Role of Pharmacists in Optimising Medication Management During Pregnancy and Lactation

Luke E Grzeskowiak

Luke E Grzeskowiak, PhD, BPharm (Hons), GCertClinEpid, FSHP

1. The Robinson Research Institute, The University of Adelaide, Adelaide, South Australia, Australia

   E-mail: *Luke.Grzeskowiak@adelaide.edu.au*

Corresponding Author:

Luke Grzeskowiak

The Robinson Research Institute, The University of Adelaide

Lyell McEwin Hospital

Haydown Road

Elizabeth Vale, 5112

South Australia, Australia

T: +61 8 8133 2133

F: +61 8 8182 9337

E-mail: *Luke.Grzeskowiak@adelaide.edu.au*

Word Count:

Main Text: 2,880

Tables: 2

Declaration of Conflicting Interests

The authors declare no conflicts of interest

Acknowledgements:

This report is based on findings from an international preceptorship on 'Optimising medication use in pregnancy and lactation' funded through the Society of Hospital Pharmacists of Australia Hospira Young Pharmacists Award (HYPA1304). This preceptorship included visits to world-renowned Teratogen Information Services including; Motherisk, based at the Hospital for Sick Kids, Toronto, Canada, and MotherToBaby California, a service of the Organisation of Teratogen Information Specialists (OTIS) based at the University of California, San Diego (UCSD), USA. Additional visits were undertaken to investigate clinical pharmacy services provided at Rady Children's Hospital and the UCSD Medical Center in San Diego and Mt Sinai Hospital in Toronto. Staff at all sites visited must be acknowledged for their overwhelming hospitality, support, patience, and willingness to share their expertise. LEG also wishes to acknowledge salary support from a National Health and Medical Research Council Australian Public Health Fellowship (ID 1070421).

Abstract (150 words)

Pregnancy and lactation has a unique effect on decisions relating to medication use. Medication safety can often be a great source of concern for women and healthcare professionals alike, leading to decisions that can negatively impact on outcomes. Compounding this is that evidence regarding the benefits and risks of medication use in pregnancy and lactation can often be lacking, contradictory or difficult to interpret and apply to clinical practice. Pharmacists represent a key source of information on medication use in pregnancy and lactation and as such play an essential role in optimising medication use. Notably, the role of pharmacists extends well beyond that of addressing concerns relating to medication safety, and includes contributing towards therapeutic decision making, providing ongoing medication management, and influencing patterns of medication use. Opportunities for improving health outcomes for mothers and their babies are aplenty and the time has come for pharmacists to stand up to the challenge and play their role.

Background

Women are commonly advised by various sources (including healthcare professionals, the media, or friends and family) against medication use during pregnancy and/or lactation unless the benefits of treating an illness outweigh the risks associated with treatment to both the mother and child. Unfortunately, information supporting medication use in pregnancy and/or lactation and evidence regarding benefits and risks is often lacking, contradictory or difficult to interpret and apply to clinical practice.[1]

Medication use during pregnancy and lactation is extremely common, with the majority of women expected to take some form of non-prescription or prescription medication in the antenatal, perinatal (including labour/delivery) and/or postnatal period.[2, 3] These medications are required for the optimal management of pre-existing chronic (i.e. diabetes) or acute (i.e. urinary tract infection) medical conditions, as well as the management of new conditions associated with pregnancy (i.e. gestational diabetes, nausea and vomiting) or lactation (i.e. mastitis). In a recent Australian study of women attending an antenatal clinic, 40% of women reported a chronic medical condition during pregnancy.[2] This associated burden is likely to increase over time, with a greater number of women entering pregnancy with co-morbidities that require ongoing medical management, or that place them at greater risk of developing pregnancy complications requiring medical management.[4] Existing challenges in decisions are further compounded through a need to consider and understand the impact of physiological changes that occur throughout pregnancy on the pharmacokinetics and pharmacodynamics of medication.[5] In certain situations these may alter a medications therapeutic or toxic effects.[5]

Pharmacists practicing in all healthcare settings often represent a key source of information on medication use in pregnancy and/or lactation. Despite this, information related to how

pharmacists can specifically contribute towards optimising medication management during pregnancy and lactation remains scarce. Therefore, this pharmacy practice review aims to provide a summary on the role of pharmacists in optimising medication management during pregnancy and lactation, while paying specific focus on highlighting key challenges and importantly, opportunities for greater involvement. It also takes the unique approach of linking areas of greater pharmacist contributions with key components of practice, with the aim that this may provide the impetus for the future development of formal standards of practice in the area.

Decisions Regarding Medication Use

Pregnancy and lactation has a unique effect on decisions relating to medication use. Medication safety can often be a great source of concern for women and healthcare professionals alike, leading to decisions that can negatively impact on outcomes. Research has demonstrated that pregnant women frequently overestimate the risk of medication use and other exposures during pregnancy.[6] In fact, it is not uncommon for pregnant women to become non-adherent to medications during pregnancy, often owing to misperception of risks associated with their use.[7, 8] These decisions may also stem from a lack of perceived benefit of medication use, rather than safety alone. These concerns are not unique to women. An Australian survey demonstrated that, over 25% of doctors would instruct their pregnant patients to decrease or discontinue asthma medication during pregnancy where asthma was well controlled by that medication.[9] This is despite knowledge of the potential harmful effects of worsening asthma on perinatal outcomes.[9]

Notably, the opposite can also be true, with pregnant women, or indeed healthcare professionals, having a poor understanding of potential risks associated with using particular medications during pregnancy. For example, a survey identified that 26% of pregnant women

were unaware of the adverse effects of using NSAIDs during late pregnancy.[10] This highlights the importance of pharmacists in addressing misconceptions regarding medication use, both in relation to their harms and benefits.

Categorising Medication Safety

In response to the well documented thalidomide tragedy in the 1960s, in which more than 10,000 children were born worldwide with major birth defects, the Australian Government established the Australian Drug Evaluation Committee (ADEC). This independent committee was responsible for advising on the safety of all medications introduced into Australia, and for monitoring and evaluating potential adverse effects of medications already in use. In recognition of the need to provide guidance regarding medication use in pregnancy, a specific working party was established by ADEC and this gave rise to a unique Australian categorisation of the risk of medications in pregnancy. Since then, ADEC has been replaced by the Advisory Committee on Prescription Medicines and its original '*Medicines in pregnancy booklet'* has been replaced with the online '*Prescribing medicines in pregnancy database'*.[11] Use of the pregnancy categories and related notes, however, has remained unchanged.

Concerns regarding the current state of pregnancy risk classification and labelling have been well voiced.[12] One of the greatest criticisms lies in its alphabetical nature, which may be misconstrued as a grading system, with levels of risk increasing from A to X. This can lead to misguided decisions regarding changes in medication therapy. For example, a decision may be made to change from sertraline (category C) to venlafaxine (category B3) in the belief that venlafaxine carries a safer pregnancy rating and would therefore be preferable to use. Further, use of categories can often lead to the erroneous belief that medications within the same category carry with them the same level of risk. For example, lamotrigine and sodium

valproate are both listed as category D, however, evidence demonstrates that sodium valproate is associated with a much higher teratogenic potential than lamotrigine.[13]

The overly simplistic nature and ready availability of the categories can lead to an overreliance on the category rating itself, without due reference to the quality and levels of evidence on which the categorisation was based. Further, categories are often assigned at the time when medications are marketed, often on the basis of animal data alone. As data emerges from human studies these categories are unlikely to change, meaning categories originally assigned may not reflect current state of evidence. There are pertinent recent examples of medications being given a more restrictive category based on new evidence. For example, in 2005 paroxetine was changed from category C to category D following the emergence of inconsistent data of an increased risk of congenital malformations, in particular, heart defects.[14] However, it is extremely uncommon for a medication to be given a less restrictive category based on the emergence of new (and often reassuring) evidence.

Rarely do the categorisations take into account important aspects like timing, dose, and route of exposure. For example, tetracycline are listed as category D, despite being safe to use during the first 18 weeks of pregnancy (16 weeks postconception) after which they may affect the formation of the baby's teeth and cause discolouration.[11] The opposite can also occur, with the combination of amoxicillin and clavulanic acid listed as category B1, suggesting safety throughout pregnancy, but clinical recommendations advise against the use of this medication in women with premature rupture of the membranes as there may be an increased risk of neonatal necrotising enterocolitis.[15] As such, blanket reference to categories alone is potentially misleading and could create unnecessary concern or harm.

Reference to categories alone also fails to acknowledge the background risk of adverse pregnancy outcomes associated with all pregnancies, irrespective of medication exposure.

This level of risk will differ according to other factors such as maternal smoking, advanced maternal age and co-morbidities (e.g. maternal overweight/obesity, pre-existing medical conditions). Understanding these factors is essential in identifying if medications increase the risk of adverse outcomes above the background risk, and what any absolute increase in risk actually is.

Additional concerns relate to confusion generated from a misunderstanding of key differences between the Australian and US classification system, which are similar, but not interchangeable. Many are also of the erroneous belief that the pregnancy categories apply to lactation, which is not the case.[12] Currently, there is no standardised endorsed approach towards the classification of medication use in lactation, although, different approaches are in use and will be commonly referenced by healthcare professionals. As with pregnancy categories, there should be a focus on individuals utilising their knowledge of underlying principles and available evidence to generate rational decisions, rather than use of categories alone.

Regrettably, current categories alone are not the only source of misleading information, with information provided in Product Information (PI) also the subject of much criticism for being overly cautious in nature, often listing medication use in pregnancy and lactation under special precautions or contraindications.[12] Such misleading information can often be further compounded by information obtained from the internet and lay sources.[16]

Changes to Categorising Medication Safety

Concerns around the use of pregnancy categories are not unique to the Australian landscape. Since 2008, the Federal Drug Administration (FDA) has taken significant steps towards major revisions to the labelling of prescription medications to allay such concerns. These changes incorporate the inclusion of a narrative labelling model, placing discussions

regarding medication use in the context of the background risk of adverse outcomes, summarising how documented risks were identified (i.e. human vs. animal studies) and providing more information on clinical considerations such as medication dosing (where available).[17] These changes are in the final stages of approval and will be gradually introduced over coming years, starting with newly listed medications. Only time will tell whether this change leads to improvements in the rational use of medications in pregnancy and lactation, and whether Australia introduces a similar labelling model.

Despite their current limitations, given a heavy reliance on the use of safety categories by healthcare professionals and the public in clinical practice, any notion of just completely boycotting their use at this stage could appear misguided. In contrast, it highlights the need for pharmacists to develop a deeper understanding and appreciation of the role they play in clinical practice. If (or indeed when) changes are introduced, the removal of categories and the loss of what could be considered a safety blanket for many, may create additional demands, and opportunities, for pharmacists to contribute towards improved decision making. Pharmacists must use their expertise to look beyond these letters and numbers and make a more qualified assessment of the true benefits and risks. Evidence-based guides are available to assist in the critical appraisal and interpretation of research findings,[18] and numerous references are available for providing detailed information (**Table 1**). In most cases, however, it is not always about having the answer, but rather knowing where to look.

Potentially underused key resources are the specialist pregnancy and lactation medicines information services that exist across Australia, as well as overseas. Such Australian services differ greatly in respect to being limited to answering from healthcare professionals, while others also answer queries from the general public. Some services such as MotherSafe, also offer a number of fact sheets covering common queries in pregnancy and lactation that are able to be downloaded from their website. The receipt of sufficient funding to maintain the

viability, reach and quality of these services is a consistent struggle within Australia, as well as internationally. In the current culture of centralisation, there is a concern that local specialist medicines information services could slowly be eroded, with the potential to negatively impact on service delivery and health outcomes.

Pharmacist Education

While pharmacists have recognised specialist knowledge on medications; including mechanisms of action, pharmacokinetics, clinical application of evidence, and assessment of adverse events, how well does this translate into areas of medication use in pregnancy and lactation?

In the United States, concerns have been raised that current undergraduate pharmacy curricula are lacking in providing students with sufficient information on medication use in pregnancy and lactation.[19, 20] While the delivery approach differs from standalone courses to the incorporation of content within other courses (i.e. pharmacology, pharmacokinetics), 59% of respondents from 81 schools/colleges of pharmacy felt that their current approach did not adequately cover this material.[19] No data are available from an Australian perspective, but would be of interest.

Such limitations with undergraduate education can have important implications for future clinical practice. For example, previous studies have demonstrated that pharmacists often do not feel adequately equipped to provide information on medication use in pregnancy and/or lactation.[21] Further, when information is provided, it is not necessarily evidence-based and at times, inaccurate and based on their own opinions.[21] While it is recognised that in a relatively evidence-free zone it can be difficult to separate personal experiences and anecdotes from

fact, pharmacists should be able to integrate available information with their medication expertise, to make appropriate individual risk/benefit decisions.

Notably, a recent survey undertaken to investigate the perspectives of community pharmacists in Australia on medication use and safety in breastfeeding identified that the majority of respondents (92%) were confident about supplying or counselling on medication during breastfeeding.[22] Remarkably, however, over one-third were unaware that ibuprofen and metronidazole are compatible with breastfeeding, with a number of pharmacists providing advice to women to stop breastfeeding.[22] This provides evidence that confidence is not always a good measure of competence.

Optimising Therapeutic Outcomes

Traditionally, investigating outcomes associated with medication use during pregnancy and lactation has tended to focus on safety, rather than efficacy. Pharmacists can play a greater role in optimising outcomes through various approaches, including; improved decision making on medication use at the point of prescribing, medication counselling (including adherence support) to address misconceptions, and therapeutic drug monitoring (TDM).

Intervening at the point of prescribing/dispensing is likely to have the greatest impact, but is not always achievable. Similarly, contributing towards decisions prior to, rather than during, pregnancy is ideal. Provision of medication counselling can provide significant benefits in correcting misperceptions, allaying fears, and hopefully improve medication-taking behaviour. An aspect not well investigated is the role of Home Medicines Reviews (HMRs) or Outpatient pharmacy services in contributing towards improvements in rational medication use.

Despite awareness of alterations in pharmacokinetics during pregnancy, for many medications which have a wide therapeutic index, the clinical relevance of alterations in pharmacokinetics in pregnancy remains unclear. For medications which have a narrow therapeutic index, monitoring would be expected regardless of pregnancy status. Understanding how pregnancy impacts on pharmacokinetics is essential in making sounds judgements relating to TDM (i.e. aminoglycoside/antiepileptic drugs dosing).[16] Further, there is still much work to be done and a significant role for pharmacists in determining the relevance of TDM programs and whether measuring drug concentrations during pregnancy ultimately improves outcomes beyond that already achieved through clinical judgement alone.[16]

Outcome Evaluation

While working in an area with much ambiguity can present many challenges for evidence-based practice, it offers many exciting possibilities for pharmacists to generate new evidence to guide best practice. Furthermore, many situations associated with medication use in pregnancy and/or lactation are unintentional or unavoidable. Integration of research within the clinical practice setting is essential in driving improvements in patient care and health outcomes and should be viewed as a core role for pharmacy practice.[23]

Evidence may develop from drug utilisation studies, developing a greater understanding of current patterns of medication use and associated behaviours and progress to observational studies aimed at investigating clinical outcomes, such as the safety or efficacy of particular medications. Further, there may be opportunities for laboratory studies aimed at developing a greater understanding of medication pharmacokinetics in pregnancy, or the levels of medications in breast milk and the clinical evaluation of outcomes. In additional to all of this, there needs to be greater emphasis on the importance of presenting, publishing, interpreting

and translating new evidence into practice as it is generated.[24] Such endeavours are likely to benefit from greater training of pharmacists in research methods,[23] and the improved collaboration, coordination and exchange of information between treatment/research settings.

Future Directions

Facilitating improvements in pharmacist's contributions towards optimising medication management during pregnancy and lactation is likely to be multifactorial. There is a need for an assessment of the quality of undergraduate and postgraduate education as it pertains to medication use in pregnancy and lactation to ensure graduates and practicing pharmacists are adequately prepared to meet current and future demands. The formation of standards of practice and advanced pharmacy practice frameworks would assist in outlining key practice responsibilities, establishing core competency levels, and providing clear opportunities for career progression. An overview of such core pharmacist responsibilities and associated examples of practice are provided in **Table 2**. Hesitancies to contribute resources towards such a specialty area is likely to require the development of further evidence highlighting the positive impact of pharmacists in improving maternal and child outcomes. In addition, there is a need for further research into the advancement of pharmacy roles within non-standard areas of clinical practice in relation to medication use in pregnancy and lactation, such as the provision of home medicines reviews and outpatient services. Within professional organisations such as the Society of Hospital Pharmacists of Australia (SHPA) there exist opportunities for the formation of reference groups and support networks of pharmacists interested in enhancing current clinical care. In addition, integration with wider support and research networks beyond pharmacy are essential for individual continual development and opportunities for the development of new evidence to support future improvements in health outcomes. This includes opportunities for interdisciplinary engagement, which can be facilitated through membership of professional organisations such as the Society of Obstetric

Medicine of Australia and New Zealand (SOMANZ) and the Perinatal Society of Australia and New Zealand (PSANZ). Lastly, there remains a key role for relevant professional organisations to lobby for additional support for pregnancy and lactation medicines information services. This should not just be restricted to organisations representing pharmacists, but also those representing key end users such as doctors and consumers.

In conclusion, this practice review provides a unique perspective on the role that pharmacists can play in optimising medication management during pregnancy and lactation. It is anticipated that the summary of key references will become an invaluable resource in assisting pharmacists in obtaining the best available evidence, while it is also hoped that highlighting key components of practice through which pharmacists can contribute to improved health outcomes may provide impetus for the future development of formal standards of practice to drive improvements in clinical practice. Clinical pharmacy services will remain an integral part of the care of pregnant patients, especially as the obstetric population ages and has an increase in comorbid conditions, such as diabetes, heart disease and hypertension.[4] The pharmacy profession needs to be ready and willing to accept this challenge and should be keen to adapt to enhanced roles.

References

1. Grzeskowiak L, Gilbert A, Morrison J. Conception and Beyond: Using Population-Based Record Linkage to Monitor Long-Term Effects of Medication Use During Pregnancy. *J Pharm Pract Res* 2010; 40: 46-9.

2. Sawicki E, Stewart K, Wong S, Leung L, Paul E, George J. Medication use for chronic health conditions by pregnant women attending an Australian maternity hospital. *Aust N Z J Obstet Gynaecol* 2011; 51: 333-8.

3. Henry A, Crowther C. Patterns of medication use during and prior to pregnancy: the MAP study. *Aust N Z J Obstet Gynaecol* 2000; 40: 165-72.

4. Rosene-Montella K, Lowe S, Nelson-Piercy C. The growing importance of medical problems in pregnancy. *Obstet Med* 2010; 3: 1.

5. Matsui DM. Therapeutic drug monitoring in pregnancy. *Ther Drug Monit* 2012; 34: 507-11.

6. Nordeng H, Ystrøm E, Einarson A. Perception of risk regarding the use of medications and other exposures during pregnancy. *Eur J Clin Pharmacol* 2010; 66: 207-14.

7. Matsui D. Adherence with Drug Therapy in Pregnancy. *Obstet Gynecol Int* 2012; 2012: 796590.

8. Sawicki E, Stewart K, Wong S, Paul E, Leung L, George J. Management of asthma by pregnant women attending an Australian maternity hospital. *Aust N Z J Obstet Gynaecol* 2012; 52: 183-188.

9. Lim AS, Stewart K, Abramson MJ, George J. Management of asthma in pregnant women by general practitioners: A cross sectional survey. *BMC Fam Pract* 2011; 12: 121.

10. Damase-Michel C, Christaud J, Berrebi A, Lacroix I, Montastruc J-L. What do pregnant women know about non-steroidal anti-inflammatory drugs? *Pharmacoepidemiol Drug Saf* 2009; 18: 1034-8.

11. Therapeutic Goods Administration. Prescribing medicines in pregnancy database. http://www.tga.gov.au/hp/medicines-pregnancy.htm (accessed 19 Feb 2014).

12. Kennedy D. A to X: the problem of categorisation of drugs in pregnancy - an Australian perspective. *Med J Aust* 2011; 195: 572-74

13. Tomson T, Battino D, Bonizzoni E, Craig J, Lindhout D, Sabers A, et al. Dose-dependent risk of malformations with antiepileptic drugs: an analysis of data from the EURAP epilepsy and pregnancy registry. *Lancet Neurol* 2011; 10: 609-17.

14. Koren G, Nordeng HM. Selective serotonin reuptake inhibitors and malformations: Case closed? *Semin Fetal Neonatal Med* 2013; 18: 19-22.

15. Kenyon S, Pike K, Jones DR, Brocklehurst P, Marlow N, Salt A, et al. Childhood outcomes after prescription of antibiotics to pregnant women with preterm rupture of the membranes: 7-year follow-up of the ORACLE I trial. *Lancet* 2008; 372: 1310-8.

16. Hotham NJ. Information on drugs and environmental influences in pregnancy in popular magazines: a critical review. *Med J Aust* 1995; 162: 417-20.

17. Kweder SL. Drugs and biologics in pregnancy and breastfeeding: FDA in the 21st century. *Birth Defects Res A Clin Mol Teratol* 2008; 82: 605-9.

18. Grzeskowiak LE, Gilbert AL, Morrison JL. Investigating outcomes associated with medication use during pregnancy: A review of methodological challenges and observational study designs. *Reprod Toxicol* 2012; 33: 280-9.

19. Eiland LS, Kelley KW. Availability of "Drugs in Pregnancy" electives in pharmacy schools. *Currents Pharm Teach Learn* 2010; 2: 160-70.

20. Ragland D, Briggs GG, Wasik M, Kelsey JJ, Ferreira E, Abe-Fukushima W, Forinash AB, Kelly BD, et al. Obstetrical opportunities: will pharmacy ever realize them? *Ann Pharmacother* 2012; 46: 297-300.

21. Samuel N, Einarson A. Medication management during pregnancy: role of the pharmacist. *Int J Clin Pharm* 2011; 6: 882-885.

22. de Ponti M, Stewart K, Amir LH, Hussainy SY. Medicine use and safety while breastfeeding: investigating the perspectives of community pharmacists in Australia. *Aust J Prim Health* 2013.

23. Grzeskowiak L, Roberts G, Bell J. Role of the Practitioner-Researcher in Pharmacy Practice. *J Pharm Pract Res* 2012; 42: 5-6.

24. Grzeskowiak L, Thomas AE. Paediatric and Perinatal Health Abstracts at SHPA National Conferences: Trends in Presentation and Subsequent Publication. *J Pharm Pract Res* 2014; 44: 22-5.

25. Pharmaceutical Society of Australia. National competency standards framework for pharmacists in Australia. Deakin: Pharmaceutical Society of Ausralia; 2010.

Table 1. Summary of commonly used references for medication use in pregnancy and lactation

Reference	Country[a]	Free Access	Comments
Pregnancy and Lactation			
Australian Medicines Handbook https://www.amh.net.au/	Australia	No	• Available in print and online • Updated at least yearly • Brief clinical recommendations for pregnancy and lactation available in medication monographs • Includes reference to pregnancy categories[b]
Drugs in Pregnancy and Lactation: A Reference Guide to Fetal and Neonatal Risk by Briggs, Freeman, Yaffe	USA	No	• Available in print and online • Published approximately every 3 years • Includes thorough review of published clinical and experimental literature

Therapeutic Guidelines http://www.tg.org.au/	Australia	No	• Available in print and online • Provides clinical recommendations for the management of a number of disease types • Includes reference to pregnancy categories[b] • Classifies medications in lactation based on risk; compatible, caution, avoid (insufficient data), and avoid[b]
Reprotox/TERIS	USA	No	• Available online • Updated regularly • Includes thorough review of published clinical and experimental literature • Includes reference to US and Australian pregnancy categories[b]
Motherisk www.motherisk.org/	Canada	Yes	• Available online

			• Only contains links to previous studies undertaken by the Motherisk team • Does not include summaries for all medications
MotherToBaby https://www.mothertobaby.org/	USA/Canada	Yes	• Available online • Fact sheets suitable for providing to patients • Does not include summaries for all medications
Specialised Medicines Information Centres; a full list of which is available from: http://www.shpa.org.au/Medicines-Info	Australia	Yes	• Available to answer queries from the general public as well as healthcare professionals
Perinatal Psychotropic Medication Information Service Royal Women's Hospital, Victoria www.ppmis.org.au	Australia	Yes	• Available online • Fact sheets suitable for providing to patients • Only contains information on

			psychotropic medications
Pregnancy and Breastfeeding Medicine Guide Royal Women's Hospital, Victoria	Australia	No	• Available in print only • Published approximately every 3 years • Includes brief clinical recommendations for >900 medications • Includes reference to Australian pregnancy categories[b]
Pregnancy Only			
Prescribing medicines in pregnancy database http://www.tga.gov.au/hp/medicines-pregnancy.htm	Australia	Yes	• Available online • Includes very brief practice points for some medications • Mainly includes reference to Australian pregnancy categories[b]
Lactation Only			
LactMed http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT	USA	Yes	• Available online • Updated regularly

Medications and Mother's Milk by Thomas W. Hale	USA	No	• Available in print and online • Published every 2 years • Classifies medications in lactation based on risk with L1 being the safest and L5 being contraindicated[b]

[a] Refers to country of publication. References may include information provided or reviewed by experts outside of that country.

[b] Caution is advised regarding the use of medication safety categories as the sole basis of decision making as categories alone may not provide an accurate reflection of the benefit-risk assessment for individualised circumstances.

Table 2. Overview of key components of practice in which pharmacists contribute towards optimising medication management during pregnancy and lactation[a]

Components of practice	Examples of practice
1. Contribution towards therapeutic decision making	
Pharmacists are responsible for:	
• Contributing towards therapeutic decision making by obtaining an accurate and complete medication history, and assessing current medication management.	Recognising that medication use during pregnancy/lactation is common and that more women are entering pregnancy with pre-existing medical conditions
• Utilising their specialist knowledge (pertaining to pharmacokinetic and therapeutic evidence of medication use during pregnancy and lactation) to improve selection, monitoring, and evaluation of individual medication treatments as part of the medication management plan.	Describing the pathophysiology of pregnancy/lactation specific conditions and their associated management
• Obtaining accurate evidence, regardless of the setting, regarding the associated benefits and risks of medication use in pregnancy and lactation and to ensure that such evidence is effectively communicated to women and their treating health professionals	Knowledge and appropriate use of key evidence-based references and guidelines relating to medication use during pregnancy and lactation
• Contributing towards an enhanced understanding of the condition and its associated treatment, with the objective of promoting self-management of the underlying condition (where applicable), and adherence to the medication treatment regimen.	Providing education and advice regarding importance of medication adherence and management of underlying disease (e.g. asthma) during pregnancy
2. Provision of ongoing medication management	
Pharmacists are responsible for:	
• Developing medication management plans and reviewing clinical progress, including investigating whether undesirable or unintended clinical effects may be related to medication treatment.	Identifying side effects in the infant which may be associated with use of specific medications taken during late gestation or lactation
• Initiating monitoring and intervention, including assessment of whether medication treatment is achieving therapeutic goals, and the recommendation for therapeutic drug monitoring where indicated.	Recommending therapeutic drug monitoring of medications known to be subject to alterations in pharmacokinetics during pregnancy
• Ensuring therapeutic drug monitoring, where indicated, is performed appropriately and for the provision of advice regarding interpretation of results and its implications for medication management.	Interpreting laboratory tests and providing recommendations for treatment alterations and further monitoring

• Identification of medication management issues impacting on the effectiveness or safety of medication treatment.	Understanding the impact of severe nausea and vomiting of pregnancy on medication administration and absorption
3. Influencing patterns of medicine use	
Pharmacists are responsible for:	
• Monitoring, assessing, and contributing to changes in existing and evolving trends related to medication use during pregnancy and lactation in order to improve quality use of medicines.	Developing and implementing evidence-based guidelines; undertaking clinical audits
[a] Components of practice modified from those outlined in the National Competency Standards Framework for Pharmacists in Australia[25]	