

**Anencephaly Advisory Committee Meeting (webinar)**  
**Minutes**  
**August 13, 2015**

**Advisory Committee Members present:**

Kathy Lofy, MD, Chair  
Susie Ball, MS  
Sara Barron, RN  
Gina Legaz, MPH  
Peter Langlois, PhD  
Amy Person, MD  
Christopher Spitters, MD  
Sarah Tinker, PhD  
Vickie Ybarra, PhD, MPH, BSN

**WA Dept of Health Staff present:**

Lillian Bensley, PhD  
Hannah Peterson (intern)  
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 at 8:00 am with a quick introduction.

Cathy Wasserman gave a presentation updating advisory committee members on the status of surveillance, investigation and prevention efforts. (attached) The presentation included new numbers of cases confirmed since April 28, 2015, and the following highlights:

**Surveillance Update:**

- 2 additional spina bifida cases have been confirmed from April 15, 2015 – August 7, 2015. In addition, two of the anencephaly cases already ascertained were discovered to be the same case. This brings the total number of neural tube defect cases in the 3 county area to 62 confirmed NTD, including 40 cases of anencephaly.
- Rate for 2010-2014 for all NTD is 13.1 cases per 10,000 livebirths and rate for anencephaly is 8.6/10,000.
- Continue to see that there is no strong pattern in the timing or seasonality when cases occurred
- Updated statewide data using vital statistics and linked files only. Have first six months of 2015 which included 15 anencephaly and 27 NTD cases. Note that these cases are from vital statistics files only and have not been confirmed. They may include false positive cases, and do not include pregnancies that were lost or terminated prior to 20 weeks gestation.

**Investigation Update:**

- DOH has interviewed 15 women to date. We have deviated from the National Birth Defect Prevention Study (NBDPS) protocol to interview newly identified cases and will continue to follow up with newly identified cases.

- Preliminary manual review of the questionnaires shows that the women have a mean age of 29.6 years, 14 mothers had prior pregnancies, average body mass index (BMI) was 24.1, 4 women with BMI > 30; pesticide exposure questions have shown 7 women had pesticide exposure of any type; most women on public water supply, folic acid information is limited (no info on dosage); occupation showed 5 mothers had agricultural occupations which included working in fields as well as processing jobs. 2 mothers had a history of a prior NTD-affected pregnancy. A variety of medical history and use of both over the counter and prescription medications were reported.
- At this point, nothing immediately apparent that is common to most or all of the women.
- Next steps are to work with CDC to input data and analyze more systematically, and to continue to reach out to mothers of newly identified cases for interview.

#### Prevention Efforts Update:

- Finalized Folic Acid fact sheet and began disseminating to community health workers and providers in three-county area.
- Yakima Health District working with Vitamin Angels for distribution of free vitamins but the logistics have been challenging.

#### Proposed Next Steps for Advisory Council:

- Suggestions from DOH:
  - o Continue stimulated passive surveillance in the three counties
  - o Continue statewide passive surveillance
  - o Interview newly identified mothers
  - o Review case data with CDC to look for common exposure
  - o Continue dissemination of materials and public messaging

#### Advisory Committee Comments

Advisory Committee (AC): Are the 15 cases all anencephaly cases?

DOH: No, the 15 cases include all NTD cases

AC: Can we make an effort to talk to their doctors about genetic testing?

DOH: We can look into whether we can get additional records from physicians to see if there has been genetic testing.

AC: Was a spatial analysis conducted on the cases? Weren't you working with a university researcher on spatial analysis?

DOH: We have not been working with a researcher on a spatial analysis. About a year ago, we did conduct spatial analysis at DOH, and I reported on those findings which had low power.

AC: Can we build capacity within local communities to help do the interviews, and I suggest we add monitoring the March of Dimes (MOD) efforts to have folic acid supplementation of corn masa flour added to the Next Steps.

DOH: Regarding conducting face-to-face interviews, our challenge has been in reaching the women. Once they have been reached, the interviews have not been an issue. We would welcome suggestions on best methods to reach women. We are using the phone to reach women. We will continue monitoring MOD process on folic acid supplementation. We had heard that the studies are ongoing and planned to finish the end of August/early September; planned meeting in November with FDA.

AC: Do you know whether the policy being pursued with the FDA is voluntary or mandatory fortification?

CDC: The proposal is for voluntary fortification. However, the primary producer of corn masa in the US is supportive of the proposal, and likely to implement it. If approved, we believe even with voluntary fortification, there will be a lot of coverage.

Chris Spitters, Yakima: Let me give some background on the logistical difficulties with accepting and distributing free prenatal vitamins. The issue is the venues have federally subsidized pharmacy prices. This program has rules about dispensing medications to a non-customer or dispensing medications outside of federal program (340B Pricing). Any community clinic or health department is limited in trying to dispense the vitamins. We have had similar barriers in other public health efforts to dispense medications for other diseases. We are working with the regional perinatal advisory network to help. Without a set number of distributors, we cannot request a specified amount of vitamins.

AC: Can you approach pharmacies and ask if they will help distribute?

Chris Spitters: Our concern has been that they are in the business to sell vitamins and wouldn't go for that, but we may approach them to see their response.

AC: I would encourage us to proceed with all of the proposed next steps.

DOH: Are there any suggestions on how to better contact women?

AC: You could work through the organizations where these women received prenatal care, FQHC's (Federally Qualified Health Centers) have perinatal outreach workers who may be able to help.

AC: Local Health Departments could also help since the number of women is small. We could make field visits with outreach workers and try to engage the women.

AC: Have there been any formal tracing procedures?

DOH: We did some tracing on the original interviews. However, we don't have that resource available through our PRAMS interviewers, currently.

AC: Health districts pay for a commercial service that helps find people through a variety of databases including prior addresses, utility bills.

AC: Is some of this we don't know how to find women? Could we have providers post fliers about our interest in interviewing?

DOH: We haven't done that with fliers. We do go to providers when we hear about new cases and ask them to help contact women first.

DOH: We don't have any more meetings scheduled. When would you like the next check in on the investigation and surveillance updates? Quarterly or 6 months?

Advisory Committee members responded and decided to follow up with quarterly calls.

AC: We need to be specific about what we are looking for with genetic testing?

DOH: Agree, we need to be advised on what we should look for in the records. I will follow up with Susie Ball to identify what we are interested in.

Open up for questions from the public:

General Public (GP): Have you considered talking to Dr Croen about nitrate in drinking water and diet and NTD.

DOH: Yes, we have reached out to researchers about this topic.

GP: We sometimes wonder whether the nitrate levels reported for community water supplies are accurate. For instance, I'm told that the Outlook well consistently is reported as 9.9 nitrates. With normal variation of test results and variations based on season of the year and water flow, how likely would it be that the nitrate levels would consistently be 9.9. Is something being hidden?

DOH: We can follow up with our drinking water experts about reported levels. [See note 1 at end of minutes for drinking water expert comment] We have been told that nitrate levels do not acutely change or spike within a few month period.

GP: Have you run ads on radio/tv asking women to come forward to help other mothers.

DOH: This has been suggested, but we have concerns about the cost for little gain in information. In addition, we might receive calls from people that did not have an NTD affected pregnancy which would also require resources.

GP: Maybe interview ALL women affected by NTD pregnancies who were included in the investigation to help improve interviewing rates.

DOH: Our concern with going back to interview women who were pregnant in 2010-2012 is with their recall. What do advisory committee members think?

AC: Yes, go back several years.

AC: I have concerns about recall bias and the ability to compare results with national data.

AC: I would prefer we interview all women moving forward instead of going backwards.

AC: I'm hesitant to go back because of recall bias.

AC: Agree, don't go back beyond two years.

DOH: It seems there's agreement we shouldn't go back, but going forward should interview all women as soon as we learn of their pregnancy.

GP: Do interviewers educate mothers to be on high dose of folate for preconception care?

DOH: The interviewers are not trained to give this advice, they are gathering information. We recommend that women speak with their providers for medical information.

GP: Depending on when wells are tested, the Yakima River may actually dilute the levels of nitrates. It would be anticipated that nitrate levels will be lower in the spring when the river is fuller from snow runoff. Tests should be run when the river is at its lowest point and for the longest time.

DOH: We will take that comment back to drinking water experts to look at what time of year tests are done in that area. [See note 2 at end of minutes for drinking water expert comment]

GP: Is the rate of SIDS correlated with rates of anencephaly?

DOH: We have not looked at rate of SIDS and have not noticed seasonality among NTDs, so are unclear what we would look for by adding SIDS.

GP: September seems to be a peak month?

DOH: There is normal variation among the months and no strong suggestion of seasonality. (slide 5)

GP: Did DOH look at air quality? April and May are heavy pesticide application months (Cd, Pb, Hg, As, U, etc) in agricultural products. Would hair analysis from the women be helpful?

DOH: That is not my area of expertise, can any AC members who are birth defects researchers respond?

AC: I have very little experience with hair analysis, but my understanding is that it can be contaminated by shampoos and other elements in the environment. There is some research on air pollution (benzene) and birth defects, but no strong associations have been found.

GP: I live in an agricultural community – not Yakima – and we have a significant number of late term pregnancy losses in April/May and again in September. These are the months when more chemicals are sprayed.

DOH: We did look at fetal deaths about a year ago, and did not notice strong season peaks in fetal deaths. We can take another look.

Next meetings:

- To be scheduled

Call ended at 9:05

Note 1: Concern about nitrate level consistently measured as 9.9 mg/l from Outlook well. Our drinking water program looked at the data for Outlook and found two systems. One is for the town of Outlook (ID64937) and one if for the Outlook Elementary School water system (ID# 64940M). The town of Outlook has only measured nitrate at 10 mg/L one time which was in

October 2006. The next measure, June 2007 was non-detectable for nitrates. Nitrate levels have been consistently non-detectable since 2009. We also reviewed sample data from 2000 to present for the Outlook Elementary School. In December of 2007, the system exceeded the nitrate MCL of 10 mg/L. Previous to that, results varied between 4 and 10 mg/L. In 2008, the school drilled a new well to mitigate the nitrate issue. Since the construction of the new well, their results have fluctuated between 0.2 and 4.48 mg/L. We don't see any instance where there were consistent sample results at around 9.9 mg/L.

Note 2: Concern about Yakima River nitrate levels. Only one public Group A water system in Washington draws its water directly from the Yakima River. That is Cle Elum which is not in our three county area.