Medicines for breastfeeding women: a postal survey of knowledge, attitudes and practices of general practitioners in Victoria, Australia

Lisa H Amir
Mother & Child Health Research,
La Trobe University

Marie V Pirotta
Primary Care Research Unit, Department of General Practice,
University of Melbourne

MOTHER & CHILD HEALTH RESEARCH LA TROBE UNIVERSITY

Acknowledgments

Other members of the Research Team: Swee Wong, Director, Pharmacy Department, Royal Women's Hospital; Jeanne Daly, Hiranya Jayawickrama and Manjri Raval, Mother & Child Health Research, La Trobe University.

Thanks also to the GP Liaison team at the Royal Women's Hospital, and to the doctors who participated in the study.

Contact

Dr Lisa Amir
MCHR, La Trobe University
324-328 Little Lonsdale St
Melbourne 3000
Australia
Email: L.Amir@latrobe.edu.au

Funding

Faculty of Health Sciences grant 2007, La Trobe University.

Statement of competing interests

The authors have no competing interests to declare.

Publications

Amir LH. GPs and medicines for breastfeeding women. *Breastfeed Med* 2008; 3(3):191 (Conference abstract).

Amir LH, Pirotta M, Daly J, Wong S. GPs and medicines for breastfeeding women. *J Hum Lact* 2009; 25(1):102 (Conference abstract).

Amir LH, Pirotta MV. Medicines for breastfeeding women: a postal survey of knowledge, attitudes and practices of general practitioners in Victoria (Letter). *Med J Aust* 2009; 191(2):126.

Jayawickrama HS, Amir LH, Pirotta M. GPs' decision making when prescribing for breastfeeding women: Content analysis of a survey. *BMC Research Notes* 2010;3:82.

Amir LH. Medicines for breastfeeding women: risky business? In: Nueland WG, editor. *Breastfeeding: Methods, Benefits to the Infant and Mother and Difficulties*. Hauppauga, NY: Nova Publishers, 2010:129-41.

Report date August 2010

SUMMARY

Background: Breastfeeding women are frequent attendees in primary care, yet medication issues for breastfeeding women receive far less attention than the more visible issue of prescribing for pregnant women. The aim of this study was to explore general practitioners' (GPs') knowledge, attitudes and practices regarding use of medicines in breastfeeding women.

Design and setting: Anonymous postal questionnaire of GPs providing antenatal care in Victoria, Australia.

Participants: 335 GPs.

Main outcome measures: GPs' attitudes to breastfeeding; knowledge of one medicine that had a side-effect of reducing milk supply; GPs' advice for breastfeeding women regarding several medicines; reports of adverse events for infants; GPs' most preferred sources of information about medicines for breastfeeding women.

Results: GPs are generally supportive of breastfeeding. 64% could correctly name one medicine that had a side-effect of reducing milk supply. Ibuprofen and metronidazole are commonly used in the postpartum period, yet less than a third of GPs knew these are considered compatible with breastfeeding. Only 18% were able to report an adverse event for the infant associated with maternal use of medicines while breastfeeding, and none of the events were serious. GPs would like practical information about medicines for breastfeeding women available via their software prescribing program (68%), or a reliable internet database (57%).

Conclusions: Although participants were supportive of breastfeeding, they lacked knowledge about the use of medicines for breastfeeding women. Practical information on use of medicines in breastfeeding women needs to be provided urgently on locally appropriate internet sites.

BACKGROUND

Breastfeeding women are frequent attendees to primary care health services. However, medication use in breastfeeding women receives far less attention than the more visible issue of medicine use in pregnant women. Many women receive medicines in the postpartum period: among 840 UK women, 54% were administered a drug in hospital (analgesics, antibiotics, others) and 55% a prescription from their general practitioner (GP) (antibiotics, analgesics, others).[1] Breastfeeding women worry about possible effects on their infant of taking medication: in one study, one in five women did not complete their prescribed course of antibiotics due to this concern.[2]

Are these concerns about adverse impacts of maternal medicines on infants warranted? In a review of all published studies and case reports of adverse events in infants caused by medications up to 2002, 100 cases were identified.[3] Of these, none were "definite", 47% were "probable", and 53% were "possible" reactions to maternal medication.[3] Most affected infants (78%) were two months or younger and about half the cases involved central nervous system drugs.[3] The authors concluded: *"First, no clear-cut infant deaths have ever been reported from a prescribed medication that passed through breastmilk. Second, the relatively small number of published reports of adverse reactions . . . stands in contrast to the common perception that taking a medication during breastfeeding places the infant at high risk".*[3, p. 335] Also, case reports are unreliable without infant drug concentrations: " *. . . an infant can be irritable and fussy without drug exposure*".[4, p. 955] Placental, rather than breast milk, transfer of medicines is more likely to be the cause of adverse events in the two weeks postpartum as trans-placental exposure is one to two orders of magnitude greater than in breast milk intake.[5, 6]

The most useful parameter for assessing the safety of medicines is the relative infant dose, which is calculated by dividing the absolute infant dose (mg/kg/day) by the maternal dose (mg/kg/day) x 100.[7] Values less than 10% are considered compatible with breastfeeding.[7] For the vast majority of medications the relative infant dose is less than 1%.[7, 8] In general, if the medicine is safe to use in infants, it will be safe for the breastfeeding mother.[9] Only a small number of medicines are contraindicated during breastfeeding: this group includes antineoplastic agents, ergotamine, methotrexate, cyclosporine, and radiopharmaceuticals.[10] A case report of a neonatal death from morphine poisoning, published since the aforementioned review, has highlighted the need for caution in the use of codeine as some women are ultrarapid metabolisers of morphine.[11]

In general, pharmaceutical companies provide most of the information about medicines that health professionals access. Product information (PI) generally provides no guidance regarding use in lactating women or is orientated to be legally defensive.[12] PI has been described as a "compendium of legal product monographs"[13, p.

[1302] and is "not helpful or reassuring"[13, p. 1301] for prescribing/recommending doctors or their patients. The over-cautious suggestion to avoid breastfeeding during maternal medication is not easy for mothers to comply with, and complications – mastitis, breast refusal – may follow even brief interruptions to breastfeeding.[1, 14] In the risk-benefit analysis, the risks of introducing infant formula are rarely considered.[15-17]

Sources of information about medicines safety for breastfeeding women are available, including books[18-21] (Figure 1) and websites.[22, 23] However, doctors' knowledge and use of these resources is not known. Also, simple provision of information may not be sufficient to influence practice.[24]

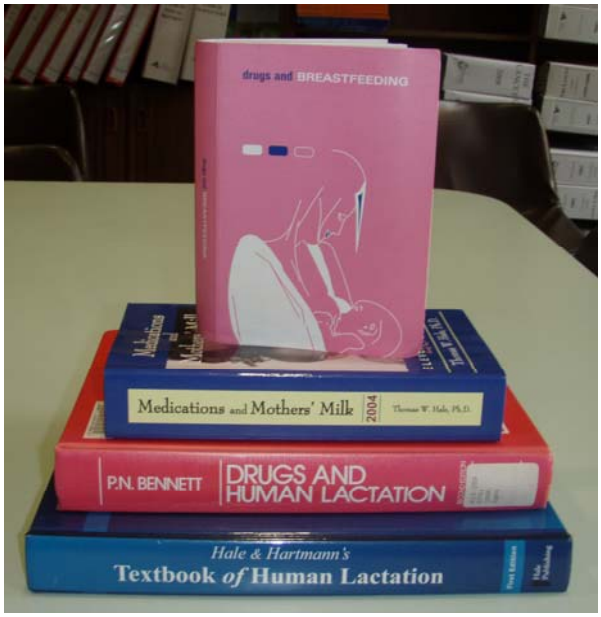

Figure 1. Books about medicines and breastfeeding available at the time of the survey

There has been little research into doctors' knowledge about breastfeeding and medication. Anecdotally health professionals appear to be increasingly concerned about this issue. From our own patients, we have heard of cases recently where women were either denied medicine because they were breastfeeding or were told to stop breastfeeding in order to take medicines, in situations where it was safe to continue breastfeeding and take the medicine.[17]

We aimed to survey GPs, who were expected to be familiar with issues relating to the use of medicines in breastfeeding women, to explore their knowledge, attitudes and practices about obtaining information and prescribing or recommending medicines for breastfeeding women, with the ultimate aim of identifying methods and resources to assist practitioners to prescribe and recommend medicines safely.

METHOD

Our sample consisted of GPs (n = 666) providing shared maternity care at Victoria's largest maternity hospital, the Royal Women's Hospital (RWH). We sent them an anonymous postal survey in November 2007 with a cover letter and reply-paid envelope. A reminder postcard was sent after two weeks, and a second copy of the survey sent in February 2008.

Open and closed questions were used to collect data on demographic variables; use of internet and other sources of information; attitudes to breastfeeding[25] and knowledge about medicines. We chose five different medicines used in general practice that vary in their safety in lactation to test GPs' practice: paracetamol, and ibuprofen (both compatible with breastfeeding); metronidazole (usually regarded as compatible[26]); St John's wort (relatively compatible[6]); and lithium (where the infant needs to be monitored and breastfeeding is usually discontinued[6]). The draft questionnaire was piloted with ten GPs in an iterative manner to refine face and content validity.

We designed a structured question asking the participant about their last experience of using a medicine for a breastfeeding woman to elicit a free-text response with depth and robustness:[27] "Thinking about the last time you had to make a decision about use of a medicine (prescription, over-the-counter or complementary) for a breastfeeding woman, please describe – what was the situation? what did you decide? your reasons for the decision, and how did you feel about the decision-making process?" We asked GPs to report "the last time" they had to make a decision, so we could avoid GPs reporting their most difficult prescribing scenarios, reduce recall bias and also gather some information on the relative frequency of conditions requiring medicines in the postpartum. The final item was a request for further comments (identified as "Comment" in Results). Results from this structured question have been published separately[28] (and can be seen in Appendix 1).

Data were entered into Epi-Data 3.1 and analysed using Stata 10. Descriptive statistics are reported. Approval for the study was obtained from the Human Research Ethics Committees at La Trobe University, University of Melbourne and the Royal Women's Hospital, Melbourne.

RESULTS

Description of the sample

The response fraction was 52% (335/640), after the exclusion of 26 ineligible participants (no longer at that address/retired/deceased). The sample (Table 1) was predominantly female, (62%, 374/605, female, when gender could be assumed) and most respondents were female (70%), and had personal experience of breastfeeding. In

comparison to Australian GPs, the participants were more likely to be working in a capital city, working less than 35 hours per week, and aged over 45 years.[29] Over two-thirds used the internet during consultations, and found it helpful (Table 2).

Table 1 Description of GP participants (n = 335)

	Sample N (%)	Australian GPs N (%)[29]*
Gender (n = 333)		**In Victoria:**
Male	100 (30)	**65**
Female	233 (70)	**35.1**
Age (years) (n = 332)		**In Victoria:**
< 35	22 (7)	**18**
35-44	104 (31)	**33**
45-54	124 (37)	**27**
55-64	71 (21)	**12**
65+	11 (3)	**10**
Country of birth (n = 333)		
Australia	223 (67)	**Not available**
Another country	110 (33)	
Country of graduation (n = 333)		
Australia	280 (84)	**73**
Another country	53 (16)	**27**
Place of work (n = 334)		
Melbourne (capital city)	273 (82)	**66**
Other metropolitan centre	26 (8)	**7**
Large rural centre	7 (2)	**6**
Small rural centre	27 (8)	**7**
Other rural	0	**11**
Remote centre	1 (0.3)	**1**
Other remote area	0	**2**
Hours of patient contact (n = 332)		
1-19	62 (19)	**10**
20-34	119 (36)	**18**
35-49	114 (34)	**32**
50-64	28 (8)	**30**
65+	9 (3)	**7**
Not stated		**3**
Number of shared maternity patients per year (n = 326)	Range: 0-400 Mean: 22 Median 10	
Children (n = 333)		
Yes	298 (90)	
No	35 (11)	
Duration of breastfeeding** (n=333)		**Not available**
Didn't breastfeed	7 (2)	
< 2 weeks	4 (1)	
2-12 weeks	19 (6)	
13-26 weeks	40 (12)	
27-52 weeks	63 (19)	
>52 weeks	164 (49)	
Not applicable	36 (11)	

*Nonspecialists billing Medicare in 2001-02 (national proportions given except where Victorian data are available).
**Breastfeeding by participant or partner.

Table 2 Participants' use of the internet (n = 335)

	Number (%)	Australian GPs %[30]*
Use of internet (n = 335)		
At least once per working day	90 (27)	
At least once per week	113 (34)	
At least once per month	54 (16)	
Less than once per month	65 (19)	
Not applicable	13 (4)	
Has broadband internet? (n = 333)		
Yes	303 (91)	78% (High-speed internet)
No	30 (9)	
Use of internet during consultations (n = 335)		
Yes	233 (70)	
No	99 (30)	
Not applicable	3 (0.9)	
Helpfulness of the internet (n = 331)		
Extremely helpful	96 (29)	
Somewhat helpful	174 (53)	
Neither helpful nor unhelpful	18 (5)	
Unhelpful	9 (3)	
Extremely unhelpful	3 (0.9)	
Not applicable	31 (9)	

*Survey of 1186 Australian GPs conducted in 2005.

Sources of information

Regarding where participants accessed information about medicines and breastfeeding, 61% used dedicated books (predominantly the RWH's *Drugs and Breastfeeding*)[31] and 51% used telephone advice (RWH pharmacy). Only 8% (28/332) relied solely on PI (Table 3). When asked where they would prefer to access this information, most nominated their software prescribing program (68%), or a reliable internet database (57%) in their top three preferences (see Table 3).

Table 3 Sources of information used about medicines in breastfeeding women (n = 335)

	Current sources*		Top 3 preferred sources**	
	n	%	n	%
Software prescribing program	242	73	226	68
Reliable internet database	33	10	191	57
Dedicated books	203	61	146	44
Australian Medicines Handbook	109	33	125	37
Printed guidelines	0	0	112	33
Telephone advice	168	51	106	32
Conference/seminars	2	< 1	23	7
Journal articles	68	11	19	6
One-on-one educational visiting (academic detailing)	0	0	10	3
Printed product information (eg. MIMS)	181	55	3	<1
Therapeutic Guidelines	33	10	3	<1
Previous experience	202	61	0	0
Pharmacist	71	21	0	0
Colleagues	61	18	0	0
Other books	3	< 1	0	0

*More than 1 option permitted
**Participants used numbers to indicate order of top 3 preferences

Attitudes to breastfeeding

Over half of the respondents were supportive of breastfeeding in general, disagreeing with statements that were not supportive, such as: *Breastfeeding and formula feeding are both acceptable methods of feeding infants* (50%, 166/333); *Formula feeding is the better choice if the mother plans to go out to work* (55%, 180/329) and *In most cases a breastfeeding mother must temporarily wean her baby while she is taking prescription medications* (89%, 295/333). Responses to all the statements about attitudes to breastfeeding can be seen in Appendix 2.

Knowledge

Nearly two-thirds (64%, 215/335) could correctly name one medicine that had a side-effect of reducing milk supply. Another 8% (n = 28) gave bromocriptine or similar medication (i.e. decreased milk supply, but as its main effect not as a side-effect). Only 17 (5%) gave an incorrect answer, but 75 (22%) skipped the question.

GPs' responses to the five medicine scenarios proposed (paracetamol, ibuprofen, metronidazole, lithium and St John's wort) can be seen in Table 4. While most participants agreed that women could continue breastfeeding while taking paracetamol, most were not aware that ibuprofen and metronidazole are also considered safe.

Table 4 GPs' responses to questions about example medicines (n = 335)

Medicine	"There is no problem taking this medicine while breastfeeding" n (%)	"I need to look into this" n (%)	"I have concerns about breastfeeding women taking this medicine" n (%)	"Other" n (%)
Paracetamol (missing = 4)	291 (88)	10 (3)	5 (2)	25 (8)
Ibuprofen (missing = 5)	102 (31)	84 (26)	114 (35)	30 (9)
Metronidazole (missing = 2)	72 (22)	141 (42)	96 (29)	24 (7)
Lithium (missing = 5)	3 (<1)	168 (51)	140 (42)	19 (6)
St Johns wort (missing = 2)	6 (2)	187 (56)	126 (38)	14 (4)

Decision-making

Table 5 shows how GPs rated potential factors involved in their decision-making about medicines for breastfeeding women. The majority (97%) expressed concern for infant safety as important or very important, and based their decision-making on previous clinical experience (90%). Participants were invited to write a free-text response to the question: What other factors do you consider? The sixty six responses are listed in Appendix 3. Comments included:

> "Need for medication vs risks to baby"
> "Quality of life for breastfeeding mother"
> "If I've seen an obstetrician prescribe it before I am likely to prescribe it; cost; side-effects; ease of administration; amount secreted in milk"
> "I always check product information"

While most participants (89%) felt confident about prescribing for breastfeeding women, concern regarding medico-legal issues was common: 76% rated this as important or very important in their decision-making (Table 6). Few GPs (n = 6) told women to stop breastfeeding when taking medications. Only 18 (5%) participants reported that they had no time to search for relevant information.

Table 5 Factors important in decision-making for medicines for breastfeeding women

Factors*		N	%
Drug company product information (eg. MIMS) (n = 325)	Very unimportant	12	4
	Not important	11	3
	Neutral	36	11
	Important	171	53
	Very important	95	29
Independent information sources (Australian medicines handbook, websites) (n = 311)	Very unimportant	9	3
	Not important	9	3
	Neutral	39	13
	Important	116	37
	Very important	138	44
Your concerns for infant safety (n = 331)	Very unimportant	7	2
	Not important	0	0
	Neutral	3	1
	Important	76	23
	Very important	245	74
Your previous clinical experience (n = 331)	Very unimportant	6	2
	Not important	5	2
	Neutral	22	7
	Important	162	49
	Very important	136	41
Your patient's views (requests or concerns) (n 329)	Very unimportant	6	2
	Not important	3	1
	Neutral	16	5
	Important	175	53
	Very important	129	39
Medico-legal risks (possible risk of litigation) (n = 330)	Very unimportant	8	2
	Not important	9	3
	Neutral	63	19
	Important	143	43
	Very important	107	32

*"What other factors do you consider?" Responses in Appendix 3.

Table 6 GPs' attitudes towards prescribing medicines for breastfeeding women

Statement		N	%
I feel confident prescribing general medications for breastfeeding women (n = 331)	Strongly disagree	1	1
	Disagree	11	3
	Neither agree nor disagree	26	8
	Agree	226	68
	Strongly agree	67	20
I follow the drug company recommendations regarding medicines for breastfeeding women (n = 332)	Strongly disagree	3	1
	Disagree	24	7
	Neither agree nor disagree	85	26
	Agree	179	54
	Strongly agree	41	12
I don't have time to investigate the safety of medicines for breastfeeding women (n = 332)	Strongly disagree	137	41
	Disagree	150	45
	Neither agree nor disagree	27	8
	Agree	12	4
	Strongly agree	6	2
When I am unsure about prescribing I discuss it with other GPs (n = 330)	Strongly disagree	14	4
	Disagree	96	29
	Neither agree nor disagree	104	32
	Agree	112	34
	Strongly agree	4	1
I tend to ignore drug company recommendations regarding medicines for breastfeeding women (n = 330)	Strongly disagree	96	29
	Disagree	160	48
	Neither agree nor disagree	58	18
	Agree	14	4
	Strongly agree	2	1
I tend to tell women to stop breastfeeding when they need to take medicines (n = 331)	Strongly disagree	147	44
	Disagree	135	41
	Neither agree nor disagree	43	13
	Agree	6	2
	Strongly agree	0	0

Reports of adverse events

GPs were asked to report any adverse events for infants associated with maternal use of medicines while breastfeeding: 18% (61/335) were able to report an event (see Table 7). The most commonly reported adverse event in infants was associated with maternal use of antibiotics (n = 41): irritability, gastro-intestinal upset, thrush. There were seven reports about psychotropic medicines, including one report of infant drowsiness associated with maternal benzodiazepines in an emergency department setting, and another report of infant irritability on withdrawal of maternal paroxetine. One baby developed "rash and feeding problems" when mother was taking a "herbal tonic".

Table 7 Adverse events of maternal use of medicines on their breastfed infants reported by GPs (n = 335)

	N	%
Drug		
Antibiotics	41	**67**
Psychotropic	7	**11**
Antihistamine/decongestant	6	**10**
Other*	5	**8**
Side-effect (for infant)		
GIT symptoms	40	**66**
CNS symptoms	11	**18**
Candida infection	6	**10**
Rash	4	**7**
Feeding problems	5	**8**
Other**	2	3

* Mylanta, progesterone-only pill, theophylline, herbal tonic, coffee.
** Decreased milk, distaste of milk

Open text comments

The themes emerging from participants open text comments have been reported in Jayawickrama et al.[28] (Appendix 1).The organising themes were:

- *certainty around decision-making;*
- *uncertainty around decision-making;*
- *need for drug information to be available, consistent and reliable;*
- *joint decision-making;*
- *the vulnerable "third party"* and
- *infant feeding decision.*

It was apparent that a number of GPs mistakenly assumed the drug categories for pregnancy[32] also applied to breastfeeding women:

> "It is easier to get info on pregnancy & medication than it is to get info on breastfeeding & medication. If in doubt, I tend to check the pregnancy category. If it is safe in pregnancy, I assume it is safe in breastfeeding. Midwives, doctors, O & Gs all seem to advice too often to wean when it is not necessary." (ID 76, Comment)

> "Some medications require more difficult judgements weighing up pros & cons. In general I try to search for a medication that is category A (for pregnancy) & considered safe for breastfeeding." (ID 117, Comment)

> "A, B, C, D guide is useful but the B classification often means the breastfeeding mother decides whether not to risk taking the medication." (ID 198, Comment)

However, some participants were aware that the categories applied only to pregnancy and expressed a wish for similar categories for breastfeeding women:

> "A guide similar to preg. category guide A, B 1,2,3, etc would be useful. (ID 93, Comment)

One GP summed up the feeling of many others:

> "Often feel unsure due to very limited info re medicines / breastfeeding being readily available or not up-to-date. Also seems to be a discrepancy between written recommendations (PI) and actual use in practice." (ID 151, Comment)

DISCUSSION

In this first Australian survey of GPs' knowledge, attitudes and practice regarding use of medicines and breastfeeding, we found that GPs who provided antenatal care were generally positive about breastfeeding and confident about use of medicines in breastfeeding women, but had concerns about medico-legal issues. GPs were confused about the recommendations for use of certain medicines by breastfeeding women, and some gave advice to withhold medication or breast milk unnecessarily. GPs would prefer to access such information from their prescribing software or a reliable internet site.

Infant safety and medicines for breastfeeding women

Breastfeeding is noted to be "invisible' to health systems around the world.[33] Despite women in the immediate postpartum period often requiring analgesia, antibiotic treatment, or antidepressant therapy,[6] less than one-third of our sample agreed that the commonly used postpartum medicines, ibuprofen and metronidazole, were safe for breastfeeding women.

GP confusion is understandable, and may be due to two major factors. Firstly, often medicine use in pregnancy and lactation is not differentiated. Taking ibuprofen as an

example, its PI (from Reckitt Benckiser, 1 April 2007) states that: "*no harmful effects are known in breastfed infants, especially if the course of treatment is short-term and within the recommended dose*". However, two-thirds of our GPs were cautious, perhaps being aware of ibuprofen's Category C pregnancy rating (and advice that ibuprofen "*should be avoided during pregnancy or if planning to become pregnant*") (Reckitt Benckiser, 1 April 2007) and extend this caution to its use in breastfeeding women.

Another factor causing confusion is conflicting information, either due to resources not being updated as new evidence becomes available or to a more "conservative" interpretation of the risk-benefit analysis. This can be exacerbated in societies where formula feeding is accepted as the norm.[34]

For example, the PI for metronidazole (Sanofi-Aventis, 1 October 2007) states "metronidazole is secreted in breast milk. In view of its tumorigenic and mutagenic potential . . . breastfeeding is not recommended". Yet, the risk of mutagenicity in humans is unconfirmed.[35] While concerns about safety have been expressed,[10] short courses of metronidazole are widely used in the postpartum period without evidence of adverse events in infants.[14, 26] However, practitioners are likely to be confused as some experts still suggest a "pump and dump" strategy for women taking metronidazole.[36]

In the past, lithium has been regarded as contraindicated when breastfeeding (Product Information, Aspen, 1 January 2008), but some authorities now recommend that the infant can be monitored.[37, 38] Safety of St John's wort has not been clearly established. One study of 33 infants exposed to St John's wort during breastfeeding found that five infants had adverse events (colic, drowsiness, lethargy), but it was not clear if these were related to the medicine and further studies are needed to establish safety during lactation.[39] Therefore it was appropriate that our sample GPs were cautious about the use of lithium and St John's wort.[6, 10]

More recently, the FDA have proposed new regulations about drug labelling on the effects of medicines used in pregnancy and lactation.[40] *The proposed labels would provide more information and clinical considerations, rather than relying on the oversimplified letter categories – used in pregnancy – at present.*[40]

An understanding of the pharmacokinetics of lactation would help medical practitioners when they are considering recommending medicines in breastfeeding women (Figure 2). Firstly, drugs which are not absorbed from the gastrointestinal tract will be poorly absorbed by the infant; thus intravenously administered drugs such as gentamicin and vancomycin, can be safely used in lactating women.[7, 26] Secondly,

drugs which are highly protein-bound in maternal plasma (≥ 85%) will have low levels in breast milk.[41] Other factors to consider are the age of the infant (more side-effects have been reported in the first two months), and that drugs used in children are likely to be safe for breastfeeding mothers' infants.[7] Health professionals are encouraged to avoid using newly developed drugs in breastfeeding women.[42] In most clinical situations, medication can be chosen that is compatible with breastfeeding.[7]

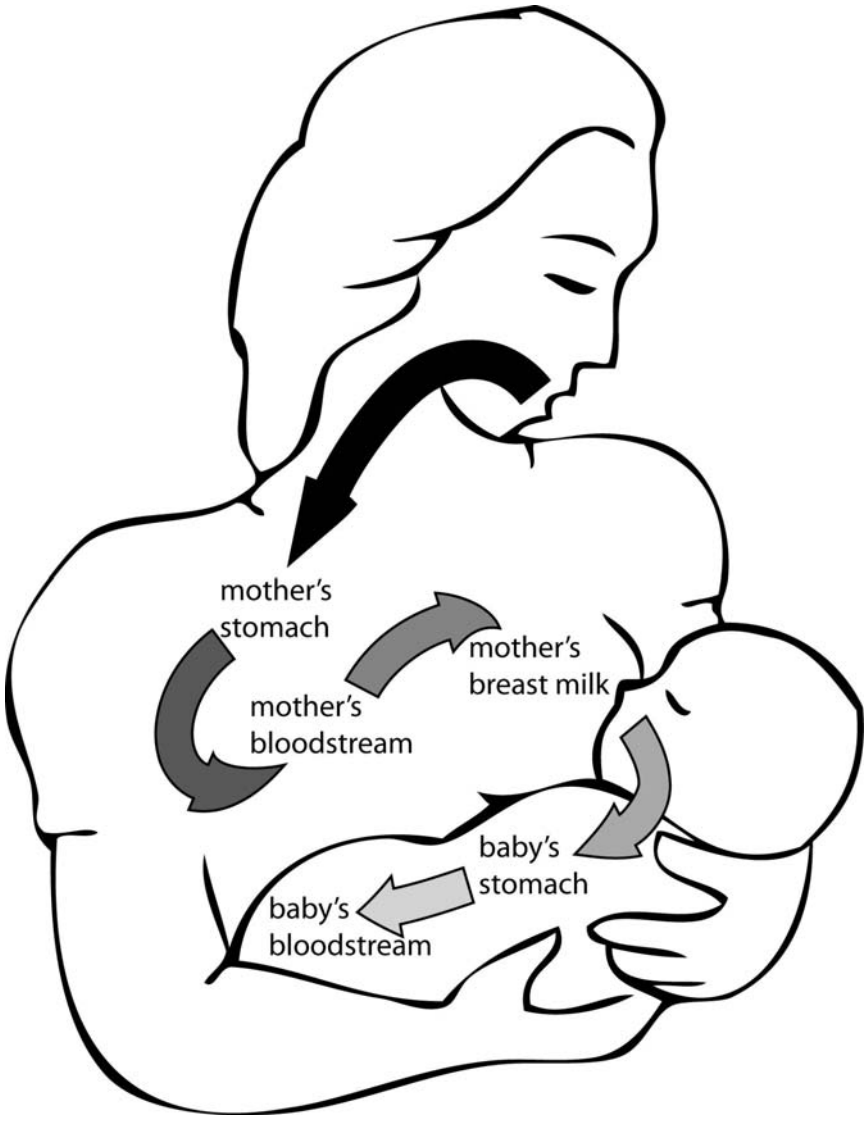

Figure 2 Diagram of drug's path through the mother's body to the baby's circulatory system

Adverse events in infants

The low rate (18%) reported for adverse events of minor severity among infants of mothers using medicines and breastfeeding in our research is compatible with a Canadian study.[43] Eleven percent of the 838 breastfed infants in their study developed

minor adverse events following maternal medication use, but none experienced major reactions requiring medical attention.[43]

Preferred information sources

In 2005, 98% of Australian GPs used their computer for prescribing.[30] Only 4% of our respondents did not use the internet in consultations in 2007-2008. Although the use of electronic information seeking has been low in the past[44] and thought to be time-consuming and complicated,[45] most GPs in our study thought that the internet was helpful. Busy clinicians are unable to search for the most rigorous evidence during consultations; they rely on summaries and practice guidelines from reputable sources and need "just in time" information, quickly accessible at the point of care.[46] We agree with Lagoy and colleagues that a central accessible source of up-to-date information about individual medications and lactation is urgently needed.[47] GPs in our study would like to see this information available on the internet. Figure 3 shows a computer in use in a general practice.

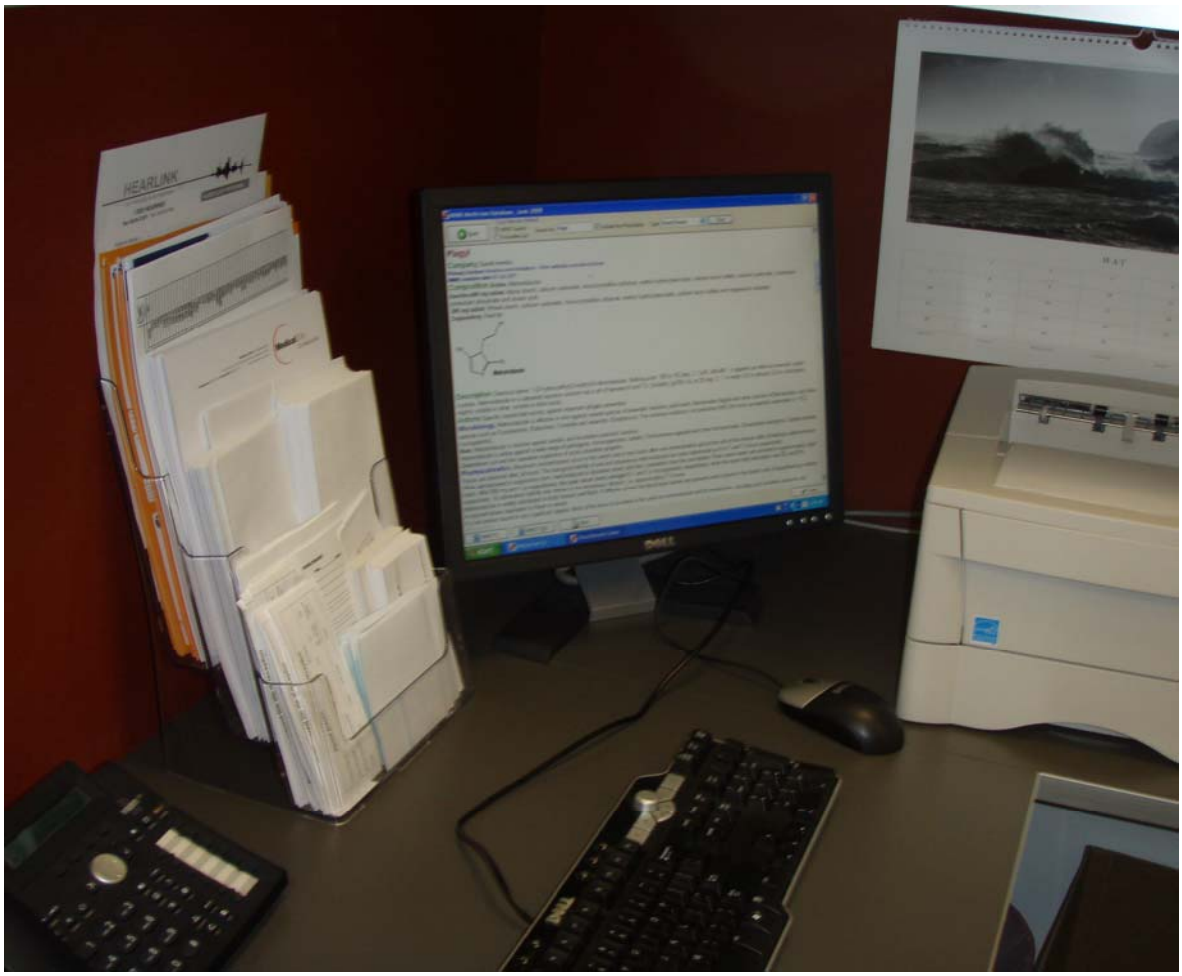

Figure 3 Computer monitor in a general practice consulting room showing *LactMed* website

Strengths and weaknesses of the study

Our response fraction of 52% is considered a reasonable response.[48] Our sample was purposefully biased, having been drawn from a large group of mainly women GPs providing antenatal care, who were therefore expected to be more familiar with issues of prescribing for breastfeeding than most GPs. Our results are likely to be a "best case scenario": non-responders may be less interested in the research topic; indeed most respondents had experience of breastfeeding (either themselves or their partner) and were supportive of breastfeeding in general. A random sample of medical practitioners may be less supportive and knowledgeable about medicines use while breastfeeding.

CONCLUSION

We agree that "The drug industry often takes an unhelpful stance on patients who wish to breastfeed whilst taking their products."[6, p. 757] This has resulted in confusion about medicine safety for both health providers and consumers. Participants in this study were supportive of breastfeeding, but lacked sufficient knowledge about the use of medicines for breastfeeding women.

Health providers need ready access to reliable, up-to-date information which is useful and not unnecessarily defensive. This information could be provided in prescribing software or locally appropriate internet sites, as GPs prefer these sources to traditional books and journals.

REFERENCES

1. Jones W, Brown D. The medication vs breastfeeding dilemma. *Br J Midwifery* 2003;11(9):550-55.
2. Ito S, Koren G, Einarson TR. Maternal noncompliance with antibiotics during breastfeeding. *Ann Pharmacother* 1993;27:40-42.
3. Anderson PO, Pochop SL, Manoguerra AS. Adverse drug reactions in breastfed infants: less than imagined. *Clin Pediatr (Phila)* 2003;42(4):325-40.
4. Anderson GD. Using pharmacokinetics to predict the effects of pregnancy and maternal-infant transfer of drugs during lactation. *Expert Opin Drug Metab Toxicol* 2006;2(6):947-60.
5. Rampono J, Proud S, Hackett LP, Kristensen JH, Ilett KF. A pilot study of newer antidepressant concentrations in cord and maternal serum and possible effects in the neonate. *Int J Neuropsychopharmacol* 2004;7(3):329-34.
6. Ilett KF, Kristensen JH. Drug use and breastfeeding. *Expert Opin Drug Saf* 2005;4(4):745-68.
7. Hale TW, Kristensen JH, Ilett KF. The transfer of medications into human milk. In: Hale TW, Hartmann P, editors. *Textbook of Human Lactation*. Amarillo, Texas: Hale Publishing, L. P, 2007:465-77.
8. Bennett PN. *Drugs and Human Lactation* 2nd ed. Amsterdam: Elsevier, 1996.

9. Briggs GG. Drug effects on the fetus and breast-fed infant. *Clin Obstet Gynecol* 2002;45(1):6-21.
10. American Academy of Pediatrics Committee on Drugs. Transfer of drugs and other chemicals into human milk. *Pediatrics* 2001;108(3):776-89.
11. Madadi P, Koren K, Cairns J, Chitayat D, Gaedigk A, Leeder JS, et al. Safety of codeine during breastfeeding: Fatal morphine poisoning in the breastfed neonate of a mother prescribed codeine *Can Fam Physician* 2007;53(1):33-35.
12. Scialli A. Drugs and lactation--another failure of product labeling. *Reprod Toxicol* 1996;10(2):91-92.
13. Einarson A, Portnoi G, Koren G. Update on Motherisk updates. Seven years of questions and answers. *Can Fam Physician* 2002;48:1301-04.
14. Chung AM, Reed MD, Blumer JL. Antibiotics and breast-feeding: a critical review of the literature. *Paediatr Drugs* 2002;4(12):817-37.
15. Baker RD. Infant formula safety. *Pediatrics* 2002;110(4):833-35.
16. INFACT Canada. Risks of formula feeding: a brief annotated bibliography. Toronto: INFACT Canada/IBFAN North America, 2006.
17. Amir LH. Medicines for breastfeeding women: risky business? In: Nueland WG, editor. *Breastfeeding: Methods, Benefits to the Infant and Mother and Difficulties*. Hauppauga, NY: Nova Publishers, 2010:129-41.
18. Hale T. *Medications and Mothers' Milk*. 13th ed. Amarillo, Texas: Hale Publishing L. P., 2008.
19. Loke YC. *Pregnancy and Breastfeeding Medicines Guide*. Melbourne, Australia: The Royal Women's Hospital, Pharmacy Department, 2010.
20. Koren G. *Medication Safety in Pregnancy & Breastfeeding: The Evidence-Based A-to-Z Clinician's Pocket Guide*. New York: McGraw Hill, 2007.
21. Schaefer C, Peters P, Miller RK. *Drugs During Pregnancy and Lactation: Treatment Options and Risk Assessment*. 2nd ed. London: Elsevier, 2007.
22. National Library of Medicine. Drugs and Lactation Database (LactMed) http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT.
23. Breastfeeding Network Leaflets and Publications http://www.breastfeedingnetwork.org.uk/leaflets-and-publications.html.
24. Grol R, Wensing M. What drives change? Barriers to and incentives for achieving evidence-based practice. *Med J Aust* 2004;180:S57-60.
25. Brodribb W, Fallon A, Jackson C, Hegney D. Breastfeeding and Australian GP registrars--their knowledge and attitudes. *J Hum Lact.* 2008;24(4):422-30.
26. Kristensen JH, Ilett KF. Antibiotic, antifungal, antiviral, and antiretroviral drugs. In: Hale TW, Hartmann P, editors. *Textbook of Human Lactation*. Amarillo, Texas: Hale Publishing, L. P, 2007:513-21.
27. O'Cathain A, Thomas KJ. "Any other comments?" Open questions on questionnaires - a bane or a bonus to research? *BMC Med Res Methodology* 2004;4:25.
28. Jayawickrama HS, Amir LH, Pirotta M. GPs' decision making when prescribing for breastfeeding women: Content analysis of a survey. *BMC Research Notes* 2010;3:82.
29. GP Communications and Business Improvement Unit. General Practice in Australia: 2004. Canberra: Primary Care Division, Department of Health and Ageing, Commonwealth of Australia, 2005.
30. McInnes DK, Saltman KC, Kidd MR. General practitioners' use of computers for prescribing and electronic health records: results from a national survey. *Med J Aust* 2006;185(2):88-91.
31. In M. *Drugs and Breastfeeding.* Melbourne: Pharmacy Department, Royal Women's Hospital, 2004.

32. Australian Drug Evaluation Committee TGA. Prescribing medicines in pregnancy: An Australian categorization of risk of drug use in pregnancy, 1999.
33. Mulford C. Is breastfeeding invisible, or did the health care system just choose not to notice it? *Int Breastfeed J* 2008;3:13.
34. Akus M, Bartick M. Lactation safety recommendations and reliability compared in 10 medication resources. *Ann Pharmacother* 2007;41(9):1352-60.
35. Bendesky A, Menéndez D, Ostrosky-Wegman P. Is metronidazole carcinogenic? *Mutat Res* 2008;511(2):133-44.
36. Keister D, Roberts KT, Werner SL. Strategies for breastfeeding success. *Am Fam Physician* 2008;78(2):225-32.
37. Viguera AC, Newport DJ, Ritchie J, Stowe Z, Whitfield T, Mogielnicki J, et al. Lithium in breast milk and nursing infants: clinical implications. *Am J Psychiatry* 2007;164(2):342-45.
38. Moretti ME, Koren G, Verjee Z, Ito S. Monitoring lithium in breast milk: an individualized approach for breast-feeding mothers. *Ther Drug Monit* 2003;25(3):364-6.
39. Lee A, Minhas R, Matsuda N, Lam M, Ito S. The safety of St. John's wort (*Hypericum perforatum*) during breastfeeding. *J Clin Psychiatry* 2003;64(8):966-68.
40. U.S. Food and Drug Administration. FDA News: FDA proposes new rule to provide updated information on the use of prescription drugs and biological products during pregnancy and breast-feeding, 2008.
41. Riant P, Urien S, Albengres E, Duche JC, Tillement JP. High plasma protein binding as a parameter in the selection of betablockers for lactating women. *Biochem Pharmacol* 2006;35(24):4579-81.
42. Hoddinott P, Tappin D, Wright C. Breast feeding. *Br Med J* 2008;336(7649):881-87.
43. Ito S, Blajchman A, Stephenson M, Eliopoulos C, Koren G. Prospective follow-up of adverse reactions in breast-fed infants exposed to maternal medication. *Am J Obstet Gynecol* 1993;168(5):1393-1399.
44. Einarson A, Park A, Koren G. How physicians perceive and utilize information from a teratogen information service: The Motherisk Program. *BMC Med Educ* 2004;4:6.
45. Skoglund I, Segesten K, Björkelund C. GPs' thoughts on prescribing medication and evidence-based knowledge: the benefit aspect is a strong motivator. A descriptive focus group study. *Scand J Prim Health Care* 2007;25(2):98-104.
46. Slawson DC, Shaughnessy AF. Teaching evidence-based medicine: should we be teaching information management instead? *Acad Med* 2005;80(7):685-89.
47. Lagoy CT, Joshi N, Cragan JD, Rasmussen SA. Medication use during pregnancy and lactation: an urgent call for public health action. *J Womens Health (Larchmt)* 2005;14(2):104-09.
48. Asch DA, Jedrziewski MK, Christakis NA. Response rates to mail surveys published in medical journals. *J Clin Epidemiol* 1997;50(10):1129-36.

APPENDIX 1

Jayawickrama et al. BMC Research Notes 2010, 3:82
http://www.biomedcentral.com/1756-0500/3/82

BMC Research Notes

RESEARCH ARTICLE Open Access

GPs' decision-making when prescribing medicines for breastfeeding women: Content analysis of a survey

Hiranya S Jayawickrama[1], Lisa H Amir*[1,2] and Marie V Pirotta[3]

Abstract

Background: Many breastfeeding women seek medical care from general practitioners (GPs) for various health problems and GPs may consider prescribing medicines in these consultations. Prescribing medicines to a breastfeeding mother may lead to untimely cessation of breastfeeding or a breastfeeding mother may be denied medicines due to the possible risk to her infant, both of which may lead to unwanted consequences. Information on factors governing GPs' decision-making and their views in such situations is limited.

Methods: GPs providing shared maternity care at the Royal Women's Hospital, Melbourne were surveyed using an anonymous postal survey to determine their knowledge, attitudes and practices on medicines and breastfeeding, in 2007/2008 (n = 640). Content analysis of their response to a question concerning decision-making about the use of medicine for a breastfeeding woman was conducted. A thematic network was constructed with basic, organising and global themes.

Results: 335 (52%) GPs responded to the survey, and 253 (76%) provided information on the last time they had to decide about the use of medicine for a breastfeeding woman. Conditions reported were mastitis (24%), other infections (24%) and depressive disorders (21%). The global theme that emerged was "*complexity of managing risk in prescribing for breastfeeding women*". The organising themes were: *certainty around decision-making; uncertainty around decision-making; need for drug information to be available, consistent and reliable; joint decision-making; the vulnerable "third party"* and *infant feeding decision*. Decision-making is a spectrum from a straight forward decision, such as treatment of mastitis, to a complicated one requiring multiple inputs and consideration. GPs use more information seeking and collaboration in decision-making when they perceive the problem to be more complex, for example, in postnatal depression.

Conclusion: GPs feel that prescribing medicines for breastfeeding women is a contentious issue. They manage the risk of prescribing by gathering information and assessing the possible effects on the breastfed infant. Without evidence-based information, they sometimes recommend cessation of breastfeeding unnecessarily.

Background

Both WHO and UNICEF recommend exclusive breastfeeding for six months and continuing breastfeeding together with appropriate complementary feeding for two years or beyond [1]. During the postpartum period and thereafter, lactating women may face numerous health issues needing medicines [2,3]. In a study conducted in Brazil 96% of women received medicines in the immediate postpartum period [4]. A study among postpartum mothers in Victoria, Australia, found that 17% of women reported feeling depressed or very unhappy for more than few weeks, 42% of having backache and 14% mastitis [5]. Lactating women may also experience incidental problems like headache and musculoskeletal pain, upper respiratory tract infections (URTI), urinary tract infections (UTI) and dental problems. Proper management of such conditions is crucial for successful breastfeeding and well-being of the mother.

* Correspondence: l.amir@latrobe.edu.au
[1] Mother & Child Health Research, La Trobe University, Melbourne, Australia
Full list of author information is available at the end of the article

However, whether GPs are equipped with the proper knowledge and skills in managing such situations is a poorly researched area. In a study among GPs in Victoria, approximately 75% claimed they were confident in dealing with mastitis in the postnatal period as opposed to 39% with neck pain and 26% with postnatal depression [6]. It has been found that physicians advise against breastfeeding when prescribing certain drugs, despite established safety during breastfeeding [7].

Prescribing medicines to a breastfeeding mother may lead to untimely cessation of breastfeeding or a breastfeeding mother may be denied medicines due to the possible risk to her infant [2,8]. Both of these situations may lead to poorer outcomes for mother and/or child.

In this paper, we explore GPs' decision-making in situations where they are considering recommending or prescribing a medicine for a breastfeeding woman.

Methods

An anonymous postal survey was conducted with general practitioners (GPs) providing shared maternity care at the Royal Women's Hospital (RWH), Melbourne, Australia, to assess their knowledge, attitudes and practices on medicines and breastfeeding (see Amir & Pirotta for more information [9]). The survey was based on items from Brodribb's questionnaire [10], the current literature and four in-depth interviews with GPs conducted by LA. A current list of GPs was obtained from the RWH (n = 666). The questionnaires consisting of closed and open ended questions and were mailed out in November 2007 and February 2008 with a cover letter and reply-paid envelope. A reminder post card was sent two weeks after the November mail out.

Relevant to this article are the last two items in the questionnaire which were open ended questions. We designed a structured question asking the participant about their last experience of using a medicine for a breastfeeding woman to elicit a free-text response with depth and robustness [11]: "Thinking about the last time you had to make a decision about use of a medicine (prescription, over-the-counter or complementary) for a breastfeeding woman, please describe - what was the situation? what did you decide? your reasons for the decision, and how did you feel about the decision-making process?" We asked GPs to report "the last time" they had to make a decision, so we could avoid GPs reporting their most difficult prescribing scenarios, reduce recall bias and also gather some information on the relative frequency of conditions requiring medicines in the postpartum. The final item was a request for further comments (identified as "Comment" in Results).

We undertook content analyses of these two items [12]. The medical conditions were tabulated and summarised; the number of words in GPs' responses were counted (median and range are reported). Inductive content analysis, in which themes and constructs were derived from the data without imposing a prior framework was conducted [12]. A thematic network was used in analysing GPs' responses by deriving basic themes emerging from the codes given to their words, phrases or sentences [13]. These basic themes were organised into clusters of similar issues, called the organising themes. These organising themes gave rise to an overall global theme, which summarises and makes sense of the clusters of lower-order themes [13].

In reporting our results, GPs' responses are identified by a study identification number after each quotation. An ellipsis (...) is used when words have been deleted. Ethical approval was obtained from the Human Research Ethics Committees at La Trobe University and the University of Melbourne, and the Human Research and Ethics Committees of the RWH. Completion of the anonymous survey was taken as informed consent to participate.

Results

Three hundred and thirty five GPs responded, giving a response rate of 52% (335/640; 26 potential participants were ineligible). Approximately 76% (253/335) of respondents described the last occasion of decision-making regarding use of medicines in a breastfeeding woman. The median (range) of words used in this item was 19 (2-116). Over one third (37%, 125/335) responded to "any comments about medicine and breastfeeding". To summarise the demographic and personal characteristics of the respondents: 70% of GPs were female; about 37% were in the age bracket of 45 to 54 years; most had obtained their medical degree in Australia (84%); 90% had children; and 49% of GPs or their partners had over 12 months of breastfeeding experience.

Table 1 presents the health issues of breastfeeding women who presented for treatment. The commonest groups of conditions were infections in general (50%, 126/253), of which half were mastitis (24%, 60/253), and depressive disorders (21%, 54/253).

Most GPs who cited an infection, especially mastitis, reported the information in a brief, precise manner (median = 12 words, range = 2-46) whereas those who mentioned a depressive disorder tended to write a lengthy explanation (median = 28 words, range = 3-90). Examples of mastitis responses:

- *"Mastitis. Treated with Fluclox [flucloxacillin]. Easy decision on clinical grounds."* (ID 8) (9 words)

In comparison, the description of depressive disorders was wordier and less confident:

- *"Breastfeeding mother with postnatal depression. Discussion took place regarding safety of medication in combination with breastfeeding. Decision was made to try Lexapro [escitalopram] 5 mg daily initially with careful*

Table 1: Health issues in breastfeeding women reported by GPs (n = 253)

Condition	Individual health issue		Categories of health issues	
	n	%	n	%
Infections			126	49.8
Mastitis	60	23.7		
Other infections	(66)	(26.1)		
Endometritis	11	4.3		
Tonsillitis	9	3.6		
RTI	8	3.2		
UTI	7	2.8		
Nipple thrush	6	2.4		
"Antibiotics"	6	2.4		
Common cold	3	1.2		
Other gynaecological infection*	3	1.2		
Sinusitis	2	0.8		
Giardia	2	0.8		
Miscellaneous infections	9	3.6		
Depressive disorders			54	21.3
Use of analgesics			13	5.1
Contraception			9	3.6
Low milk supply			8	3.2
Atopy			8	3.2
Hay fever	3	1.2		
Asthma	2	0.8		
Antihistamines	2	0.8		
Urticaria	1	0.4		
Other conditions**			23	9.1
General comments (no specific situation)			10	4.0

*v. discharge/vaginitis/pelvic infection
**gastritis/reflux, anaemia, epilepsy, anal fissure, drugs, breast engorgement

monitoring of the baby and maternal symptoms. No adverse effects were detected. Mother is currently on Lexapro 10 mg, improvement in symptoms with no adverse effects on the baby noted - baby is thriving." (ID 158) (62 words)

Emerging themes

Analysis of the 253 responses revealed six organising themes that emerged from the responses: *certainty around decision making; uncertainty around decision-making; need for drug information to be available, consistent and reliable; joint decision-making, the vulnerable "third party"*; and *infant feeding decision*. There was one global theme identified: *complexity in managing risk in prescribing for breastfeeding women* (see Table 2).

Certainty and uncertainty around the decision-making process

The first two organising themes which emerged from the comments GPs made with regard to their decision-making process related to their emotional response. GPs either reported positive feelings which were mainly asso-

Table 2: Basic, organising and global themes

Basic themes	Organising themes	Global theme
Comfortable	Certainty around decision-making	
Confident		
Routine		
Happy		
Difficult	Uncertainty around decision-making	
Concerned		
Doubt		
Accessing available drug information	Need for drug information to be available, consistent and reliable	
Problems with available drug information		
Time-consuming		
Issues with pharmacists		Complexity of managing risk in prescribing for breastfeeding women
Involving other health professionals in decision-making process	Joint decision-making	
Involving mother in decision-making process		
Risk	The vulnerable "third party"	
Safety		
Exposure to infant		
To continue breastfeeding	Infant feeding decision	
To give infant formula		

ciated with a certainty about the decision or negative feelings when they were less certain.

Positive feelings on decision-making process

The basic themes used to describe positive feelings were *comfortable, confident, routine* and *happy*. Of the 60 GPs who reported treating mastitis, 48 (80%) were comfortable with their decision: *"... Mastitis unlikely to resolve without Ab [antibiotic]. Very comfortable."* (ID 300)

GPs were also confident about treating other infections: *"Antibiotic - needed to be suitable for breastfeeding otherwise no concern. Advised re baby effects of no significance."* (ID 131)

Negative feelings on decision-making process

GPs reported negative feelings such as *difficult, concern* and *doubt*. These feelings were more evident with prescribing antidepressants than with antibiotics; of the 23 negative feelings, only one related to mastitis, while eight related to depression/anxiety: *"... Concerns about SSRI during breastfeeding by both me and patient. Decision-making process is always fraught and made difficult by conflicting information."* (ID 115) and *"... I think the risks of depression (postpartum) often outweigh the risks of the antidepressants. I felt that there are no right answers to the problem."* (ID 24)

Need for drug information to be available, consistent and reliable

Before prescribing for a breastfeeding woman, many GPs needed to check sources for information on safety of the medicine; this was not straight forward as sources gave conflicting responses, and sometimes pharmacists' opinion on medicines in breastfeeding was at odds with their own decision.

Accessing available drug information

The need to verify the suitability of the drug to be used in breastfeeding women arose in many situations. Sources of information ranged from Therapeutic Guidelines [14], MIMS (a commercial medicines inventory) [15], RWH drug advisory line, pharmacists, specialists (psychiatrists, microbiologist), to Product Information. GPs accessed

this information using printed books, online sources, telephone consultations, as well as medical journals and magazines.

"Depression ... Consulted RWH book, psychiatrist, discussion with pt. [patient] re risk etc." (ID 199)

"Considering antibiotics for skin infection. I check product information (PI) on computer to determine safety status of the medication for breastfeeding. I try always to confirm safety on the PI first." (ID 331)

"Hay fever. Rhinocort [budesonide]. Avoid antihistamines. Time consuming. Used 2 books + Medical Director [software program] information. Different recommendations re: safety of antihistamines." (ID 144)

GPs mentioned seeking drug information from pharmacists at several maternity hospitals in Melbourne. These professionals were highly regarded *("The pharmacist at RWH excellent - gives various sources of information and good opinion re: overall management. If not in, she always rings you back - very reliable."* ID 301 Comment).

In the comments section, a number of respondents requested easy access - preferably online - to evidence-based information on the use of medicines for breastfeeding women:

"I would appreciate ready access to detailed information - books often get misplaced, so internet access would be great." (ID 60 Comment) and *"... We need a dedicated reliable easy access source."* (ID 164 Comment)

Problems with available drug information

Non-availability of easily accessible, evidence based, up to date information on medicines in breastfeeding was mentioned. GPs often mentioned that their sources of information were conflicting and often "over cautious".

"Depression. Most information is 'personal decision' i.e. no good evidence. Reasons for decision - local psychiatrist opinion, RWH pharmacist's opinion. Difficult finding up to date info." (ID 152)

"SSRI in a breastfeeding woman. That it was acceptable. I had to look back at past Australian Doctor [magazine] articles b/c [because] the online sources of MIMS info was too overcautious. OK once I had read the article. I feel able to make an informed decision." (ID 161)

The process of seeking information was mentioned as time-consuming by three GPs:

"Depression. Efexor [venlafaxine]. Checked with Box Hill Hospital pharmacist via phone. Got the most reliable and up to date info but the information took hours to obtain. ie. too long." (ID 321)

Some GPs mentioned wanting more information or that they would have liked guidelines:

"Antibiotics for mastitis. Decided to use antibiotics + continue breastfeeding/expressing. Mum needed medication. I still lacked clear guidelines as to possible effects on baby + what could have been better option." (ID 283)

"A guide similar to preg[nancy] category guide A, B 1,2,3, etc would be useful" (ID 93 Comment)

Although the questionnaire did not directly address the drug categories for pregnancy, it was evident that there is confusion among some GPs about the appropriate use of these categories. Some GPs incorrectly believed that pregnancy categories could be used to assess safety in breastfeeding:

"... In general I try to search for a medication that is category A (for pregnancy) & considered safe for breastfeeding". (ID 117 Comment)

"It is easier to get info on pregnancy & medication than it is to get info[rmation] on breastfeeding & medication. If in doubt, I tend to check the pregnancy category. If it is safe in pregnancy, I assume it is safe in breastfeeding...." (ID 76 Comment)

Several GPs mentioned the need for safety information for complementary medicines: *"We need more access to info[rmation] relating to complementary medicine ..."* (ID 177 Comment)

Issues with pharmacists

Several GPs brought up the issue of pharmacists' advice regarding medicines in breastfeeding conflicting with their decision. Two GPs described the pharmacist as *challenging* the GPs' decision:

"Diflucan [fluconazole] for nipple thrush ... But I have been challenged by pharmacists for this before re. issue of infant exposure, so I don't feel entirely comfortable with it." (ID 175)

"... It was difficult as the pharmacy rang to challenge the Flagyl [metronidazole] use, but I double checked the RWH breastfeeding book & it said it could be used, so we went ahead." (ID 2)

One GP stated that *"Pharmacist[s] tend to be too conservative and advise against taking anything. Also, they sometimes provide advice against what I say and alarm patients ..."* (ID 246 Comment)

Joint decision-making

GPs felt that certain situations warranted involvement of several parties in the decision-making process rather than a quick decision on their part. Although this would involve more time and work for GPs, they thought this would help to make a more appropriate and safe decision and increase mothers' compliance with the recommended/prescribed medicine.

Involving other health professionals in decision-making process

Seeking advice from specialists was deemed necessary in many instances especially when treating postnatal depression.

"Had to prescribe an antidepressant. Discussed situation with patient and her psychiatrist ... OK with decision as it involved team care co-ordination ..." (ID 104)

Involving mother in decision-making process

Many GPs discussed the situation and medicines issues at length with the woman herself before arriving at a decision especially with regard to postnatal depression, but in many other instances as well.

"Postnatal depression. Antidepressant prescribed after long discussion with patient re: prob. areas and current literature/discussion re: safety and proven side effects. I was happy with the decision and I felt the patient was happy." (ID 22)

"Acute mastitis. Put on Amoxil [amoxicillin] after D/W [discussing with] Mo. [mother] re relative safety of this antibiotic and need for antibiotic, Mo. initially concerned but happy to take after addressing her issues." (ID 58)

The vulnerable "third party"

The fifth organising theme concerned issues of prescribing for one person, the breastfeeding woman, thereby exposing the vulnerable "third party" - the breastfed child - to the effects of the medicine. The basic themes were *risk, safety* and *exposure to the infant.*

Risk

A general statement such as "benefits outweigh risks" was stated by 15 GPs. In some cases, the GP specifically mentioned considering the risk to the breastfed infant:

"Recently prescribed Cipramil [citalopram] for postnatal depression to a woman who was breastfeeding. I felt the risk to the baby was low & the drug was important to the woman. I felt reassured that I have been to talks where psychiatrists have said they use this drug in lactating women." (ID 78)

One respondent added: *"Be careful & know the potential dangers."* (ID 68 Comment)

In some cases, the GP was aware that the breastfeeding woman was more concerned about the possible adverse effect of her medicines on the breastfed infant than the GP was: *"... Patient's reluctance despite reassurance +++. No problem for me, but patient very reluctant to take anything.* "(ID 14) and *"Headache ... Paracetamol 2 tds & r/v [review] ... patient unkeen on medication."* (ID 47)

Some GPs commented that the general public are apprehensive about potential risks with any medicine while breastfeeding (*"Patient concern is very high ..." ID 164 Comment*). One GP suggested that this perception of risk could be negatively affecting breastfeeding rates: *"... public perception is they can't take anything. This may partly be impacting on low uptake of breastfeeding."* (ID 5 Comment)

Safety

There were some medicines that GPs regarded as "safe" for breastfeeding women; the examples given were drugs with a longer history of use:

"Panadol [paracetamol]. To give to her. Safety. Safe and sure." (ID 287)

"Gastritis - in patient while breastfeeding? Safety of Nexium [esomeprazole] or Pariet [rabeprazole]. Decided to use Zantac [ranitidine] - older drug more information regarding safety." (ID 299)

Exposure to the infant

Although it could be expected that GPs consider the amount of medicine the infant would receive through the breast milk as an essential part of decision-making, this was rarely alluded to. This is the only quote that refers directly to infant exposure:

"Sleep difficulties. Advice sleep well hints. Occasional dose of temazepam 10 mg at night and avoidance of overnight feeding to minimize infant exposure. This medicine has relatively short half life. Decision-making process was difficult as lethargy and poor feeding could occur." (ID 189)

Deciding how the infant will be fed

In some scenarios it was obvious that the decision whether the mother could or should continue breastfeeding was discussed as a separate issue from the decision about using a medicine.

To give infant formula

GPs advised cessation of breastfeeding and the introduction of infant formula in several instances, even in situations that did not warrant such measures:

"A woman needed Flagyl [metronidazole] for ?anaerobic infection. Information accessed via MIMS Annual (internet). Decided to express + discard for 1 wk + 3 days + formula feed, then resumed thereafter". (ID 304)

To continue breastfeeding

However, many GPs stressed the importance of continued breastfeeding together with medicines:

"Pt. on antiepileptic. Continue BF. Checked literature and phoned RWH. Content." (ID 192)

"Postnatal depression. Prescribed Zoloft [sertraline] advised to continue breastfeeding. Benefit outweigh risks. I felt Okay with decision." (ID 138)

Global theme: Complexity of managing risk in prescribing for breastfeeding women

From GPs' responses about their most recent experience of making a decision concerning a medicine for a breastfeeding woman, it emerged that this was a contentious area, often involving uncertainty and requiring consultation with various colleagues and data sources. GPs were aware that prescribing for a breastfeeding woman leads to the inadvertent exposure of her infant to a potentially harmful medicine, and their role was to manage this risk.

It was also evident that decision-making is a spectrum, from a reflex action - *"there was no decision-making process (ID 76)"* - to a complicated process requiring multiple inputs and consideration. Consensus emerged among respondents that in some conditions, such as infections

like mastitis, the decision-making was straight forward and the reports were brief and used positive sentiments, like *comfortable, confident* and *routine*. In these examples, GPs appeared to use their own knowledge and experience and make the decision quickly and on their own. In contrast, GPs found decisions around more complex problems, such maternal depressive disorders, were often time-consuming and difficult. In these examples, a number of processes involving external sources of information may need to be employed: phone calls to specialist doctors or pharmacists, a range of information sources searched and long discussions conducted with the woman and her family.

Discussion

This study is the first in-depth examination of Australian GPs and their decision-making about use of medicines in breastfeeding women. This paper is based on open-text comments from a survey, which limits our ability to draw conclusions. With only written responses, we were unable to probe the respondents for further explanation for their answers. In some studies, free-text comments may not be representative of all participants: more articulate or less satisfied respondents may bias the response [11,16]. However, three-quarters of our respondents completed the structured question about decision-making, providing us with 253 responses to analyse. Although analysis and reporting of free-text comments are rarely mentioned in textbooks of survey methods or qualitative analysis [16], qualitative analysis can be used with free-text data that are collected in depth [11]. Our findings provide context around how doctors view the issues and have been supported by discussions with GPs - informally and at conferences [17,18].

We found that the overarching theme for these GPs was "*complexity of managing risk in prescribing for breastfeeding women*". Our results confirm the findings of a study conducted among GPs in the north of England, which revealed that the decision-making process of prescribing medicines was regarded as a complex issue due to various reasons such as concerns about drug toxicity and appropriateness of the treatment, and uncertainty about management [19]. The authors found that "prescribing discomfort is a universal, or near universal, experience of prescribers" [19] p. 295. Concern about drug toxicity was the most common reason for GPs' discomfort. So, it appears that prescribing is often an uncomfortable part of any consultation, but this is heightened when prescribing for lactating women. A Danish study found that adopting a conservative attitude and prescribing familiar medicines was one strategy GPs employed to save time and energy as well as reducing the level of uncertainty [20]. A study of GPs' prescribing behaviour in London also found a striking picture of stability, with GPs making very few changes in their prescribing patterns [21].

The concept of risk has become central to our everyday thinking [22], yet a range of cognitive biases can alter our risk perception [23]. Lyerly and colleagues found common patterns in risk perception and reasoning affecting medical decision-making in pregnancy [23]: a tendency to "pursue zero risk to the fetus, independent of the absolute size of the risk, of competing considerations, or of recognition that fetal risk exists in other acceptable contexts" [23] p. 981. Another tendency they identified was that the risks of intervening are given precedence over the risks of *failing* to intervene; for example, maternal medicines for severe asthma may be halted in pregnancy [23]. The same faulty reasoning lies behind the failure to treat lactating women with medicines when appropriate - mother and baby are best served by appropriate medical treatment of the mother and continued breastfeeding for the baby in the majority of prescribing scenarios [8,24].

The public often assumes that all medicines are too risky for breastfeeding women to take. Bellaby explains that responsible parents will avoid an action if they believe there is any risk to their child [25]. The community often believes that a breastfeeding woman must be completely "pure" and her milk absolutely free from contaminants - an impossibility in today's world [26]. In the risk-benefit analysis, the risks of introducing infant formula are rarely considered [27,28]. "It is the physician's obligation not to *eliminate* risk, but to help patients weigh risk, benefit, and potential harm, informed by best scientific evidence and guided by a patient-centred ethic" [23] p. 982.

Risk communication expert, John Paling, states that "*... patients' assessment of risk is primarily determined not by facts but by emotions*" (p. 745) and suggests that doctors remind patients that virtually all treatments are associated with some risk [29]. His advice includes avoidance of descriptive terms "*low risk*" (give numbers, eg. 1 in 10 000) and to offer positive and negative outcomes (eg. how many infants will not have an adverse effect) [29].

It appeared from our study that GPs' perception of risk in prescribing is on a spectrum, from low in certain circumstances to high in others. GPs appeared to make straight forward independent decisions when treating certain conditions such as mastitis and other infections. These decisions seem similar to the "*rules of thumb*" used by Swedish doctors [30]. Our findings confirm those of a study conducted among GPs in Victoria in the mid 1990s, which revealed a similar picture regarding confidence in treating mastitis: approximately three-quarters of GPs reported that they were very confident in treating mastitis in comparison to one quarter for treating postnatal depression [6].

However, this reflex decision-making and lack of reflection, at times led to increased risk - in this case, not for the infant - but risk of poorer outcome for the mother. In some cases, the GP was confident in their management, but prescribed an inappropriate medicine for mastitis (e.g. penicillin [ID 76], amoxycillin [ID 58]). The Australian antibiotic guidelines have recommended a penicillinase-resistant penicillin for at least ten years [31,32]. Although mastitis is a common problem in the postnatal period, it is not always well managed by health professionals [33].

In contrast to the reflex decisions, other decisions required multiple inputs involving much thought and time spent on arriving at the decision. Although this more involved process might help GPs arrive at the most appropriate solutions, in certain instances it did not. GPs reported advising mothers to stop breastfeeding when taking sertraline, metronidazole, and other medicines, although generally these are considered safe for breastfeeding women [34,35].

These poor decisions may indicate a lack of reliable, evidence-based information on the use of medicines for breastfeeding women. Many GPs recognised that product information was overly cautious, that different sources of information gave conflicting recommendations on safety of the same drug in lactating women, and that it took time to gather information on which to base their decisions. Comments on the need for easily accessible evidence-based information supported data from the quantitative part of the survey where 57% of respondents indicated they would prefer a reliable internet database [9].

Although some GPs reported being challenged by community pharmacists, drug information pharmacists were highly regarded. In Toronto, Canada, the Motherisk program provides information about medicines in pregnancy and lactation; 89% of physicians who had called the program commented that the service was very valuable to them [36].

In Australia, as in other countries, drug categories have been created to designate the safety of medicines in pregnancy [37,38]. Similar categories have not yet been created for safety during lactation. The results of this survey, and the interviews conducted with GPs in preparation for the survey, have indicated that many GPs do not differentiate between prescribing during pregnancy and lactation. Concerns about teratogenicity when using medicines in pregnancy are not relevant in the postpartum period, and the amount of medicine transferred to the infant via breast milk is considerably less than that transferred through the placenta to the fetus [8]. GPs in this study did not mention the factors considered important when pharmacologists consider risk-benefit analysis: drug transfer into milk, dose regimen and infant age [8], suggesting that education in this area could be beneficial.

Recently, the Food and Drug Administration in the US has suggested major revisions to the physician labelling for prescription drugs to provide better information about the effects of medicines used during pregnancy and breastfeeding [39].

There are several limitations to this study. It is likely that GPs more interested in the topic have responded to the survey, but we had a sample of 253 GPs, with over a 50% response rate to the survey and over 75% completing these open comment items. If other GPs were less interested in this issue and less confident in their management of postnatal issues requiring medicines, then our results may lead to an underestimation of the actual problem. Our respondents used a range of sources of information, which reflected their familiarity with prescribing for breastfeeding women. GPs not associated with the RWH would be likely to be less familiar with the RWH *Drugs and Breastfeeding* book [35] or hospital pharmacy telephone advice service. Although other sources of evidence-based information are available [40], it is likely that GPs who do not provide shared maternity care would be less familiar with them.

Although we are not able to accurately determine the prevalence of these postpartum conditions, the frequencies reported indicate which conditions were commonly encountered for treatment among the respondents, and were similar to those found previously in Australia [5].

Analysis of written text does not allow an in-depth iterative approach to deeper discovery of meanings. Some GPs' responses were not clear cut and clarification was not possible in this study. The structured nature of the open-text comments - and the large number - enabled an analysis that we feel is robust, but which needs to be further explored in qualitative research in the future.

Conclusions

The decision to prescribe medicine for a breastfeeding woman is not always easy or simple. Doctors need to manage the risks by balancing the need to treat the mother for a medical condition and concurrently support breastfeeding of the infant. The public has great concerns about taking medicines while breastfeeding. Guidance for making the appropriate decision in the form of evidence based clear guidelines and online databases are not always available or readily accessible. Current available information may actually be contradictory, thus contributing to the complexity of decision-making for GPs. Therefore in many instances GPs are faced with great difficulties, even with commonly prescribed medicines like metronidazole. Hence, at present GPs believe that many decisions are "personal decisions" rather than evidence-based and they feel a need for easily accessible evidence

based clear guidelines available in print as well as electronically on prescribing medicines for breastfeeding women.

Competing Interests
The authors declare that they have no competing interests.

Authors' contributions
HSJ conducted the content analysis with input from LHA and MVP. LHA and MVP designed the project and obtained funding. All authors contributed to writing the paper.

Acknowledgements
Funding: Faculty of Health Sciences grant 2007, La Trobe University.
Other members of the Research Team: Swee Wong, Director, Pharmacy Department, Royal Women's Hospital, and Jeanne Daly, Adjunct Associate Professor, Mother & Child Health Research, La Trobe University.

Author Details
[1]Mother & Child Health Research, La Trobe University, Melbourne, Australia, [2]Centre for Women's Health, Gender and Society, University of Melbourne, Carlton, Australia and [3]Primary Care Research Unit, Department of General Practice, University of Melbourne, Carlton, Australia

Received: 15 March 2010 Accepted: 23 March 2010
Published: 23 March 2010

References

1. **Expert consultation on the optimal duration of exclusive breastfeeding. Conclusions and recommendations** [http://www.who.int/inf-pr-2001/en/note2001-07.html]
2. Jones W, Brown D: **The medication vs breastfeeding dilemma.** *Br J Midwifery* 2003, **11**:550-555.
3. Schirm E, Schwagermann MP, Tobi H, de Jong-van den Berg LT: **Drug use during breastfeeding. A survey from the Netherlands.** *Eur J Clin Nutr* 2004, **58**:386-390.
4. Lamounier JA, Cabral CM, Oliveira BC, Oliveira AB Jr, A M, Silva AP: **[Does drug therapy in the postpartum period interfere with breastfeeding recommendations?].** *J Pediatr (Rio J)* 2002, **78**:57-61.
5. Gunn J, Lumley J, Chondros P, Young D: **Does an early postnatal check-up improve maternal health: results from a randomised trial in Australian general practice.** *Br J Obstet Gynaecol* 1998, **105**:991-997.
6. Gunn JM: **The role of the general practitioner in postnatal care: an early intervention study (Thesis).** In *PhD* University of Melbourne, Department of Public Health and Community Medicine; 1997.
7. Lee A, Moretti ME, Collantes A, Chong D, Mazzotta P, Koren G, Merchant SS, Ito S: **Choice of breastfeeding and physicians' advice: a cohort of women receiving propylthiouracil.** *Pediatrics* 2000, **106**:27-30.
8. Ilett KF, Kristensen JH: **Drug use and breastfeeding.** *Expert Opin Drug Saf* 2005, **4**:745-768.
9. Amir LH, Pirotta MV: **Medicines for breastfeeding women: a postal survey of general practitioners in Victoria (Letter).** *Med J Aust* 2009, **191**:126.
10. Brodribb W, Fallon A, Jackson C, Hegney D: **Breastfeeding and Australian GP registrars--their knowledge and attitudes.** *J Hum Lact* 2008, **24**:422-430.
11. O'Cathain A, Thomas KJ: **"Any other comments?" Open questions on questionnaires - a bane or a bonus to research?** *BMC Med Res Methodol* 2004, **4**:25.
12. Holloway I: *A-Z of Qualitative Research in Healthcare* 2nd edition. Oxford, UK: Blackwell Publishing; 2008.
13. Attride-Stirling J: **Thematic networks: an analytic tool for qualitative research.** *Qualitative Research* 2001, **1**:385-405.
14. **Therapeutic Guidelines** [http://www.tg.org.au/]
15. **MIMS Australia** [http://www.mims.com.au]
16. Garcia J, Evans J, Reshaw M: **'Is there anything else you would like to tell us' - methodological issues in the use of free-text comments from postal surveys.** *Qual Quant* 2004, **38**:113-125.
17. Amir L, Pirotta M, Wong S, Daly J: **GPs and medicines for breastfeeding women.** *WONCA Asia Pacific Regional Conference; 23-27 July; Melbourne* 2008:66.
18. Amir L, Jayawickrama H, Pirotta M: **GPs' decision making when prescribing for breastfeeding women: Content analysis of a survey (Poster).** *General Practice & Primary Health Care Research Conference; Melbourne* 2009:139.
19. Bradley CP: **Uncomfortable prescribing decisions: a critical incident study.** *Br Med J* 1992, **304**:294-296.
20. Henriksen K, Hansen EH: **The threatened self: general practitioners' self-perception in relation to prescribing medicine.** *Soc Sci Med* 2004, **59**:47-55.
21. Armstrong D, Reyburn H, Jones R: **A study of general practitioners' reasons for changing their prescribing behaviour.** *Br Med J* 1996, **312**:949-952.
22. Lupton DA: **Lay discourses and beliefs related to food risks: an Australian perspective.** *Sociol Health Illn* 2005, **27**:448-467.
23. Lyerly AD, Mitchell LM, Armstrong EM, Harris L, Kukla R, Kupperman M, Little MO: **Risks, values, and decision making surrounding pregnancy.** *Obstet Gynecol* 2007, **109**:979-984.
24. Hale T: *Medications and Mothers' Milk* 13th edition. Amarillo, Texas: Hale Publishing L. P.; 2008.
25. Bellaby P: **Communication and miscommunication of risk: understanding UK parents' attitudes to combined MMR vaccination.** *Br Med J* 2003, **327**:725-728.
26. Hausman BL: **Contamination and contagion: environmental toxins, HIV/AIDS, and the problem of the maternal body.** *Hypatia* 2006, **21**:137-156.
27. Baker RD: **Infant formula safety.** *Pediatrics* 2002, **110**:833-835.
28. Amir LH: **Medicines for breastfeeding women: risky business?** In *Breastfeeding: Methods, Benefits to the Infant and Mother and Difficulties* Edited by: Nueland WG. Hauppauga, NY: Nova Publishers In press.
29. Paling J: **Strategies to help patients understand risks.** *BMJ* 2003, **327**:745-748.
30. André M, Borgquist L, Mölstad S: **Use of rules of thumb in the consultation in general practice--an act of balance between the individual and the general perspective.** *Fam Pract* 2003, **20**:514-519.
31. Therapeutic Guidelines: **Antibiotic, Version 10.** North Melbourne, Australia: Therapeutic Guidelines Limited; 1998.
32. Therapeutic Guidelines: **Antibiotic, Version 13.** North Melbourne, Australia: Therapeutic Guidelines Limited; 2006.
33. Amir LH, Ingram J: **Health professionals' advice for breastfeeding problems: Not good enough!** *Int Breastfeed J* 2008, **3**:22.
34. Chung AM, Reed MD, Blumer JL: **Antibiotics and breast-feeding: a critical review of the literature.** *Paediatr Drugs* 2002, **4**:817-837.
35. *M: Drugs and Breastfeeding* Melbourne: Pharmacy Department, Royal Women's Hospital; 2004.
36. Einarson A, Park A, Koren G: **How physicians perceive and utilize information from a teratogen information service: The Motherisk Program.** *BMC Med Educ* 2004, **4**:6.
37. **Prescribing medicines in pregnancy: An Australian categorization of risk of drug use in pregnancy** [http://www.tga.gov.au/docs/pdf/medpreg.pdf]
38. Yankowitz J: **Use of medications in pregnancy: general principles, teratology, and current developments.** In *Drug Therapy in Pregnancy* 3rd edition. Edited by: Yankowitz J, Niebyl JR. Philadelphia: Lippincott Williams & Wilkins; 2001:1-4.
39. Felbus KB: **FDA's proposed rule for pregnancy and lactation labeling: Improving maternal child health through well-informed medicine use.** *J Med Toxicol* 2008, **4**:284-288.
40. Amir LH: **Medicines and breastfeeding: information is available on safe use (Letter).** *Med J Aust* 2007, **186**:485.

doi: 10.1186/1756-0500-3-82
Cite this article as: Jayawickrama *et al.*, GPs' decision-making when prescribing medicines for breastfeeding women: Content analysis of a survey *BMC Research Notes* 2010, **3**:82

APPENDIX 2

GPs' attitudes towards breastfeeding*

Statement		N	%
Breastfeeding and formula feeding are both equally acceptable methods of feeding infants (n = 333)	Strongly disagree	44	13
	Disagree	122	37
	Neither agree nor disagree	41	12
	Agree	102	31
	Strongly agree	24	7
Formula feeding is a good way of letting fathers care for the baby (n = 333)	Strongly disagree	29	9
	Disagree	81	24
	Neither agree nor disagree	124	37
	Agree	89	27
	Strongly agree	10	3
Breastfeeding is more convenient than formula feeding (n = 331)	Strongly disagree	6	2
	Disagree	7	2
	Neither agree nor disagree	42	13
	Agree	146	44
	Strongly agree	130	39
Formula feeding is the better choice if the mother plans to go our to work (n = 329)	Strongly disagree	29	9
	Disagree	151	46
	Neither agree nor disagree	116	35
	Agree	30	9
	Strongly agree	3	1
A woman being treated for postpartum depression can continue to breastfeed (n = 333)	Strongly disagree	1	0.3
	Disagree	12	4
	Neither agree nor disagree	35	11
	Agree	192	58
	Strongly agree	93	28
In most cases a breastfeeding mothers must temporarily wean her baby while she is taking prescription medications (n = 333)	Strongly disagree	93	28
	Disagree	202	61
	Neither agree nor disagree	29	9
	Agree	8	2
	Strongly agree	1	0.3

*Statements from survey by Brodribb et al.[25]

APPENDIX 3

When you are considering prescribing a general medication for a breastfeeding women, how important are each of the following factors in making your decision?
(Responses listed in Table 5)
What other factors do you consider? (n = 66)

"The necessity of the medication being considered"
"Efficacy"
"Compliance, ease of use"
"Quality of life for breastfeeding mother"
"Risk vs benefit"
"Degree of necessity to treat with a drug at all"
"Severity of illness in the patient"
"Concern for mother"
"Risk vs benefit"
"Relative risks of treatment vs non treatment"
"What is the frequency of a problem"
"Frequency of breastfeeding, how old the child?"
"How long the medication will be used – 5 days antibiotics – months for antidepressants"
"The necessity of prescribing in the first place, of course"
"Common sense ie. erring on the side of caution when there is insufficient info"
"Risks vs benefit balance eg. SSRI in breastfeeding mother -benefits outweigh possible small risk."
"Age of baby"
"Risk vs benefit of prescribing particular medication"
"If I've seen an obstetrician prescribe it before I am likely to prescribe it; cost; side-effects; ease of administration; amount secreted in milk"
"How new the medication is (i.e. how much experience we have), how much of drug gets into breast milk + theoretical impact on infant"
"Cost"
"RWH drug advice"
"Keep drugs to a minimum in b/f"
"The consequences of not treating the condition."
"Compliance, side-effects"
"Importance of medication"
"Drug interactions, allergies"
"Cost, side-effects"
"Specialist opinion – e.g. if product information not useful ("limited data available, therefore not recommended to BF") then specialists experience and opinion based on recent research is very useful – and perceive that they are likely to have a balanced opinion"
"Nationality"
"Ease of use – patient friendly"
"Practicality / efficacy"
"The seriousness of the illness/risk to mother of not treating"

"The importance of the indication for the medication"
"Appropriate use of medication. Is it absolutely necessary for Rx. Side effects – maternal & infant, excretion in breast milk"
"If medication is needed / can be done without"
"Necessity of any medication in BF women"
"Other people's recommendations"
"Efficacy vs safety"
"Possible side-effects, interactions, cost"
"I always check product information"
"Timing of BF + tablet intake, age of baby, expected side-effects for mum / baby"
"Severity of the problem requiring the medication (eg. severe depression)"
"Risk; benefit assessment"
"Cost for patient"
"Any recent changes / any interactions with other medications, wellbeing of mother"
"Efficacy, Need for pharmacological treatment"
"Potential benefits"
"Need for medication vs risks to baby"
"Age of baby, is baby prem / other health issues, how many feeds/ availability of expressed milk (is there some in freezer) . . ."
"Cost to patient and family"
"Patient allergies/past history"
"Benefit vs risk"
"Drug interaction"
"Seriousness of illness for mum vs risk for baby"
"Available alternatives. Length of exposure. Age if infant, i.e. younger the baby more important effect of meds. on infant"
"Balance of risk vs benefit"
"Need for medication use vs risks"
"Side-effects of mother and child"
"Using non-medicine alternatives"
"Though the medications may not be indicated for lactation; what is the no. of pt.s have used the meds. in the past& no sig. outcome eg. Antidepressant"
"Pros & cons of giving and not giving"
"How necessary is any pharmaceutical treatment at all. eg dangers of not treating with meds."
"Necessity of medication at all"
"Risk vs safety, efficacy"
"The seriousness of need, the unlikelihood of systemic effect (eg. chloromycetin eye drops are used despite knowledge of theoretically & remotely possible effect on bone marrow"