# SLHD Guideline

## Newborn Infants Exposed to SSRI / SNRI Antidepressant Medication during Pregnancy and Lactation

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<thead>
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<tr>
<td><strong>Policy Reference</strong></td>
<td>SLHD_GL2020_028</td>
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<tr>
<td><strong>Related MOH Policy</strong></td>
<td><a href="#">Neonatal Abstinence Syndrome Guidelines GL2013_008</a></td>
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<tr>
<td><strong>Keywords</strong></td>
<td>Newborn; Adaptation; Syndrome; Serotonin; Reuptake; Inhibitors; Depression; Antidepressant; SSRI; SNRI</td>
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<tr>
<td><strong>Applies to</strong></td>
<td>All clinical staff providing maternity care in SLHD</td>
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<tr>
<td><strong>Clinical Stream</strong></td>
<td>Women’s Health, Neonatology &amp; Paediatrics</td>
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<td>Executive Director Clinical Governance and Risk SLHD, Clinical Director Women’s Health, Neonatology &amp; Paediatrics</td>
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<td><strong>Date approved by SLHD Policy Committee</strong></td>
<td>13/08/2020</td>
</tr>
<tr>
<td><strong>Authors</strong></td>
<td>Jill Martin RN, Newborn Family Support Team, Clinical Associate Professor David Osborn, Neonatologist</td>
</tr>
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## Version History

| **Current Version** | V.1 – 13/08/2020 |

Compliance with this Guideline is Recommended.
Newborn Infants Exposed to SSRI/SNRI Antidepressant Medication during Pregnancy and Lactation

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Newborn Infants Exposed to SSRI/SNRI Antidepressant Medication during Pregnancy and Lactation

1. Introduction

Adequate treatment of depression in pregnancy is very important for the health and well-being of both mother and baby. An individual risk-benefit decision must be made concerning antidepressant use in pregnancy including selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs), bearing in mind the following:

- Untreated prenatal depression is associated with pre-eclampsia, low birth weight and prematurity, as well as an increased risk of adverse effects on the mother and child;
- SSRI neonatal behavioural syndrome (poor neonatal adaptation syndrome – PNAS) is common but usually mild and transient;
- The absolute risk for persistent pulmonary hypertension is low; and,
- Evidence suggests SSRIs as a group may result in a small increase risk of congenital malformation.

While other classes of antidepressants are prescribed to pregnant and lactating women, these guidelines will primarily focus on SSRIs and SNRIs.

2. The Aims / Expected Outcome of this Guideline

Babies with late-trimester SSRI / SNRI exposure should be observed in hospital for neuro-behavioural or respiratory symptoms for a minimum of 24 hours. Families should receive anticipatory guidance on the possible effects of SSRIs on their infant, including the need for observation after birth.

3. Risk Statement

SLHD Enterprise Risk Management System (ERMS) Risk #1 - Unwarranted Deviation from standards of clinical care:

- Failure to identify infants with serotonin toxicity.
- Failure to identify infants who develop Poor Neonatal Adaptation Syndrome (PNAS), which may impact feeding and weight gain.
- Failure to identify infants with respiratory distress and/or persistent pulmonary hypertension of the newborn.

4. Resources

MHPOD: Pharmacological Interventions. This 30 minute eLearning module is accessible via My Health Learning (MHL) and gives clinical staff an overview of commonly used psychotropic and antidepressant drugs.

5. Implementation

- This guideline will be published on the SLHD intranet and accessible to all staff.
- Distribution and notification of this policy to midwifery, nursing and medical staff within SLHD via usual processes (i.e. Memo, emails, staff meetings).
- Neonatal nursing and medical staff responsible for the Neonatal Abstinence follow-up clinic (The Pygmy Possum clinic) RPAH, are available on request to deliver unit-based in-service presentations throughout SLHD.
- NSW Health required training accessible via MHL responding to policy risk statement.
- Completion of current mandatory infant and adult resuscitation annual requirements.

Compliance with this Guideline is Recommended
6. **Key Performance Indicators and Service Measures**

- Monitoring admissions to the neonatal nursery with Poor Neonatal Adaptation Syndrome (PNAS), respiratory distress and/or Persistent Pulmonary Hypertension of the Newborn (PPHN) attributed to SSRI/SSNI use in pregnancy.
- Staff completion of online education resources is recorded in MHL.
- Managers monitor staff completion of mandatory training requirements.

7. **Overview**

7.1 **Perinatal Depression (PND) - Incidence**

The World Health Organization listed depression as the leading cause of disability worldwide in 2015. The proportion of the global population with depression in 2015 was estimated to be 4.4%, with depression more common among females (5.1%) than males (3.6%)\(^2\). Rates in women of childbearing age range from 4.5% in 15-19 year olds to 7% in 40-44 year olds. There is limited data for prevalence of depression among pregnant and postpartum women. However, the estimated prevalence of depression among pregnant and postpartum women in the US was 9.1 and 10.2 percent, respectively in 2004-2005\(^3,4\). Australian studies have reported the 4-year period prevalence of antenatal depression as up to one in ten women and the 12-month period prevalence of postnatal depression as one in six in the first postnatal year.\(^5\)

7.2 **Perinatal Depression – effect on the mother and infant**

Untreated prenatal depression is associated with pre-eclampsia\(^6,7\), low birth weight and prematurity\(^8,9\), as well as negative effects on the mother and child\(^3,4,8\). Although acts of harming oneself or others during PND remain rare, depression increases the risk of suicide and suicidal ideation among postpartum women\(^3\). Depressed mothers report more thoughts of harming their infants, exhibit higher levels of negative maternal behaviours and disengagement from their infants, and display lower levels of positive maternal behaviour\(^3,8\). Elevated risks of sudden infant death syndrome have also been reported in relation to depression in pregnancy and the postnatal period\(^8\). Infants of mothers with depression receive fewer preventive health services (e.g. vaccinations), are at risk for early breastfeeding cessation, and mothers are also more likely to engage in smoking and not place their children in car seats as frequently\(^3\). Depression in pregnancy has been associated with internalising and externalising disorders in the children, and depression in adolescents and young adults\(^8\).

7.3 **Perinatal Depression – Management Overview**

Early detection of perinatal depression and anxiety is essential in the management and support of mental health and wellbeing. A variety of psychological treatments (e.g. cognitive behavioural therapy; interpersonal therapy), and other psycho-social measures (e.g. physical activity, education, support, sleep, debriefing, expressive writing) and pharmacologic interventions have been found to be effective in the treatment of mild perinatal depression\(^3,4\). Interventions with clinical trial proven effectiveness for prevention of perinatal depression include counselling interventions, cognitive behavioural therapy and interpersonal therapy, physical activity, education, peer support and sleep\(^4\).

For a woman with moderate or severe depression in pregnancy or the postnatal period, either a tricyclic antidepressant, selective serotonin reuptake inhibitor (SSRI) or serotonin-noradrenalin reuptake inhibitors (SNRI) is recommended\(^8\).

Information should be provided to the woman about the risk of relapse if medication is ceased, as well as risks associated with continuing medication\(^8\).
7.4 Selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs)

Selective serotonin reuptake inhibitors (SSRIs) and, to a lesser extent, serotonin-noradrenaline reuptake inhibitors (SNRIs), are commonly used in the treatment of depression during pregnancy. Published data show that 2.4% of pregnant women in Sweden during years 2006–2012\(^\text{10}\), and 6% in USA during the years 2001–2013 who were treated with SSRIs\(^\text{11}\).

Selective serotonin reuptake inhibitors and SNRIs carry potential risks to the fetus and mother. The NICE guideline review\(^\text{8}\) identified a statistically significant association between all SSRIs and congenital malformations (p=0.04) with an absolute risk difference of 9 more per 1000. Significant associations were found for paroxetine and congenital (p=0.05), major congenital (p=0.04) and cardiac (p=0.006) malformations, and fluoxetine with major congenital (p=0.008) and cardiac (p=0.02) malformations, citalopram and escitalopram and ventral septal defects.

SSRIs use in late pregnancy is associated with persistent pulmonary hypertension (p=0.00001), although the absolute risk difference is low with only 2 more per 1000 in the SSRI exposed group\(^\text{8,12,13}\). Larger effect sizes were found for an association between any antidepressant and poor neonatal adaptation syndrome (PNAS) (280 more per 1000), respiratory distress (90 more per 1000) and tremor (352 more per 1000). There was also some evidence for greater risk of preterm delivery (17 more per 1000) and miscarriage (12 more per 1000) associated with the SSRI group. There are also several case reports of serotonin syndrome (toxicity) in newborn infants or mothers on fluoxetine\(^\text{14,15,16,17}\), paroxetine\(^\text{18}\) and citalopram\(^\text{19}\), but not for sertraline\(^\text{20}\).

PNAS (withdrawal) should be distinguished from serotonin syndrome (toxicity). PNAS is more likely with agents with shorter plasma elimination half live (e.g. sertraline\(^\text{20}\)), whereas toxicity has been reported with agents with a longer elimination half live of the agent and/or its metabolite (fluoxetine, paroxetine and citalopram).

7.5 Poor Neonatal Adaptation Syndrome (PNAS)

Poor Neonatal Adaptation Syndrome (PNAS), also described as SSRI neonatal behaviour syndrome\(^\text{21,22,23}\), comprises of central nervous system, respiratory, and gastrointestinal symptoms\(^\text{21,22,23,24,25,26,27}\). Most symptoms develop within 48 hours of birth and resolve without treatment within two to six days. Severe PNAS reaching treatment criteria on the Finnegan score (Neonatal Abstinence Score) was reported to be uncommon, occurring in 7 of 220 infants (3%) exposed to SSRIs or SNRIs. In contrast, hypoglycaemia (plasma glucose <2.6 mmol/L) was reported in 42 infants (19%)\(^\text{24}\).

Infants should be observed for signs of SSRI withdrawal including increased muscle tone, loose or watery stools, mild or marked tremors while undisturbed, less than 1 or 2 hour sleep after feeding, poor feeding (breastfeeding code <5) or a markedly hyperactive Moro reflex (i.e. startle)\(^\text{28}\). If present, infants can be monitored for severe withdrawal using the Finnegan Neonatal Abstinence Score\(^\text{23}\). Severe withdrawal has been variably defined as two or three consecutive scores of 8 or over\(^\text{23}\). An adapted Finnegan Neonatal Abstinence Score (see Appendix) comprising of 8 items has been validated a sensitivity of 97.7% and specificity of 37.0% using a cut-off of 1, and a sensitivity of 41.9% and specificity of 86.2% using a cut-off of 2\(^\text{28}\). Guidelines for the monitoring and observation of SSRI / SNRI exposed infants vary, however, where available predominantly suggest an initial observation period of 48 – 72 hours, continuing until symptoms are resolved\(^\text{22,23}\).

If severe withdrawal is present (3 modified Finnegan NAS scores ≥8) obtain paediatric review and consider commencing Phenobarbital which has been recommended as per the Neonatal Abstinence Syndrome Guideline\(^\text{29}\).
7.6 Serotonin toxicity (syndrome)

Serotonin syndrome is a drug induced syndrome characterised by a cluster of dose related adverse effects that are due to increased serotonin concentrations in the central nervous system. Serotonin (5-hydroxytryptamine, 5-HT) is a neurotransmitter with many effects, including modification of mood, sleep, vomiting, and pain. Severe or life threatening effects (rigidity and hyperthermia) result from stimulation of 5-HT2 receptors. The mothers of symptomatic infants should be assessed for signs of serotonin toxicity by history and examination. The Hunter Serotonin Toxicity Criteria Decision Rules are more accurate for diagnosis of serotonin toxicity: In the presence of a serotonergic agent:

1. IF (spontaneous clonus=yes) THEN serotonin toxicity=YES;
2. ELSE IF (inducible clonus=yes) AND [(agitation=yes) OR (diaphoresis=yes)] THEN serotonin toxicity=YES;
3. ELSE IF (ocular clonus=yes) AND [(agitation=yes) OR (diaphoresis=yes)] THEN serotonin toxicity=YES;
4. ELSE IF (tremor=yes) AND (hyperreflexia=yes) THEN serotonin toxicity=YES;
5. ELSE IF (hypertonic=yes) AND (temperature > 38C) AND [(ocular clonus=yes) OR (inducible clonus=yes)] then serotonin toxicity=YES;
6. ELSE serotonin toxicity=NO.

In adults and children, moderate to severe serotonin toxicity is managed with sedation to reduce muscle hyperactivity (such as midazolam infusion or oral diazepam), active cooling (fans with water sprays, ice packs, or cooling blankets), and even paralysis and ventilation may be useful in severe cases. Serotonin antagonists including intravenous chlorpromazine and oral cyproheptadine have been used to treat moderate serotonin. With intravenous chlorpromazine, fluid loading is essential to prevent hypotension.

There are several case reports of serotonin syndrome (toxicity) in newborn infants or mothers on fluoxetine, paroxetine, and citalopram, but not for sertraline. Fluoxetine has a long elimination half-life reported to range 1 to 3 days after a single dose, and 4 to 6 days after long-term use. Its active metabolite, norfluoxetine has a half-life up to 16 days.

In the newborn, reported signs of serotonin toxicity include irritability; increased muscle tone; mild or marked tremors while undisturbed; ankle clonus elicitable on examination; and low grade fever. These infants may still be feeding efficiently as serotonin is involved in appetite. Continued mother’s milk feeding is a risk factor for toxicity, particularly with fluoxetine.

Perform a plasma drug level of the relevant agent and its active metabolite to differentiate PNAS from serotonin toxicity. Reports of toxicity have usually been associated with plasma levels of the agent and / or active metabolite in the therapeutic range for adults:

- Fluoxetine and norfluoxetine (active metabolite);
- Paroxetine;
- Citalopram and desmethylcitalopram.

Treatment of neonatal toxicity includes changing or reducing the mother’s medication (as directed by her physician or psychiatrist), or changing the infant’s feed. The half-life of many agents and their metabolites may very prolonged. Serial plasma levels of the agent and its active metabolite may be required to guide management.

Diazepam has been used to treat neonatal serotonin toxicity and has not been the agent of choice in RPAH Newborn Care. We have used phenobarbital with good effect as per the Neonatal Abstinence Syndrome Guideline.
There are no reports of use of serotonin antagonists in newborn infants with serotonin toxicity although chlorpromazine has been used for neonatal abstinence syndrome secondary to opioids or sedatives, and cyproheptadine use has been reported in infants with feeding difficulties. The dosages, efficacy and safety of these agents is unclear in newborn infants.

7.7 SSRI and Breastfeeding

If serotonin toxicity is suspected, plasma drug and metabolite levels should be taken and exposure eliminated along with supportive therapy. Preferred medications during the perinatal period include sertraline and citalopram.

For infants with SSRI withdrawal, postpartum use of SSRIs is not a contraindication to breastfeeding, and women who choose to breastfeed should be supported. The NICE guidelines recommend that when assessing the risks and benefits of tricyclic antidepressants (TCAs), SSRIs or SNRIs for a woman who is considering breastfeeding, taking into account:

- the benefits of breastfeeding for the woman and baby;
- the uncertainty about the safety of these drugs for the breastfeeding baby; and,
- the risks associated with switching from or stopping a previously effective medication.

SSRIs and SNRI-exposed infants have detectable serum levels of antidepressants due to placental and breast milk transfer. Serotonin syndrome (toxicity) has been reported in newborn infants of mothers on fluoxetine, paroxetine, and citalopram, but not for sertraline. Developmentally delayed maturation of CYP2D6 over the first 2 to 4 weeks of life may contribute to symptoms consistent with serotonin toxicity in neonates exposed to fluoxetine or paroxetine during pregnancy.

Breastfeeding is encouraged with sertraline recommended as a preferred medication. Undetectable sertraline levels in infant serum have been reported 87% of exposed infants with no reported adverse events.

8. Guideline

8.1 Practice points: Women

- All women, on their first antenatal visit, are asked questions relating to mental well-being and a psychosocial assessment. The Edinburgh Postnatal Depression Scale (EPDS) is used.
- If a woman scores 13 or more on the EPDS, she may have high anxiety or be experiencing depression.
- If there is any concern about responses to the questions in the screening tools, the woman is to be offered referral to the Perinatal Mental Health CNC and/or Perinatal Consultation Liaison Psychiatry, via the relevant sites Perinatal Psychosocial Referral pathway.
- Women with a history of moderate or severe depression, or currently on antidepressants, should be offered referral to the Perinatal Mental Health CNC and/or Perinatal Consultation Liaison Psychiatry, via the relevant sites Perinatal Psychosocial Referral pathway.

8.2 Practice points: Newborns

- Babies with late-trimester SSRI / SNRI exposure should be observed in hospital for neuro-behavioural or respiratory symptoms for a minimum of 24 hours.
- Babies may have signs of SSRI withdrawal or serotonin toxicity (more common with fluoxetine use).
• **Signs of serotonin toxicity:**
  - Irritability;
  - Increased muscle tone;
  - Mild or marked tremors while undisturbed;
  - Ankle clonus elicitable on examination;
  - Low grade fever;
  - These infants may still be feeding efficiently as serotonin is involved in appetite. Continued mother’s milk feeding is a risk factor for toxicity, particularly with fluoxetine.

• **Signs of SSRI withdrawal (PNAS) in the infant include:**
  - Increased muscle tone;
  - Loose or watery stools;
  - Mild or marked tremors while undisturbed;
  - Less than 1 or 2 hour sleep after feeding, poor feeding (persistent breastfeeding codes <5) or a markedly hyperactive Moro reflex (i.e. startle).

• **A plasma drug and its active metabolite level** can be taken to differentiate between signs of serotonin toxicity and SSRI withdrawal.

• If present, commence the modified Finnegan NAS score as per the NSW Health Neonatal Abstinence Syndrome Guidelines GL2013_008.¹

• If severe withdrawal is present (3 modified Finnegan NAS scores ≥8) obtain paediatric review and consider commencing phenobarbital (phenobarbitone) which has been recommended as per the MoH Neonatal Abstinence Syndrome Guideline GL2013_008.¹

• Families should receive anticipatory guidance on the possible effects of SSRIs on their infant, including the need for observation after birth. An extended postpartum hospital stay should be offered.

• Babies with late-trimester SSRI / SNRI exposure with neuro-behavioural or respiratory symptoms should have a screening blood glucose performed to exclude hypoglycaemia, and a paediatric assessment to exclude serious or other morbidity.

**8.3 Practice point: Breastfeeding**

For infants with SSRI withdrawal, postpartum use of SSRIs is not a contraindication to breastfeeding, and women who choose to breastfeed should be supported.

If serotonin toxicity is suspected, plasma drug and metabolite levels should be taken and exposure eliminated along with supportive therapy.
## 9. Summary of Practice Guidelines

### Antenatal

- Identification and documentation of women prescribed antidepressant medication (including medication, dosage, commencement and / or cessation date), by midwifery and obstetric staff.
- Provision of balanced information regarding risks of relapse if medication ceased, and risks to neonates exposed to antidepressant medication during pregnancy and lactation.
- Offer referral to Perinatal Psychiatry/mental health services.
- Provide information about Poor Neonatal Adaptation Syndrome and non-pharmacological care of infants exhibiting signs of neonatal withdrawal to women and their families.

### Delivery Ward / Birth Centre

- Midwives to document risk during transfer of care to the Postnatal Unit and to the Newborn Care Unit where infants require admission.

### Postnatal Unit

- Oxygen saturations (PPHN risk –Neonatal Early Assessment Program).
- Maximise supportive care:
  - Skin-to-skin
  - Encourage breast feeding
  - Frequent demand feeding
  - Quiet environment
- Skin care, particularly where loose stools present.
- Newborn vital signs to be documented electronically via iView on the BTF SNOC in the newborn’s eMR.
- Observe for signs of withdrawal:
  - Increased muscle tone
  - Loose or watery stools
  - Mild or marked tremors while undisturbed
  - Less than 1 hour sleep after feeding
  - Poor feeding, or
  - Hyperactive Moro reflex (startle).
  - If present, commence the Modified Finnegan Neonatal Abstinence Syndrome Score, 4/24 TPR and oxygen saturation levels, 6/24 blood glucose monitoring

### Newborn Care Unit

- Assess for risk of serotonin toxicity:
  - Maternal use of fluoxetine, paroxetine or citalopram
  - Irritability
  - Increased muscle tone
  - Mild or marked tremors while undisturbed
  - Ankle clonus elicitable on examination
  - Low grade fever
- Perform a plasma level for the drug and its active metabolite if serotonin toxicity is suspected.
- If 3 consecutive NAS scores ≥8, then Paediatric review and admission to Newborn Care Unit.
- Cardio-respiratory observations to continue 4/24 until ceased by a medical officer.
- Blood glucose monitoring to continue 6/24 until three consecutive normal levels and full enteral feeds well tolerated.
10. Definitions

<table>
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<th>Description</th>
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<tr>
<td>BTF</td>
<td>Between the Flags</td>
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<tr>
<td>eMR</td>
<td>Electronic medical record</td>
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<td>PND</td>
<td>Perinatal depression</td>
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<td>Poor Neonatal Adaptation Syndrome (PNAS)</td>
<td>A collection of symptoms suggesting a withdrawal syndrome including: jitteriness, irritability, insomnia and poor feeding.</td>
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<td>PPHN</td>
<td>Persistent pulmonary hypertension of the newborn</td>
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<td>Serotonin toxicity</td>
<td>Manifest in the newborn as tachypnoea, jitteriness, irritability, hypertonia, hyperreflexia and clonus, fever and a compensated metabolic acidosis.</td>
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<td>SNOCC</td>
<td>Standard Newborn Observation Chart</td>
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<td>SNRI</td>
<td>Serotonin-noradrenaline reuptake inhibitors</td>
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<td>SSRI</td>
<td>Selective serotonin reuptake inhibitor</td>
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11. Consultation

Centre for Education and Workforce Development SLHD
Clinical Nurse Consultants, Perinatal Mental Health RPAH
Director National Poisons Register & Clinical Toxicology RPAH
Medicines Information-Mental Health Pharmacist, Department of Pharmacy RPAH
Neonatologist, RPAH
P&FDH Team, SLHD
Perinatal Psychiatrist RPAH
SLHD Maternity Policy Committee

12. References


11. National Safety and Quality Standards, 2nd Ed

Clinical Governance Standard
Partnering with Consumers Standard
Medication Safety
Recognising and Responding to Acute Deterioration
### NEONATAL ABSTINENCE SCORE

**Frequency:** Date and time in 24 hour clock

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<td></td>
<td>Continuous high pitched cry</td>
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<tr>
<td></td>
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<td></td>
<td>Sleeps &lt; 2 hrs between feeds</td>
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<td>Increased muscle tone</td>
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<td>Generalised convulsions</td>
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<td>Fever (39.4°C &amp; higher)</td>
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<td>Nasal stuffiness</td>
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**TOTAL SCORE:**

**SCORER’S INITIALS:**

**SCORER’S SIGNATURE:**