

MINUTES

Evidence-based Guidelines Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
April 7, 2016
2:00-5:00pm

Members Present: Wiley Chan, MD, Chair; Eric Stecker, MD, MPH, Vice-Chair (by phone); Beth Westbrook, PsyD; George Waldmann, MD (by phone); Alison Little, MD, MPH; Kim Tippens, ND, MPH.

Members Absent: None

Staff Present: Darren Coffman; Catherine Livingston, MD, MPH; Jason Gingerich.

Also Attending: Adam Obley, MD, Moira Ray, MD, MPH and Craig Mosbaek (OHSU Center for Evidence-based Policy); Erica Pettigrew, MD (OHSU); Charles Bentz, MD and Duncan Neilson, MD (Legacy Health); Kim Wentz, MD (by phone) and Jessie Little (OHA); Joanne Rogovoy (March of Dimes), Maria Rodriguez (OHSU), Emily Elman (OHA Public Health).

1. CALL TO ORDER

Wiley Chan called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 2:00 pm.

2. MINUTES REVIEW

No changes were made to the February 4, 2016 minutes.

Minutes approved 6-0.

3. STAFF REPORT

Coffman welcomed Tippens to the subcommittee. She introduced herself as a naturopath and acupuncturist. She is an assistant professor at the National College of Natural Medicine. She will be serving on HERC as well.

Coffman reported that the HERC has referred the draft coverage guidance on Skin Substitutes for Chronic Skin Ulcers back to EbGS and requested that it be put out for an additional public comment period. This coverage guidance will come back to the subcommittee at its June meeting.

4. DRAFT COVERAGE GUIDANCE: Timing of Long-Acting Reversible Contraceptive (LARC) Placement

Ray reviewed the draft coverage guidance and evidence as presented in the meeting materials. Coffman introduced Maria Rodriguez as appointed expert on the topic. She is an assistant professor at OHSU in the Obstetrics & Gynecology/Generalist Division. Her research has focused on the evaluation and monitoring of family planning programs, including reproductive health outcomes and disparities among the Medicaid Population. She has received research funding from the National Institutes of Health as a Women's Reproductive Health Research Fellow. She has consulted for the World Health Organization. She has been trained as a trainer for Nexplanon insertions.

Livingston also invited Dr. Duncan Neilson to participate as he is familiar with the topic and was already present in preparation for the upcoming discussion of Tobacco Cessation During Pregnancy. Dr. Duncan Neilson is Clinical Vice President, Legacy Health System, Portland. His responsibilities include program development in Women's Services, Quality and Patient Safety measurement and program implementation. He has served in the past as clinical vice president of Legacy's Women's Services and Surgical Services. He has served the commission as an expert on previous obstetric-related topics, including Out-of-Hospital Birth and Elective Induction of Labor.

Chan asked what the comparison was for the observational study which reported higher perforation among women who had delayed insertion and who were breastfeeding. Ray said that the study followed women over time and collected baseline data as well as information about expulsion events, perforation events and other adverse events, then looked retrospectively to find risk factors for the adverse events. Breastfeeding was found to be an independent risk factor for perforation over other factors like nulliparity and recent pregnancy. Chan said that breastfeeding is clearly correlated with time after delivery, but Ray said she believes the association was stronger than one would expect even given that fact.

Waldmann asked why breastfeeding would be associated with a higher risk than immediate postpartum status. Ray explained that it is believed to be related to hormonal changes affecting the uterus after delivery, and that six weeks postpartum is a vulnerable time; Neilson and Rodriguez confirmed this understanding. Rodriguez said it could also be that the placement was guided by ultrasound in the postpartum setting but not in the outpatient setting at 6 weeks. Chan said it may just be time after delivery rather than breastfeeding that is the major risk factor.

Livingston reviewed the resource allocation, values and preferences and other factors influencing the recommendation in the GRADE table. She also explained that despite lack of evidence specific to the timing question, there is CDC guidance saying that it is appropriate to place an implant postpartum or post abortion.

Little asked about the administrative issues surrounding reimbursement for these services. Staff recognized that with this intervention, ensuring appropriate reimbursement is key as the devices are expensive and providers can't be expected to stock them and pay for them if not reimbursed. Neilson shared of his experience at Legacy where they started offering LARC immediately postpartum, but were asked by administrators to stop because it was cost-prohibitive. This is because the global rate for delivery paid to a hospital isn't adjusted as a matter of course if a LARC is placed. He said that there are two separate issues—device manufacturers charging providers hundreds of dollars for a simple device

costing under two dollars to the manufacturer, and insurance companies failing to reimburse providers for their acquisition costs for the devices. Ray said that some states use outpatient billing to pay, while others do a periodic query of their claims data and make an extra payment to reimburse for LARC. Waldmann asked about using a modifier on professional claims. Others stated that there are ways of getting reimbursement for professional services; the issue is paying for the device itself.

Kim Wentz spoke about research she and Oregon Health Plan staff have been doing on reimbursement for LARC devices in the inpatient setting. There are three methods used by 18 states. She believes there are ways for the Oregon Health Plan to pay for these devices, along with their insertion, in all settings, but they need to be implemented. Rodriguez said OHSU has been providing postpartum LARC to uninsured women because of a charitable gift, but that they haven't been available for insured women because of the reimbursement issues. They have not had success getting reimbursement for these devices after discussions with state officials and legislators. The hospital has been donating the physician services, which are fairly minimal in the postpartum setting.

Livingston said that this coverage guidance will advance efforts to get health plans to pay for these devices in all setting. Waldmann said this shouldn't be difficult and that he doesn't understand why we can't solve this problem. Westbrook and Little also expressed support for the coverage guidance. Little requested a separate document to address implementation issues and motivate policymakers to find a solution. Livingston said that Wentz is already beginning some of these discussions now, even though the coverage guidance wouldn't be officially implemented until January for the Oregon Health Plan. The hope is that by January there will be a clear plan.

The subcommittee discussed various options for emphasizing that both the device and insertion should be reimbursed appropriately and bureaucratic barriers addressed. They considered adding language to the recommendation box but decided that this policy aspect should be kept separate from the evidence-based report. Several members and attendees expressed frustration that this issue has not been solved in Oregon despite a lack of philosophical opposition. Livingston directed the subcommittee's attention to sections of the coverage guidances which do address payment and administrative issues.

After discussion the subcommittee requested that staff draft a cover letter to accompany the report, addressing implementation issues and barriers to reimbursement, and describing the administrative issues in the coverage guidance more thoroughly. Waldmann specifically requested that the cover letter address the hospital's discontinuation of postpartum LARC placement as described by Neilson.

Because of an issue with posting sources, the subcommittee deferred voting on the draft coverage guidance until its June meeting.

5. DRAFT COVERAGE GUIDANCE: Tobacco Cessation During Pregnancy

Livingston introduced the report, reminding the subcommittee that this is the first evidence-based report to include multisector interventions (which may occur outside of the clinical setting, and not require any coverage changes from health plans, but nonetheless be effective ways of achieving health outcomes). Staff ran into challenges with the subcommittee's request to separate the document into two separate reports, and so has kept the report together as shown in the meeting materials.

Coffman introduced Dr. Charles Bentz who is the appointed expert on this topic. He is a Medical Director and Professor at the Pacific University College of Health Professions and is in private practice at Fanno Creek Clinic in Portland. In addition to his clinical and academic work, he has published several articles on tobacco-related topics. He has also worked on tobacco-related quality measurement, smoking cessation programs and reimbursement strategies. He has received funding from the National Institutes of Health, the Robert Wood Johnson Foundation, state health organizations, as well as manufacturers of all tobacco cessation products (including nicotine patches, lozenges, gums and sprays as well as bupropion and varenicline).

Coffman also re-introduced Neilson, who has been appointed as an expert for this topic. Neilson declared no conflicts of interest with respect to this topic.

Bentz said other interventions have been studied, such as provider and health system incentives. He asked why they were not included in the review. Bentz said beyond simply covering services, promoting them in the provider community and providing incentives to providers can be important. Obley said that evidence was not found in the evidence review. Bentz also asked about carbon monoxide as feedback. This was not included in the Cochrane review. Livingston asked whether these would have been included in scope. Obley said they may have been grouped under behavioral interventions. This grouping includes everything from the “Five A’s” program advocated by the Centers for Disease Control to more intensive interventions. Bentz said that his practice uses carbon monoxide as feedback and that it is actually helpful. Livingston noted that these interventions could be submitted as public comment. Bentz said some of the studies he is referring to were not conducted in pregnant women, and this may explain why they weren’t included. Livingston said we would need evidence in the pregnant population.

Chan asked whether there is any reason to think that most interventions effective in other populations would have differential effectiveness in pregnant women? Obley said that the Patnode review does divide pregnant women from the general adult population. He assumes this is because pregnant women may have been excluded from general population studies. Bentz said that pregnant women can be particularly motivated to quit. Sometimes they spontaneously quit or suspend smoking during the pregnancy. He agreed that the behavioral interventions would work in pregnant women. But in designing interventions for pregnant women you need to think about special issues including relapse after the birth. Bentz said all behavioral interventions are tailored by type of tobacco use and cultural factors and pregnancy is another similar factor.

Coffman noted that the Commission has already approved a statement on multisector interventions for tobacco. He suggested that when implemented on the prioritized list, a special statement about pregnant women could be added to that section.

Westbrook asked about levels of addiction. Neilson said that interventions would need to be tailored to women based on the number of years they smoked and how much they smoked. For instance, behavioral interventions would more likely be effective in a casual smoker. Both clinicians and researchers are reluctant to do drug research on pregnant patients. Thus the drugs are generally reserved for the most nicotine dependent patients, resulting in a biased population for any research that would be done (that is, the study population would include the most difficult-to-treat patients). However, he also said that more dependent patients generally show a better response to nicotine replacement therapy (NRT), because they have more nicotine receptors. He said that there is a strong dose response for behavioral interventions (more intensive counseling is more effective) and that at any intensity of counseling, NRT doubles the quit rate.

Livingston turned the group's attention to the GRADE table for NRT. Most outcomes showed equivalence, though it showed effectiveness for tobacco abstinence during pregnancy. Ordinarily the staff recommendation might be to recommend noncoverage based on this evidence profile. Federal law, however, requires coverage of medication therapy for tobacco cessation for pregnant women in Medicaid, and the prohibition on prior authorization of tobacco cessation aids in the Affordable Care Act would make it difficult for most commercial insurers to restrict coverage. Based on this, the staff recommendation is for the subcommittee to state that it makes no recommendation for this population.

Bentz said that study designs for tobacco cessation during pregnancy are fatally flawed because of high relapse rates among postpartum women. Most studies weren't designed to include postpartum support. He advocated for coverage because there is no harm and because getting people to quit is the most important thing. Because of the ethical issues around conducting trials in this population, it is unlikely that evidence is likely to change. Neilson agreed.

Chan noted that there is no good evidence that NRT has harms. Obley confirmed this, noting that the studies included the pregnancy outcomes for the purpose of showing that NRT is no more harmful than continued smoking based on these outcomes, not to show a benefit of NRT for these outcomes. Chan asked if a recommendation could be made based on the broader evidence base for NRT in nonpregnant populations. Livingston noted that for the nonpregnant population, the outcomes of interest would be chronic obstructive pulmonary disease, asthma and lung cancer, which is different than the outcomes of interest in the pregnant population. Bentz and Neilson agreed that the population is distinct.

After discussion the subcommittee accepted the lack of recommendation for pharmacologic therapy and changed the recommendation for noncoverage for electronic nicotine delivery devices in pregnant women to a strong recommendation.

The subcommittee affirmed the recommendation for coverage for behavioral interventions with little discussion.

For high feedback ultrasound, the subcommittee discussed the large effect size, balanced by the fact that it is based on a single RCT from 1982 with 129 participants. The subcommittee also discussed that in another context, high feedback ultrasound can be considered coercive, as it is used by abortion opponents to influence women's reproductive choices. Westbrook stated that sometimes this is termed "obstetric violence." Bentz noted that even with carbon monoxide feedback, clinicians need to be careful, or patients can become anxious and not return for care. Livingston noted that concerns about psychological distress appear in the values and preferences column.

After discussion, the subcommittee decided that the context of tobacco smoking is sufficiently different than in the case of counseling about abortion and that in this context, smoking cessation can only improve outcomes for the mother and baby. Obley noted that the GRADE assessment from the Cochrane review was low. Livingston noted that with skin substitutes, low quality evidence was considered sufficient. Bentz noted that the cost would be relatively small cost on top of the existing cost of the ultrasound. After discussion the subcommittee decided to make a weak recommendation for coverage, while noting the age of the study.

The subcommittee accepted staff recommendations for financial incentives, partner support, interventions to reduce secondhand smoke exposure, smoke-free legislation and tobacco excise taxes.

There was discussion about how social supports including partner support are supported by evidence in the general population, but the evidence may not exist in pregnancy. Livingston noted that behavioral interventions are covered in general, it would just be an intervention targeted solely at partner support that would not be recommended.

Bentz suggested adding system-level interventions such as provider and plan incentives, though they are difficult to implement. He said systems interventions may be the most important thing that can be done to increase tobacco cessation. Livingston said we didn't find evidence about these interventions, so evidence that these interventions affect pregnancy-related outcomes would need to be submitted during public comment in order to add statements about them in this document.

The subcommittee discussed options for distinguishing between coverage recommendations and statements on multisector evidence. After discussion the subcommittee agreed to use the current format with different colors to highlight the distinctions between the coverage recommendations and evidence statements on multisector interventions as well as the distinctions between the GRADE tables and evidence tables. Chan requested that staff include an explanation of what a multisector intervention is along with the evidence statement. Staff will also make heading changes to clearly delineate which sections relate to multisector interventions.

After brief additional discussion, the subcommittee decided to remove the description of the effects of the multisector interventions to be consistent with the coverage guidance recommendations.

The subcommittee voted to put the draft coverage guidance (as amended) out for a 30-day public comment period by a vote of 5-0 (Stecker absent).

6. ADJOURNMENT

The meeting was adjourned at 5:00 pm. The next meeting is scheduled for June 2, 2016 from 2:00-5:00 pm at Clackamas Community College, Wilsonville Training Center, Rooms 111-112, 29353 SW Town Center Loop E, Wilsonville, Oregon 97070.