

Evolution of the Midwifery Education Program in Response to Legislative Amendments to the Midwifery Drug Regulation in Ontario

Évolution du programme de formation en pratique sage-femme en réponse aux amendements législatifs apportés à la Midwifery Drug Regulation en Ontario

By Crestina L. Beites, PhD

ABSTRACT

Recent new amendments to the Midwifery Drug Regulation in Ontario have given registered midwives in the province the much anticipated and much needed authority to independently prescribe from an extended list of drugs. These legislative changes have steered and focused the pharmacotherapeutics and science curriculum of the Midwifery Education Program (MEP) in Ontario. The aspects of the curriculum that have evolved with the goal of delivering a solid foundation in the concepts of pharmacotherapeutics in pregnancy and a good understanding in the principles of prescribing in pregnancy are discussed. Perspectives for continuing professional development and competency in pregnancy pharmacotherapeutics are also provided.

KEY WORDS

Drug therapy, pregnancy, education, prescription drugs, midwifery

This article has been peer reviewed.

RÉSUMÉ

Les récents et nouveaux amendements apportés à la Midwifery Drug Regulation en Ontario ont accordé aux sages-femmes autorisées de la province l'autorité tant souhaitée et requise de prescrire, de façon indépendante, des agents faisant partie d'une longue liste de médicaments. Ces modifications législatives ont orienté et précisé le curriculum pharmacothérapeutique et scientifique du programme de formation en pratique sage-femme (PFPSF) en Ontario. Les aspects du curriculum qui ont été modifiés en vue d'offrir une base solide pour ce qui est des concepts de pharmacothérapie pendant la grossesse, ainsi qu'une bonne compréhension des principes de prescription pendant la grossesse, font l'objet d'une discussion dans cet article. Des points de vue en ce qui concerne le perfectionnement professionnel permanent et la compétence dans le domaine de la pharmacothérapie pendant la grossesse sont également offerts.

MOTS CLÉS

Pharmacothérapie, grossesse, formation, médicaments d'ordonnance, pratique sage-femme

Cet article a été évalué par des pairs.

INTRODUCTION

Pharmacological intervention in pregnancy can pose challenges for health care providers, because the administration of drugs during pregnancy can adversely affect the mother and cause fetal teratogenicity. Despite this, a recent study revealed that 56% of Quebec women are nonetheless dispensed a prescription drug during pregnancy, and more than 6% of expectant mothers fill prescriptions for drugs that are known to be harmful to their fetus.¹ More globally, in a study involving 22 countries, 86% of pregnant women took some form of medication during pregnancy,² and a retrospective study of eight US health maintenance organizations revealed that approximately one third of pregnant women who were prescribed drugs received a drug rated by the Food and Drug Administration (FDA) as a category C, D or X, categories for which there is clear evidence of some fetal risk.³ Unfortunately, the use of drugs during pregnancy, including those in a high risk FDA category, is not only a reality but often a necessity since pregnant women continue to be affected by the very same infections and illnesses that face the non-pregnant population (e.g. depression, epilepsy and urinary tract infections) and in many cases, the condition is exacerbated in pregnancy. For instance, the incidence of asymptomatic bacteriuria is similar in both pregnant and non-pregnant women, but an increased risk of pyelonephritis is associated with pregnancy.⁴ This is due to physiological and hormonal changes associated with pregnancy: the ureters elongate, dilate and are laterally displaced by the growing uterus while smooth muscle relaxation (due to increased progesterone levels) results in decreased ureter motility, increased bladder capacity and urinary stasis. Furthermore, changes in renal hemodynamics in pregnancy alter the protein, glucose and amino acid levels in urine providing an ideal microenvironment for the growth and reproduction of bacteria. Complications arising from untreated asymptomatic bacteriuria during pregnancy affect not only the woman but also her fetus: preterm labour and low neonatal birth weight are potential adverse outcomes associated with maternal infection.^{5,6} As the primary care provider, the midwife is therefore confronted with the unique dilemma surrounding pharmacological treatment of

their client: her goal is to alleviate maternal suffering while preventing harm to the fetus.

Although midwives and their clients are traditionally committed to a more natural and holistic approach to care, the evolution of the profession has naturally led to important and recent legislative changes: amendments to the Midwifery Drug Regulation in Ontario has given registered midwives in the province the much anticipated and much needed authority to independently prescribe from an extended list of drugs. Although Ontario was the first Canadian province to regulate midwifery, the pharmacopoeia of Ontario midwives was grossly deficient in therapeutics that were nonetheless represented in the pharmacopoeia of other provinces more recently regulated thus prompting the necessary amendments. This paper will address the expanding roles of midwives in the management of drugs during pregnancy in Ontario and will describe how the curriculum presented in the Midwifery Education Program (MEP) has evolved to teach midwifery students the skills necessary for providing pharmacological interventions. Perspectives for continuing competencies and continuing professional development in pregnancy pharmacotherapeutics will also be discussed.

Prescribing in Pregnancy: A Brief Historical Perspective

As early as the 1950s, the Medieval-born belief that the placenta acted as a barrier between the transfer of substances between mother and child was still widespread among doctors. It is therefore not surprising that a drug was not initially linked to the sudden surge in 1956 of a birth defect so rare that it had formerly affected only one in four million infants. In fact, for the next five years thalidomide was aggressively marketed as a completely safe human sedative due to the striking absence of toxicity in laboratory rats. Astonishingly, the drug's German developers did not find it peculiar that although thalidomide had no observable or measurable systemic toxicity in rats (thus encouraging human consumption) it did not produce the same sedative effect in rats as it did in humans. The possibility that the drug has variable effects in different mammals and thus unpredictable toxic outcomes in humans was not considered at the

time. Despite the high rates of characteristic malformations that are virtually pathognomonic for this drug, thalidomide continued to be produced and was soon to flood the US and Canadian markets. But Canadian-born Dr Frances Oldham Kelsey, a medical reviewer for the FDA at the time, was concerned about the drug. Her previous graduate work with anti-malarial drugs and pregnant rabbits led her to believe that, contrary to the prevailing theories of the time, drugs could indeed cross the placental barrier.⁷ As a result of her decision, the German drug manufacturers formally withdrew their application for approval in the United States. Despite this, many Canadian doctors had already distributed samples of the drug resulting in the birth of approximately 125 infants affected by severe malformations and most likely countless spontaneous abortions that went unreported.⁸ The thalidomide tragedy conclusively demonstrated placental transfer of substances and revealed that even a one-time fetal exposure to this drug, especially during critical periods of development, resulted in severe limb malformations and organ defects. This case led to the widespread acceptance that every drug has the potential to be the next thalidomide and in some cases prompted the withdrawal of presumed teratogenic drugs despite the existence of evidence-based proof of its safety. Bendectin, an anti-nausea drug (manufactured as Dialectin in Canada), was removed from the American market notwithstanding the evidence indicating that the rate of defects in children born of mothers taking Bendectin did not differ from that of the general population.⁹

Largely because of the ethical concerns for fetal protection and reproductive safety arising from the thalidomide incident, pregnant women are prohibited from enrolling in drug research studies. The process of establishing risk or safety of drugs in pregnancy therefore relies on animal and pharmacoepidemiologic studies. However, to date, many drugs still have inadequate data to ensure safety during pregnancy. Although traditionally midwives have cared for "low-risk" clients and "normal" births, it was inevitable that their roles have evolved and changed to provide pregnancy care to women with pre-existing conditions, often sharing care with a physician. Undoubtedly their

roles will continue to evolve to care for women who may develop serious complications during pregnancy that may necessitate pharmacological interventions. Without adequate evidence-based proof of safety, the midwife is left with the predicament of balancing risk to the fetus and benefits to the mother. Communicating this risk-benefit situation to the client can be a challenge for any health care provider, especially in a situation where there is limited knowledge of the parameters that determine teratogenicity and limited knowledge of the pharmacodynamics (actions of the drug on the body) and pharmacokinetics (how the body handles the drugs) of a particular drug. Furthermore, clients with a serious pre-existing condition that is being managed pharmacologically by their physician may develop infections (such as UTIs) that can be treated by their midwife. The midwife must then, in this situation, recognize the potential of drug-drug interactions, be vigilant of side-effects and be able to efficiently communicate these risks to her client. A solid foundation in the concepts of pharmaco-therapeutics in pregnancy and a good understanding in the principles of prescribing in pregnancy will be essential for good client care and education and will form a basis for continuing education as older drugs are replaced by newer drugs. Given the recent legislative changes to the Midwifery Drug Regulation in Ontario, the MEP in Ontario has evolved to meet the needs of the changing profession and competently prepares the student midwife to meet the current and evolving pharmacological needs of her clients.

The Midwifery Education Program in Ontario

The Ontario government first announced the Bachelor of Health Sciences in Midwifery in December of 1992 and since then the MEP has graduated 487 midwives. The program is a collaborative venture jointly offered at three different sites in Ontario, with each site offering distinctive characteristics: Laurentian University offers full-time bilingual programs (French or English streams) with a focus on northern rural and remote community health; McMaster University offers a full time English program while Ryerson University officially offers a part-time program. Through the School of Continuing Education, Ryerson also offers a one-year bridging program for

internationally educated midwives with the goal of upgrading them to current Ontario practice standards. Regardless of the site, courses in the MEP program share about 70% course content with course descriptions varying slightly from site to site. The fundamentals of pharmacy, pharmacology and therapeutics relevant to the practice of midwifery in Ontario are introduced in the first year. It is important to recognize that before the legislative changes described below, midwives could already independently prescribe certain drugs for well-woman and well-baby care such as Diclectin, oral ergonovine maleate, Phytonadione and the Hepatitis B vaccine (for a complete list see <http://www.bprac.org/en/projects/resources/bprac-drug-MidwiferyJurisdictionalReviewNov08.pdf>). They could also administer any drug on the order of a member of the College of Physicians and Surgeons of Ontario and prescribe and administer any drug or substance that could lawfully be purchased or acquired without a prescription. The key changes to the current regulation therefore involve autonomy surrounding prescription of: a) antibiotics to treat urinary tract infections (UTIs), breast infections, bacterial vaginosis and to provide intrapartum GBS prophylaxis, b) uterotonics for the management of postpartum bleeding, c) anaesthetics for the management of pain during perineal repair, d) a galactagogue, e) several vaccines, f) an immune globulin and g) several non-steroidal anti-inflammatory drugs for postpartum pain. This autonomy will primarily increase the midwifery client's quick access to treatment without the need for unnecessary referrals to physicians. Although the pre-existing curriculum at the three sites already provided a good foundation in the principles of prescribing in pregnancy, changes were primarily implemented at the level of the first and second year science courses to address issues relating to safe, effective and judicious drug therapy.

Science Education in the MEP

An introduction to the basic biology and physiology of all systems in the human body occurs in the first year with the Human Anatomy and Physiology course. The co-requisite to this course is the Life Sciences for Midwifery course. Initial exposure to the concepts of pharmacotherapeutics is presented at this time. The course covers the biomechanisms

of anti-fungals and anti-virals, addressing issues specifically related to pregnancy and the neonate along the way. This course also provides an overview of the basic concepts of chemistry, biochemistry and microbiology with a special emphasis on the principals of microbial growth and the mechanisms by which bacteriostatic and bacteriocidal agents control their growth. Given the amendments to the Drug Act, special consideration is now given to the responsibilities facing antimicrobial control as well as accountability for the ever growing problem of bacterial resistance.

It is today's reality that physicians and midwives often treat certain common infections, such as UTIs, empirically, based on signs and symptoms alone, in an effort to alleviate client discomfort and minimize risk to the fetus.¹⁰ The rationale for this approach is a sound one: it is based on the highly predictable spectrum of bacterial agents causing UTI, which are mainly Gram-negative bacteria, as well as their patterns of resistance. However this often leads to over-use of broad-spectrum antibiotics, and coupled with inappropriate prescribing practices, plays a significant role in the emergence of resistant Gram-negative bacteria. Curriculum changes now place an emphasis on prescriber accountability as well as client 'education' factors contributing to resistance. Also, because widely varying rates of resistance have been reported in different countries¹¹ and from different regions within the same country,¹² the curriculum changes also address the reality of geographical patterns of resistance and how this may influence client response to anti-microbial therapy.

In the second year of the program, students begin their formal training in all aspects of pharmacology. Through the Pharmacotherapeutics course in the MEP, midwives in Ontario already received considerable training in the principles of pharmacology with due regard to relevant biochemical principles of drug actions, evidence based practices and the pathophysiologies necessitating pharmaceutical intervention antepartum, intrapartum and postpartum. The expansion of the list of drugs that can now be prescribed solely on authority of the midwife demanded an enhanced emphasis in the curriculum on drug dose calculations, accurate administration of

medications, specific modes of action of each one of the newly added drugs and direct instruction about the indications and contraindications for the drugs, and at various stages of gestation. Also, any minor and major adverse effects associated with a particular drug in the list are comprehensively addressed. Because all drugs may cause adverse effects, active monitoring and early recognition of both rare and more common signs and symptoms allows intervention to minimize their severity.

Literature searches and reviews of emerging best practices with respect to drugs have also been introduced into the Pharmacotherapeutics curriculum. Students are required to familiarize themselves with websites of specific organizations and databases (Table 1) as an effective way to keep up-to date on breaking federal news releases, health advisories and warnings concerning drugs and products relevant to midwifery care. These websites prove to be an invaluable resource for the students and will undeniably serve to enhance the future midwife's ability to maintain her competency throughout her career and remain aware of emerging

best practices in order to provide optimal client care.

Finally, midwives also have a pivotal role in educating women and their partners: they are a valuable and trusted source of information for the client. The Pharmacology second year course has been enhanced by the use of case studies with a focus on safe medication use and client care. These case studies prepare the student midwives to: 1) efficiently communicate the diagnosis to the client, 2) describe the mechanism of action of a particular drug and its indications for use in lay language, 3) outline drug efficacy and safety for both the client and the fetus (or infant), 4) explain the dose and administration, and 5) convey any adverse side effects of the drug. Especially important is client education regarding self-administered drugs such as antibiotics. Understanding the factors that contribute to bacterial resistance of drugs will aid the midwife in clarifying the importance of completing the prescribed therapy even when symptoms are relieved. This type of client education is an essential part of counselling because increases in antibiotic

Table 1: List of resources integrated into the Pharmacotherapeutics course in the Ontario MEP

Organization	Website	Relevance
Health Canada (HC)	www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/index-eng.php	Students subscribe to the HC Media News Service to receive current drug recalls and news releases.
Public Health Agency of Canada	(http://origin.phac-aspc.gc.ca/std-mts/sti-its/pdf/604pregnancy-eng.pdf)	Contains a continuously updated Canadian Guidelines on Sexually Transmitted Infections and Antimicrobial Therapies in pregnancy
Motherisk	www.motherisk.org	Provides updates regarding best practices in treatment of infections in pregnancy, drugs and breastfeeding, etc.
National Institute of Health	www.nlm.nih.gov/medlineplus/druginformation.html	Lists drug interactions with non-prescription and herbal remedies
Natural Medicines Comprehensive Database	http://naturaldatabase.therapeuticresearch.com/ce/ceCourse.aspx?s=ND&cs=&pc=11%2D102&cec=1&pm=5	A source of scientific clinical information on complementary and alternative therapies
The College of Midwives of Ontario	www.cmo.on.ca	Contains the Standard and Guideline to prescribing drugs in Ontario

resistance occur when clients deviate from the pharmacologic plan of care.^{13,14}

The Midwifery Skills course, which prepares the student for their first midwifery clinical placement, complements and is offered concurrently with the Pharmacotherapeutics course. The Skills course allows students to undertake dose calculations and build a collection of drug information cards. Students are also presented with midwifery-specific drug case scenarios which serve as the basis of class discussions. Concepts presented in the Pharmacotherapeutics class will be evaluated on an ongoing clinical basis. The third year advanced skills courses (ASC) I and II, as well as the clinical and community placement courses which cover complications in pregnancy and maternal and newborn pathology (in year 4), now integrate drugs listed in the expanded regulation and reinforce the content introduced in Pharmacotherapeutics. For example, anti-haemorrhagic indications, uses and doses are now covered on multiple levels in the curriculum to ensure safe and effective drug therapy. Through clinical practice of the concepts surrounding the extended pharmacopoeia, students master an entry to practice level of knowledge and skill.

Registered midwives and certification for the revised drug regulation

Currently, there are approximately 489 registered midwives in the province of Ontario. Of these, 82% graduated from either the MEP or from the International Midwifery Pre-registration Program, both of which provide a solid foundation in the basics of safe drug administration. Of the remaining 18%, 34 women had become midwives in Ontario pre-regulation (before 1993), seven were trained in Canada but outside of Ontario, and another 26 were trained outside of Canada (D. Adams, CMO, personal communication). Although many of the drugs found in the amended drug list are currently and competently administered by practicing midwives in Ontario, it is difficult to assess whether all of the members (whether they have passed through the MEP or not) possess the necessary knowledge and skills to a) prescribe from the expanded list and b) counsel clients, at various stages of pregnancy, on the possible adverse effects of the

expanded drug list. To address this, the CMO Council approved the Standard on Certification for Prescribing and/or Administering Certain Drugs Designated in the Regulation "requiring that all members successfully complete a certification exam prior to prescribing and/or administering the drugs included in the amended regulation."¹⁵ Members have only two opportunities to pass the exam and are required to obtain 80% to pass.

To ensure the competency of each active and registered member in Ontario, three online pharmacology modules were created by the CMO. The first module describes the amendments to the Midwifery Act of 1991 while modules two and three describe: 1) the modes of action, adverse effects and contraindications of the different antibiotics found within the expanded drug list, and 2) the biomechanisms of the analgesics, anti-hemorrhagics, galactogogues, vaccines, immunoglobulins & local anesthetics. The first exam was subsequently offered online from September 27, 2010 to November 14th 2010. Eighty-eight percent of registered midwives wrote the test and of these, 92.2% were successfully certified. The remaining 11% of registered midwives who did not write the test in 2010, as well as the 7.85% who failed the exam on their first attempt were required to write the exam in early 2011 in order to receive a letter from the College confirming that they have demonstrated competency to prescribe and administer from the expanded list of drugs. After the second offering of the exam, which took place from January 10, 2011 to February 20, 2011, only 6.5% of registered midwives remain to be certified.

Maintaining and developing competence beyond certification

Because of the current amendments to the Midwifery Drug Regulation in Ontario, midwives now, more than ever, have a professional, legal, and ethical responsibility to develop ongoing competence in pharmacological interventions. The onus then lies with the midwife to maintain and further develop the competence she has achieved during her initial certification. Maintaining these new competencies is not only integral to her commitment to well-woman care but become an important component in client education and informed choice. Midwives in Ontario, like in many

other provinces, are already required to demonstrate continuing competency in the areas of cardiopulmonary resuscitation, emergency skills (both biennial requirements) as well as neonatal resuscitation (recertified annually) and so it seems only logical that a continuing professional development standard in the area of prescription and administration of drugs will soon follow. The standard need not be met by participation in lengthy academic courses but may instead take the form of web-based learning modules, attendance at relevant conferences, education sessions within their own place of work or intensive weekend courses that demonstrate and simulate the skills necessary to keep au courant of evolving best practices regarding drug prescription and administration.

CONCLUSION

The recent new amendments to the Midwifery Drug Regulation in Ontario have finally brought the province in line with the standard of midwifery care across Canada. Shifting and evolving paradigms in midwifery practice naturally influence the future of the profession and as a result, midwife educators must also evolve and progress to meet the needs of the profession. The profession must guide the training programs so that these equip the next generation of midwives with the tools necessary for well-woman care. Although these recent advancements to the legislation may challenge the midwife's non-interventionist approach to care, it necessarily confronts and simultaneously forecasts the needs of midwifery practice to include wider responsibilities for women's reproductive health. Appropriate use of pharmaceutical interventions and appropriate education in these therapies are crucial to ultimately support women in their choices regarding antenatal, prenatal and postnatal health.

REFERENCES

1. Kulaga S, Zagarzadeh A, Bérard A. Prescriptions filled during pregnancy for drugs with the potential for fetal harm. *BJOG*. 2009 Dec;116(13):1788-95.
2. Blackburn ST. Maternal, fetal and neonatal physiology. 3rd ed. St. Louis: Elsevier; 2007.
3. Andrade SE, Gurwitz JH, Davis RL, Chan KA, Finkelstein JA, Fortman K, et al. Prescription drug use in pregnancy. *Am J Obstet Gynecol*. 2004 Aug;191(2):398-407.

4. Dafnis E, Sabatini S. The effect of pregnancy on renal function: physiology and pathophysiology. *Am J Med Sci* 1992;303:184205.
5. Goldenberg RL, Hauth JC, Andrews WW. Intrauterine infection and preterm delivery. *N Engl J Med*. 2000 May 18;342(20):1500-7.
6. Mittendorf R, Williams MA, Kass EH. Prevention of preterm delivery and low birth weight associated with asymptomatic bacteriuria. *Clin Infect Dis*. 1992 Apr;14(4):927-32.
7. Oldham FK, Kelsey FE. Studies on antimalarial drugs : the distribution of atabrine in the tissues of the fowl and the rabbit. *J Pharmacol Exp Ther*. 1945 Apr;83(4):288-293
8. Thalidomide.ca [Internet]. Montreal, QC : Thalidomide Victims Association of Canada; c2011 [cited 2011 Feb 11]. Available from: <http://www.thalidomide.ca/>.
9. Koren G, Pastuszak A, Ito S. Drugs in Pregnancy. *N Engl J Med*. 1998 Apr 16;338(16):1128-37.
10. Schieve LA, Handler A, Hershow R, Persky V, Davis F. Urinary tract infection during pregnancy: its association with maternal morbidity and perinatal outcome. *Am J Public Health*. 1994 Mar;84(3):405-10
11. Kahlmeter G. An international survey of the antimicrobial susceptibility of pathogens from uncomplicated urinary tract infections: the ECO.SENS Project. *J Antimicrob Chemother*. 2003 Jan;51(1):69-76.
12. McIsaac WJ, Mazzulli T, Permaul J, Moineddin R, Low DE. Community-acquired antibiotic resistance in urinary isolates from adult women in Canada. *Can J Infect Dis Med Microbiol*. 2006 Nov;17(6):337-40.
13. Kohanski MA, DePristo MA, Collins JJ. Sublethal antibiotic treatment leads to multidrug resistance via radical-induced mutagenesis. *Mol Cell*. 2010 Feb 12;37(3):311-20.
14. Patrick DM, Hutchinson J. Antibiotic use and population ecology: how you can reduce your "resistance footprint". *CMAJ*. 2009 Feb 17;180(4):416-21.
15. Standard on Certification for Prescribing and/or Administering Certain Drugs Designated in the Regulation [Internet] 2010 Feb 10 [updated 2010 Feb 10; cited 2011 Feb 28]. Available from: <http://www.cmo.on.ca/binder.php>.

AUTHOR BIOGRAPHY

Crestina L. Beites, PhD is an Assistant Professor in the Midwifery Education Program at Laurentian University in Sudbury, Ontario.