigorous and careful

iii. Will there be changes to CDC STD treatment guidelines?
    1. It is not a question of whether changes will be a made, it is a question of when
    2. EPT is going to really be a problem for GC if there are no oral antibiotics

iv. Can you discuss age-specific screening?
    1. Most studies have shown that the best predictor of risk was age, so that is the basis for screening recommendations
    2. Some people for whom screening is not recommended are then diagnosed with CT infections
    3. There is the idea of phase-specific interventions, i.e. we need to screen the population at large to reduce overall rates and only then can we begin to target
    4. By and large, the argument now is that we are still not at the point at which we can target

v. What will happen when we no longer have efficacious drugs to treat GC?
    1. Salvage therapy is being looked at
        a. There are alternative regimens being explored
            i. For instance, Azithromycin and Fluoroquinolones
        b. There are also a few other drugs on the horizon
        c. Unfortunately, the drug industry can make a lot more developing lifestyle drugs than antibiotics

vi. By treating CT, are we interfering with patients' immune response?
    1. There was a study in British Columbia a few years ago that addressed this issue
    2. We do not know a lot about immunity in humans; we have mostly studied immunity in various animals
    3. We are starting to do immunity studies in humans
    4. The "arrested immunity" hypothesis asserts that chlamydial infection is good for you because you get it over and done with
    5. It is an important consideration but is complex in its potential for application and in the context of infertility prevention

vii. Regarding the 77% cure rate for Azithromycin, what do you think that says about re-screening recommendations? We are currently basing re-screening recommendations on a much higher cure rate than 77%.
    1. The data are small and they have to be replicated
    2. In animal models, Azithromycin is less effective, but this treatment has to be replicated in humans

a. E.g. A study is treating adolescents who have been incarcerated because there is less sexual contact and therefore less possibility of re-infection
b. There is the opportunity to do sequencing of isolates
c. There is no collection of cultures

3. The data mentioned were in men, so there is also a question of difference between men and women
4. There is a fair amount of data to suggest that re-infection seems quite likely
5. Partner notification and treatment does not work as well as we would like it to
6. There needs to be re-screening to detect late treatment failures

viii. Thoughts on how long we will be dually treating GC?
1. There are two opposing arguments regarding GC dual therapy
a. Dual therapy might be inducing resistance
b. Dual therapy might also be more effective because there are two drugs that kill bugs through different mechanisms
2. Dr. Hook thinks that dual therapy for GC remains the way to go because of issues of CT co-infection but also because of the potential for post-gonococcal inflammatory disease
a. 60-70% of patients have residual inflammatory problems that do not go away and the dual therapy is efficacious for that

ix. The current recommendation is a Cefixime 400 mg dose – has anyone tried a higher oral dose?
1. Dr. Hook's recollection is that there is not enough of an elevation in drug levels when you double the dose, because some gets absorbed in the GI tract

x. Are there ways to merge population databases with birth registries and see who are less inclined to give birth?
1. This is tough, because demographically women who have the highest rates of CT also have the highest rates of unplanned pregnancies

d. Final remarks
i. There is a report available online from CDC that addresses rethinking the approach to STD prevention
ii. The idea is that we have over 100 years in which we have framed all STD and infertility prevention measures in terms of loss frame (i.e. "or you'll get chlamydia and….")
iii. Since the beginning of the 20th century, there has been a prominent belief that if you get an STD part of you will stop working – but this philosophy has not worked!
iv. There is a movement at CDC to promote the concept that we need to reverse our messages; therefore, we should now say, "You have to be screened to preserve your health. Screening is a benefit. The good news is that STDs can be detected and managed!"
v. This new philosophy meshes with CDC's initiative on program coordination
vi. Preliminary report on new sexual health framework was posted last week
vii. We can do better with a "health promotion" framework instead of a "disease" framework

C. CDC Update (Steve Shapiro)

a. CSPS 2011[1]
    i. Anticipated funding at 2010 levels
    ii. 70% of awards already went out; the remaining 30% are going out shortly
    iii. CDC took more than 10% cut, but IPP did not get cut in STD at all (TB took a huge hit)
    iv. All IPP has to worry about is a .2% rescission, which was explained in a letter from Dr. Bolan; this percentage will come out of the total annual award
    v. Under normal circumstances, procurement would ask each state to submit a revised budget reflecting the rescission
        1. In most states, this would not be a major revision
        2. CDC is currently negotiating with the Procurement and Grants Office (PGO) to see if the revision can be in just one line item, not across all three components (i.e. just CSPS)
        3. Hopefully, PGO will agree to applicants submitting individual revised budget pages instead of a whole new budget
        4. PGO should have a response soon
    vi. There was an additional $1.546 million in FY 2010,
        1. An IPP supplement was announced in January
        2. Proposals were due in March
        3. Grant awards are being made now
b. CSPS 2012
    i. We expect to be funded at 2010 levels
    ii. The CSPS application is due August 2, 2011
    iii. The continuation guidance went out the first week of May
        1. CSPS has streamlined the application
        2. All requirements from FOA 09-902 remain in effect
            a. The Title X grantee letter must be included
            b. CDC wants to see work on maintaining or working toward 3% positivity
            c. CDC wants to see continued progress on targeted GC plans with a burden calculation
            d. CDC wants to see progress on general IPP objectives
    iv. Starting January 1, 2012, performance measures in the cooperative agreement become optional
        1. CDC encourages states to submit at least 2 or 3 performance measures that will be useful for program planning
        2. Current performance measure requirements are still in effect for 2011 data (i.e. September 2011 and March 2012 reporting)
    v. Additional guidance
        1. An STD Program Manager (or another person with decision-making power for the STD program) must attend the National STD Conference, and this attendance must be reflected in the travel budget
            a. In MA, the Syphilis Program Manager must attend because MA receives Syphilis elimination dollars
        2. Attendance at regional IPP meetings is mandatory and language included
c. GC Burden calculation example

[1] This is based on the calendar year but on fiscal year dollars.

i. This is the same burden calculation from years past
ii. This calculation can be used to determine the minimum amount of IPP dollars that must be used for GC screening

d. DSTDP update
    i. Personnel changes
        1. Gail Bolan is the new director of the division
            a. She has worked as direction of the California STD program for the last 15 years
            b. She joined CDC DSTDP the last week of January
            c. A new division structure will be in place by August
    ii. Current activities
        1. Program collaboration and service integration (PCSI)
            a. The division has been collaborating across disciplines for almost 20 years
        2. Data security and confidentiality guidelines
            a. Collaboration with HIV prevention
            b. HIV programs are going to be expected to share data with Advisory Board members
        3. The antibiotic resistance gonorrhea outbreak response plan is not a theoretical discussion – it is something we need to act on
    iii. Publications
        1. GISP profiles (available on the web)
        2. Community Approaches to Reducing STDs (green paper)
        3. CDC Grand Rounds – Chlamydia Prevention (available on the web)
        4. NG with Reduced Susceptibility to Azithromycin – San Diego
        5. DCL – Azithromycin Resistance in Hawaii
e. Health care reform
    i. CDC cannot comment on health care reform
    ii. What are states up to?
        1. Funding cuts dominate IPP needs to figure out how we fit in to the Accountable Care Act (ACA)
    iii. Fitting IPP into the national HIV strategy
        1. IPP fits into broad public health messages for adolescents and adults
        2. IPP fits into teen pregnancy prevention
        3. IPP fits into addressing GC resistance
    iv. The Future of IPP Project
        1. The CDC is conducting a national assessment of IPP's Future.
            a. Region I IPP Infrastructure is assisting with the assessment
        2. IPP may look very different next year and even more so five years from now
        3. The Future of STD prevention (2012 and beyond)
            a. STD programs will be moving away from direct service (MA has already done this by shutting down STD clinics)
            b. Reductions in direct service are not due solely to ACA; the direct service infrastructure has been a crumbling infrastructure for the last 15 years and ACA accelerated its decline
            c. Assurance

i. IPP must have a functioning surveillance system, which includes developing relationships with other entities to ensure that STD prevention is occurring
ii. IPP must have local epidemiology support, meaning that every project area should have an epidemiologist on staff for STD prevention (even if he/she is only available a fraction of the time)
iii. IPP will need to up its PCSI evaluations

d. Policy developments
    i. IPP must use all sources of data, e.g. HEDIS, geographic data, etc. to make policy decisions
e. Assessment and Accountability
    i. Monitoring
    ii. Evaluation
f. Safety net coverage
g. There will be a quick turnaround for these changes
h. Programs have to be able to bill and they have to be able to get reimbursed; otherwise, programs will struggle to survive in the new health care environment
i. If programs have state statutes that prohibit them from collecting money, they will need to figure out how to change those statutes

f. Gonorrhea
    i. GC rates by age among women 15-44
        1. It looks like GC has decreased during 2000-2009
    ii. GC rates by age among men 15-44
        1. There is the same trend among men as there is among women
    iii. GC rates by race/ethnicity
        1. There is a significant downward trend among African Americans
        2. There has been an increase among American Indians/Alaska natives, though the cause is unclear
            a. Alaska especially has had a huge increase in GC
    iv. GC rates by county
        1. GC is most prominent in the Southern/ Southeastern regions
        2. However, if we were to look at GC among African Americans by county, then the Midwest would have the highest rates
        3. Wisconsin has the highest GC rates among women
    v. Is GC decreasing?
        1. There are issues with morbidity data, so we must look at other data sources, e.g. the National Job Training Program (NJTP)
            a. The NJTP is a federally funded job preparation program extended to economically disadvantaged 16-24 year olds in mainland US
            b. Everyone in the NJTP is screened at entry and all specimens are analyzed at one lab, which shares the both positive and negative data with CDC
            c. The data set includes: sex, age, race/ethnicity, test technology, and place and date tested
        2. Why use NJTP data?
            a. Information is available on all GC tests

b. This is a large, "stable" population (almost 100,000 men and about 90,000 women were tested for GC from 2004-2009)
c. NJTP entrants have a higher GC risk than the general US population

3. NJTP results
   a. Among NJTP men and women, there is a downward trend in GC prevalence
   b. By race/ethnicity, there is also a downward trend in GC prevalence (which mirrors NETSS data)
4. NETSS data
   a. 2009 v. 2010
      i. Increase in GC in ME, MA, NH, and VT
      ii. GC in Conn. has remained about the same
      iii. GC in RI has decreased by 9%
      iv. There have been significant GC increases (up to 40%) elsewhere, e.g. LA, SF, Philly, Baltimore
      v. We must keep in mind, that these rates were very small numbers to begin with

vi. Resistance MDR GC

1. GC surveillance
   a. Emergence of FQ resistance: Hawaii
      i. Cipro was available in the 1980s (no resistance)
      ii. By the early 1990s, we started to see Fluoroquinolone resistance; by the late 1990s, there was a lot of resistance
      iii. Fluoroquinolone stopped being recommended in the US around 2006
   b. Geographic distribution of Cephalosporin (Cefixime or Ceftriaxone) alerts, 2005
      i. Alerts do not mean decreased susceptibility or resistance; they indicate antibiotic sensitivity testing
      ii. There were about 10 alerts around the country in 2005, and a similar number in 2006
      iii. In 2009, the number of alerts increased about five-fold
      iv. GISP is a delayed sentinel surveillance system
      v. These data indicate that we have to look at these isolates
      vi. In 2010, there were a lot of alerts in San Diego
   c. International trends
      i. Europe
         1. There are increasing numbers of isolates that have decreased susceptibility to Ceftriaxone
      ii. Japan
         1. Over the past ten years, there has been a possible treatment failure with Cefdinir, decreased susceptibility to Cefixime, and an isolate with Ceftriaxone MIC of 2 μg/ml
      iii. China
         1. From 2001-2009, ~30-40% of isolates have MICs to Ceftriaxone of ≥ 0.06 μg/ml (~3% in the US in 2010)
   d. Summary

i. Alert does not mean that there is resistance – it means that we should pay attention to an increase in cases
ii. We do not know if increased MICs are connected to treatment failures
iii. If there is a treatment failure, the protocol is to collect a culture and re-treat the patient with at least 250 mg Ceftriaxone

g. Question & answer
    i. If we are not a part of GISP, do we rely on treatment failure to detect a resistant strain?
        1. Yes
        2. The first indication of resistance will likely come from private providers seeing patients on a regular basis who notice that the bug is not going away
        3. Our job to get this information out to the wider provider community so that they can be looking for this
        4. In most surveillance systems, if someone has two positive tests in 30 days, we throw out the second positive
            a. The potential for resistance will have to make us stop and re-evaluate all testing data
            b. This will take manpower, resources, and re-prioritization
            c. This is a priority because there a lot of co-infection of GC and HIV among MSM community,
    ii. Is there talk of developing a CDC surveillance network similar to the influenza surveillance network?
        1. There is an existing SUN network
        2. But most work will be done at the state level, not at the national level

D. Cost of Screening Outside IPP Guidelines (Andee Krasner)
    a. Background
        i. A cost analysis was conducted last year for three states
        ii. Infrastructure then thought it would be beneficial for all states
        iii. Infrastructure piloted the tool in October 2010, and disseminated it at the November 2010 Advisory Board meeting
        iv. Programs used the tool for the first time in April 2011 after 2010 annual data had been cleaned and submitted to CDC
    b. Methods for developing the tool
        i. Key informant interviews were conducted in 2009
        ii. These key informant interviews were used to determine all steps of testing
        iii. From these interviews, Infrastructure learned that state testing programs vary widely; therefore, the tool had to be flexible while also collecting uniform data
    c. Methods for data collection
        i. Some programs have data from budgets, and others estimate the data
        ii. More than half of data were estimated
    d. 2010: Percent of CT tests done outside guidelines
        i. Outside guidelines means that patients were 25/26 or older with no risk factors and no clinical signs of infection
        ii. 2,214 tests were done outside guidelines (average of 6% outside guidelines)
    e. Positivity rate of tests outside guidelines

i. There was 2% positivity outside guidelines, which is less than the 3% recommended positivity for IPP

f. Average cost of test paid for by IPP
   i. The average cost of a test is $11.29 – this data is likely not reproducible since it was derived from estimated data
   ii. No one uses IPP funds to pay for all parts of the test cost
   iii. Test steps: purchase test, distribute specimen collection, collect specimen and send to lab, , lab processes specimen and communicates results to clinic, communicate results to client and data management
   iv. This average IPP cost is much lower than the true cost of a test, because this cost represents just IPP expenditures

g. Impact on IPP budget
   i. 2% of the IPP budget was spent on tests outside screening guidelines
   ii. However, the impact goes beyond the IPP budget

h. Conclusions
   i. CT positivity does not support screening outside guidelines
   ii. This money could be used to target populations with higher positivity
   iii. The true cost of screening outside CT guidelines goes beyond IPP paid tests, and impacts clinic and lab costs

i. Comments
   i. It would be great to think about this within project areas
   ii. It would be good for states to have a presentation to deliver to providers
   iii. The difference between 1% and 17% (i.e. the range of testing done outside guidelines) is substantial

E. IPP Infrastructure Updates (Jennifer Kawatu)
   a. GIS Maps
      i. The GIS maps that we wanted to produce were not the ones we were able to produce due to data limitations
      ii. Infrastructure looked at site positivity and poverty and site positivity % black population
      iii. % black population is more useful at a state/local level in terms of informing allocation of resources
      iv. The maps can help inform where clinics may need to be funded by IPP to service the most at risk demographic populations

F. IPP Data Update (Andee Krasner)
   a. Chlamydia data – IPP regional and state trends
      i. There is a clear trend that IPP funded testing is declining regionally (despite an increase in testing at the national level, which includes both IPP funded and non-IPP funded tests. We are the only region that tracks IPP funded testing so we don't know if other regions are also seeing decrease in IPP funded tests.
      ii. Positivity has increased slightly, to about 5% in 2010,
      iii. Comment: there has been a decrease in the youth population at some family planning sites; also, the youth population is decreasing overall in some states
      iv. When we look at IPP funded testing only, we are not meeting objective 1.1
      v. We are doing much better on objective 2.2
         1. NH and VT are nearing the goal of 95% screened according to screening guidelines

LUNCH AND STATE MEETINGS

G. State Report Backs
    a. Connecticut
        i. Enthusiastic about the Get Yourself Tested (GYT) campaign
        ii. Changes at the state level
            1. Unions are negotiating a contract
            2. If the contract is not agreed upon, there will be massive layoffs
            3. There is a new system of preventive health among state employees
        iii. Health reform
            1. The plan is to do Medicaid family planning expansion, which would also include STD (will hopefully get it through in next year or two)
    b. Rhode Island
        i. Implementing IPP
            1. RI receive funds from CDC; about $30,000 goes to the state lab for testing and the remainder goes to health centers
                a. In 2009, RI came up with formula for allocating funds
                    i. Each site had to have 3% positivity to get IPP dollars
                    ii. Then sites were asked if they wanted to participate; about 7 sites said they did
                    iii. The amount of money allocated to each site is based on the number of tests conducted
        ii. RI has no health care reform updates
        iii. Changes at the state level
            1. Dr. Gifford, who was the Director of the RI State Department of Health, resigned and there is now an interim director (Dr. Fine)
            2. Last year RI saw a big increase in infectious syphilis cases (68 cases)
                a. There were 27 HIV-positive among the syphilis cases
                b. With CDC, RI is coordinating efforts to administer a survey to MSM
                c. RI will also put together a survey for providers that addresses HIV prevention messages to MSM
        iv. GYT campaign
            1. RI went to five or six college health centers
            2. The students were very receptive
            3. College health centers from CT, MA & RI get together monthly and RI STD will try to get on the agenda in the fall
        v. There have been no changes to screening guidelines
        vi. Lab slips
            1. There has been an issue with the new PTO box
            2. There is some confusion around what PTO means, even though providers have been trained on how to complete the forms
            3. RI will continue to work on this
    c. Massachusetts
        i. Implementing IPP
            1. MA creates its own lab slips, which they send to clinics and the clinics send back for processing
            2. MA does not disseminate any funds directly to clinics

3. MA has closed its STD clinics, but now HIV testing sites are filling in the gap on CT/GC testing, paid for by the Office of HIV/AIDS (OHA)
    a. OHA is providing funding that is allowing DPH to integrate services with HIV clinics
4. Hepatitis C screenings are being performed in MA

ii. State level changes
1. Layoffs have been happening

iii. GYT campaign
1. MA mailed a lot of resources to every college health center in the state

iv. Screening Patients >26
1. Positivity is close to 0% among the >26 population, even among women with risk factors
2. MA has explored the possibility of not accepting specimens from women without risk factors or excluding this population from the IPP screening guidelines

v. No changes are planned for lab slips
1. People appreciated the webinar on lab slip changes that was presented several months ago

vi. Lab
1. Lab has retained STD lab staff (though this is not the case with Hepatitis and HIV testing)
    a. MA is taking it on a month by month basis
2. Lab has advanced to QX extraction technology for CT NAAT testing, which streamlines the lab process
3. MA is rolling out electronic reporting of results on a clinic by clinic basis

d. New Hampshire

i. Implementing IPP
1. NH receives funding through the STD program and IPP sites send specimens
2. NH has worked to eliminate screening of the >26 population without risk factors by billing those tests back to the site
3. It has been a difficult transition, though it has made some sites do a better job of filling out the lab slip
4. NH does not disseminate funds to sites or use funds for labor time

ii. State changes
1. The House and Senate have eliminated funds for some STD services
2. NH is working on what its new program model will look like and how they will provide services
3. NH may then look at IPP differently, because it will not have state funds as a cushion anymore, e.g. NH may re-evaluate screening guidelines and exclude the >26 population altogether
4. NH will be deciding on changes in the next 6 weeks

iii. Lab slips
1. NH made changes in the last year that have helped enforce guidelines

iv. Lab is getting a new LIMS system

v. All IPP sites are family planning
1. Family planning sites have taken a hit from the governor's budget and the House, and there have been federal cuts to Title X – all of which will have an impact on IPP

2. With ACA and the Medicaid waiver, NH will need to defend Title X

e. Vermont
   i. IPP overview
      1. Just under $50,000 are awarded to VT for IPP
         a. Over 70% of funds go to PPNNE, which distributes to its 10 VT sites in operation
         b. VT awards an additional $10,000 of state funds to ensure that contacts/partners are treated
      2. PPNNE is a prime partner
   ii. Health care reform
      1. VT technically has programs to provide universal coverage, but most people on fixed incomes cannot afford it
      2. The new administration wants to see health care reform as a cornerstone, and therefore the commissioner wants action
      3. The administration wants to make sure its goals are in line with Healthy People 2020, and is therefore creating measures based on these objectives
   iii. Screening guidelines
      1. There have been no changes to the screening guidelines
      2. IPP sites act as STD clinics, but may need to be changes in future
   iv. The lab slips are working
   v. VT lost its DIS in 2009 and lost two PPNNE clinics in 2010
   vi. VT is projected to hit 1,300 CT cases this year
f. Maine
   i. IPP
      1. ME conducts under 3000 IPP tests
   ii. State changes
      1. ME has a new governor
      2. ME has a new commissioner of the Department of Health and Human Services and a new director of ME CDC
      3. There is no decision on the state budget yet
      4. ME passed a law for EPT one year ago, which requires some guidelines from the state that are in development
   iii. ME is grateful for the webinar on lab slip changes and is happy with the new lab slips
      1. ME is tracking re-screen, PTO, and other gender
   iv. There is the potential for verification for rectal/oral testing for GC
   v. ME has been successful screening according to state guidelines
      1. ME will probably continue screening women 25 and older, but will try to cut down on those with no risk factors

H. The Accountable Care Act (Naomi Seiler)
   a. Background
      i. This is now a great opportunity to take a step back and say what it health reform means, particularly in terms of public health
   b. The 1st opportunity in health reform is expanded coverage for preventive services
      i. A or B level of the US Preventive Services Task Force (USPSTF) will encompass CT screening for all sexually active women and for all older sexually active women at increased risk, and GC screening for women with increased risk

ii. Plans are grandfathered in if they already exist but if plans make significant changes then they lose their grandfather status and must comply with new guidelines for preventative services
iii. It is anticipated that over the next couple of years most health plans will be required to cover these preventive services, as well as others
iv. Medicaid benchmark plans will be a big piece of expanded insurance coverage
v. ACA will expand Medicaid so that all adults up to 133% poverty level will be covered; the group most affected will likely be childless adults, so this is a huge expansion
vi. Health insurance exchanges
    1. These exchanges will be set up in states
    2. States have to demonstrate to HHS by January 2013 that they will be able to manage an exchange by January 2014

c. The 2nd opportunity is integration with primary care
    i. This opportunity applies to community health centers (CHCs), whether they are federally-qualified health centers (FQHCs) or not
        1. CHCs will receive a large increase in funding under ACA
        2. CHCs will be able to bill private insurance, Medicaid,
        3. CHCs will be able to get training for providers using these funds
        4. CHCs will be getting more reimbursement, because more patients will be eligible for coverage
        5. CHCs will remain an important site for care
d. The 3rd opportunity is the potential to be defined as an essential community provider
    i. An essential community provider is defined as an entity serving primarily medically underserved, low-income individuals, e.g. those in the 340 B program
    ii. Health insurance exchanges will have to network with community providers
        1. It is not yet established who will be an essential community provider
        2. It is not yet clear whether every plan in a state will need to coordinate with every single essential community provider
e. Other opportunities
    i. National Prevention Strategy
        1. The strategy is being put together by all parts of the federal government (not just public health agencies)
        2. The strategy is not public yet but there is a draft framework, consisting of 4 priorities and an additional set of targeted priorities
            a. Sexual health is a targeted priority
            b. There is no clear link yet between the strategy and IPP
    ii. Prevention and Public Health Fund
        1. The fund is designated for a few things under ACA
            a. Funds are going toward workforce and infrastructure
            b. There are some rolling funding opportunities
    iii. Community transformation grants
        1. The funding announcement has come out for community transformation grants, which focus on chronic illness, nutrition, obesity, etc.
        2. An entity can apply to transform a state or a large city
        3. It appears that entities can work on STD issues, as well as other issues that have a link to healthy people 2020, as long as there are also focuses on health promotion
        4. Applications are due in July

5. IPP programs can find out who, if anyone, in the state is applying for the a grant and see if they can be part of that consortium
    a. CDC will have some information on who is applying on the web site
6. The grants will total $100 million

iv. Novel service delivery mechanisms
1. Accountable care organizations and other ways to use payment/delivery systems to improve quality and reduce cost
2. Funds are going to PCPs to coordinate care
3. Will need to look broadly at population health and need

f. What is the prognosis for all of ACA?
i. With this Senate and President in place, it is unlikely that ACA will be repealed
ii. The law suits may go to the Supreme Court, possibly as early as this fall
iii. The primary issue in question is whether an individual mandate in constitutional
iv. If the Supreme Court determines that it is not constitutional, that may not mean the total end of ACA
1. If there is no individual mandate, there would need to be some mechanism to sustain expansions of coverage
2. It is likely that Elena Kagan will not recuse herself, in which case she will likely vote that it is constitutional

g. Funds
i. Deficit cap
1. Congress can vote to increase the deficit cap
2. The public is hearing a lot about it now because many tea party/conservative congress people are promoting making severe cuts if there is an increase in the deficit cap
3. If nothing happens to deficit cap, the federal government has until August 2nd before it runs out of money

ii. Discretionary funding and Medicare/Medicaid are being scrutinized more than ever before

h. Question & answer
i. What web site can you recommend for getting more information on ACA?
1. Kaiser Family Foundation
    a. http://www.kff.org/
    b. It has good timelines and fact sheets
2. GW and Robert Wood Johnson Foundation Health Reform GPS
    a. http://www.healthreformgps.org/
    b. This is a great set of information, a step beyond basic
3. Federal government website on health reform
    a. www.Healthcare.gov

ii. How do family planning agencies position themselves to create contracts with exchanges?
1. Claire Coleman has done a lot in this area
    a. She recently did a presentation on how you get a plan to contract with you if they do not have to
2. IPP programs could look at partnering with entities that are essential community providers with whom plans are required to partner
3. Just because plans do not have to contract with an entity does not mean they will not (look at what is done in a normal world to get plans to contract with you, i.e. Claire Coleman's work)

4. Steve Shapiro has Claire Coleman's slides

iii. Do we have an idea of which entities will be designated essential community providers?
1. It is likely that Title X or categorical STD clinics will be essential community providers because they are 340B designated
2. However, would like to make sure that the definition does not stop there
3. When the regulations come out later this year, there will be a comment period

iv. What is the role of family planning expansions and other pre-ACA things?
1. There are a few overall Medicaid expansions going on
2. CA is doing a Medicaid expansion earlier than 2014, which would include family planning expansion
3. A number of states have stopped work on state plan amendments, because they are not sure how that will look with ACA
4.

I. Continuing Education Module (Jennifer Kawatu)
a. A few years ago, Infrastructure conducted an assessment asking providers questions about their familiarity with CDC screening guidelines, IPP guidelines, the legal status of EPT, etc.
i. There was a great range in responses
b. As a result, and in response to AB request for online educational opportunities, Infrastructure decided to create an educational tool that would provide regional and state-specific information
c. This is phase two of follow-up; the first phase was the provider materials
d. The module presents epidemiology testing and treatment scenarios
e. Infrastructure plans to launch the module in the fall
f. Kathy Hsu conducted medical review and a few Advisory Board members also reviewed the script
g. The module will be hosted on the IPP web site, free of charge
h. Course participants may receive nursing CEUs
i. JSI could provide the module for adaptation by other Regions.

J. Lab Update (John Papp)
a. CDC is looking for a new branch chief who will take over for Ron Ballard
i. The branch will be realigned
b. Lab guidelines for CT and GC
i. The new guidelines have been in development since a consultation in 2009
ii. The CT and GC guidelines will be separate from syphilis guidelines
iii. CDC is discussing internally whether guidelines should be a MMWR or not
iv. 2002 Recommendations
1. NAAT test on an endocervical swab specimen, if a pelvic exam is acceptable; otherwise, NAAT test on urine
2. Culture performed on an endocervical swab specimen
v. 2011 Recommendations
1. NAAT performed on a vaginal/endocervical swab specimen
a. Vaginal swabs are the optimal specimen type for NAATs
i. Urine is recommended if vaginal swabs are not accepted by/convenient for the patient

b. Culture should be performed on an endocervical swab when there is a need to assess GC isolates for resistance to front line antibiotics

2. Rectal/Pharyngeal infection recommendations for CT
   a. 2002
      i. Culture on rectal or pharyngeal swabs
   b. 2011
      i. NAAT on rectal swab
         1. NAAT is not cleared for rectal specimens by FDA
         2. Can be validated at state level
         3. CDC funded an external specimen bank to facilitate an off-label establishment study
         4. List now available of labs that have validated
         5. The CLIA checklist available on APHL web site (www.aphl.org)
      ii. There are too few pharyngeal CT infections for meaningful comparison
3. Supplemental testing for CT/GC
   a. 2002
      i. Consideration should be given to routinely performing an additional test after positive screening if the positive predictive value is low
   b. 2011
      i. Routine repeat testing of NAAT positives are not recommended for CT
      ii. Routine repeat testing of NAAT positives are not recommended for GC unless there are significant number of false positive results, in clinical studies, due to cross-reaction with non-gonococcal Neisseria species
4. Possible sexual assault/abuse
   a. 2002
      i. Culture
   b. 2011
      i. NAATs in urogenital specimens for CT and GC
      ii. There is limited data on use in children

vi. Overview of Association of Public Health Laboratories (APHL)/CDC STD steering committee
1. Priority 1: Development of new testing guidelines for CT, GC and syphilis
   a. Continue to monitor the progress of guidelines development
   b. Develop and distribute communications once guidelines are released on rectal and pharyngeal testing for CT/GC using NAATs
   c. John will distribute the new guidelines to the lab subcommittee to review
2. Priority 2: Assessment of PHL STD capabilities, capacity and practice
   a. Develop a survey tool
   b. Launch a survey in January 2011
   c. Assess the impact
3. Priority 3: Develop a green paper on the role of PHLs in STD testing

a. Draft a green paper that addresses the issue of privatization of STD testing and question of what role PHLs will play in STD testing in the future
b. Address feedback from the ID committee and BOD
c. Determine committee

4. Priority 4: Development of herpes testing guidelines
    a. Identify workgroup to develop key questions on herpes test methods and resting practices
    b. Perform a literature review
    c. Determine additional data needed
5. Priority 5: Assist interested labs in implementation of off-label NAAT for CT/GC in non-genital anatomic sites
6. Priority 6: Development of trichomonas testing guidelines

c. Question & answer
    i. NH uses the BD Probe Tech, which is not approved for vaginal swabs, and it is unclear if there are plans to validate it for vaginal swabs. What should NH do? Could BD validate the Probe Tech for vaginal swabs?
        1. John meeting with vendors face-to-face
        2. John wants to give vendors a sense of priorities
        3. Rectal and pharyngeal testing area l priority, and CDC would like buy-in from vendors on this so that they can all get FDA clearance, which the vendors agreed; it is still being determined whether CDC will pursue this or off-label testing
        4. It seems possible that self-collected vaginal swabs will be popular, especially for re-screening purposes
        5. John will talk with BD, though he has in the past and BD did not seem inclined to approve Probe Tech for vaginal swab
    ii. Why is there such a push to move from urine to self-collected vaginal swabs given that the difference is so minor?
        1. Vaginal swabs are slightly more sensitive (around 2-4% based on studies)
        2. John might put data tables on APHL web site so the reason for the recommendation is clear
        3. The ease of collection is a lot better for vaginal swabs,
        4. With urine specimens, there are some rejection criteria from labs

K. Rhode Island CT Screening and PID Rates (Mike Gosciminski)
    a. Are we really reducing PID prevalence?
    b. Surveillance case report form for CT and GC includes the following information:
        i. Whether the infection is asymptomatic/symptomatic
        ii. Whether there is PID (and if it is related to CT or GC)
    c. From 1997 (when IPP began in RI) through to 2010 there has been a steep decline in reported PID from CT and GC
        i. Even with the high case rate, PID rates have decreased
    d. PID is reportable in RI
    e. Question & answer/Comments
        i. If the STD program does not receive a case report form in certain amount of time, DIS will call to get it
        ii. How is PID confirmed?

1. PID is recorded based on whether it is indicated on the case report form; it is not validated with medical records

iii. What is the time frame between filling out the case report form and receipt of a test result?

2. Some providers send the form in after treatment, but it is usually 14 days

iv. Often PID shows up at the time of testing

L. Collecting Site Positivity Data in Region I (Andee Krasner)
   a. In 2006, Region I began collecting only IPP-funded CT testing data
   b. In 2010, CDC requested moving to total site positivity for IPP sites
   c. Goals
      i. With minimum burden to Advisory Board members, Infrastructure wants to collect site positivity to report to CDC
   d. CSPS
      i. There is a goal of 3% minimum positivity
      ii. CSPS assumes that Region I states report site positivity, because that is what the rest of the nation uses
      iii. We do not know how IPP positivity compares to site positivity
      iv. If states have site positivity data, they should use that
      v. In the absence of site positivity data, states can use IPP data
   e. If states have only a few sites that can give site positivity and others that cannot, states should still send site positivity for those few sites and indicate that the other sites represent IPP positivity
   f. Nevertheless, states should be moving toward site positivity in PM database
   g. Infrastructure's plan for collecting site positivity
      i. Infrastructure will work with state STD and lab representatives to figure out what data is collected at the state level; it will then get this data extract and feed it back into the prevalence monitoring system
      ii. Some IPP sites use private labs, so the second step is to work with those clinics to figure out which labs they are using and request data directly from the labs
   h. Requested data fields:
      i. Medical record number
      ii. Test facility ID
      iii. State
      iv. Age
      v. Gender
      vi. Test for CT/GC
      vii. Test result
      viii. Date of test performed
   i. Other data fields that would be nice to have:
      i. Race/ethnicity
      ii. Clinical history
      iii. Payment
      iv. Risk history
   j. Infrastructure is requesting client level data (i.e. not aggregate)
   k. Progress
      i. RI provided a data extract for all tests from IPP sites
      ii. PPNNE provided a data extract from all PPNNE IPP sites in VT, NH and ME
      iii. The NH state lab will provide an extract of all state-funded tests at IPP sites

l. Infrastructure does not expect programs to delineate which tests are IPP and which are not; Infrastructure can figure that out
m. All data from each state will not necessarily come from one source
n. If states are looking to add IPP sites, they can just ask new site for its site positivity according to the state screening criteria- aggregate data is fine
o. Next steps
    i. Develop a feedback system to have data all in the prevalence monitoring system for each state
    ii. Work with Advisory Board members to request a limited dataset from IPP sites/labs
        1. NH
        2. ME
        3. CT
        4. MA
    iii. It would be optimal to collect race/ethnicity, but is not necessarily feasible across the board in the short term
    iv. It would be ideal for IPP lab slips to be used universally at all IPP sites, so that we would have uniform data (though that might not work for all labs)
        1. It is difficult to ask non-state labs for required data elements, let alone the enhanced data elements

    The Title X system is a potential data source. Infrastructure considered this option but there is no positivity data so we can't use it

M. IPP Futures Project (Jennifer Kawatu)
a. JSI Denver is lead on the assessment, though each region is participating in data collection efforts
b. Purpose
    i. Strengthen IPP in context of PPACA
    ii. Improve and leverage partnerships
    iii. Maintain IPP's role in communicating best practices
    iv. Address service area gaps
    v. Anticipate changes in data collection and reporting practices
c. Infrastructure needs the help of the Advisory Board to carry this out
d. Methodology
    i. Review of health reform literature
    ii. Primary data collection involving Advisory Board members
        1. Advisory Board members will fill out surveys
        2. AB members will send out clinic surveys to their networks
        3. Advisory Board members will ideally help identifying partners who can provide insight through key informant interviews
    iii. Review, synthesis and analysis of secondary data sources
e. Time line
    i. Infrastructure will begin scheduling interviews in late June/July
    ii. Hopefully the interviews will be conducted before August 5th
    iii. Three surveys
        1. Family planning and STD state partner survey (July)
        2. Lab survey (July)
        3. Clinic survey (August)
f. How will the data be used?
    a. The data will be analyzed and reported in six domains
        1. Insurance coverage

2. Health information technology
3. Innovation and quality improvement
4. Minority health and health disparities
5. Workforce
6. Prevention

b. The report will be used by CDC to repurpose IPP to complement PPACA services

N. An Evaluation of Region I IPP Provider Materials (Jaya Mathur)
   a. Background
      i. Mouse pads, pocket cards and provider materials were distributed in spring 2011
      ii. Advisory Board members weighed in on the development and feedback was incorporated into the materials (people agreed/strongly agreed with this)
   b. Materials evaluation by Advisory Board and providers (result highlights)
      i. Poster evaluation
         a. The poster was more effective at raising awareness among patients than among providers
         b. The poster was age appropriate and at the right literacy level
      ii. Pocket card evaluation
         a. The pocket card effectively presented the guidelines but was not considered a very effective reminder to providers
      iii. Mouse pad evaluation
         a. The mouse pad was the least useful tool by providers to remind them to screen
      iv. Providers thought the CT Screening Site Report helped them understand IPP screening goals and clinic screening rates, but that it did not modify their screening practices
   c. Material overall effectiveness
      i. Overall, the Advisory Board member and provider respondents somewhat agree or agree that the materials are effective
   d. Use of extra materials
      i. Extra materials can be used in connection with the GYT campaign and for non-IPP sites

Next IPP Advisory Board meeting scheduled for November 9, site TBD