MEDICINES INFORMATION & ADVICE ALERT

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IRMIS ALERT
Learning from Practice

Handling medicines and breastfeeding enquiries

Background

- In 2023 there was an increase in IRMIS (Incident Reporting in Medicines Information) reports regarding breastfeeding enquiries (13% of all reports in 2023 compared to 3% in 2022).
- Advising on the use of medicines during breastfeeding is a high risk area since advice issued can affect the safety of the infant and influence feeding choices.
- This has prompted a review of all incidents relating to breastfeeding enquiries over the past 5 years to highlight some useful learning points.

Why do we think it happened?

- Making assumptions about the medicine in question or the clinical scenario.
- Lack of training or experience in certain scenarios which may be beyond your level of competence.
- Using a skill set which might not be required in your every-day practice, therefore some principles and knowledge may need refreshing.
- Lack of confidence in interpreting breastfeeding data, particularly pharmacokinetics.
- Not aware of, or not feeling confident, to use or signpost to available specialist resources.

Actions for safer practice

General

- When tackling high risk or unfamiliar enquiry, ensure you have uninterrupted time to work through it.
- High risk questions should be second checked before responding, either after taking a break or by another colleague.
- Always get calculations checked by a colleague, no matter how simple.
- Consider escalating the enquiry to UKDILAS (UK Drugs in Lactation Advisory Service), if you feel this is beyond your remit. Examples would include: milk donation, use of galactagogues, premature infants, or maternal overdose.

Key breastfeeding learning points

- Breastfeeding is a huge public health intervention. Robust evidence supports short- and long-term benefits to both the mother and infant. It is also environmentally friendly. Advising not to breastfeed is therefore not a 'no harm' option.
- Serious adverse effects on infants due to medicine exposure via breast milk are rare, so start with a 'Yes'. If you are considering advising against breastfeeding/taking the medicine, ensure you have a good rationale for this. Consider contacting UKDILAS for advice before advising "no".
- Ensure you have the infant's age. This determines how they will handle medicines exposed to, and how much breast milk they will consume (sole nutrition for a newborn vs comfort in an older infant); this influences the infant 'dose' and the risk of adverse effects.
- When assessing, use your toolkit to build the picture – resources, evidence, pharmacokinetics, and clinical situation.
- Ensure you know how to interpret the available data. For example, when calculating excretion from breast milk, it's like any other body compartment, and will be excreted after 5 to 7 elimination half-lives.
- Ensure you understand the terminology. For example, Relative Infant Dose (RID) is a way of expressing how much of the maternal dose the infant may be exposed to via breast milk, taking into account maternal and infant weight. It is not an absolute percentage.
- To be a problem, the infant must also absorb any medicine that gets into breast milk in significant enough amounts to cause adverse effects. Consequently, medicines that are not well absorbed orally are often safer than they first appear.
- Risks can usually be managed with good monitoring—ensure your recommendations are practical and achievable for the situation.
- UKDILAS have published supporting articles for many medicines on the Specialist Pharmacy Services website and written the patient-friendly breastfeeding information on the NHS Medicines A – Z pages.

Refreshing your knowledge

- The Medicines Learning Portal is a good place to start.
- UKDILAS training materials on how to tackle breastfeeding enquiries, are available on the SPS website.
- For the benefits of breastfeeding, check out the most up-to-date evidence from the UNICEF UK Baby Friendly Initiative.

Real examples from MI services

Terminology: in an overdose enquiry, weight was not adjusted for when calculating the infant dose. Infant exposure was therefore overestimated, and the carers were instructed to take the infant to hospital.

Pharmacokinetics:

- The safe time to re-start breastfeeding following codeine ingestion used '4 half-lives' rather than '4-hours' in the calculation.
- Tmax used to calculate the time for apixaban excretion from breast milk, instead of elimination half-life.
- Plasma half-life used to calculate the time for dihydrocodeine excretion from breast milk, instead of elimination half-life.

Background Information: Incorrectly documented that the infant was 6 months old when they were 6 weeks old.

Specialist topic: Fexofenadine for milk donation dealt with as a 'regular' breastfeeding enquiry and incorrect advice was issued.

When something does go wrong

- Follow your in-house procedure for errors or near misses
- Submit an anonymous report to the UKMi Incident Reporting in Medicines Information Scheme (IRMIS)
- Learn as a team

For further details, resources and supporting materials see www.ukmi.nhs.uk.
For any enquiries about this alert, email QRMG.ukmi@nhs.net