The Use of Mood Stabilizers During Breastfeeding

Zachary N. Stowe, M.D.

The literature and majority of professional organizations endorse breastfeeding as a means to provide a number of health benefits to both mother and child. Notably, the postpartum period heralds an increased vulnerability for both new onset and symptom worsening of neuropsychiatric disorders, particularly bipolar disorder in women. While pharmacologic treatment is important for these patients, many physicians have been hesitant to prescribe medication for women who choose to breastfeed, despite the fact that a variety of medical illnesses are routinely treated in breastfeeding women (e.g., epilepsy, infection, allergies, and migraine) and that nursing infants may also directly receive medications for colic and reflux. To date, all psychotropic medications studied enter human breast milk, and many of these medications have undergone detailed investigations. While breastfeeding may complicate pharmacotherapy, it does not preclude it. There are limited scientifically derived guidelines in the treatment of women who choose to breast-feed. The pharmacokinetic properties and potential impact of infant exposure to mood stabilizers must be considered in the decision to breastfeed infants born to mothers receiving pharmacologic treatment for bipolar disorder. Past practices and methodologies for determining continuation of treatment are discussed in this article, as well as the current data for newer categories of drugs being used to treat bipolar disorder and their indications during pregnancy and breastfeeding. Treating pregnant women with neuropsychiatric illnesses in their childbearing years who are breastfeeding involves a thorough risk:benefit analysis to determine the relative safety of pharmacologic therapy. Familiarity with the extant literature and its limitations and practical considerations will enable optimizing treatment plans that maintain maternal mental health, minimize nursing infant exposures, and provide infant monitoring.

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Breastfeeding has been accepted by the majority of the medical field as the ideal form of nutrition for infants. There is considerable effort to promote breastfeeding and to inform doctors and new mothers about the benefits of breastfeeding throughout the postpartum period. Given the risk of onset and exacerbation of neuropsychiatric illness in the postpartum period, it is important to understand the potential effects of pharmacotherapy on the mother-infant relationship and the mother’s overall mental health. By including the potential for breastfeeding during the initial treatment planning for childbearing-age women suffering from psychiatric illness and understanding appropriate approaches to treating women in the prenatal period helps to make the decision for and transition to breastfeeding much smoother for women who are undergoing pharmacotherapy.

Unfortunately, the current classification systems for the safety of medication use during breastfeeding are limited in their direct clinical utility and there remains a lack of consensus for the best methodology to select individual medications. Over the past decade, the quantitative data on psychotropic medications in breastfeeding have demonstrated considerable growth. Consistent with the goal of minimizing nursing infant exposure to medications is consideration of unique factors such as the rate of excretion of medications into the human breast milk and the potentially immature metabolic systems of infants.

The take-home message for clinicians treating women in the perinatal period is to deliver care within their comfort zone. Clinicians who are uncomfortable with prescribing medication to a breastfeeding woman certainly should not be encouraged to do so. Expanding the clinician’s knowledge base by reviewing scientific data may serve to widen this comfort zone.

BREASTFEEDING AND MATERNAL MENTAL ILLNESS

Every professional medical group supports breastfeeding as the primary form of infant nutrition. According to the American Academy of Pediatrics, American College of Obstetricians and Gynecologists, and the American
mental health with information about pharmacotherapy
mental health programs focused specifically on women's
sites are increasingly available, and there are now several
when researching particular medications. Academic Web
tions, which are another important source to consider
recommendation.8 However, numerous sources discuss this assessment,
ment during breastfeeding continues to rise given that the
United States6 and that the majority of neuropsychiatric
of admission than women with unipolar depression or
women with a history of bipolar disorder had a greater risk
illness has onset prior to family planning.7 Further, more
than 60% of women are choosing to breast-feed in the
United States.1,4
Similarly, there is no evidence that mental illness im-
proves during the postpartum period and the risk of severe
illness requiring hospitalization rises. Kendall et al.7 found
the risk of admission to a psychiatric hospital was
extremely high in the first 30 days after childbirth, and
women with a history of bipolar disorder had a greater risk
of admission than women with unipolar depression or
schizophrenia.

The most concise, straightforward approach in design-
ing the initial treatment plan for women with bipolar dis-
order includes

1. Assume that pregnancy is imminent for all female
patients between the ages of 8 and 48 years.
3. Recommend supplemental folic acid (800–1000
µg) for all women and higher doses (2000–4000
µg) for women treated with an antiepileptic drug.
4. Assume that women will want to breast-feed.
5. If pharmacotherapy is the best option, consider the
following axiom “new and improved = no data.”

Newer medications have limited or no data on use
during pregnancy, the postpartum period, and
breastfeeding. Prescribing the newest medication
means that if the patient becomes pregnant and
wants to breast-feed, there will be little or no data
to assist the clinician and patient in making an in-
formed decision.

Currently, few guidelines exist for determining the
risk:benefit assessment for pharmacotherapy during lacta-
tion.6 However, numerous sources discuss this assessment,
and it is important to keep in mind that the patient may
have access to these sources, as well as colleagues in pe-
diatrics and obstetrics. The most common reference is
Hale’s book Medications and Mother’s Milk.9 This com-
prehensive source for information about medication indi-
cations during lactation is frequently updated. The Amer-
ican Academy of Pediatrics Committee on Drugs1 meets
about once every 4 years to update their recommenda-
tions, which are another important source to consider
when researching particular medications. Academic Web
sites are increasingly available, and there are now several
mental health programs focused specifically on women's
mental health with information about pharmacotherapy
in pregnancy and breastfeeding.1 Journal articles can also
be useful, although methodological differences among
individual studies make it difficult to establish scientific
guidelines from which to derive definitive decisions on
the continuation of pharmacotherapy during breastfeed-
ing.1,8 Independent of the extant data, reference material,
and “academic opinions,” the decision to breast-feed while
taking psychotropic medication should be made on an
individual basis.3,11–15

THE POSTPARTUM ENVIRONMENT
AND INFANT EXPOSURE

The course of bipolar illness during the postpartum pe-
riod has received limited investigation, but shows an over-
all relapse rate of 40% in a total of 183 women studied to
date.7,16–26 There are several unique features in the breast-
feeding patient that warrant attention. First, many women
have never experienced an extended low-estrogen environ-
ment, with fluctuations of prolactin and oxytocin, which
may affect mood. Second, breastfeeding patients typically
experience greater sleep disruption, which can be detri-
mental to the bipolar illness. Third, oral contraceptives27
and fluctuations in estrogen28 can affect mood and anxiety
as well, and the majority of breastfeeding women who
also take oral contraceptives receive progestin-only com-
pounds. Fourth, some women may have difficulty produc-
ing enough breast milk, and a common medication to en-
hance milk production (metoclopramide) has the potential
to affect mood as well.29

Our group and others30–33 have demonstrated that all
psychotropic medications cross the placenta and are pre-
sent in amniotic fluid. Overall, the majority of medications
demonstrate placental passage > 70% (e.g., umbilical
cord blood is > 70% maternal serum concentration at de-
ivery). Many of the mood stabilizers (i.e., lithium, lamot-
trigine, and valproate) cross the placenta at > 100%.32,34
In contrast, determining nursing infant exposure is more
complex.

All psychotropic medications enter the breast milk as
well, although medication exposure for a nursing infant
is substantially less than the exposure to a fetus during
pregnancy (i.e., blood-to-blood in pregnancy and blood-
to-milk-to-gut-to-blood in breastfeeding). The majority of
psychotropic medication concentrations in human breast
milk are typically micrograms/milliliter for antiepileptic
drugs and nanograms/milliliter for antipsychotics and anti-
depressants. As such, nursing infant exposure relative to
pregnancy is magnitudes of order difference35; clinical
concern or changing medications for breastfeeding once
exposure has occurred in pregnancy is not consistent with
exposure data.

There remains an international disparity in the method-
ology for determining infant exposure in utero versus
while nursing. Historically, investigators have relied on the
milk-to-plasma (M/P) concentration ratio of the drug in
the mother’s milk and blood to determine the infant daily
dose.11,36–41 Our group has demonstrated that this is woe-
fully inaccurate and, at best, a coarse estimate.42,43 Psych-
otropic medications typically display variable excretion
over a 24-hour period that parallels the gastrointestinal ab-
sorption and a gradient from foremilk to hindmilk with
higher concentrations in the hindmilk. Pharmacokinetic
modeling for antidepressants, while complicated, is the
best predictor of infant serum concentration. Detailed in-
vestigations42–45 have demonstrated that discarding breast
milk during peak medication concentrations may signifi-
cantly reduce nursing infant exposure.

Another method of determining nursing infant expo-
sure in breastfeeding has been to determine the infant dose
by percentage of body weight using the M/P ratio, but this
assumes that the volume of distribution for these medica-
tions by kilogram would be the same in an infant as in an
adult, which is likely to be a false assumption. The stan-
dard evaluation for medication safety that seems to em-
ploy such methods and be consistent in pediatrics and ob-
stetrics is what has become known as the 10% rule.46 If the
estimated infant daily dose is less than 10% of the mater-
nal dose, physicians tend to be less concerned about med-
ication exposure to the infant; however, this methodology
is completely empiric.

More recently, measuring infant serum concentrations
has become the more direct, although unsubstantiated,
method for ascertaining infant exposure. Notably, there is
a tendency to view detectable concentrations in nursing in-
fant sera as an indication that the medication should be
avoided. Meta-analysis of data sets has been extremely
difficult and most likely inaccurate because of the varia-
tion in laboratory assay methodology and lack of consen-
sus on assay techniques.

When considering the risk:benefit assessment, it is
important to consider the risks of nontreatment. The child
is potentially exposed to either the mother’s untreated ill-
ess or a psychotropic medication. Nonexposure only ex-
ists when the mother has nonpharmacologic treatment
and/or remains well in the absence of treatment. Maternal
mental illness, when untreated, can expose the infant to
adverse effects.47–50 Hendrick et al.47 found that infants
who were exposed to antidepressants through breast milk
did not have low weight at 6 months; however, infants
who were exposed to maternal depression 2 months or
more postpartum weighed significantly less at 6 months
than infants whose mother’s depression lasted less than 2
months or infants of euthymic mothers. Exposure to ma-
ternal psychiatric illness has been demonstrated to have
adverse effects on children later in life.49,50 For example,
one study49 found that infant exposure to maternal depres-
sion was the most significant predictor of high cortisol
levels in children who were exposed to higher levels of
maternal stress compared with children who were exposed
to moderate or low levels of maternal stress. Another
study50 suggested that exposure to maternal depression is
also associated with criminality in male offspring. More
recently, a study51 derived from the Sequenced Treatment
Alternatives to Relieve Depression (STAR*D) program
found that maternal depression was associated with much
higher rates of psychiatric illnesses in the children.

Bottle feeding is a viable alternative to breastfeeding with
certain advantages for women undergoing pharma-
cotherapy. First, the infant would not be exposed to the med-
ications, and second, some women might be relieved to
have permission not to breast-feed. Bottle feeding could
also be helpful in reducing sleep pattern disruptions for
patients who are able to obtain additional support for help
with night feedings. Of course there are downsides, in-
cluding maternal guilt over not breast-feeding and the loss
of potential benefits to both mother and infant. Also, if a
woman has been informed that breastfeeding is the right
thing to do, and then her physician suggests that she forgo
breastfeeding during treatment, that may encourage her
to stop her medication without the physician’s knowledge
and lead to risks of the untreated illness.

**MEDICATION RATINGS SYSTEMS**

The current medication ratings systems regarding the
safety of medications during breastfeeding send mixed
messages that fail to inform the decision-making process.
Hale’s book *Medications and Mother’s Milk*52 provides
the most commonly used rating system of L1 through L5, with
L1 being considered the safest medication to use during
nursing. For a medication to obtain a rating of L1 requires
a large number of women and/or a controlled study with
a large data set. Notably, the term “large” is poorly de-
defined. That type of information is unavailable for most
drugs, though some drugs have earned L1 ratings in Hale’s
book despite the lack of controlled data, which suggests
that the ratings are inconsistent. The American Academy
of Pediatrics ratings scale3 consists of 4 ratings: (1) usu-
ally compatible with breastfeeding, (2) unknown but of
concern, (3) associated with significant side effects and
should be used with caution, and (4) requires cessation of
breastfeeding. Table 1 compares the Hale and the Ameri-
can Academy of Pediatrics ratings for several medications
typically utilized in patients with bipolar disorder. As
shown in the table, the ratings do not consistently reflect
the data. For example, fluoxetine has a total of 202 infant
blood samples and a Hale rating of L3/L2 (the L3 rating
is for premature infants). However, despite the relatively
substantial group of 202 blood samples from infants
exposed to fluoxetine, the American Academy of Pediatric
ratings fluoxetine as unknown but of concern. Ci-
talopram, as another example, is listed by Hale as an L3.
This rating, compared with the other antidepressants that
are rated L2, is based on its relatively small sample
size compared with the others. These inconsistencies in
ratings can be confusing, so it is important to understand
that the guidelines set forth for prescribing medications in nursing women are primarily derived from small samples and case studies.

There are obvious discrepancies with ratings of mood stabilizers as well. For example, carbamazepine has a cumulative sample size of >50 nursing infant serum collections, has a Hale rating of L2, and is considered compatible with breastfeeding. This rating is not driven by the data, because there are several reports of elevated liver enzymes in nursing infants. Valproate has far fewer cases and is given the same ratings both by Hale and the American Academy of Pediatrics. In the case of lithium, the rating also seems unrelated to the data. Lithium received a Hale rating of L4 based on several cases in which mothers took lithium during pregnancy and the infants were evaluated soon after delivery and described to have tremor and shakes within the first week of life. However, this effect may have had nothing to do with breastfeeding, but rather was a result of lithium ingestion during pregnancy, demonstrated by a recent article by Newport et al. When lithium is compared with valproate, there is an imbalance in the ratings. Valproate received an L2 rating and is considered compatible with breastfeeding, even though it has an only slightly larger sample size than lithium and one of the 38 cases reported a drop in infant platelet levels.

For Hale, the ratings for the atypical antipsychotics are ranked by which have the most information relative to other medications in that class. However, this method assumes that the medicines are clinically equivalent, which is certainly not the case. Some patients, as we know, respond better to some medications than others. Also, some of the data can be problematic. For example, the sample data for risperidone are misleading because one infant did not actually nurse; the measures were purely from breast milk, but the mother was bottle-feeding.

Although new data are continuously becoming available, 2 drug classes that still have little information regarding safety during breastfeeding are the newer antiepileptic drugs and the atypical antipsychotics. Table 2 shows available information on adverse events with frequently prescribed newer anticonvulsants and atypical antipsychotics available for use in women with neuropsychiatric illnesses. No adverse effects have been found in any of the studies so far. However, the sample sizes are low, and only a total of 8 blood samples have been taken to measure infant serum drug concentrations. Several of the atypical antipsychotic studies either did not discuss infant serum drug concentrations or obtained infant daily dose based on maternal serum concentration and milk concentrations. On the other hand, the data for the newer anticonvulsants are rapidly accumulating. Data for lamotrigine in nursing are on the rise because of its expanding use in pregnancy. Infants studied have had higher-than-expected concentration levels after breast-feeding exposure even though only 60% of the drug is transferred to the breast milk accounting for the ratings. However, as with the antipsychotics, the cumulative sample sizes for

### Table 1. Breastfeeding and Psychotropic Medications Commonly Utilized in Bipolar Patients: Comparing the Safety and Organization Ratings

<table>
<thead>
<tr>
<th>Drug</th>
<th>Exposed Infants (N)</th>
<th>Hale Rating</th>
<th>American Academy of Pediatrics Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupropion</td>
<td>17</td>
<td>L3</td>
<td>Unknown but may be of concern</td>
</tr>
<tr>
<td>Citloperam</td>
<td>69</td>
<td>L3</td>
<td>Not rated</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>202</td>
<td>L3/L2</td>
<td>Unknown but may be of concern</td>
</tr>
<tr>
<td>Sertraline</td>
<td>180</td>
<td>L2</td>
<td>Unknown but may be of concern</td>
</tr>
<tr>
<td>Paroxetine</td>
<td>105</td>
<td>L2</td>
<td>Unknown but may be of concern</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>51</td>
<td>L2</td>
<td>Usually compatible with breastfeeding</td>
</tr>
<tr>
<td>Valproate</td>
<td>38</td>
<td>L2</td>
<td>Usually compatible with breastfeeding</td>
</tr>
<tr>
<td>(valproic acid)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>16</td>
<td>L3</td>
<td>Unknown but may be of concern</td>
</tr>
<tr>
<td>Lithium</td>
<td>32</td>
<td>L4</td>
<td>Significant side effects; should be given with caution</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>16</td>
<td>L2</td>
<td>Not rated</td>
</tr>
<tr>
<td>Risperidone</td>
<td>3</td>
<td>L3</td>
<td>Not rated</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>7</td>
<td>L4</td>
<td>Not rated</td>
</tr>
</tbody>
</table>

### Table 2. Mood Stabilizers and Atypical Antipsychotics in Breastfeeding

<table>
<thead>
<tr>
<th>Medication Studied</th>
<th>Mother/Infant Pairs (N)</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mood stabilizers: newer anticonvulsants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Risperidone</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>10</td>
<td>None</td>
</tr>
<tr>
<td>Lithium</td>
<td>4</td>
<td>None</td>
</tr>
<tr>
<td>Atypical antipsychotics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clozapine</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Risperidone</td>
<td>3</td>
<td>None</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>3</td>
<td>N/A</td>
</tr>
<tr>
<td>Lithium</td>
<td>3</td>
<td>None</td>
</tr>
</tbody>
</table>

Abbreviation: N/A = no available data.

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Table 3. Recommendations for Infant Monitoring

<table>
<thead>
<tr>
<th>Drug</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium</td>
<td>Lithium level</td>
</tr>
<tr>
<td></td>
<td>Complete blood count</td>
</tr>
<tr>
<td></td>
<td>Blood urea nitrogen/chromium</td>
</tr>
<tr>
<td></td>
<td>(BUN/Cr) levels</td>
</tr>
<tr>
<td>Valproate</td>
<td>Valproate level (free and total)</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Carbamazepine (free and total)</td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>Rash</td>
</tr>
<tr>
<td>Typical antipsychotics</td>
<td>Stiffness</td>
</tr>
<tr>
<td></td>
<td>Creatine phosphokinase, if indicated</td>
</tr>
</tbody>
</table>

the newer anticonvulsants are still considerably small. The pharmacologic armamentarium for the treatment of many neuropsychiatric illnesses, especially bipolar disorder, has been expanding and will continue to expand partly because these disorders typically require more complex pharmacologic interventions. As the armamentarium expands, it will be necessary to learn more about the drugs, not just in treatment, but in pregnancy and breastfeeding as well.

INFANT MONITORING

Currently, there are no established guidelines for nursing-infant monitoring, and developing guidelines will require all groups—pediatrics, psychiatry, neurology—to come together for multidisciplinary action. In the meantime, there are certainly several take-home points to remember. First, monitoring of breastfed infants whose mothers take psychotropic medications is extremely important and not often discussed. After childbirth, the infant loses maternal metabolic supports, and the rate of maturation of the various infant metabolic systems is variable. Premature infants raise additional concerns because metabolic maturation takes place at an even slower rate than in full-term infants. Infant monitoring should be consistent with the side-effect profile of the individual medication and the indices potentially affected by that medication. From a medicolegal standpoint, all indices that can be affected by mood stabilizers or antipsychotics medication should be checked in an infant as often or more often as an adult is monitored. Recommendations for serum monitoring indices for frequently prescribed medications in bipolar disorder are listed in Table 3. We acknowledge that these are currently empiric and derived from the conservative approach of reducing both risk to the infant and medicolegal consequences.

Second, if an adverse event is suspected, breastfeeding should be suspended immediately. Simply suspending breastfeeding will provide a good indication of whether or not the adverse event was caused by the medication.

Third, it is important not to load the infant’s metabolic system with more than one medication, unless there is clear evidence that the mother’s first medication is not working. It is also important to avoid medications that increase infant exposure. For example, if a nursing woman is taking an antiepileptic drug, she should refrain from giving the baby children’s acetaminophen very often. Similarly, breastfeeding mothers taking lithium should be advised to practice caution when taking non-steroidal anti-inflammatory drugs and avoid becoming dehydrated, just as any patient taking lithium should be cautious in these circumstances. Recent advances in pharmacogenetics have provided theoretical concerns for coprescribing medications that inhibit the multidrug resistant proteins both in pregnancy and breastfeeding, which could potentially result in increased fetal/infant exposure.

RECOMMENDATIONS

The lack of available data and the controversy surrounding psychotropic medications in nursing require a complex clinical decision and a thorough risk:benefit assessment. Achieving the goal of treatment during lactation requires minimizing infant exposure and adverse effects while maintaining maternal mental health. There are numerous opinions and recommendations for the treatment of nursing women for neuropsychiatric illness, and no one source should be considered the absolute. A conservative approach to treating women with neuropsychiatric illness during lactation is shown in Table 4.

Table 4. Conservative Approach to Treating Women With Neuropsychiatric Disorders During Lactation

All women of the reproductive years should be treated as if they are pregnant or breastfeeding from the very first visit.

Bottle-feeding is a viable option. Document the method of birth control and remind breast-feeding women that they can get pregnant.

If a medication was effective during pregnancy, medication should not be switched after birth as this exposes the infant to a second medication and there is virtually no data on 2 medication exposures. Similarly, the clinician cannot apply the majority of breast-feeding data to support this approach because these breast-feeding studies did not have women taking different medications in pregnancy.

Use medications that have previously been efficacious for the individual. Trying new medication because it has more data in breastfeeding risks medication exposure and continued maternal illness.

Infant monitoring should be consistent with the impact of medications in adults. Routine nursing infant serum monitoring for antidepressants is not recommended.

The current classification systems do not reliably reflect the available data and are typically both class- and illness-specific, though they fail to inform the clinician of this specificity.

Academic Web sites with peer-reviewed information provide the most accurate information.
Clearly, clinical treatment decisions should not be guided solely by case reports or small case series. Maternal mental illness can have significant adverse effects on both the mother and the infant. Breastfeeding complicates treatment but certainly does not preclude it.

**Drug names:** aripiprazole (Abilify), bupropion (Wellbutrin and others), carbamazepine (Tegretol and others), citalopram (Celaexa and others), clozapine (Clozaril and others), fluoxetine (Prozac and others), lamotrigine (Lamictal and others), lithium (Eskalith, Lithobid, and others), metoclopramide (Reglan and others), olanzapine (Zyprexa), oxcarbazepine (Trileptal), paroxetine (Paxil and others), quetiapine (Seroquel), risperidone (Risperdal), sertraline (Zoloft), topiramate (Topamax), valproic acid (Depakene and others), ziprasidone (Geodon).

**Disclosure of off-label usage:** The author has determined that, to the best of his knowledge, no psychiatric medication is approved by the U.S. Food and Drug Administration for use in breastfeeding women.

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