Title: Utilisation of a NSW Teratology Information Service by pharmacists and patients

referred by a pharmacist from 2000 - 2018

Authors: Helen Elizabeth RITCHIE¹, Bandana SAINI², Michael J TWIGG³, Debra

KENNEDY⁴

¹Associate Professor, School of Medical Sciences, University of Sydney, New South

Wales, Australia. helen.ritchie@sydney.edu.au

²Associate Professor, School of Pharmacy, University of Sydney, New South Wales,

Australia. bandana.saini@sydney.edu.au

³Lecturer, School of Pharmacy, University of East Anglia, Norwich, United Kingdom.

M.Twigg@uea.ac.uk

⁴Director, Mothersafe, The Royal Hospital for Women, Randwick, New South Wales,

Australia. Debra.Kennedy@health.nsw.gov.au

Corresponding author:

School of Medical Sciences,

University of Sydney, NSW 2006

Telephone: +61 2 8627 8875

Facsimile: +61 2 9351 3638

helen.ritchie@sydney.edu.au

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Abstract

Background. MotherSafe is a free telephone counselling service for exposures during pregnancy and breastfeeding. As the last health professional seen prior to consumption of medicines, community pharmacists' opinion on the use of medications in pregnancy/breastfeeding is likely to be particularly sought by women presenting in pharmacies. However, a recent qualitative study revealed that community pharmacists feel unsupported in their role as medicine information providers to pregnant/breastfeeding women.

Aim The aim of the current study was to undertake a descriptive analysis of calls made by pharmacists or pharmacist referred patients to MotherSafe across the time period 2000-2018.

Materials and Methods A retrospective, descriptive study was conducted of call data from January 2000 to December 2018. Aggregate data was examined by type of caller, reason for call, pregnancy category and exposure type.

Results Most calls (57%) related to pregnancy or breastfeeding (39%) with calls equally distributed throughout gestation. Calls regarding potential pregnancy exposures to uncategorised drugs were the most frequent (mainly complementary medicines). Unlike pharmacists, calls from pregnant consumers referred by pharmacists were also frequently regarding category A drugs.

Conclusions

This study highlights the need for reliable evidence-based information sources regarding the use of prescribed medications, over the counter and complementary preparations during pregnancy and breastfeeding. There is a need for better education of pharmacists about appropriate information sources and the need to use evidence—based resources other than the A-X categories to advise their clients about the safety or otherwise of medications in pregnancy and breastfeeding.

Introduction

In 2018, there were around 90,000 births in New South Wales (NSW), Australia ¹. While the overall birth rate has declined, more women aged over 35 years are giving birth and the average age of first pregnancy has also been steadily rising ². The rate of pre-existing and gestational conditions increases with maternal age and thus there will be more pregnant women with conditions such as hypertension and diabetes (e.g. 8.2/1000 pregnant women have pre-existing hypertension, and 7.3/1000 report pre-existing diabetes) ². Appropriate treatment of chronic conditions is generally recommended to optimise perinatal outcomes. Almost 80% of pregnant women will also experience common pregnancy symptoms such as nausea, back pain, constipation, and insomnia or non-pregnancy related conditions such as cold, flu and allergies for which medications may be required ³⁻⁵. However, common concerns about birth defects and the general lack of clarity around safety leaves many women uncertain about medication use in pregnancy ⁶. This highlights the importance of accessible and accurate information provision through health professionals and medicine information centres in decision making about medication use by pregnant women ⁴. Indeed studies report that up to 80% of pregnant women perceive a high level of need for information about medication use in their condition ⁷ with higher information needs in women who are primiparous, have lower health literacy or use several medications, herbal or over the counter products. ⁵. Results of a multinational survey of ~7000 pregnant women identified the preferred sources of information were physicians, pharmacists, nurses and the internet ⁷.

Community pharmacists are some of the most accessible and highly trusted ⁸ health professionals in the primary health care space and are often the last professional to be consulted prior to consumption of medicines. Seen as medication experts by the public, their opinion on the use of medications in pregnancy/breastfeeding is likely to be particularly sought by women

who are presenting in pharmacies to purchase over the counter medicines, prescription products or complementary medicines.

In a recent qualitative exploratory study with community pharmacists in NSW ⁹, findings suggested that pharmacists feel unsupported in their role as medicine information providers to pregnant/breastfeeding women. Pharmacists who participated in this study admitted adopting a highly cautious approach when counselling pregnant women on medication use and reported increasingly relying upon telephone support services. The study concluded that community pharmacists should be upskilled, better supported and encouraged to play active roles in providing maternal care.

One of the major supports needed and used by participating pharmacists in the aforementioned study was MotherSafe. In NSW, MotherSafe is the main source of specialised information about medication use in pregnancy and breastfeeding for both health professionals and consumers. MotherSafe was established in January 2000 as a state-wide teratogen information service. Modelled on similar services around the world, it is a free-of-charge, telephone-based service, staffed by trained healthcare professionals (pharmacists and doctors), providing evidence-based counselling about exposures during pregnancy and breastfeeding. To better address future information needs and support for pharmacists who often call while their patient is in the pharmacy requesting information, it is important to analyse the pattern of calls made or referred by pharmacists. Such analysis can provide direction about workforce requirements, training and sourcing information for frequently called about medications/products by agencies and the clear information needs of MotherSafe users. Conducting this calls audit over the period since this service has been offered can also highlight key trends or shifts in information needs. The aim of the current study was to undertake a descriptive analysis of calls made by pharmacists or pharmacist referred patients to MotherSafe across the time period 2000-2018.

Materials and Methods

A retrospective, descriptive study was conducted to examine Mothersafe call data for the 19-year period from January 2000 to December 2018.

Data from calls made to MotherSafe, are entered into the MotherSafe database by the counsellors as they are received. The service runs in office hours Monday to Friday and the time each call is received is not recorded in the database. Urgent after-hours queries are referred to the Poisons Information Centre which is a 24-hour service and callers are also advised to look at the Mothersafe website which includes factsheets which may be of assistance for some more common exposures and scenarios. Minimum data collected include: date of call, caller name, caller type (eg. *Consumer*- pregnant woman/partner or *healthcare professional*-pharmacist, midwife etc), maternal age, infant age, postcode and telephone number, reason for call (ie pregnant, planning pregnancy or breastfeeding) and the exposure of concern. An exposure is defined as contact, ingestion, inhalation or injection of a prescribed or over-the-counter (OTC) medication, radiation, chemical, substances, infection or food. Exposures are grouped into one of 40 categories based on their general class. Callers might mention several potential exposures at each call, and these are listed separately.

Aggregate data for the number of calls and individual enquiries received by MotherSafe were extracted for the 19-year period 2000 to 2018 and examined in a retrospective, descriptive and non-identifiable manner for: (1) calls from consumers who were referred by pharmacists to the service; (2) calls from pharmacists. General enquiries "with no specific named exposure" were excluded.

Information from the MotherSafe database was reviewed for spelling mistakes and omitted details during data entry. Subsequently, manual data analysis of reason for call, pregnancy

category (A, B1-3, C, D, X or Unclassified under Product Information in MIMS, an Australian drug reference system) and exposure type was performed using Microsoft Excel.

The study was approved by South East Sydney Illawarra Area Health Service's Human Research Ethics Committee, reference number 07/131.

Results

In total, MotherSafe received 315,158 telephone enquiries during the period 2000 – 2018. Of these, 10,853 were from pharmacists or patients referred by pharmacists. Of these, 7,253 (66.8%) were directly from pharmacists whilst the remainder were from patients who were asked to call MotherSafe themselves. In total, 5,925 (56.6%) were related to pregnancy, 4,122 (39.4%) were regarding breastfeeding and 425 (4.1%) related to pregnancy planning.

While MotherSafe is a NSW service, 185 calls (approximately 1.8% of all calls) came from interstate and another 154 calls (1.5%) were from the ACT. Generally these calls were dealt with directly at the time of the call but callers are advised that for more complex or ongoing cases and for future calls Drug Information services located in the caller's State or territory should be contacted ¹⁰.

Data relating to stage of pregnancy was also available for some calls from pharmacists (2474 calls). For calls regarding pregnancy, the median (IQ) gestational age was 18 (10 - 28) weeks; 31% related to medication use in the first trimester, 38% in the second and 31% in the third trimester. Figure 1 illustrates the number of enquires by year according to whether they were initiated by a pharmacist or patient. In summary, the number of enquiries has plateaued since the steady increase of the initial years of MotherSafe.

When calls by pharmacists were further refined to those specifically relating to exposures during pregnancy, it was clear that the overwhelming number of calls related to exposures to uncategorised drugs. While it is important to emphasise that the ADEC categories are not relevant to breastfeeding, reservation about using a drug in a pregnancy category may extend

to use in breastfeeding in consumer perception. Hence, it is interesting to note that the calls concerning breastfeeding exposures were more evenly distributed across pregnancy categories. Frequently the calls by pharmacists and patients referred by pharmacists refer to more than one exposure. While 72% of calls by pharmacists relate to only one exposure, referred patients will frequently mention several exposures (45%).

When all queries are considered, the calls made by pharmacists differ when the patient is pregnant compared to breastfeeding (Table 1). Queries relating to pregnancy exposures to topical medicines dominated but were rarely a cause of concern during breastfeeding while exposures to antihistamines, antibiotics and CNS agents dominated breastfeeding related calls. Table 2 compares the number of enquires by medication risk category according to contact by a pharmacist or patient. Of note almost twice as many patients sought more advice regarding medications with risk category A compared to pharmacists themselves.

Postcodes were obtained from most calls with approximately 60% coming from metropolitan Sydney. There were some differences in the types of calls from metropolitan versus non-metropolitan locations eg. more calls from pharmacists in metropolitan Sydney concerned complementary medicine use during pregnancy and more calls were related to antidepressant and CNS medicine use during lactation in rural NSW (Table 3).

The specific exposures in the unclassified range are detailed in Table 4 by caller type. The data illustrate that the most common enquiries in the unclassified category related to topical preparations, complementary medicines, vitamins and minerals, cold and flu preparations and gastrointestinal medicines. There appeared to be no difference between the two groups for type of medicine enquiry in this group of medications.

Of those drugs with risk categorisations, calls regarding gastrointestinal medicines (11.2%), antihistamines (7.7%), antibiotics (7.35%), antivirals (7.1%), antifungals (5.7%) and antidepressants (5.5%) predominated from pharmacists.

Drugs for the treatment of nausea and vomiting in pregnancy (NVP) as well as inadvertent use of contraceptives prior to confirmation of pregnancy (including emergency contraception) (75% of calls), were more common in the first trimester (68% of calls) as were antidepressants (49%) and antipsychotics (47%). Cold and flu and head lice and topical treatments predominated in the second trimester (>45%) while antifungals, antihistamines and anorectal medications were more frequent cause of calls in the third trimester (>40% of calls). Over 80% of calls regarding non-steroidal anti-inflammatory drugs (NSAIDS) occurred in the first and second trimesters.

Over the last 5 years, the proportion of calls from pharmacists regarding antivirals, complementary medicines and contraceptives have steadily increased. Among queries from referred patients calls regarding antifungals and gastro-intestinal treatments have also increased. Temporal trends regarding types of exposures are noted with an overall increase in the number of calls by pharmacists or referred by pharmacists occurring in winter months. Calls by pharmacists about cough and cold preparations in both pregnant and breastfeeding women increased in winter and calls referred by pharmacists regarding over-the-counter medications use in pregnancy similarly nearly doubled in winter.

Discussion

To the best of our knowledge this is the first detailed analysis of calls regarding medication exposures during pregnancy and/or breastfeeding made by pharmacists and patients referred by pharmacists to a Teratogen Information Service such as MotherSafe. The data show that pharmacists and their patients frequently used this service. Analysis of the pattern of calls indicates that the medication queries related mainly to calls during pregnancy and breastfeeding

and rarely to the use of medications in a planned (future) pregnancy. Medications not classified into the standard pregnancy categories (i.e. complementary medicines or vitamins) were the most frequent reason for calls to MotherSafe relating to use in pregnancy.

Although pharmacists profess a need for succinct information ⁹, the A to X categorisation of drugs in pregnancy should not be used as the definitive resource in prescribing medications in pregnancy, for women planning to conceive or those breastfeeding as categories do not apply to the latter. Unfortunately, however, pharmacists rely heavily upon the letter categories categories (which are included in prescribing references as well as in product and consumer medicines information) when managing pregnant patients 9. Misuse of categories can result in significant harm including undue anxiety due to heightened perception of risk and cessation of needed medications on supposed fetal safety grounds, thereby potentially compromising both the mother's and baby's health. Better training and access to evidence-based information sources would obviate the need for pharmacists to rely on these categories. For example, the AMH ceased including the pregnancy categories, opting for more relevant statements or advice regarding safety or otherwise of a particular medication in pregnancy. Likewise the FDA in the USA have abandoned their letter categories so that all new drugs now have a descriptive label as per the new PLLR Pregnancy and Lactation Labelling Rule (PLLR) which came into effect in 2014 11. In this changing environment it is critical that pharmacists and other health professionals develop skills in compiling a decision to recommend or not recommend a drug for use in pregnant/lactating women based on a thorough knowledge of first principles such as mechanism of teratogenic potential, drug structure /pharmacokinetics and the benefit versus risk of use.

In addition, many products which pregnant women may consider taking are exempt from classification. These include many commonly used products such as complementary

medicines, laxatives, diagnostic agents, many topical preparations, vitamins (other than vitamin A and nicotinic acid) and minerals. Most women will take at least one medication (prescribed or OTC) during pregnancy to treat acute or chronic illnesses ¹².

Almost twice as many patients sought more advice regarding medications with risk category A compared to pharmacists themselves. Although in general, clinical hesitancy about counselling pregnant women about drugs was subliminally evident in a previous qualitative study with Australian pharmacists, pharmacists in the study still appeared reasonably confident in counselling women about drugs in categories A, D and X, where they probably felt the evidence supporting the allocation of that particular category was straightforward ⁹. Analysis of MotherSafe calls in this study, reinforced this finding regarding pharmacists, confidence in counselling about drugs in Category A. However, as part of good practice and as a risk aversion strategy, most pharmacists may also provide patients with information about MotherSafe and encourage calls, despite their clinical confidence about the safety of using a particular drug in pregnancy. Alternatively, patients using drugs in Category A may be using MotherSafe as a second opinion to reassure themselves about the safety of drug use. This suggests perhaps that pharmacists training needs to ensure confidence in counselling pregnant women about medication use in addition to clinical knowledge on the topic. Another explanation could be that consumers need reassurance about all exposures (regardless of category) and do not necessarily take the categories into account when seeking further information about the safety or otherwise of any product they intend to use.

Over half the calls referred by or from pharmacists related to exposures during pregnancy with one third relating to breastfeeding. Medications which had no pregnancy category comprised 40% of pregnancy exposure calls. This suggests that although pregnant women use or consider

using complementary medicines and vitamins/dietary supplements they worry about their safety, resulting in a significant proportion of calls to MotherSafe regarding these products. Complementary medicine use in pregnancy is well documented in the literature (although pregnancy safety data is extremely limited) with perceived benefits cited by women including 'natural products', self-determination and belief in a holistic approach ^{13, 14}. Not surprisingly Australian health professionals are uncertain about the safety of complementary medicines in pregnancy and how to source or provide appropriate information ¹⁵.

A recent qualitative study also described significant uncertainty among community pharmacists in providing advice to pregnant women regarding uncategorised medications despite being some of the main suppliers of complementary medicines ⁹. An analysis of complementary medicine use by pregnant women indicates that there is often potential for significant drug-herb interactions as many women also use conventional medicines, not to mention concerns about the purity of the compounds and paucity of evidence-based data about their efficacy ¹⁶. In addition, complementary products may include excipients which may have unknown or unanticipated side effects or interactions with prescribed medications. Health professionals therefore should have the ability to relay this lack of evidence using appropriate risk communication skills to patients. Consultative patient communication would also be important so that pregnant/breastfeeding women feel secure in disclosing use of complementary medicines to conventional health professionals ^{17,18}.

While it is likely that a significant number of women also use complementary medicines during breastfeeding, calls to MotherSafe suggest there are less safety concerns during breastfeeding than pregnancy, which is not altogether surprising. During breastfeeding women may feel they have more control over an exposure for example by withholding feeds when using the medication. As with pregnancy, there is a lack of confidence amongst Australian health professionals including community pharmacists in counselling women about the use of complementary medicines whilst breastfeeding ¹⁹.

While the small number of calls regarding medications with suspected or known teratogenic risks (Categories D and X) probably reflects the relatively low dispensing frequency in this

population, it may also reflect pharmacists' greater confidence in advising women in these higher risk categories ⁹. This perhaps relates to the less ambiguous nature of the use information of medications in these categories. However, there are examples of unnecessarily worrying counselling given to patients based on misleading categorisation eg tetracyclines²⁰. There is also the need to balance risks of an untreated disease such as epilepsy in pregnancy with relatively small potential teratogenic risks of antiepileptic drugs such as carbamazepine ²¹.

Many calls reflected common medications that might be required regardless of pregnancy eg. cold and flu preparations, antihistamines, antibiotics, simple analgesics and topical medications. Medications for chronic conditions such as depression are also a common source of enquiry. Although there was no difference in the number of calls as they related to risk categories of drugs across the three trimesters, the type of medication did change. Unsurprisingly calls regarding treatment of nausea and vomiting of pregnancy were more common in the first trimester. Queries regarding NSAIDs were also more frequent in the first and second trimesters. This likely relates to the risk of this drug class on prostaglandin synthesis inhibition resulting in contraindication during the third trimester of pregnancy (category C).

The median gestational age for calls regarding pregnancy was 18 (10 - 28) weeks and this is contrary to what one would expect given that the crucial period for potential teratogenic effects is 4-10 weeks of gestation. One possible explanation is that women are unaware of the importance of the embryonic stage of development or alternately that they sought advice from another source eg their family doctor about early pregnancy exposures at the time that their pregnancy was confirmed 22,23 .

Preconception planning is ideal so that women with chronic conditions can switch from potentially teratogenic to safer medications and optimise their health and improve pregnancy outcomes ²⁴.²⁴. This could and should be incorporated into opportunistic counselling by

pharmacists at a time when women are buying products such as ovulation or even pregnancy testing kits.

The main weakness of the study is that it is an observational retrospective cohort study without a control group and without follow up. Clearly a significant number of calls from consumers were not ascertained as being referred from a pharmacist.

This study highlights the need for community pharmacists and their clients to have access to reliable evidence-based information sources in order to optimise the use of prescribed medications, over the counter and complementary preparations during pregnancy and breastfeeding. It is important that pharmacists feel comfortable in counselling patients about exposures in pregnancy and breastfeeding based on whatever data (albeit limited) is available and to be aware of and utilise or refer their patients to services such as MotherSafe and other Obstetric Drug Information Services. In addition, they should understand the limitations of the product information and consumer medicines information when advising customers about the safety or otherwise of exposures during pregnancy and breastfeeding. Importantly, pharmacists need to have the clinical skills to overlay many different clinical variables to estimate exposure risk in the event where specific pregnancy/lactation data is unavailable. For example, if a drug has minimal oral absorption known via pharmacokinetic data (eg infliximab and other biologics) then one can be reassured regarding use in breastfeeding. Similarly, a drug that is clinically used in the neonatal/ paediatric population is likely safe for use in breastfeeding mothers given amounts of drug an infant is likely to receive via breastmilk would be significantly lower than through direct administration to an infant.

Pharmacists are uniquely placed to advise their clients about medications in pregnancy. They should take the opportunity to discuss pregnancy planning with their clients of childbearing age who are taking regular prescribed medication so that their medications can be optimised

prior to pregnancy and other issues like supplementation with folate and prenatal multivitamins as well as immunisation can be discussed. There is a need for better training of pharmacists about appropriate information sources and the need to use evidence—based resources such as AMH other than the A-X categories to advise their clients about the safety/risks of medications in pregnancy and breastfeeding.

Table 1: Number of enquiries by Class of medicine, type of caller and reason

Pregnant		Breastfeeding	
Pharmacist	Patient referred	Pharmacist	Patient referred
(n=5443)	(n=3188)	(n=3,913)	(n=1823)
Number (%)	Number (%)	Number (%)	Number (%)
Topical	Over the counter	Antibiotics	Antibiotics
613 (11.3%)	311 (9.8%)	346 (8.8%)	162 (8.9%)
Gastro-intestinal	Gastro-intestinal	Cold and flu	Antihistamines
459 (8.4%)	305 (9.6%)	331 (8.5%)	158 (8.7%)
Over the counter	Topical	Antihistamines	NSAID
398 (7.3%)	303 (9.5%)	300 (7.7%)	143 (7.8%)
Cold and flu	Antihistamines	CNS	Over the counter
342 (6.3%)	243 (7.6%)	272 (6.9%)	141 (7.7%)
Vitamins/minerals	Complementary	Complementary	Gastro-intestinal
335 (6.2%)	208 (6.5%)	253 (6.5%)	121 (6.6%)
Complementary	Cold and flu	Gastro-intestinal	Cold and flu
445 (8.2%)	193 (6.1%)	251 (6.4%)	118 (6.5%)

Table 2 Number of enquiries relating to pregnancy by medication risk category

Risk category	Pharmacist (5.077)	Pharmacist referred
	(n=5,077) Number (%)	(n=3,046) Number (%)
A	684 (13.5)	792 (26.0)
B1	387 (7.6)	248 (8.1)
B2	386 (7.6)	225 (7.4)
В3	623 (12.3)	316 (10.4)
C	706 (13.9)	334 (11.0)
D	274 (5.4)	77 (2.5)
X	7 (0.1)	1 (0.0)
unclassified†	2010 (39.6)	1053 (34.6)

[†] Drugs which have no pregnancy classification

Table 3: Number of enquiries by Pharmacists by Class of medicine, location of caller and reason

Pregnant		Breastfeeding	
Metro NSW	Rural NSW	Metro NSW	Rural NSW
(n=2517)	(n=1573)	(n=1815)	(n=1114)
Number (%)	Number (%)	Number (%)	Number (%)
Topical	Topical	Cold and flu	Antibiotics
302 (12.0%)	152 (9.7%)	165 (9.1%)	109 (9.5%)
Complementary	Gastro-intestinal	Antibiotics	Cold and flu
231 (9.2%)	144 (9.2%)	155 (8.5%)	103 (9.1%)
Gastro-intestinal	Over the counter	Antihistamines	Antihistamines
223 (8.9%)	122 (7.8%)	142 (7.8%)	98 (8.2%)
Cold and flu	Complementary	Complementary	Gastro-intestinal
170 (6.8%)	113 (7.2%)	126 (6.9%)	76 (6.5%)
Vitamins/minerals	Antihistamines	Gastro-intestinal	Antidepressants
169 (6.7%)	108 (6.9%)	118 (6.5%)	71 (6.4%)
Over the counter	Cold and flu	Antifungals	CNS
165 (6.6%)	100 (6.4%)	NSAID	64 (6.3%)
		110 (6.1%)	

Table 4: Number of enquiries regarding unclassified drugs and pregnancy exposure

Class of medicine	Pharmacist (n=2,010) Number (%)	Patient enquiries (n=1053) Number (%)
Topical	521 (25.9)	249 (23.6)
Complementary	439 (21.8)	199 (18.9)
Vitamins/minerals	284 (14.1)	132 (12.5)
Over the counter	200 (10.0)	95 (9.0)
Cold and flu	147 (7.3)	71 (6.7)
Gastro-intestinal	146 (7.3)	81 (7.7)

Figure 1 Number of pharmacy-related calls to Mothersafe by year

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