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Chapter 7

MEDICINES FOR BREASTFEEDING WOMEN: RISKY BUSINESS?

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ABSTRACT

In the postpartum period, many women experience conditions which require treatment with medicines, such as analgesics or antibiotics. However, pharmaceutical companies remain cautious about the use of medicines in women who are lactating. Their advice to physicians is usually to weigh the risks against the benefits. Yet, what are these risks and benefits?

How risky is it for a breastfeeding woman to take medication? Considering the large numbers of women who breastfeed and take medicines, very few ill-effects are reported for the infant.

The drug companies claim that breastfeeding while the mother is taking medication may be risky. But what are the alternatives if the mother does not breastfeed? Preferred infant feeding options include mother's stored milk or milk from other mothers (human milk bank or wet nurse). However, most parents would use infant formula in this situation. Yet the risks of using infant formula are rarely considered by parents or health professionals. The recent melamine crisis in infant formula in China serves to remind us that infant formula is not risk-free. Powdered infant formula may be contaminated with bacteria, pesticides or other environmental contaminants, or even intentionally poisoned with a chemical such as melamine.

Breastfeeding is being actively promoted in many countries, yet the issue of maternal medication during breastfeeding has received little attention. Many health professionals and mothers are unsure about the safety of using medicines during lactation. In some instances, women are being told to stop breastfeeding unnecessarily by their health providers, or women may feel too unsure about the safety of their medication and do not comply with medication use or give their child formula, "to be on the safe side".

Action is urgently needed to develop evidence-based guidelines for the use of medicines by breastfeeding women. This information needs to be readily accessible to all women and health providers.

INTRODUCTION

In the postpartum period, many women experience conditions which require treatment with medicines. Some women have chronic conditions such as hypertension or arthritis, while others experience acute illnesses such as such as infections or injuries. Studies have shown that the majority of women receive medicines in the postpartum period: among 840 UK women, 54% were administered a drug in hospital (analgesics, antibiotics, others) and 55% were given a prescription by their general practitioner (antibiotics, analgesics, others) [1]. An audit of 2004 maternal medication charts in the postnatal wards of three Irish hospitals in 1982, found that only 14 women (<1%) received no drug treatment [2]. Most medicines are taken short-term; only 4% of breastfeeding women required long-term treatment in the Irish study [2].

The use of medicines in women who are lactating is a unique situation, as the medication is being given to one individual and the other – the infant – is the "innocent bystander" [3]. Pharmacology textbooks traditionally have not supported the use of medicines for breastfeeding women. Here is a typical example from a book in my university library:

> "Breast-feeding mothers (Heading)
> Most drugs that enter the maternal circulation are distributed into breast milk. . . . For many drugs there is insufficient evidence to be certain of safety, thus it is prudent only to expose the infant to such risks if it is absolutely essential" [4 p. 412].

The language implies that there is no risk of not breastfeeding (or restricting maternal drug use) and the "prudent" pharmacy student would be led to believe that infants should not be exposed to any medicines at all. Pharmaceutical companies also remain cautious and their advice to physicians is usually to weigh the risks against the benefits. Yet, what are these risks and benefits?

The level of medicine in the mother's milk is generally far below the therapeutic level for an infant – mostly under 3% of a therapeutic dose per kg bodyweight [5]. The list of medicines risky for breastfeeding women is short: antineoplastic agents, ergotamine, methotrexate, cyclosporine, radiopharmaceuticals [6].

Considering the large numbers of women who breastfeed and take medicines, very few ill-effects have been reported for the infant. Anderson and colleagues reviewed all case studies of adverse events in infants caused by medications, published before June 2002 [7]. They evaluated papers describing adverse reactions in 100 infants, of which none were "definite", 47% were "probable", and 53% were "possible [7]. They concluded that their review does not support the common belief that maternal medicines are harmful to infants [7].

Since that review, the first case of an infant fatality was published [8]. Following maternal codeine intake, the infant experienced central nervous system (CNS) depression and death on day 13 postpartum [8]. This mother had three functional cytochrome p450 2DS genes and would be classified as an "ultrarapid metabolizer". Individuals with this inherited phenotype have increased transformation of codeine into morphine, leading to an increased risk of CNS depression in their breastfed infants. It is now recommended that physicians avoid routine use of codeine in the postpartum period in favour of nonsteroidal anti-inflammatory drugs [8].

Ito and colleagues investigated the type of side-effects reported by 838 mothers using a variety of medicines [9]. Eleven percent of mothers reported symptoms in their infants possibly related to medication: mostly gastrointestinal changes associated with antibiotics, sedation with analgesics and CNS medications, and irritability with antihistamines [9]. The effects were short-term and no infants experienced serious side-effects [9]. In another study of 34 women taking anti-epileptic therapy, no mother reported an adverse reaction in her infant [3].

HOW RISKY IS IT FOR AN INFANT TO BE WITHHELD BREAST MILK?

The drug companies claim that breastfeeding while the mother is taking medication may be risky. But what are the alternatives if the mother does not breastfeed? Preferred infant feeding options include mother's stored milk or milk from other mothers (human milk bank or wet nurse). However, most parents would use infant formula in this situation. Yet the risks of using infant formula are rarely considered by parents or health professionals.

The recent melamine crisis in infant formula in China serves to remind us that infant formula is not risk-free [10]. Powdered infant formula may be contaminated with bacteria [11], pesticides or other environmental contaminants [12-15], or even intentionally poisoned with a chemical such as melamine [16].

Most families use powdered infant formula which needs to be reconstituted with water before use. Adding water risks adding contaminants in the water (chemicals or microorganisms), or even inadvertently reconstituting the formula with a toxic fluid [17].

Yet most of the community view infant formula as a safe product. Where formula feeding is the cultural norm, the risks are not noticed by health professionals or consumers [18]. When risks are being discussed, the substantial risks to mother and child of not breastfeeding need to be included [18].

MEDICINES, BREASTFEEDING AND THE BREASTFED BABY

When considering risks and benefits we need take into consideration the range of breastfeeding experiences that occur. At one end of the spectrum is the newborn infant with an immature metabolism whose complete nutrition comes from breast milk, at the other end, the young child who has a well developed metabolic system and breast milk is only one component of their diet.

We also need to follow the drug's path through the mother's body to the baby's circulatory system [18]. See Figure 1 for illustration of this process. Maternal medicines used topically, eg ointments on the skin or nasal sprays, will not appear in significant amounts in the mother's bloodstream and so will not be present in the milk. Medicines that are in the mother's circulation may transfer into milk, but usually only in small amounts. Drug transfer into milk depends on a number of factors, for example, drugs that are highly bound to proteins in the mother's plasma will be less likely to transfer into milk, because only a small proportion of the drug is free to cross the alveolar epithelium [19]. When choosing medicines for breastfeeding women, the medicine with the higher protein-binding is always preferable

[20]. Some medicines have such a large molecular weight that they do not enter milk; heparin is one example [19]. Then we need to determine if the drug is absorbed from the gastro-intestinal tract (GIT); for example, antibiotics like gentamicin need to be given intravenously or intramuscularly to the mother because of poor GIT absorption, and thus will be poorly absorbed by the infant's GIT and most of the dose will be passed in the infant's bowel motions [19].

Passage of medications from maternal plasma to breast milk is a dynamic process – drugs are entering and exiting in an active manner [21]. So the level in breast milk will usually drop as the maternal plasma level drops, and it is rarely necessary to suggest that women express and discard milk [21]. Drugs with shorter half-lives are preferred, as mothers' plasma levels will drop more rapidly and therefore there will be less drug transfer into milk.

Drugs that reach the infant will need to be metabolised by the infant itself, so we need to take care when prescribing for mothers of preterm infants or infants in the first months whose kidneys and liver may not be fully mature [21]. Anderson found that 78% of the adverse drug events in infants were reported in infants aged two months or less [7]. Older infants are better able to tolerate medicines. With increasing age, infants' organs mature, their weight increases and, after six months, they will be taking other nutrition in addition to breast milk.

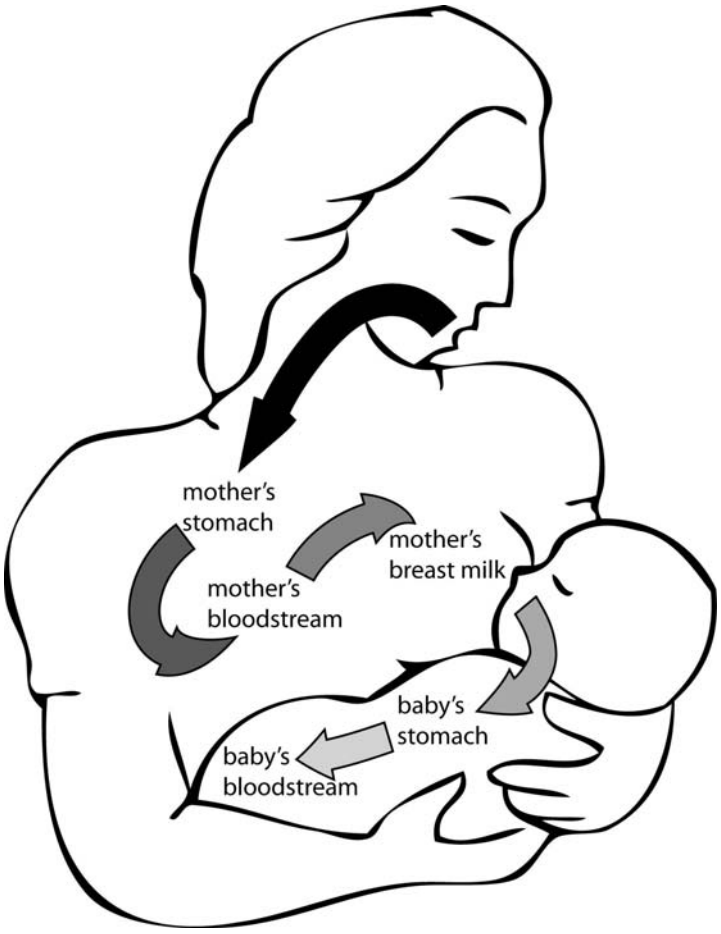

Figure 1. Passage of medicine from mother to child via breast milk.

Medicines taken during pregnancy have the potential to cause defects in organogenesis. The classic example is thalidomide, which was associated with upper limb anomalies (absence of long bones) when taken days 27-30 post-conception, while days 30-33 were associated with lower limb anomalies [22]. Medicines taken during lactation do not have this risk. Furthermore, in pregnancy the fetus receives five to ten-fold higher levels of drugs than the breastfed infant receives [19]. So it cannot be assumed that drugs that are not safe in pregnancy are not safe in lactation [18]. Yet health professionals often rely on the safety ratings given to medicines in pregnancy when making decisions about prescribing for breastfeeding women [23].

Another consideration when prescribing for breastfeeding women is: Do we use this medicine in children? Many medicines are used for infants and children, and it will therefore be safe for the breastfed infant to receive small amounts of these medicines in breast milk.

MANAGING RISK

When there is an element of risk to the infant, there are several options – to postpone maternal treatment, to stop breastfeeding completely, to withhold milk temporarily or to monitor the infant. Infants may be monitored when the mother requires a drug that is not totally contraindicated, but could lead to unwanted effects on the child. In the past, breastfeeding women requiring lithium were advised not to breastfeed because of concerns of potential toxic levels in the infant, however, more recent recommendations advise monitoring the infant via regular blood tests (for lithium levels and thyroid function) in order to maintain breastfeeding [24]. Infant thyroid function can also be monitored when the mother needs to take propylthiouracil for thyroxicosis (see Table 1). In these cases, infant lithium levels and/or thyroid function can be assessed and the potential risk can be monitored.

DRUG INFORMATION AND WOMEN

In the past, all women were excluded from drug trials because it was considered too risky to include them. The National Institutes of Health and the Food and Drug Administration (FDA), in the USA, issued guidelines (1993/1994) to make sure that (1) women were included in clinical trials and (2) data were analysed by biological sex to determine if there were differences or similarities [25]. Many researchers and ethics committees (Institutional Review Boards) continue to regard pregnancy as a virtual cause for exclusion in drug trials [26]. Breastfeeding women are usually regarded in the same way.

Bert Spilker of Pharmaceutical Research and Manufacturers in America stated at a workshop in 1999 that, “industry does not want to include pregnant or lactating women in investigational studies of new drugs because the risk may be significant for a woman and her fetus” [25 p. 611]. We can see that there is no differentiation between pregnancy and lactation and that there is no recognition that in the real world, pregnant and breastfeeding women will need to take medicines – we can’t completely protect them from all potential risks.

Table 1. Medicines and breastfeeding: vignettes and evidence-based information

Breastfeeding and medicines*	**Evidence-based information [33, 34]**
An obstetrician told a new mother that she should not take ibuprofen for pain relief following caesarean section.	Ibuprofen is safe in lactation. Current product information (Reckitt Benckiser, April 2007): "Ibuprofen and its metabolites can appear in breast milk in very low concentrations (0.0008% of maternal dose) and no harmful effects are known in breastfed infants, especially if the course of treatment is short-term and within the recommended dose". (This is a drug that should be avoided in the third trimester of pregnancy, but is safe in lactation).
A woman with an infected episiotomy was told by her GP that she needed to take two antibiotics and therefore had to stop breastfeeding.	The majority of antibiotics (including metronidazole) are safe in lactation.
A GP told a woman with mastitis that flucloxacillin was "too strong" and prescribed penicillin.	Antibiotic guidelines recommend flucloxacillin or dicloxacillin for mastitis in lactating women [53]. The most common organism isolated in infective mastitis is *Staphylococcus aureus*, which is usually resistant to penicillin. Flucloxacillin is safe in lactation.
A woman with MRSA mastitis was told by the hospital doctor and pharmacist to throw out her milk because she was being treated with vancomycin.	Intravenous medicines, like vancomycin, are poorly absorbed by the gastrointestinal tract, therefore the infant would only absorb a minimal dose.
A woman with nipple/breast candidiasis was prescribed fluconazole by her GP, who instructed the woman to express and throw out her milk for 48 hours.	Fluconazole is safe in lactation.
A breastfeeding woman with nipple eczema was prescribed a steroid ointment to apply thinly once daily after feeds. Her community pharmacist advised the woman that she not use it.	Topical steroids can be safely used in lactation. The ointment should be sparingly applied to the nipple/areola after feeds.
A woman with thyrotoxicosis was being treated with propylthiouracil (PTU) while breastfeeding. Her specialist wanted to increase the dose and recommended that she stop breastfeeding her eight month old child. She asked her family doctor about monitoring the child's thyroid function, but was advised to stop breastfeeding.	The breastfed infant can be monitored if the mother requires high doses of PTU.
A woman with past history of lymphoma was required to have a radio-isotope scan at two months postpartum. The metropolitan cancer hospital could not give her clear guidelines on how long to express and discard her milk.	The total clearance time is 5X the half-life of the drug [54]. By this time, only 3% of the dose remains and it should be safe to recommence breastfeeding [55].

*Recent cases seen in the author's breastfeeding medicine practice.

At present, some countries use a letter category system to describe the risks of drug use during pregnancy [27, 28]. For example, FDA category A is defined as "Adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the first

trimester or pregnancy (and there is no evidence of risk in later trimesters)" [29]. However, this system has been found to lead to inaccurate and over-simplified views of these risks [29]. The US FDA have recently proposed major revision to the labelling of prescription drugs [29]. The proposed new format would provide more detailed information about drug safety in pregnancy and lactation, using three sections: risk summary, clinical considerations, and data [29]. It is anticipated that this new format will facilitate well-informed risk/benefit decision-making [29].

HOW ARE DECISIONS MADE?

The response of many health professionals considering drug safety is "when in doubt, don't breastfeed" [18 p. 1353]. In my breastfeeding medicine practice, I hear many stories of mismanagement of medicines in breastfeeding women; some recent examples are listed in Table 1. Mastitis is a common problem for breastfeeding women, however health professionals are frequently prescribing the wrong antibiotic, the wrong dose or giving inappropriate advice about continuing breastfeeding [30].

Rather than advising women to stop breastfeeding, health professionals can seek help with their decision-making. There are a number of specialised books, websites and drug information services available [31]. Books that provide this information include Briggs et al's *Drugs in Pregnancy and Lactation* [32], Hale's *Medications and Mother's Milk* [33], the Royal Women's Hospital's *Drugs and Breastfeeding* [34] and *Drugs during Pregnancy and Lactation* [35]. The US National Library of Medicine's online open access resource, LactMed, [36] provides summaries of available evidence and has been found to have the most extensive and current citations [18].

One review of enquiries from health professionals about drug safety to an expert centre found that advice was given to stop breastfeeding in only 1.7% of queries [37]. On the other hand, the US Physician's Desk Reference (PDR) did not give a safe recommendation for any of the fourteen commonly used drugs evaluated in another study [18].

MATERNAL CONCERNS

Women are often anxious about the potential effect of their medicine on their child because they have been told to take care with medicines during pregnancy, and may not realise that lactation is a much safer time to take medicines. As discussed above, the infant's organs are already formed and there are large physiological differences between maternal-fetal drug distribution and medication transfer in lactation.

Maternal concerns about medicines can lead to poor compliance with medication advice [5]. Women may not take the prescribed medicine, or may choose not to breastfeed because of their concerns about taking medicines [3, 38]. Despite receiving reassuring advice about their prescribed antibiotic therapy, one in five women either did not initiate therapy or did not continue breastfeeding [38]. Another study investigating women with epilepsy found that they had half the rate of breastfeeding compared to other women [3]. When physicians were less reassuring about the safety for breastfeeding, women were less likely to breastfeed [3]. A

study in Lithuania found that 22% women who discontinued breastfeeding cited medication as the reason for stopping [39].

It is well known that prescribed medicine is not always taken, and that doctors need to involve the patient in the process of decision-making around prescribing [40]. Decision-making should be seen "as a process and not an outcome" [40 p. 866]. The tasks of informing the patient of the pros and cons of taking medicines, and involving them in the treatment decisions are crucial when the patient is a lactating woman. Patients' priorities need to be taken in consideration [40]; when the family is keen to continue breastfeeding, it is the doctor's duty to investigate the treatment options and not automatically recommend cessation of breastfeeding.

PURITY AND BREASTFEEDING MOTHERS

Ulrich Beck has referred to our society as a "risk society" in which individuals have a pervasive awareness and fear of risk in everyday life, particularly emanating from science and industry [41]. Individuals are encouraged to know their risks and make healthy choices [42]. "Making the right choice is central for constructing the self as 'normal' and distinguishing the self from risky others" [43 p. 90]. Individuals are increasingly concerned about potential risks, in particular risks from foods, such as dietary fat, food additives, and "mad-cow disease" [44, 45]. Parents feel the need to control their children's food intake in order to reduce risk and ensure a healthy diet [44]. I suggest that there is a belief that breast milk above all foods must be free from any form of contamination.

Bernice Hausman has examined the issues of HIV infection and environmental contamination in relation to breastfeeding. She concludes: "… we must accept that the ordinary mother is an impure mother, and refuse purity as a way to conceptualise good maternal embodiment and practice" and "[o]ur sometimes desperate gestures to purify ourselves, however promoted by medicine and public health, are enacted against the material conditions of modern embodiment. As such, they represent the impossible dreams of a sacred motherhood separated from the world, its dirt, and its communicable diseases" [46 p. 153].

Glenda Wall reminds us of the "ever-increasing list of self-regulatory behaviors for pregnant women to abide by" [47 p. 602]. Pregnant women must not drink alcohol, smoke cigarettes, take illegal drugs, and must eat a well-balanced diet. These rules have extended to include lactating women. Wall states that the purity of breast milk is "contingent on the proper self-management of the maternal body" [47 p. 603]. The latest alcohol guidelines released by the Australian National Health and Medical Research Council advise breastfeeding women to avoid alcohol [48], despite the lack of evidence of harm in an occasional alcoholic drink after the first month postpartum [49].

Our society's focus on risk, and possibly medico-legal concerns, has led to an increased cautiousness about use of medicines for breastfeeding women. I suggest that we should be wary of adding extra "rules" for new mothers, and we should challenge the message that only "pure" women should breastfeed.

NEED TO BALANCE RISKS AND BENEFITS

Health professionals need to balance the full profile of risks. They need to discuss the risks of not breastfeeding with parents, and understand that maternal well-being is a legitimate consideration [26]. The infant will benefit from having a healthier mother, and the "price" of a small amount of medication is a worthwhile risk. Figure 2 shows breast milk at the top of the ladder for infant health; infant formula ranks much lower than breast milk containing medication.

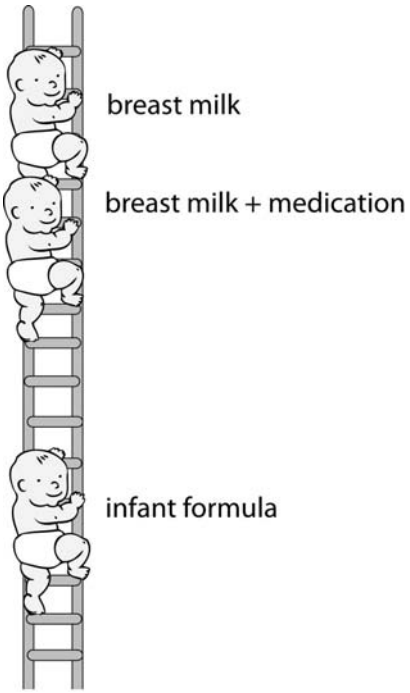

Figure 2. Breast milk is at the top of the ladder for infant health; infant formula ranks much lower than breast milk containing medication.

Information produced by pharmaceutical companies has been described as a "compendium of legal product monographs" which are "not helpful or reassuring" for prescribing / recommending doctors or their patients [50 p 1301]. Health professionals need information based on the available evidence of safety: pharmacologic characteristics and published studies. Action is urgently needed to develop evidence-based guidelines. Furthermore, these guidelines for the use of medicines in breastfeeding women need to be readily accessible to all health providers.

CONCLUSION

When considering the risk/benefit analysis of medicines for breastfeeding women, the risks of not breastfeeding greatly outweigh the risks of the vast majority of medications [21]. Yet many sources of drug information "inappropriately interfere with breastfeeding" [18 p.

1358]. Although some health professionals follow expert advice in providing information about drug safety for breastfeeding women, many do not [3]. The current situation is often confusing for patients who are the recipients of this contradictory information [18].

Breastfeeding is being actively promoted in many countries. Yet the issue of maternal medication during breastfeeding has received little attention. Breastfeeding women need evidence-based advice about taking medicines [51]. Health professionals need to look drugs up in a reliable source [18] and to involve the mother and her partner in developing a therapeutic plan [19]. They can reassure families that serious adverse drug reactions in infants are rare, particularly in infants over one month of age [7].

The US Centers for Disease Control have called for public health action to ensure that evidence-based information about safety of drugs during lactation is easily accessible to women and health professionals [52]. They suggest that a panel of experts could set priorities and standards, interpret data, and make recommendations [52]. An internet-based central resource could enable clinicians and consumers around the world to make the best decisions when considering medicines for breastfeeding women.

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