

## ABM Clinical Protocol #21: Guidelines for Breastfeeding and Substance Use or Substance Use Disorder, Revised 2015

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*A central goal of The Academy of Breastfeeding Medicine is the development of clinical protocols for managing common medical problems that may impact breastfeeding success. These protocols serve only as guidelines for the care of breastfeeding mothers and infants and do not delineate an exclusive course of treatment or serve as standards of medical care. Variations in treatment may be appropriate according to the needs of an individual patient.*

### Purpose

**T**HE CHOICE OF BREASTFEEDING by a pregnant or newly postpartum woman with a history of past or current illegal/illicit drug abuse or legal substance use or misuse is challenging for many reasons. The purpose of this protocol is to provide literature-based guidelines for the evaluation and management of the woman with substance use or a substance use disorder who is considering breastfeeding.

### Background

Illicit drug use and legal substance use/abuse remain a significant problem among women of childbearing age. The 2013 National Survey on Drug Use and Health revealed that among pregnant women 15–44 years of age in the United States, 5.2% had used illicit drugs in the past month, 9.4% reported current alcohol use, 2.3% reported binge drinking, 0.4% reported heavy drinking during the pregnancy, and 15.4% reported cigarette use in the past month.<sup>1</sup>

The healthcare provider presented with a pregnant or recently postpartum woman with a history of current or past illegal drug abuse or legal drug use or misuse who desires to breastfeed often faces multiple significant challenges. Substance use disorders frequently engender behaviors or conditions that independently signify risk for the breastfed infant, in addition to the drug exposure per se. These mothers may have coexisting risk factors such as low socioeconomic status (although substance use crosses all socioeconomic lines), low levels of education, poor nutrition, and little to no prenatal care. Multiple drug use is common, in addition to the

use of other harmful legal substances, including tobacco and alcohol. Illicit drugs are frequently mixed and extended with dangerous adulterants that can pose additional threats to the health of the mother and the infant. Drug users are at high risk for infections such as human immunodeficiency virus and/or hepatitis B and C. Psychiatric disorders that require pharmacotherapeutic intervention are more prevalent with substance use, making breastfeeding an even more complicated choice, as breastfeeding may not be recommended for women taking some psychotropic medications.

Despite the myriad factors that may make breastfeeding a difficult choice for women with substance use disorders, drug-exposed infants, who are at a high risk for an array of medical, psychological, and developmental issues, as well as their mothers, stand to benefit significantly from breastfeeding. Although many of the factors listed above may pose a risk to the infant, the documented benefits of human milk and breastfeeding must be carefully and thoughtfully weighed against the risks associated with the substance that the infant may be exposed to during lactation. Confounding many efforts to examine longer-term developmental outcomes in infants exposed to some substances is the lack of data evaluating infants who were not exposed during pregnancy but only during lactation.

Ideally, women with substance use disorders delivering an infant and desiring to breastfeed are engaged in comprehensive healthcare and substance abuse treatment during pregnancy, but this is not always the case. Substance abuse treatment for these women is often not available, not gender specific, and not comprehensive, forcing the mother's healthcare provider

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during and after pregnancy to rely on maternal self-report and a “best guess” at adequacy of services, compliance to treatment, length of “clean” time, community support systems, etc. In a recent retrospective study in the United Kingdom, significantly lower rates of breastfeeding initiation occurred in mothers who used illicit substances or opioid maintenance therapy during pregnancy (14% versus 50% of the general population).<sup>2</sup> In Norway, among opioid-dependent women on opioid maintenance therapy, 77% (compared with 98% in the general population) initiated breastfeeding after delivery.<sup>3</sup>

The specific terms used to describe use and misuse of various legal and illegal substances continue to evolve and may vary from country to country and among different organizations. The 5th edition of the *Diagnostic and Statistical Manual of Mental Disorders* combines the previous categories of substance abuse and substance dependence into the category single substance use disorder, which is measured on a continuum from mild to severe.<sup>4</sup>

Of important note is that we would like to make it clear that drugs of any type should be avoided in pregnant and breastfeeding women, unless prescribed for specific medical conditions. The casual use of drugs—legal, illegal, illicit, dose appropriate or not—still may have ramifications for the developing fetus and infant that we have yet to determine, and hence, in general, drugs of all types should be avoided unless medically necessary.

### Specific Substances

Perhaps the most critical challenge facing the healthcare provider for the woman with a substance use disorder who wishes to breastfeed is the lack of research leading to evidence-based guidelines. Table 1 gives two online Web sites, one in English and one in both English and Spanish, that are kept updated and are easily accessible for current information on drugs and breastfeeding. There have been several comprehensive reviews of breastfeeding among substance-using women, essentially concluding that breastfeeding is generally contraindicated in mothers who use illegal drugs.<sup>5–8</sup> (III) (Quality of evidence [levels of evidence I, II-1, II-2, II-3, and III] is based on the U.S. Preventive Services Task Force Appendix A Task Force Ratings<sup>9</sup> and is noted throughout this protocol in parentheses.) Yet, research on individual drugs of abuse remains lacking and difficult to perform. Pharmacokinetic data for most drugs of abuse in lactating women are sparse and based on small numbers of subjects and case reports.<sup>7</sup> Most illicit drugs are found in human milk, with varying degrees of oral bioavailability.<sup>7</sup> Phencyclidine hydrochloride has been

detected in human milk in high concentrations,<sup>10</sup> as has cocaine,<sup>11</sup> leading to infant intoxication.<sup>12</sup> There is little to no evidence to describe the effects of even small amounts of other drugs of abuse and/or their metabolites in human milk on infant development aside from those discussed further below.

### Methadone

For pregnant and postpartum women with opioid dependence in treatment, methadone maintenance has been the treatment of choice in the United States, Canada,<sup>13</sup> and many other countries. In contrast to other substances, concentrations of methadone in human milk and the effects on the infant have been studied. The concentrations of methadone found in human milk are low, and all authors have concluded that women on stable doses of methadone maintenance should be encouraged to breastfeed if desired, irrespective of maternal methadone dose.<sup>3,14–22</sup> (II-1, II-2, II-3) Previously, no apparent effects of methadone exposure prenatally and in human milk were reported on infant neurobehavior at 30 days.<sup>19</sup> Recently an ongoing longitudinal follow-up study of methadone-exposed infants with 200 methadone-exposed and nonexposed, demographically matched families has shown neurocognitive delays in methadone-exposed 1-month-old infants compared with nonexposed infants. When retested at 7 months, methadone-exposed infants were similar to nonexposed, comparison infants. At 9 months of age, 37.5% of this sample of methadone-exposed infants showed clinically significant motor delays ( $\geq 1.5$  standard deviation) compared with low but typical development in the comparison group.<sup>21</sup> Exposed infants typically have high environmental risk profiles, which continue at birth, posing ongoing risk to the developing child.

The current thought is that environmental risk factors combine with prenatal exposures to promote epigenetic changes in gene expression and methylation patterns that have both immediate and long-term implications related to developmental programming.<sup>22</sup> Note that these findings relate to infants exposed to methadone both prenatally and after birth via breastfeeding, and there is little information available on infants with chronic methadone exposure via breastfeeding alone.

In addition, about 70% of infants born to women prescribed methadone during pregnancy will experience neonatal abstinence syndrome (NAS),<sup>23</sup> the constellation of signs and symptoms often presenting following in utero opioid exposure. Infants with significant NAS can experience difficulties with attaching and sucking/swallowing during breastfeeding that can impact their ability to breastfeed.

TABLE 1. ONLINE WEB SITES WITH UPDATED BREASTFEEDING AND DRUG INFORMATION

| Web site  | URL   | Language           |
|---|---|--------------------|
| U.S. National Library of Health, National Institute of Health, U.S. Department of Health and Human Services, “LactMed”                        | <a href="http://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm">http://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm</a>   | English            |
| e-Lactancia<br>Association for Promotion and Cultural and Scientific Research of Breastfeeding Under a Creative Commons International License | <a href="http://e-lactancia.org/">http://e-lactancia.org/</a><br>(Also contains medical prescriptions, phytotherapy, homeopathy and other alternative products, cosmetic and medical procedures, contaminants, maternal and infant diseases and more) | English<br>Spanish |

However, given that there is increasing evidence supporting the conclusion that there is a reduction in the severity and duration of treatment of NAS when mothers on methadone maintenance therapy breastfeed, breastfeeding for these dyads should be encouraged.<sup>3,17-19</sup> (II-1, II-3) Unfortunately, the rate of breastfeeding initiation in this cohort is generally low, less than half that reported in the U.S. general population.<sup>24</sup> A small recent qualitative study demonstrated that lack of support from the healthcare community and misinformation about the dangers of breastfeeding while on methadone therapy are significant, yet modifiable, barriers to breastfeeding success in these women.<sup>25</sup> Given the benefits to these mothers and infants to remain on methadone maintenance therapy and breastfeed, it is important for us to provide robust ongoing support for this vulnerable group.

### Buprenorphine

Buprenorphine is a partial opioid agonist used for treatment of opioid dependency during pregnancy in some countries and increasingly in the United States. Multiple small case series have examined maternal buprenorphine concentrations in human milk. All concur that the amounts of buprenorphine in human milk are small and are unlikely to have short-term negative effects on the developing infant.<sup>26-31</sup> In one study, 76% of 85 maternal-infant pairs breastfed, with 66% still breastfeeding 6-8 weeks postpartum. The breastfed infants had less severe NAS and were less likely to require pharmacological intervention than the formula-fed infants, similar to methadone discussed above, although this did not reach statistical significance with the size of the sample studied.<sup>31</sup>

### Other opioids

Use of opioids in the United States has increased substantially over the last decade. A retrospective cross-sectional analysis of NAS in hospital births in the years from 2000 to 2009 found an increase in incidence from 1.2 to 3.39 per 1,000 births. Antepartum maternal opioid use was also found to have risen from 1.19 to 5.63 per 1,000 hospital births from 2000 to 2009; any use of opioids was included in data collection.<sup>32</sup> A recent Centers for Disease Control and Prevention *Morbidity and Mortality Weekly Report* highlighted data demonstrating that approximately one-third of women of reproductive age filled a prescription for opioids each year between 2008 and 2012.<sup>33</sup>

When use of narcotics during pregnancy is determined to be consistent with an opioid use disorder rather than a modality for short-term pain relief, consideration of initiation of maintenance methadone or buprenorphine as previously discussed is strongly encouraged,<sup>13,34,35</sup> and these mothers should be supported in breastfeeding initiation. (III) Short courses of most other low-dose prescription opioids can be safely used by a breastfeeding mother,<sup>36,37</sup> but caution is urged with codeine, as *CYP2D6* ultra-rapid metabolizers may experience high morphine (metabolite) blood levels, and there has been a single case report of a breastfeeding neonatal death after maternal use.<sup>38</sup> (III) Information is lacking on the safety of breastfeeding when moderate to high doses of opioids are used for long periods of time. There is also a lack of information available about transitioning mothers from short-acting opioids to opioid maintenance therapy while breastfeeding rather than during pregnancy.

### Marijuana

Uniform guidelines regarding the varied use of marijuana by breastfeeding mothers are difficult to create and cannot hope to cover all situations. The legality of possessing and using marijuana varies greatly from country to country; in the United States, there are increasing numbers of states where it is legal for "medicinal use" with a prescription, and a few states where it is legal for "recreational use," but under federal law, it remains illegal in all states. Therefore, basing recommendations on marijuana use and concurrent breastfeeding from a purely legal standpoint becomes inherently complex, problematic, and impossible to apply uniformly across all settings and jurisdictions. As laws shift and marijuana use becomes even more common in some areas, it becomes increasingly important to carefully weigh the risks of initiation and continuation of breastfeeding while using marijuana with the risks of not breastfeeding while also considering the wide range of occasional, to regular medical, to heavy exposure to marijuana.

In addition to the potential legal risk, the health risks to the infant from the mother's marijuana use must be carefully considered.  $\Delta^9$ -Tetrahydrocannabinol (THC), the main compound in marijuana, is present in human milk up to eight times that of maternal plasma levels, and metabolites are found in infant feces, indicating that THC is absorbed and metabolized by the infant.<sup>39</sup> It is rapidly distributed to the brain and adipose tissue and stored in fat tissues for weeks to months. It has a long half-life (25-57 hours) and stays positive in the urine for 2-3 weeks,<sup>40</sup> making it impossible to determine who is an occasional versus a chronic user at the time of delivery by urine toxicology screening. Evidence regarding the effects of THC exposure on infant development via breastfeeding alone is sparse and conflicting,<sup>41,42</sup> and there are no data evaluating neurodevelopmental outcomes beyond the age of 1 year in infants who are only exposed after birth. Also notable in this discussion of risk is that the potency of marijuana has been steadily increasing, from about 3% in the 1980s to 12% in 2012, so data from previous studies may no longer even be relevant.<sup>43</sup> Additionally, current concern over marijuana use during lactation stems from possible infant sedation and maternal inability to safely care for her infant while directly under its influence; however, this remains a theoretical problem and has not been well established in the literature.<sup>44</sup>

Human and animal evidence examining the behavioral and neurobiological effects of exposure to cannabinoids during pregnancy and lactation shows that the endocannabinoid system plays a crucial role in the ontogeny of the central nervous system and its activation, during brain development. As Campolongo et al.<sup>45</sup> concluded, cannabinoid exposure during critical periods of brain development can induce subtle and long-lasting neurofunctional alterations. Several preclinical studies highlight how even low to moderate doses during particular periods of brain development can have profound consequences for brain maturation, potentially leading to long-lasting alterations in cognitive functions and emotional behaviors.<sup>45</sup> Exposure to second-hand marijuana smoke by infants has been associated with an independent two times possible risk of sudden infant death syndrome (SIDS)<sup>46</sup> (III); because breastfeeding reduces risk of SIDS, this needs to be additionally considered. Thus careful

contemplation of these issues should be fully incorporated into the care plans of the lactating woman in the setting of THC use. Breastfeeding mothers should be counseled to reduce or eliminate their use of marijuana to avoid exposing their infants to this substance and advised of the possible long-term neurobehavioral effects from continued use. (III)

### Alcohol

Use of alcohol during pregnancy is strongly discouraged, as it can cause fetal alcohol syndrome, birth defects, spontaneous abortion, and premature births, among other serious problems.<sup>47,48</sup> (III) Many women who significantly decrease or eliminate their alcohol intake during pregnancy may choose to resume consuming alcohol after giving birth, with approximately half of breastfeeding women in Western countries reported to consume alcohol at least occasionally.<sup>49</sup> Alcohol interferes with the milk ejection reflex, which may ultimately reduce milk production through inadequate breast emptying.<sup>50</sup> (III) Human milk alcohol levels generally parallel maternal blood alcohol levels, and studies evaluating infant effects of maternal alcohol consumption have been mostly mixed, with some mild effects seen in infant sleep patterns, amount of milk consumed during breastfeeding sessions, and early psychomotor development.<sup>50</sup> (III) Possible long-term effects of alcohol in maternal milk remain unknown. Most sources advise limiting alcohol intake to the equivalent of 8 ounces of wine or two beers, and waiting 2 hours after drinking to resume breastfeeding.<sup>5-7,35</sup> (III) To ensure complete elimination of alcohol from breastmilk, mothers may consult a normogram devised by the Canadian Motherisk program to determine length of time needed based on maternal weight and amount consumed.<sup>51</sup> (III)

### Tobacco

Approximately two-thirds as many pregnant women as nonpregnant women smoke tobacco, with decreasing numbers of women smoking as pregnancy progresses.<sup>1</sup> Many mothers quit during pregnancy, but postpartum relapse is common, with about 50% resuming tobacco use in the first few months after birth.<sup>52-54</sup> Data on the epidemiology of breastfeeding mothers who smoke cigarettes remains complex, and smoking in many series has been found to be associated with reduced rates of breastfeeding.<sup>55,56</sup> Nicotine and other compounds are known to transfer to the infant via milk, and considerable transfer of chemicals via second-hand smoke also occurs when infants are exposed to environmental tobacco smoke. Increases in the incidence of respiratory allergy in infants and in SIDS are just two significant well-known risks of infant exposure to environmental tobacco smoke.<sup>8</sup> (III) Most sources endorse promotion of breastfeeding in the setting of maternal smoking while vigorously supporting smoking cessation.<sup>57</sup> (III) Some smoking cessation modalities (nicotine patch, nicotine gum, and possibly bupropion) are compatible with breastfeeding and can be encouraged in many circumstances.<sup>6,7,58</sup> (III)

## Recommendations

### General (Circumstances favorable with consideration)

Infants of women with substance use disorders, at risk for multiple health and developmental difficulties, stand to

benefit substantially from breastfeeding and human milk, as do their mothers. A prenatal plan preparing the mother for parenting, breastfeeding, and substance abuse treatment should be formulated through individualized, patient-centered discussions with each woman. This care plan should include instruction in the consequences of relapse to drug or excessive alcohol use during lactation, as well as teaching regarding potential for donor milk, formula preparation, and bottle handling and cleaning should breastfeeding be or become contraindicated. In the perinatal period each mother-infant dyad should be carefully and individually counseled on breastfeeding prior to discharge from maternity care. This evaluation must consider several factors, including (III)

- drug use and substance abuse treatment histories, including medication-assisted treatment with methadone or buprenorphine
- medical and psychiatric status
- other maternal medication needs
- infant health status (to include ongoing evaluation for NAS and impact on ability to breastfeed)
- the presence or absence and adequacy of maternal family and community support systems
- plans for postpartum care and substance abuse treatment for the mother and pediatric care for the child.

Optimally, the woman with a substance use disorder who presents a desire to breastfeed should be engaged in treatment pre- and postnatally. Maternal written consent for communication with her substance abuse treatment provider should be obtained prior to delivery if possible. (III)

Any discussion with mothers who use substances with sedating effects should include counseling on safely caring for her infant and instruction on safe sleep practices. (III)

Encourage women under the following circumstances to breastfeed their infants (III):

- Engaged in substance abuse treatment; provision of maternal consent to discuss progress in treatment and plans for postpartum treatment with substance abuse treatment counselor; counselor recommendation for breastfeeding
- Plans to continue in substance abuse treatment in the postpartum period
- Abstinence from drug use for 90 days prior to delivery; ability to maintain sobriety demonstrated in an outpatient setting
- Toxicology testing of maternal urine negative at delivery
- Engaged in prenatal care and compliant.

### Opioids/narcotics

- Encourage stable methadone- or buprenorphine-maintained women to breastfeed regardless of dose
- Management of mothers who use chronic opioid therapy for pain should be closely supervised by a chronic pain physician who is familiar with pregnancy and breastfeeding (III):

- a. Length of time on these medications, total dose, and whether the medications were used during pregnancy should all help inform the decision of whether breastfeeding may be safely undertaken in certain cases.



- b. Judicious amounts of oral narcotic pain medication, when used in a time-limited situation for an acute pain problem, are generally compatible with continued breastfeeding if supervision and monitoring of the breastfeeding infant are adequate.<sup>36,37</sup>
- Rapidly increasing narcotic dosing in a breastfeeding mother should prompt further evaluation and reconsideration of the safety of continued breastfeeding.

#### Nicotine

- Counsel mothers who smoke cigarettes after giving birth to reduce their intake as much as possible, and not to smoke around their infant, to reduce infant exposure to second-hand smoke. Smoking cessation and nicotine replacement modalities such as nicotine patches and gum may be useful for some mothers. (III)
- Give mothers who smoke tobacco additional support, as maternal smoking appears to be an independent and associated risk factor for noninitiation and early cessation of breastfeeding, to help ensure its success. (III)

#### Alcohol

- Counsel mothers who wish to drink occasional alcohol that alcohol easily transfers into human milk. Recommendations from the American Academy of Pediatrics, the World Health Organization, and others advise waiting 90–120 minutes after ingesting alcohol before breastfeeding, or expressing and discarding milk within that time frame.<sup>5,6,7,35</sup> (III)

#### Cannabis (THC)

- Information regarding long-term effects of marijuana use by the breastfeeding mother on the infant remains insufficient to recommend complete abstinence from breastfeeding initiation or continuation based on the scientific evidence at this time. However, extrapolation from in utero exposure and the limited data available helps to inform the following recommendations (III):
  - a. Counsel mothers who admit to occasional or rare use to avoid further use or reduce their use as much as possible while breastfeeding, advise them as to its possible long-term neurobehavioral effects, and instruct them to avoid direct exposure of the infant to marijuana and its smoke.
  - b. Strongly advise mothers found with a positive urine screen for THC to discontinue exposure while breastfeeding and counsel them as to its possible long-term neurobehavioral effects.
  - c. When advising mothers on the medicinal use of marijuana during lactation, one must take into careful consideration and counsel on the potential risks of exposure of marijuana and benefits of breastfeeding to the infant.
  - d. The lack of long-term follow-up data on infants exposed to varying amounts of marijuana via human milk, coupled with concerns over negative neurodevelopmental outcomes in children with in utero exposure, should prompt extremely careful consideration of the risks versus benefits of breastfeeding in the setting of moderate or chronic marijuana use.

A recommendation of abstaining from any marijuana use is warranted.

- e. At this time, although the data are not strong enough to recommend not breastfeeding with any marijuana use, we urge caution.

#### General (Circumstances contraindicated or requiring more caution)

Counsel women under any of the following circumstances not to breastfeed (III):

- Not engaged in substance abuse treatment, or engaged in treatment and failure to provide consent for contact with counselor
- Not engaged in prenatal care
- Positive maternal urine toxicology screen for substances other than marijuana at delivery [see (b) above]
- No plans for postpartum substance abuse treatment or pediatric care
- Women relapsing to illicit drug use or legal substance misuse in the 30-day period prior to delivery
- Any behavioral or other indicators that the woman is actively abusing substances
- Chronic alcohol use.

Evaluate carefully women under the following circumstances, and determine appropriate advice for breastfeeding by discussion and coordination among the mother, maternal care providers, and substance abuse treatment providers (III):

- Relapse to illicit substance use or legal substance misuse in the 90–30-day period prior to delivery
- Concomitant use of other prescription medications deemed to be incompatible with lactation
- Engaged later (after the second trimester) in prenatal care and/or substance abuse treatment
- Attained drug and/or alcohol sobriety only in an inpatient setting
- Lack of appropriate maternal family and community support systems
- Report that they desire to breastfeed their infant in order to either retain custody or maintain their sobriety in the postpartum period.

In the United States, women who have established breastfeeding and subsequently relapse to illegal drug use are counseled not to breastfeed, even if milk is discarded during the time period surrounding relapse. There are no known pharmacokinetic data to establish the presence and/or concentrations of most illicit substances and/or their metabolites in human milk and effects on the infant, and this research is unlikely to occur given the ethical dilemmas it presents. The lack of pharmacokinetic data for most drugs of abuse in recently postpartum women with substance use disorders precludes the establishment of a “safe” interval after use when breastfeeding can be reestablished for individual drugs of abuse. Additionally, women using illicit substances in the postnatal period may exhibit impaired judgment and secondary behavioral changes that may interfere with the ability of the mother to care for her infant or to breastfeed adequately. Passive drug exposures may pose additional risks to the infant. Therefore, any woman relapsing to illicit drug use or legal substance misuse after the establishment of lactation should be

provided an appropriate human milk substitute (donor milk, formula) and intensified drug treatment, along with guidance on how to taper milk production to prevent mastitis. (III)

The woman with a substance use disorder who has successfully initiated breastfeeding should be carefully monitored, along with her infant, in the postpartum period. Ongoing substance abuse treatment, postpartum care, psychiatric care when warranted, and pediatric care are important for women with substance use disorders. Lactation support is particularly important for infants experiencing NAS and their mothers. Communication among all care providers involved with the health, welfare, and substance abuse support of the mother and the child should provide an interactive network of supportive care for the dyad. (III)

### Recommendations for Future Research

1. Long-term randomized controlled trials or paired cohort evaluations of infants exposed to methadone or buprenorphine via human milk, including infant developmental assessments
2. Further evaluations of maternal milk and plasma and infant plasma pharmacokinetic data regarding prescription opioids and lactation, especially for mothers who were on chronic high-dose medications during pregnancy that are continued when breastfeeding
3. Long-term controlled evaluations of infants exposed to marijuana via human milk, to include infants and later neurodevelopmental outcomes, including those exposed to marijuana in a controlled manner, such as with legalized medical marijuana
4. Evaluation of nicotine replacement patches, gum, and vaporized cigarettes as substitutes for tobacco smoking in pregnant and lactating women, to determine if these can or should be widely recommended in place of tobacco products.

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ABM protocols expire 5 years from the date of publication. Evidence-based revisions are made within 5 years or sooner if there are significant changes in the evidence.

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