

**Anencephaly Advisory Committee Meeting (webinar)  
Minutes  
July, 28 2014**

**Advisory Committee Members present:**

Kathy Lofy, MD, Chair  
Susie Ball, MS LCGC  
Sara Barron, RN  
Nora Coronado, PhD, MPH, MSW  
Philip Halvorsen, MD  
Peter Langlois, PhD  
Gina Legaz, MPH  
Jennie McLauren, MD, MPH  
Amy Person, MD  
Melissa Schiff, MD, MPH  
Christopher Spitters, MD, MPH  
Vickie Ybarra, RN, MPH

**WA Dept of Health Staff present:**

Lillian Bensley, PhD  
Riley Peters, PhD  
Mandy Stahre, PhD, MPH  
Cathy Wasserman, PhD

Interested parties were sent information about the meeting and asked if they wanted to participate. There were several interested parties on the call, including representatives from the media.

**I. Welcome and Introductions**

Kathy Lofy began the meeting a few minutes past 8:00 am with introductions. She introduced a new advisory committee member, Jennie McLaurin who was asked to join the committee at the recommendation of the other members. Kathy also noted that DOH contacted the Yakama Nation to participate, but no one has been identified to date.

Kathy shared comments from the public regarding the last advisory committee meeting which included several offers of assistance, possible prevention strategies, and a few media inquiries. Two specific comments to share with group:

- A member of the public was concerned that Hispanic women were referred to as “liars” by Advisory Committee members, and was offended by this assertion. This person urged us to interview these women to get their perspective.
- The same person was concerned about Infant Mortality rates in Yakima due to congenital malformations. Using publicly available data, this person constructed graphs of the trend in infant death rates due to malformations from 1990-2010 in Washington State, and King, Pierce, Spokane, Whatcom and Yakima counties. We looked at the death rates in Yakima due to malformations from 1990-2012 and it does appear higher than the state rate for the same time period. As we told this person, it is hard to make any firm conclusions from this data, as the deaths due to malformations may be influenced by the number of infants born with malformations, the type and severity of the malformation, and access to healthcare for treatment.

No additional comments on draft minutes.

**Minutes approved from June 16<sup>th</sup>.**

Cathy Wasserman gave presentation (attached) Some main points of slides that are not directly apparent are listed below.

What we've learned since the last advisory committee meeting:  
Surveillance Questions

1. Do we know we identified all cases in the 3-county area? (Slide 4)
  - a. Confident we ascertained most cases
  - b. May have missed cases if mothers moved out of the area before delivery or
  - c. Cases diagnosed early and terminated in a clinic outside of the 3-county area
2. How do the rates compare with other agricultural communities? (Slides 5-6)
  - a. Compared with central valley California (1997-2006) and rural Texas
  - b. Overall, rates appear higher in the 3-county area, but not statistically different than central valley California
  - c. Rates from California registry (larger than Central Valley and including 30% of the state) for 2006-2010 are significantly lower than the 3-county area in Washington
  - d. Texas information is similar to California registry for anencephaly
3. Do we know if the cluster is new or an increased rate? Do we know the rates of anencephaly in the area are different from the rest of the state? (Slides 7-10)
  - a. Using vital statistics (live births and fetal deaths) DOH performed analyses. Diagnoses are not verified on birth or fetal death certificates.
  - b. Texas compared registry and certificate data for accuracy. They found a positive predictive value of 34%, and sensitivity of 58%. We do not know if the results would be similar for Washington.
  - c. We did look at the accuracy and sensitivity of the cases in the three county area. When comparing birth certificate data with data from the investigation results showed a 95% accuracy and sensitivity of 85-88%.
  - d. We looked statewide from 2003-2013 at vital statistics data and found 408 anencephaly and SB cases combined on both birth and fetal death certificates.
  - e. Anencephaly rate based on vital statistics was 2.4/10,000 for entire time period.
  - f. Our fetal death certificates include both fetal losses and terminations after 20 weeks gestation
  - g. The rate for anencephaly and SB based on vital statistics is higher than the 1.0 per 10,000 for 2004-2006 that the Parker et al article reports for live births and stillbirths. (This is the article used as a comparison for national estimates). We don't know that we are comparing exactly the same thing, since the Parker article reports a rate for "live births and stillbirths" combined. Our vital statistics rate is based on live births and fetal deaths combined. Our fetal deaths include stillbirths and terminations.
  - h. We looked at the trend in anencephaly based on vital statistics reports. Statewide, there appears to be an increasing trend over time. This may be due to population changes. It is also important to remember that vital statistics do not include all cases. The increase in vital statistics based rates may reflect changes in termination of pregnancy after diagnosis over time.
  - i. We did not see a trend in the vital statistics based rates in the 3-county area, but numbers are quite small.
  - j. The three county area does appear to have an increased rate compared to the state for the entire time period. There were 45 vital statistics based cases found in the 3-county area resulting in an overall vital statistics based NTD rate of 5.0/10,000 compared with 2.4/10,000 for the state. We don't know if this is a true difference, a reflection of differences in termination of pregnancy after diagnosis or a difference in demographics.
  - k. We used SatScan (a statistical analysis program) to explore clustering. We found a statistically significant cluster that included most of eastern Washington.

- i. The analyses were rerun for space/time cluster and there appeared to be one in central Washington, but it was not statistically significant.
- ii. Only included cases reported by vital stats
- iii. Could not control for race/ethnicity
- iv. Clusters could reflect different terminations of pregnancies with anencephaly diagnoses
- v. Very low power to detect clusters in a small area

Based on overall vital statistics data, the increase in anencephaly rates may have existed for a longer period of time. It appears the 3-county region has a higher rate, but there are uncertainties given limitations of vital statistics data.

4. What are ongoing options for surveillance? (slide 13)
  - a. Summary of surveillance types used across the US
    - i. Passive – cases reported by hospitals, healthcare facilities, or doctors – used by Washington State and 12 other states.
    - ii. Passive with active follow-up – 20 states engage in this methodology, some states receive CDC funding
    - iii. Active surveillance – 10 states, abstractors look at medical records, 4 are funded by CDC
  - b. Different conditions are reported in different systems

**Possible additional investigation of possible cause of cluster in 3-county area (slides 14-16)**

- Desire to know as much as possible
- No strong/specific hypotheses – not enough evidence or specificity; For example, people are concerned about pesticides, but the scientific literature based on large scale studies is mixed. There is no scientific consensus regarding pesticides as a cause of neural tube defects generally, nor which specific pesticides to study.
- What is feasible? – While the number of cases is large for this area, it is relatively small from a statistical perspective. We need large numbers to discern if a particular exposure is associated with a disease and not due to chance variation.
- We have discussed our approach and findings with researchers and CDC staff
- Presented at annual Teratology Society meeting – experts cautioned before committing more staff and resources on a study that is not likely to yield results.
- One possibility for additional study includes collaborating with existing study. It could help ensure we have not missed an exposure causing a large proportion of cases.
  - o National Birth Defects Prevention Study – mothers of more than 30,000 babies with and without birth defects; interviewed through March 2013 (delivered through March 2011); 60-minute telephone interview
    - Comprehensive study exploring maternal health, pregnancy history, nutrition and diet, substance use, water use, demographics, occupation, residence
    - Investigators estimate \$500/interview

**Prevention:**

- Public education, provider education, developing folic acid resources
  - o Public education:
    - March of Dimes (MOD) has approached 45 radio stations in Eastern Washington and asked them to download public service announcements (PSAs) on folic acid – 18 stations agreed to air messages
    - Public health officers contacting stations
    - MOD distributed folic acid brochures to colleges and hair/nail salons, community and technical colleges for dissemination
    - MOD will contact newspapers in the area

- Hispanic health commission has dedicated an upcoming 30-minute radio show to the investigation and prevention efforts
- Provider education:
  - Local health officers are drafting letters to send to providers
  - Presentations scheduled at obstetrics grand rounds in Yakima on Aug 27<sup>th</sup> planning similar presentation in Tri-cities area
  - Provider education is planned by UW Pediatric Environmental Health Specialty Unit faculty on asthma, health issues related to nitrates in drinking water, and anencephaly investigation.
- Folic acid resources:
  - The FDA in their review of folic acid fortification of corn masa flour has asked petitioners for research on the stability of folic acid in corn masa flour.
  - MOD is working with food additives supplier to develop a protocol and then testing will take about 6-9 months
  - MOD is also looking for funding to perform the stabilization tests

**Questions/comments:**

**AC = Advisory Committee Member**

AC: Offered assistance to set up grand rounds at Kadlec

AC: Has the rest of the state been alerted about the investigation? A presentation with WSHA could alert more record keepers and epidemiology staff.

AC: Have you included churches to market preventive actions and included outreach with promotoras?

DOH – DOH has been in contact with the organization that does training for promotoras, but are unsure if they are in place in Yakima.

AC: Is there a way to involve WIC? From a policy perspective could look at the benefit package to see if there are opportunities to add folic acid rich food.

DOH – WIC does put out messages on folic acid, will follow up.

**Action Plan:**

Primary goals include:

- Identify ways to improve reporting of NTD
- Determine if additional investigation should be conducted to assess potential exposures
- Identify actions to prevent or reduce NTD in the area
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Surveillance:

- Conduct state-wide passive surveillance with vital stats data through July 2015
- Conduct stimulated passive surveillance in the 3-county area through July 2015

AC: WSHA reports pregnancies and diagnoses; may be able to have them send information directly to DOH.

AC: Are grand rounds and perinatal advisory groups the only ways you are contacting providers in the area?

DOH: That is correct, there are no plans in place for broader communications with providers.

Additional Investigation:

- Conduct interviews with mothers of anencephaly with estimated date of delivery after Aug 2012 following protocol of National Birth Defects Prevention Study (NBDPS).
- Identify exposure information among case mothers
- Begin interviews in August
- Work with CDC

AC: Can we see the survey before implementation? Just want to make sure it includes culturally appropriate questions for migrant populations.

DOH: We can talk with CDC to see if it can be shared publicly.

AC: Agreement with this approach. Have you considered extending the estimated date of delivery past the original timeframe (study protocol). Having worked with NBDPS we worked with 2-year cut-off because of data quality, but have you considered including all of the women from the original cluster. CDC would have opinions. NBDPS questionnaire has been designed in English and Spanish.

#### Prevention:

Public outreach:

- MOD radio spots, public service announcements
- Folic acid brochures in English and Spanish in grand rounds and trainings
- MOD will contact newspapers for folic acid banners
- Hispanic Health Commission radio show
- Anencephaly website at DOH (with folic acid weblink to CDC) and also includes info on testing water for nitrates and bacteria

Provider outreach:

- Blast fax to providers in Benton/Franklin and Yakima area include recommendations for women of child-bearing age
- Developing articles for local society newsletters
- Grand Rounds in Yakima 8/27/2014 and Benton/Franklin TBA
- Develop and disseminate materials around pregnancy planning and promoting folic acid use to women of reproductive age
- Convene monthly phone call with state and local public health staff to coordinate ongoing prevention efforts

AC: Why would not send blast fax to everyone in the state?

DOH: Should be able to do that. We would need to change the wording for the rest of the state. We should distribute health alert to interested party list and committee for distribution.

AC: You have our full support with prevention plan

#### Folic acid:

- Would like to identify resources to subsidize folic acid or vitamins containing folic acid for low-income women of reproductive age.
- Washington state will write letter of support to FDA regarding fortification of corn masa flour

AC: Washington State does not need to write a letter of support for the FDA process right now. The issue is with March of Dimes (MOD) and the stabilization study.

AC: Does MOD have funding to do the studies?

AC: The estimate the FDA gave is over a million dollars. MOD is asking other researchers if they could do the study to bring cost down. They are actively looking for funding for that project.

AC: Why wouldn't that be funded from a public policy perspective? Is it possible to advocate for public funding?

AC: Groups are requesting fortification so the work is on the group making the request. If the government (like CDC) was requesting, then it would be covered. Will contact national office of MOD to advocate.

Any additional comments on action plan – please contact Cathy Wasserman.

#### **Opened for public comments:**

Public comment: Are you going to open the interviews up to mothers of spina bifida?

DOH: The study is open to mothers of anencephaly because the rates for anencephaly are elevated. We are not planning to interview mothers of infants with spina bifida as those rates are lower than expected.

Public comment: How close is Washington state to digitizing birth data? Could you digitize data for health defects of all kinds? Do you do that digitally versus long-hand?

DOH: Currently have electronic reporting of several facilities included in the current system.

Public comment: Is that using ICD-9 coding?

DOH: Yes

Public comment: Is that hospital reports? Or on-site physicians?

DOH: It's from hospital discharge data.

Public comment: Could we move to more active assessment for more accurate coding?

DOH: What do you mean?

Public comment: Could we have people in place to do more active assessment?

DOH: The active ascertainment of birth defects is an option for us, but it is expensive. We can continue with passive birth defects surveillance with active follow-up.

Public comment: I'm suggesting this because this is not the only study that will come up. This may be the way to get toxicological data as well. To provide active assessment would be a first step.

DOH: There are currently 67 birthing hospitals. It would be a lot of resources to have people in all of those hospitals.

Public comment: It would be worthwhile. It's 67 people. Better to not have to guess and have accurate data.

AC: The Interagency Council of Health Disparities (Governor's office) is very interested in supporting any efforts to help promote folic acid fortification at the federal level. We would like to know about timing of letter writing with the FDA or federal officials or getting funding.

DOH: Thank you, we will do that.

Public comment: You have done a lot of work and should be congratulated on it.

DOH: Thank you.

DOH: Opinions on when to meet next to update where DOH is in the action plan?

AC: 6 weeks

DOH will plan meeting for 1-hour for updates in 6-8 weeks

**Adjourned 9:30am**