

Protocol #16

Drugs and Breastfeeding



Protocol #16: Drugs and Breastfeeding

Most drugs can be safely used by breastfeeding mothers, but a risk-benefit assessment for both mother and baby is required prior to use. With the proper choice of medication, maternal conditions should be treated and breastfeeding can continue during drug therapy. In contrast, the risks to the infant of artificial baby milk (ABM) are significant and should not be trivialized (Adapted from Hale, 2010 Hale, 2010).

Suggestions

Encourage the mother in understanding:

1. There are possible benefits and risks related to the use of a medication during breastfeeding and that she may require support from a health care provider to make a fully informed decision.

2. It is rarely appropriate for a mother to forego the benefits of necessary pharmacological therapy in order to breastfeed. This includes physical and mental health therapies.

3. If the use of a drug is necessary or it can be postponed, e.g., for a medical condition that does not need to be urgently diagnosed or treated.

4. Medications and herbs not absolutely necessary should be avoided (Hale, 2010b).

5. When it is necessary for the her to take a drug, the drug that is chosen should ideally:

- Be compatible with breastfeeding.
- Be taken with at minimum dose that is effective and for the shortest duration.
- Be used in paediatric drug therapy.
- Have the least toxic effect on the baby.
- Have the shortest half-life.
- Have the least concentration in breast milk, e.g., low breast milk-to-plasma ratio.
- Have the poorest oral bioavailability to limit oral absorption.
- Have published controlled studies.

6. Before the mother takes any drug, it should be checked for compatibility with breastfeeding with:

- the prescribing health care provider.

- Thomas Hale’s website: <http://www.infantrisk.com/category/breastfeeding>, or

- a breastfeeding clinic.

7. Before she takes a drug there should be an evaluation of the age, stability, and condition of the baby to determine if the baby can handle exposure to the medication.

8. If the drug chosen is compatible with breastfeeding, she should be encouraged to take the drug during or immediately after breastfeeding, especially at times when the baby sleeps for longer periods. This will maximize the clearance of the drug from the breast milk before the next feeding.

9. If she is prescribed a necessary drug that is contraindicated with breastfeeding, she should inquire whether there is an alternative drug that is compatible with breastfeeding. Information about specific drugs and breastfeeding can be obtained from:

- the prescribing health care provider

- Thomas Hale’s website: <http://www.infantrisk.com/category/breastfeeding>

- a breastfeeding clinic.

10. If she is prescribed a necessary **drug that is contraindicated with breastfeeding** and there is no alternative drug that is compatible with breastfeeding, she should be encouraged to:

- Discontinue breastfeeding until it is safe to resume.

- Express both breasts on a regular basis in order to maintain her breast milk supply. Generally, this should be at least 8 times a day, with a minimum of 1 expression overnight, to mimic the normal feeding pattern. The mother may need to express more often if her breasts become uncomfortable or full. Discard the expressed breast milk (EBM) (*Protocol #19: Expressing and Storing Breast Milk*).
- Feed the baby with a supplement using an alternative method not at the breast, e.g., cup, spoon, syringe, finger feeding (*Protocol #18: Alternative Feeding Methods*). EBM that was collected prior to the use of the drug can be used as the supplement. If previously collected EBM is not available, an appropriate supplement should be offered (*Protocol #17: Indications for Supplementation or Cessation of Breastfeeding*).

11. The following drugs should be avoided or limited when breastfeeding:

Tobacco

If the mother smokes cigarettes, inform her that:

Smoking is not recommended in breastfeeding mothers.

- Breastfeeding remains the recommended method of infant feeding even if the mother smokes.
- Nicotine rapidly concentrates in breast milk immediately after smoking. Nicotine and its major metabolites have also been found in the breast milk of mothers who are exposed to second-hand smoke.
- Excessive nicotine in breast milk may irritate the baby's gastrointestinal system and may cause vomiting, diarrhea, increased heart rate, and fussiness.
- Smoking can affect breast milk production and may negatively impact infant growth and alter the baby's sleep patterns in the short term (Health Canada, 2012).

Encourage the mother to:

- Decrease the number of cigarettes she smokes or try to quit smoking. Information about smoking cessation is available from the Smokers' Helpline at 1-877-523-5333 or <http://www.smokershelpline.ca/>.
- Try to smoke immediately after breastfeeding when the baby is sleeping for longer periods (the half-life of nicotine in breast milk is between 60–90 minutes (AAP, 2001)).
- Avoid exposing the baby to second-hand smoke

from any source. Do not smoke indoors or in the car. Children exposed to second-hand smoke have an increased risk of health problems such as asthma, bronchitis, pneumonia, ear infections, and Sudden Infant Death Syndrome. (*Adapted from information from CAMH (2003)*).

Caffeine

If the mother consumes caffeinated beverages, encourage her in understanding that:

- Caffeine passes into breast milk and reaches peak levels within 60–120 minutes of maternal consumption (Hale, 2010a).
- Excessive caffeine in breast milk may cause the baby to become overstimulated, e.g., wide-eyed, active, alert, have difficulty sleeping, and unusually fussy (Mohrbacher, 2010).
- Caffeine can be found in many foods and drugs in addition to beverages, e.g., foods containing chocolate, some analgesics and cold remedies, coffee, tea, most cola soft drinks, and some energy drinks. (*Source: Adapted from Health Canada, Fact Sheet – Caffeine It's Your Health, 2011 and Fact Sheet – Caffeine in Food, 2011.*)

Encourage the mother to:

- Limit her intake of caffeine to 300 mg per day from all sources. On average (where 1 cup is equal to 8 fluid ounces or 250 ml), 300 mg of caffeine would be contained in:
 - less than 2 cups of filter drip coffee
 - 3 cups of instant coffee
 - 6 cups of tea
 - 6 cans of cola beverages (where a can is 12 fluid ounces or 355 ml)
- Try to consume caffeinated beverages, foods or drugs immediately after breastfeeding when the baby is sleeping for longer periods. (*Source: Adapted from Health Canada, Fact Sheet – Caffeine It's Your Health, 2011 and Fact Sheet – Caffeine in Food, 2011.*)

Alcohol

Moderate, occasional alcohol consumption is not likely to pose a problem to an infant, but heavy alcohol consumption is to be avoided. Wait at least 2 hours before breastfeeding the baby to avoid unnecessary infant exposure (Best Start, 2005).

If the mother consumes alcohol, inform her that:

- Alcohol passes into breast milk. Any alcohol consumed by a breastfeeding mother will pass into her breast milk in concentrations similar to her own bloodstream.
- Alcohol is not stored in breast milk.
- Just moderate levels of alcohol in breast milk have potential or proven adverse effects for the baby.
- Alcohol has been associated with impaired motor development.
- Alcohol has been associated with altered sleep patterns in the baby.
- Alcohol has been associated with a risk of hypoglycemia in the baby.
- Alcohol may inhibit the letdown reflex (Coiro et al., 1992, and Cobo, 1973).
- Alcohol may alter the odour or taste of breast milk (Mennella, 1998, 1993).
- Alcohol has been associated with decreased breast milk intake by the baby (Mennella, 2001).
- Excessive alcohol consumption may impair her ability to care for her baby.
- Alcohol content in non- or low-alcohol beverages may be higher than declared (Goh et al., 2010).
- 1 drink = 340 g (12 oz) of 5% beer, or 141.75 g (5 oz) of 11% wine, or 42.53 g (1.5 oz) of 40% alcohol (Koren, 2002; Best Start, 2005).

Encourage the mother to:

- Avoid or limit her intake of alcohol to an occasional drink.
- If the mother decides to consume alcohol on a limited basis, advise her that she can ensure that her baby is not exposed to any alcohol by:
 - careful planning of the breastfeeding schedule, i.e., breastfeed first, drink after (CAMH, 2003),
 - storing EBM before drinking, and/or
 - waiting for complete alcohol elimination (Ho et al., 2001).

12. The following drugs should be avoided when breastfeeding:

- **Cannabis**, e.g., marijuana, hashish

- **Cocaine**, e.g., coke, crack
- **Club drugs**, e.g., rohypnol, ketamine

(Please see *Protocol #12: Insufficient Breast Milk Supply* for a discussion regarding the use of galactagogues.) (Adapted from information from *Best Start (2005)*, and *CAMH (2003)*.)

General Principles

Most drugs are quite safe to be used by breastfeeding mothers. The hazards of using artificial baby milk (ABM) are well documented (Hale, 2010a).

Although most drugs will pass into breast milk to some degree, the amount is low and the majority of prescription and over-the-counter drugs are compatible with breastfeeding. Only rarely does the amount transferred into breast milk produce clinical doses in the infant (Hale, 2010a).

Avoid using medications that are not necessary. Herbs, high-dose vitamins and supplements, etc. are not necessary and should be avoided (Hale, 2010a).

It is rarely necessary for a mother to discontinue breastfeeding in order to take a medication. Similarly, it is rarely appropriate for a mother to forego the benefits of necessary pharmacological therapy in order to breastfeed.

When a drug is incompatible with breastfeeding, there is usually an alternative drug that can be safely prescribed.

Drugs that are generally safe when breastfeeding include:

- Drugs that are safely prescribed for babies, e.g., antibiotics, analgesics.
- Drugs that are inhaled or applied to the skin, eyes, or nasal passages. They are poorly absorbed and rarely reach significant maternal plasma levels. Doses given by intravenous therapy or intramuscular generally accumulate in breast milk faster.
- Drugs with low oral bioavailability are not readily absorbed in the stomach or intestines of the mother or baby.
- Drugs with a large molecular structure do not readily pass through the alveolar membranes of the breast into breast milk.
- Drugs that have short half-lives.

Drugs that are usually considered contraindicated or incompatible with breastfeeding include:

- Antineoplastics and immune suppressants.
- Chemotherapy drugs, which can be toxic to an infant at very low levels.
- Anticonvulsants. Only a few anticonvulsants are excreted in high concentrations into breast milk, e.g., phenobarbitol, ethosuximide, and primidone.
- “Street” drugs, e.g., cocaine, marijuana, heroin, amphetamines (CAMH).
- Benzodiazepines.
- Radiopharmaceuticals including iodide (I-131).
- Bromocriptine.
- Lithium.
- Ergotamine alkaloids (with the exception of methylergonovine on a short-term basis, which is compatible with breastfeeding).

Caution is recommended regarding the use of oral contraceptives. Estrogens have a long but poorly documented history of suppressing breast milk production; Riordan (2010) reports variable sensitivities among mothers. Progesterone has a poor oral bioavailability; however, Hale advises that the effect on breast milk production is poorly studied (Hale, 2010). Low-dose progestin-only birth control pills are suggested for use after breast milk supply is established or at about 6 weeks postpartum. All mothers should be advised to wait to start oral contraceptives for as long as possible and to observe for a possible reduction in breast milk supply.

PPD – A mother affected by postpartum depression (PPD) should discuss the risks and benefits of various treatment options with her health care provider. It is important to support mothers in understanding that medications may be necessary but that breastfeeding can continue. It is important to provide prompt and effective breastfeeding support so that there is minimal impact on a new mother’s mental health (TPH, 2011).

The above list is not inclusive and may have been updated since the printing of these protocols. In addition, some drugs that are usually contraindicated may be given on an individual basis if closely monitored by a physician. Before the mother takes any drug, it should be checked for compatibility with breastfeeding with their prescribing health care

provider or a breastfeeding clinic.

Drugs that should be avoided or limited when breastfeeding include:

- Tobacco (nicotine)
- Caffeine
- Alcohol
- Cannabis – Although there is limited scientific data available about the passage of delta-9 tetrahydrocannabinol (THC), the principal psychoactive compound in marijuana, into breast milk, Centre for Addiction and Mental Health (CAMH) reports that it appears to be excreted into breast milk in moderate amounts. However, it is stored in fat and can be detected for up to a month after use in chronic users. Similarly, THC can accumulate in breast milk to high concentrations with chronic use, potentially affecting infant brain development. Cannabis exposure via breast milk has not been shown to increase risk to the baby, but babies need close monitoring.
- Cocaine – Cocaine passes into breast milk in notable concentrations and it may accumulate in infants, as they are less able to metabolize it. Although there is limited data about cocaine in breast milk, irritability, trembling, vomiting, diarrhea, and seizures have been observed in infants.
- Opioids – At therapeutic levels, most opioids are excreted into breast milk in minimal amounts and can be compatible with breastfeeding. However, toxicity may occur when the mother is abusing a drug. Recent research suggests that codeine may not be safe for all breastfed babies, as there is a minority of mothers who may metabolize codeine into morphine. Infants and mothers need to be observed for central nervous system [CNS] depression. It is now advised that pain management beyond Day 4 postpartum be changed to a non-codeine analgesic, or the dose of codeine

be decreased. Methadone is compatible with breastfeeding (Adapted from Madadi, 2009 and CAMH et al., 2007).

- Non-alcoholic beverages – Previous research supported recommendations to choose non-alcoholic beverages as a safer choice over alcohol; Mennella found that infants consumed 23% less breast milk following maternal ingestion of alcohol compared with a non-alcoholic option (Mennella et al., 1993). However, more recent research has found that it may be difficult for women to make a safe choice, as the amount of ethanol (alcohol) was higher than stated in almost 30% of the non-alcoholic beverages tested (Goh et al., 2010).
- Alternative therapies, natural health products (herbs) and over-the-counter preparations – Both clients and health care professionals must approach the use of over-the-counter and natural health products with caution. At this time, there is not enough scientific information about the safety of various herbs and natural health products to either determine standardized dosages, mechanisms of action or recommend their general use during breastfeeding. Breastfeeding women should always consult with their health care provider and/or a breastfeeding expert knowledgeable about the use of herbs and natural products in breastfeeding mothers for information, as well as a risk-benefit assessment for both mother and baby.

If the mother inquires about the use of medications or herbs when she is breastfeeding, it is important to first explore with her any contributing factors related to her concerns, as well as her breastfeeding self-efficacy. It is also important to inquire about her previous breastfeeding history, current breastfeeding management and attempts to manage her concerns, and then offer suggestions to optimize basic breastfeeding.

It is important for mothers to understand the possible benefits and risks associated with the use of herbs and natural health products in order to make an informed decision about their use.

Caution is recommended regarding the use of alternative therapies or natural products such as herbs when breastfeeding, as many contain chemical substances that may be dangerous to the baby (Hale, 2010a). Similar caution applies to the use of over-the-counter medications. All of these products contain chemical substances that may be dangerous to an

infant. There is mixed evidence to support their use. Limited information is available from formal scientific research to establish dosages, benefits, and risks, or possible interactions with other medications. However, several products have traditionally been used in breastfeeding (*Protocol #12: Insufficient Breast Milk Supply; Protocol #6: Plugged Ducts; Protocol #15: Candidiasis (Thrush)*).

Health Canada has regulations to ensure the quality, effectiveness, and safety of natural health products (herbs). Natural health products approved under these regulations will have a Natural Product Number (NPN) or Drug Information Number – Homeopathic Medicine (DIN-HM) on the label. Few products have been tested for safety in pregnancy and breastfeeding and are therefore not recommended by Health Canada for use in breastfeeding.

Health Canada follows the precautionary principle, advising that breastfeeding women should consult with their health care provider before using any natural health products to minimize possible risk (2011c). However in the most recent edition of *Medications and Mothers' Milk* (Hale, 2010a), Thomas Hale lists some herbs commonly used in breastfeeding management as rated L3 (moderately safe) for use by breastfeeding women. For example, blessed thistle and fenugreek are rated L3.

For advisories and warnings about specific drugs and health products, go to the following Health Canada website: <http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/index-eng.php>.

It is important to note that herbal products may not be standardized, so there may be different doses of the active ingredient used by various manufacturers. In addition, there may be increased risk of allergic reactions because the product may contain pollen, mould, or mould spores.

If a mother inquires about the use of alternative therapies or natural health products, refer her to a health care provider and/or breastfeeding expert knowledgeable about the use of herbs and natural products in breastfeeding mothers. These products should only be used under the supervision of a health care provider with breastfeeding expertise. It is essential that there be a comprehensive plan that includes a thorough assessment to clarify need, screening for contraindications and side effects, discussion of the information (or lack thereof) regarding efficacy, safety, timing of dosages, and

potential risks, and appropriate follow-up assessment.

General concerns about drugs and breastfeeding include:

- Whether the drug will affect the baby’s health.
- Whether the drug will affect breastfeeding, e.g., decrease breast milk supply, change the quality of the breast milk, or inhibit the letdown reflex.
- Whether there is a risk of weaning and how this may impact the mother and baby, e.g., severe engorgement and mastitis resulting from abrupt weaning, or baby may refuse supplementation.
- Whether there are other options to taking the drug, e.g., avoid taking the drug if it is not necessary or find alternative drugs that are compatible with breastfeeding.
- Whether there is the potential for impairment in care of the baby if the mother’s judgment of her level of sedation is affected.

Drugs will have less impact on breastfed babies who are:

- Heavier.
- Older.
- Born as healthy and full-term versus premature (the more premature the baby is, the more impact the drug will have).
- Taking solid foods at an appropriate age in addition to breastfeeding.

The impact of a drug on the breastfed baby will also depend on the mother’s kidney and liver function. If the mother’s kidneys and/or liver are compromised, the clearance of the drug from breast milk may be impaired and prolonged.

If the baby becomes drowsy as a result of a drug or substance ingested by the mother, the baby may show less interest in breastfeeding or may not suck as effectively.

Subramanian (1988) found that alcohol did not alter baseline serum prolactin levels. It was associated with an inhibition of suckling-induced prolactin release and milk consumption in rats. These results have shaped our understanding of the relationship between alcohol and lactation. Research has also identified a link between a family history of alcoholism in first degree relatives of non-alcoholic lactating women with a blunted prolactin response to

breast stimulation (suckling); mothers with a positive family history also reported more frequent daily breastfeeding (Mennella et al., 2010).

For more comprehensive discussions about medications and breastfeeding please refer to:

- “Drug Therapy and Breastfeeding” by Thomas Hale, in Riordan’s *Breastfeeding and Human Lactation* (4th ed.) (2010).
- “Medications” in Hale and Hartmann’s 2007 *Textbook of Human Lactation*.
- “Medications, Herbal Preparations, and Natural Products in Breast Milk” by Ruth Lawrence, in *Breastfeeding: A Guide for the Medical Profession* (2011).
- Further references or websites as cited below.

For a discussion of specific medications, please refer to:

- Prescribing health care provider.
- *Medications and Mothers’ Milk* (2010a) by Thomas Hale, as cited below.

- Thomas Hale’s website for professionals: <http://www.ibreastfeeding.com/>.
- Thomas Hale’s website for parents: <http://www.infantrisk.com/category/breastfeeding>.

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