

School of Pharmacy

**The Use of Herbal Medicines in Lactation:
Perspectives of Breastfeeding Women and Pharmacists**

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**This thesis is presented for the Degree of
Doctor of Philosophy - Pharmacy
of
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DECLARATION

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgement has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

Signature: 

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PUBLICATIONS AND PRESENTATIONS

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THESIS ABSTRACT

Many herbal medicines have over the years become a component of self-care by the general public. Despite their increasing popularity, there are currently limited data available on the use and safety of these medicines during breastfeeding. The use of herbal medicines by lactating women during breastfeeding remains a relatively under-researched, yet increasingly important area of research. The advantages of breastfeeding have been well documented, which have led to the development of many strategies and efforts to encourage successful breastfeeding practices in Australia. Providing women with continuity of care during the postnatal transition period is vital to successful breastfeeding practices. The accessibility of community pharmacists places the profession in an ideal position to intervene and ensure women receive appropriate continuity of support and care after birthing, at the community level. Furthermore, herbal medicines and other complementary products are available in most community pharmacies, and pharmacists and pharmacy support staff are a common source of advice and information on the use of these products. Pharmacists have legal and ethical obligations to ensure the safe and effective use of all medicines, including complementary medicines. This study explored breastfeeding women and community pharmacists' perspectives on herbal medicine use in breastfeeding. This research comprised three stages: Stage 1 investigated the prevalence and pattern of use of herbal medicines amongst breastfeeding women; Stage 2 explored breastfeeding women's experiences of the use of herbal galactagogues and their perspectives on pharmacists' roles; Stage 3 explored community pharmacists' perspectives of their role in promoting safe and effective use of these medicines and supporting breastfeeding in the community.

Stage 1 involved a population-based survey of 304 breastfeeding women who had breastfed in the past 12 months. Participants were recruited through four avenues: i) mothers and parenting groups, ii) community pharmacies, iii) immunisation clinics and child health centres, and iv) advertising in newspapers and local parenting papers. Simple descriptive statistics were used to summarise the demographic profile and attitudes of respondents. The mean ages of respondents were 32.8 ± 4.2 years for users of herbal medicines and 32.3 ± 5.0 years for non-users. The majority of

respondents resided in the Perth metropolitan area, were born in Australia or New Zealand, had completed secondary school education, had a relatively high total annual household income (\geq AUD\$ 80, 000), had only one child and were not living with their parents. Of the 304 participants, 182 (59.9%) indicated that they had used one or more herbal preparations for various medicinal purposes during breastfeeding (95% confidence interval 54.4-65.4%), while 60.4% of these users indicated that the reasons for use of these herbal medicines were breastfeeding-related. Seventy-four participants (24.3%, 95% CI: 19.5% - 29.1%) took one or more herbal medicines specifically to help increase milk production or supply during breastfeeding. Respondents with an Asian birthplace and those from middle income families (total annual household income of AUD\$ 37, 000 – 80, 000) were more likely to use herbal medicines.

Amongst the 51 herbal medicines identified by the participants, the top ten most commonly used were fenugreek (18.4%), ginger (11.8%), dong quai (7.9%), chamomile (7.2%), garlic (6.6%), blessed thistle (5.9%), cranberry (4.9%), fennel (4.9%), aloe vera (3.3%) and peppermint (3.3%). The proportion of women who perceived the herbal medicine as helpful varied from 20.0% to 83.3%. The top seven herbal medicines commonly used as galactagogues were fenugreek (18.4%), blessed thistle (5.9%), fennel (4.9%), goat's rue (2.3%), nettle (1.6%), blackthorn berry (1.6%) and shatavari (1.3%). Approximately two-thirds of the users ($n = 112$) had chosen to use herbal medicines during breastfeeding based on recommendations from their families. The majority of the users ($n = 105$) had obtained or purchased their herbal products from community pharmacies. Only 52 (28.6%) of the users had made their doctors aware of their decision to use herbal medicines whilst breastfeeding. Over 70% of respondents ($n = 304$) agreed that there was a lack of information resources available to them. Many of the respondents (43.4%) believed that herbal medicines were generally safer when compared to conventional medicines when used in breastfeeding. Most (71.6%) indicated a previous refusal or avoidance of medicine treatments during breastfeeding due to concerns regarding safety of their infants. When given a choice, 75.9% of respondents preferred more information to be available regarding the use of herbal medicines during breastfeeding.

Stage 2 was exploratory research conducted through in-depth semi-structured interviews with 20 women living in Western Australia, who were using herbal galactagogues during breastfeeding. The study employed purposeful and subsequent snowball sampling methods to recruit participants. Interviews took an average of 33.9 minutes (18 - 78 minutes). All of the 20 participants had used fenugreek either as a sole ingredient or in combination with other herbal ingredients. Reasons for using herbal galactagogues were perceived insufficient milk supply (n = 9), diagnosed insufficient milk supply (n = 8), as a supplement in the absence of perceived or diagnosed insufficient milk supply (n = 2), or as part of tradition (n = 1). Most of the participants (n = 16) had “perceived” or “observed” that these herbal galactagogues were effective in promoting breastfeeding performance. Overall, most participants reported a positive experience on milk supply with the use of herbal galactagogues during breastfeeding.

Five main themes emerged when participants were asked to describe their experiences and general perspectives: i) perseverance and determination to breastfeed, ii) confidence, self-empowerment and reassurance, iii) concerns over breastfed infants’ safety, iv) role and expectations of health professionals, and v) peer and parental influence. Four main themes were apparent in the interviews as participants described their views on the resources available to them regarding the effectiveness and safety of herbal medicines in breastfeeding: i) information needs ii) credibility and reliability of information iii) expectations of health professionals, and iv) role of community pharmacy. Although their views varied widely, participants perceived community pharmacy in general as a convenient source of information that can be trusted. The facilitators for an increased role of community pharmacists were convenience and accessibility, client-pharmacist relationship, staff knowledge and credibility and cost factors. The barriers were a lack of advertisement, publicity and promotion, inconsistent approach by pharmacists, pharmacists’ lack of breastfeeding-related experience or awareness, pre-conceived negative perception towards herbal medicines, concerns over the potential for overlap of roles with other health professionals, and privacy issues associated with inappropriate pharmacy layout. The issues raised by breastfeeding women through the interviews in this stage of the research identified areas of pharmacy practice which require improvement and

revealed opportunities for expansion of the community pharmacists' role to better support breastfeeding women and promoting breastfeeding in the community.

Stage 3 was an exploratory study conducted through in-depth semi-structured interviews with 30 pharmacists practising in community pharmacies in Western Australia. Interviews took an average of 39.4 minutes (26.2 - 70 minutes). Participants' experience in community pharmacy practice ranged from one month to 42 years and they represented a range of positions or roles in the pharmacy. The majority of the participants received enquiries from the public about the use of various medicines during breastfeeding on a weekly basis. Common health issues presented by breastfeeding women to pharmacists were cough and cold, allergies, pain and inflammation, general health using complementary and alternative medicines and inadequate breast milk supply.

Five major themes emerged regarding participants' attitudes, knowledge and confidence level towards promoting the safe and effective use of non-prescription medicines and other over-the-counter products during breastfeeding and their role in supporting breastfeeding in the community: i) attitudes towards complementary medicines use in breastfeeding and pharmacy practice, ii) perception of roles, iii) self-awareness of knowledge level and confidence, iv) facilitators and v) barriers and challenges to achieving effective support for breastfeeding women in the Australian community pharmacy context. Five subthemes or issues were apparent in terms of participants' attitudes towards the use of CMs in breastfeeding and pharmacists' responsibilities: i) complexity and dilemma in making clinical recommendations, ii) duty of care, legal and ethical obligations of the pharmacist, iii) pharmacists' support and willingness for expanded professional roles, iv) provision of evidence-based recommendations and v) process and approach in handling health and medicine-related enquiries. The study also explored participants' perspectives of implementing breastfeeding-related strategies and public health services within the community pharmacy setting. A need for on-going training was also highlighted in this study, where participants identified topics of continuing professional development.

The use of herbal medicines is common amongst survey respondents of this study, however there was a mismatch between the perceptions of breastfeeding women and

pharmacists with regards to the issue of safety and toxicity of herbal medicines. In conclusion, this study has revealed that community pharmacists are perceived favourably by breastfeeding women in the Western Australian community. There was a high level of trust in community pharmacists which could be seen as a main facilitator for expanding pharmacy services in meeting the needs and expectations of breastfeeding women. The findings arising from the perspectives of breastfeeding women and community pharmacists in this research support the argument that community pharmacists are well placed to provide advice and support to breastfeeding women using herbal medicines as galactagogues, at least amongst the participants of this research, with due consideration of the barriers and challenges raised by the participants.

ABBREVIATIONS

AACP	Australian Association of Consultant Pharmacy
ABA	Australian Breastfeeding Association
ABM	Academy of Breastfeeding Medicine
ABS	Australian Bureau of Statistics
AHPRA	Australian Health Practitioner Regulation Agency
AMH	Australian Medicines Handbook
APF	Australian Pharmaceutical Formulary and Handbook
ARGCM	Australian Regulatory Guidelines for Complementary Medicines
ARTG	Australian Register of Therapeutic Goods
AUD\$	Australian dollar
BSES	Breastfeeding Self-Efficacy Scale
BW	Breastfeeding women
CACH	Child and Adolescent Community Health
CAM	Complementary and alternative medicine
CHC	Complementary Healthcare Council of Australia
CHIRI	Curtin Health Innovation Research Institute
CI	confidence interval
CM	Complementary medicine
CMs	Complementary medicines
CONSORT	Consolidated Standards of Reporting Trials
CP	Community pharmacist
CPD	continuing professional development
CPE	continuing professional education

EMPOWER	Enhancing Breast Milk Production with Domperidone in Mothers of Preterm Neonates trial
EWL	evaporative water losses
FDA	Food and Drug Administration
GP	General practitioner
GRAS	Generally Regarded As Safe
HDWA	Health Department of Western Australia
HMs	Herbal medicines
HREC	Human Research Ethics Committee
KEMH	King Edward Memorial Hospital
MIMS	Monthly Index of Medical Specialities
N	number
NHMRC	National Health and Medical Research Council
NHPs	Natural health products
NHS	National Health Survey
NICM	The National Institute of Complementary Medicine
NSAIDs	non-steroidal anti-inflammatory drugs
OR	odds ratio
OTC	over-the-counter
PBS	Pharmaceutical Benefits Scheme
PSA	Pharmaceutical Society of Australia
RCT	randomised controlled trial
SD	standard deviation
SIDS	Sudden Infant Death Syndrome
SPSS	Statistical Package for the Social Sciences

SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TG	Therapeutic Guidelines
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code
UK	United Kingdom
USA	United States of America
WA	Western Australia
WHO	World Health Organization

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Chapter 1
Introduction



Chapter 1 provides an introduction to the study and an overview of the thesis. The synopsis includes an overview and background of the study, the definitions and descriptions of the terminologies used in this study, significance, the overall objectives and an outline of this thesis.

1.1 Overview and Background of the Study

Over the years, many herbal medicines (HMs) have gained recognition and a positive reputation by the general public and health professionals. Despite the increasing popularity, there are currently limited data available on the use and safety of these medicines during breastfeeding. The use of herbal medicines by lactating women during breastfeeding remains a relatively under-researched, yet increasingly important, area of study. A review of the literature (Chapter 2) has revealed that the attitudes and perspectives of breastfeeding women and community pharmacists towards the use of herbal medicines in breastfeeding is an area that has not been well researched.

The advantages of breastfeeding have been well documented, which has led to the development of many strategies and efforts to encourage successful breastfeeding practices in Australia (1). Previous studies have reported the various factors which may affect a woman's decision to initiate or continue breastfeeding (1-3). Breastfeeding women's attitudes and perspectives were seen as influential to their breastfeeding practices. Women's perceptions of inadequate breast milk supply, their concerns over infants' safety while using medicines, and their experiences of the lack of continuity of care and support at the community level may all hinder breastfeeding initiation or contribute to unnecessary early cessation of breastfeeding (1, 2).

Pharmacists practising in the community have regular contact with the public, including breastfeeding women and their families (4, 5). Furthermore, herbal medicines and other complementary products are available in most community pharmacies, and pharmacists are a common source of advice and information on the use of these products (6, 7). Hence, community pharmacists and pharmacy support

staff are ideally placed to provide advice and information to breastfeeding women, particularly where complementary medicines, including herbal medicines, are purchased from pharmacies. Considering the skills and accessibility of community pharmacists, these health professionals may be able to support breastfeeding women's experiences and contribute to successful breastfeeding practices or outcomes. This may be achieved by promoting the safe and effective use of medicines if required in breastfeeding, including both conventional medicines and herbal medicines, and the provision of support or continuity of care to women in the form of advice and relevant professional services in the community pharmacy setting.

The issues and arguments mentioned above formed the background and also informed the design of this research. An overview of the present research is shown in Figure 1.1.

This research comprised three stages:

- **Stage 1** of the research involved a population-based survey to determine the prevalence and explore the patterns of herbal medicine use amongst breastfeeding women in Western Australia, using a self-administered structured questionnaire.
- **Stage 2** of the research employed an interview-based qualitative approach using a semi-structured interview guide to explore breastfeeding women's perspectives on the use of herbal galactagogues during breastfeeding, as well as their perception of the pharmacist's involvement and potential role.
- **Stage 3** of the research involved in-depth interviews with community pharmacists to explore their perspectives on the use of non-prescription medicines, including herbal medicines during breastfeeding, and their role in supporting breastfeeding in the community.

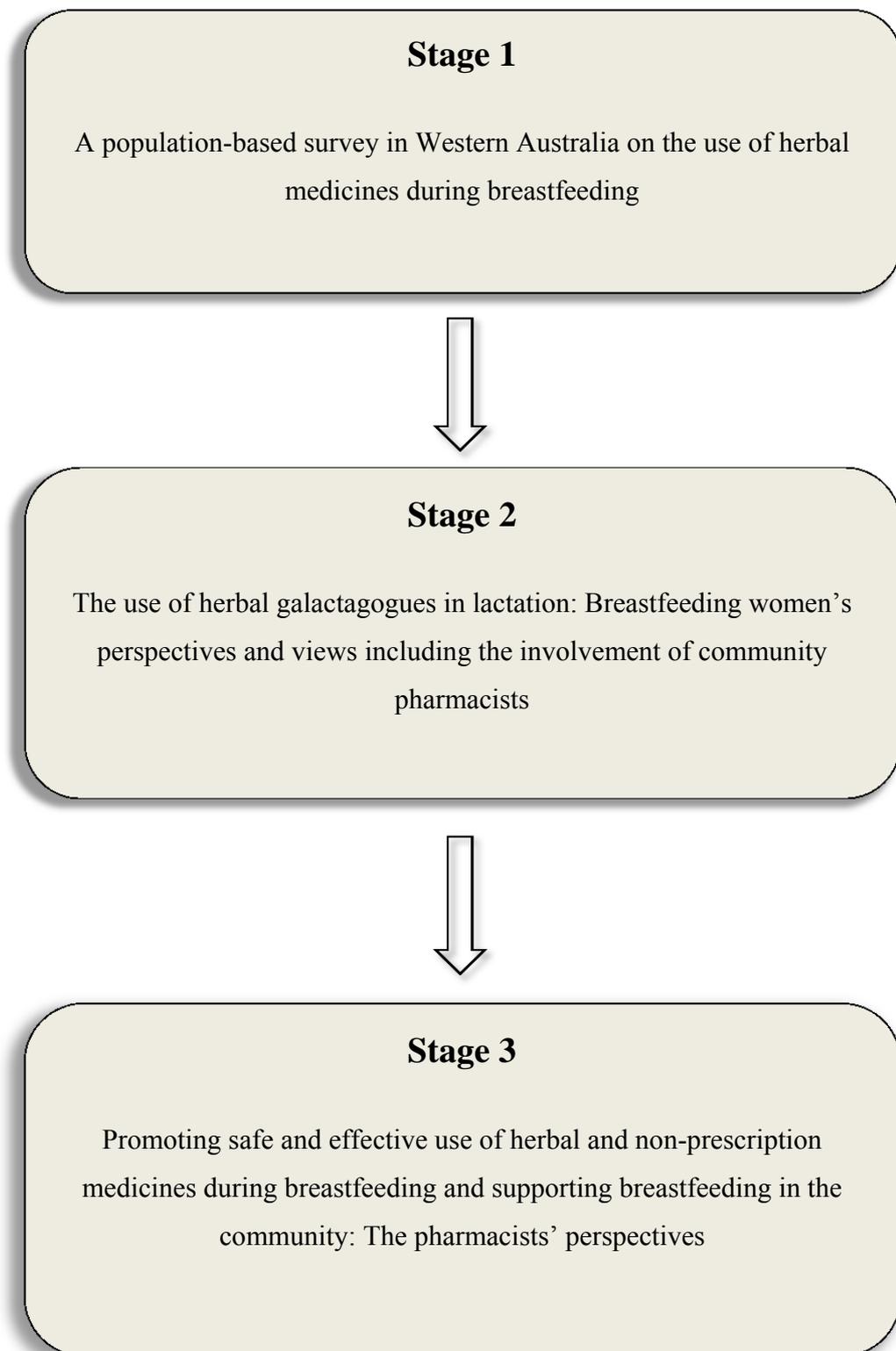


Figure 1.1: An overview of the research plan

1.2 Definitions and Descriptions

1.2.1 Complementary and Alternative Medicine (CAM), Complementary Medicines (CMs) and Herbal Medicines (HMs)

A review of the Australian and international literature identified that there is no consistent and internationally agreed definitions for complementary and alternative medicine (CAM) and complementary medicines (CMs) due to their diversity and the varying cultures in different countries. The umbrella term, CAM, commonly refers to a collection of diverse approaches to prevention, diagnosis and treatment (8, 9). Medicines and health-related terminologies used in Australia show some resemblance to those of the United Kingdom (UK). In a review of CMs in the UK, Barnes (9) describes that “over 50 diverse complementary therapies have been listed, from homeopathy (which involves the use of infinitely dilute preparations) to herbal medicine (which involves the use of chemically rich preparations of plant material), and from acupuncture (which involves the insertion of needles into specific points on the body) to spiritual healing (including ‘distant’ healing, which does not require the laying on of hands).” Several organisations within Australia and in other countries have defined CAM and CMs in different manners, therefore the definitions of terminologies used by the authors in their publications have to be given thorough consideration when interpreting findings from the studies.

The Cochrane Collaboration is an independent international network of contributors from over 120 countries, working collaboratively to prepare, update and promote the Cochrane Reviews, aiming to assist policy-makers, healthcare practitioners, patients and carers in making well-informed healthcare-related decisions based on reliable, accessible and evidence-based health information (10). The Cochrane Collaboration’s work in Australia is funded by the Australian Government through the National Health and Medical Research Council (NHMRC), and their work has gained international recognition as the benchmark for high quality information about healthcare effectiveness (11). Personal communication with the Systematic Review Trainer at the Australasian Cochrane Centre, with confirmation from the Coordinator of Cochrane Collaboration Complementary Medicine Field, revealed that there is

currently no official Cochrane Collaboration definition for CAM (Kelly A 2015, personal communication, February 10). However, an operational CAM definition (12) was drafted by the staff of the Cochrane Collaboration Complementary Medicine Field for the purpose of screening Cochrane reviews for their relevancy with CAM (Kelly A 2015, personal communication, February 10). In a review published by Zollman and Vickers (8) in 1999, the authors stated that the CAM definition adopted by Cochrane Collaboration was the following:

Complementary and alternative medicine (CAM) is a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being. Boundaries within CAM and between the CAM domain and that of the dominant system are not always sharp or fixed. (8)

This Cochrane Collaboration definition of CAM, as provided by Zollman and Vickers (8), is commonly used and has also been cited by other researchers and organisation in this field, for example the National Institute of Complementary Medicine in Australia (13) as well as in a review published by Barnes (9). The above definition of CAM was originally formulated by the National Institutes of Health Panel on Definition and Description at the Office of Alternative Medicine CAM Research Methodology Conference in the United States of America in 1995 (14).

Nevertheless, for the purpose of this thesis, it is important to explore the understanding of CAM and CMs from an Australian perspective. In Australia, therapeutic goods including vaccines, sunscreens, medical devices, blood and blood products, conventional medicines and CMs, are all regulated by the TGA (15). The definition for CMs provided by the TGA excludes alternative therapies that fall outside of the scope of what is categorised as a “therapeutic good” within Australia, for example, acupuncture. According to the TGA, “In Australia, medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homeopathic and certain aromatherapy preparations are referred to as ‘complementary medicines’ and are regulated as medicines under the Therapeutic

Goods Act 1989” (16). The supporting Therapeutic Goods Regulations 1990 defines a CM as “a therapeutic good consisting principally of one or more designated active ingredients mentioned in Schedule 14 of the Regulations, each of which has a clearly established identity and traditional use” (16). As previously mentioned, the use of terminologies may differ in different countries. For example, CMs are referred to as natural health products (NHPs) in Canada, which are governed by the Natural Health Products Regulations since January 2004 and include herbal remedies, vitamins and minerals, traditional medicines, homeopathic medicines, probiotics, essential fatty acids and amino acids (17). The term “NHP” used by the Canadian regulatory authorities is therefore almost synonymous with the term “CM” used by the Australian TGA. This supports the premise that it is essential to consider the context of the terms and definitions used by specific authors of publications in this field, so as to accurately understand and compare research findings.

The terms and definitions used in this field may differ from one organisation to another, even within a specific country. For example, in Australia, the definition of CM given by the National Institute of Complementary Medicine (NICM) is broader than the one provided by the TGA. NICM, hosted by the University of Western Sydney, Australia, was established following the 2003 recommendation by the Expert Committee on Complementary Medicines in the Australian Health System in recognition of the popularity of complementary medicines and therapies in the Australian community. NICM provides support and leadership for research into complementary medicine and related therapies with the final aim of benefiting the health of Australians by improving relevant policy and clinical practice. NICM adopted but further modified the Cochrane Collaboration definition of CAM by substituting the term CAM with the term complementary medicine (CM) (13). As part of their definition of CM in the Australian context, NICM included the statement provided by Zollman and Vickers (8), “We use it synonymously with the terms ‘complementary therapies’ and ‘complementary and alternative medicine’ found in other texts, according to the definition used by the Cochrane Collaboration” (8, 13). NICM further states that “We use the term complementary medicine to describe healthcare practices such as those listed: acupuncture, chiropractic, naturopathy, osteopathy, cranial osteopathy, nutritional therapy, Alexander technique, environmental medicine, reflexology, applied kinesiology, healing, Reiki,

anthroposophic medicine, herbal medicine, relaxation and visualisation, aromatherapy, homeopathy, autogenic training, hypnosis, Shiatsu, Ayurveda, massage, therapeutic touch, meditation and yoga” (13). NICM’s decision to substitute “CAM” with “CM” may create confusion unless careful attention is given to consider the context of the findings in the relevant studies. NICM classifies CM into four domains, namely “mind-body medicine”, “biologically-based practices”, “manipulative and body-based practices”, and “energy medicine”. Of these four domains, “biologically-based practices” is of relevance to this thesis. According to the definition provided by NICM (13), “Biologically based practices in CM use substances found in nature, such as herbs, foods, and vitamins. This includes what the Australian TGA defines and regulates as Complementary Medicines”. Examples of this approach include herbal medicines, vitamins and minerals, and other nutrient and non-nutrient substances derived from plant, animal and marine sources (18).

Herbal medicine conventionally falls under the broader definition of CMs, although review of the literature suggests that there is no clear, specific definition for herbal medicine in Australia. The Therapeutic Goods Regulations 1990 (19) defines herbal substances as “all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin)”. Barnes (9) describes herbal medicines from a UK perspective as preparations which are “made from plants or plant parts”. These include crude drug, for example, dried leaves used by herbalists, and also manufactured products containing one or more herbal ingredients in various formulations such as tablets, capsules, lozenges, tinctures and creams. A herbal ingredient is defined as “a specific individual medicinal plant and the plant part, present in a herbal medicine, e.g. St John’s wort herb present in St John’s wort tablets” (20). As a herbal medicine may contain multiple herbal constituents and because these constituents are directly related to the safety profile of the specific herbal medicine in breastfeeding, it is important to define herbal constituents in this context. Using St John’s wort as an example, hyperforin is a specific chemical compound found in this herbal ingredient, hence hyperforin is known to be a herbal constituent of St John’s wort (20).

This thesis adopts the Australian TGA definition of CMs (which include herbal medicines, vitamins and minerals, nutritional supplements and homeopathic

medicines). Where the term CAM is used in this thesis, it refers to the use of CMs as per the Australian TGA definition, as well as inclusion of other alternative therapies, for example, acupuncture.

1.2.2 Breastfeeding Practices

Internationally agreed terms exist when defining breastfeeding practices, as recommended by the World Health Organization (WHO) (21). Those of relevance to this thesis are:

- Exclusive breastfeeding: Infant receives only breast milk (including expressed milk or milk from a wet nurse) and medicines (including vitamins and minerals, oral rehydration solutions), but precludes any other solids or liquids (that is, no non-human milk or infant formula).
- Complementary feeding or partial breastfeeding: Infant receives solid or semi-solid foods (including any food or liquid, non-human milk and formula) in addition to breast milk.
- Breastfeeding or any breastfeeding: Include the above, or when any breast milk is given to the infant, with or without other solids, semi-solids or liquids.

1.2.3 Community Pharmacists

Community pharmacists refer to those registered to practise as a pharmacist with the relevant professional organisations, such as the Australian Health Practitioner Regulation Agency (AHPRA) in Australia (22) and the General Pharmaceutical Council (GPhC) in Great Britain (23), and are practising in community pharmacies.

1.3 Significance of Study

Breastfeeding may increase the risk of medicine exposure to nursing infants via breast milk if lactating mothers are receiving medicine treatment. Another concern is the effect of medication administration on the quantity and quality of breast milk, which may impact on the exclusivity, duration and thus success of breastfeeding. While medicine treatments include both conventional and complementary medicines, most available studies have focused on evaluating the compatibility of conventional medicines with breastfeeding. Many herbal medicines have gained recognition over the years and the general public as well as many health professionals are supportive of their use (7, 24, 25). Despite their increasing popularity, there are currently very limited data available on the use, safety and efficacy of herbal medicines during breastfeeding. A study published in 2006 in Australia showed that 36% of the survey respondents had used at least one herbal medicine whilst pregnant (26). It was also suggested that women were more likely to use medicines in breastfeeding compared to while they were pregnant (27). To date, no study exists to investigate the prevalence and pattern of use of herbal medicines specifically amongst breastfeeding women living in Australia, their attitudes towards herbal medicines and information-seeking behaviour. This study will provide current information on the prevalence and pattern of herbal medicines used during breastfeeding. Identification of the commonly used herbal medicines in this population will also help inform and direct further clinical research.

Many studies have been conducted to investigate the factors which may hinder the initiation and/or continuation of breastfeeding (1, 28). Women's negative attitudes towards breastfeeding, inaccurate perception of insufficient milk supply, concerns over breastfed infants' safety while mothers are receiving medical treatments, and the lack of continuity of support and care at the community level have all been associated with unsuccessful breastfeeding practices (28). Previous studies have also shown that women constantly seek reassurance and self-empowerment during breastfeeding (29-31). It has also been shown that some women may choose to use herbal remedies or alternative therapies to combat the sense of an inadequate milk supply (30). Ayers (29) suggested that breastfeeding women's confidence can be

bolstered with the use of galactagogues. Therefore, it is important to appreciate breastfeeding women's perspectives, as their perceptions and attitudes may influence their decision to initiate or discontinue breastfeeding. It will also be instructive to explore the perspectives of women who have used herbal galactagogues during breastfeeding in Australia, to explore the potential value of specific herbal medicines as galactagogues, and at the same time to gain an appreciation of why women have chosen to use alternative therapies instead of conventional medicines to enhance breastfeeding performance.

In acknowledging the advantages and health benefits of breastfeeding, several national strategies have been implemented to promote successful breastfeeding practices in Australia, for example, the *National Breastfeeding Strategy (1996-2001)* (32) and the current *Australian National Breastfeeding Strategy 2010-2015* (1). The latter strategy supports "collaborative care", which encourages health professionals from different disciplinary backgrounds to work collaboratively to support breastfeeding women and their families at the primary healthcare level (1). "Continuity of care" is also regarded as one of the principles of this strategy, emphasizing the importance of continuing support and postnatal care for breastfeeding women and their infants during the transition period between birthing at hospital and living in their own home, and through the following months postpartum (1).

Providing women with continuity of care during the postnatal transition period is vital to successful breastfeeding practices. The accessibility of community pharmacists places the profession in an ideal position to intervene and ensure women receive appropriate continuity of support and care after birthing, at the community level. Pharmacists have an obligation to ensure the safe and effective use of all medicines including non-prescription medicines, classified as Pharmacists Only Medicines (Schedule 3), Pharmacy Medicine (Schedule 2) and other non-scheduled products sold in the pharmacy (33, 34). Prior to implementation of strategies to enable greater involvement or to expand the role of pharmacists, it is important to understand the perspectives and attitudes of them towards the current topic of discussion. However, limited studies have explored the practical and professional roles of pharmacists in this context. This study will provide an insight into the

perspectives and views of stakeholders, in this case community pharmacists practising in Western Australia.

Understanding the attitudes and perspectives of breastfeeding women in terms of their experiences, specific breastfeeding-related needs and expectations of pharmacists at a community level will assist in the identification of research gaps and evaluate the potential for role expansion of pharmacists. It will also serve as a guide to the development of university teaching tools, training packages or modules for pharmacists and pharmacy staff, and support programs in community pharmacies, which could ultimately improve health outcomes of breastfeeding women and their infants. Utilising the knowledge, skills and accessibility of community pharmacists as part of a breastfeeding woman's postnatal healthcare team provides an opportunity to promote the safe and effective use of medicines, including herbal medicines and other over-the-counter (OTC) products, as well as supporting breastfeeding in the community. From the profession's perspective, the expanded role of community pharmacists in the provision of breastfeeding and postnatal-related health services may lead to greater recognition of the profession by the public as part of the primary healthcare team and for the provision of assistance.

1.4 Outline of Thesis

This thesis comprises six chapters. **Chapter 1** provides an introduction to the research, a brief background, overall objectives and significance of the study.

Chapter 2 is a review of the relevant literature, and includes an overview of the advantages and significance of breastfeeding, the prevalence and pattern of use of herbal medicines amongst breastfeeding women, the perspectives and attitudes of breastfeeding women and community pharmacists on the topic of study. It also includes the primary aims of the thesis.

Chapter 3 reports on the process and findings of Stage 1 of the research, which involved a population-based survey of women living in Western Australia on the use of herbal medicines during breastfeeding.

Chapter 4 reports on the process and findings of Stage 2 of the research, which explored breastfeeding women's perspectives and attitudes towards the use of herbal galactagogues during breastfeeding and their views on the involvement and potential role of community pharmacists.

Chapter 5 reports on the process and findings of Stage 3 of the research. This stage further explored community pharmacists' perspectives and attitudes towards their role in promoting safe and effective use of herbal and other non-prescription medicines during breastfeeding and supporting breastfeeding in the community. The potential for role expansion and increased involvement of community pharmacists in supporting mothers with infants is also discussed.

Within **Chapters 3, 4 and 5**, an introduction, objectives, research methods, results and discussion specific to the respective stages of the research are provided.

Chapter 6 concludes this thesis by providing a general discussion of the research work and findings, presenting the conclusions arising from the studies and recommendations for future studies arising from this research.

Lastly, the Participant Information Sheets, Consent Forms, Questionnaires, Interview Guides, paper publications arising from this thesis and other relevant documents are provided in the **Appendices**.

Chapter 2
A Review of Literature



Chapter 2 provides an extensive critical review of the literature relevant to the area of the study up until June 2014. This chapter begins with an overview of the advantages and significance of breastfeeding, followed by a review of breastfeeding practices in Australia, including the relevant national breastfeeding-related strategies, and the factors that may affect successful breastfeeding practices. The clinical implication of using medicines in breastfeeding, factors that affect infants' exposure to medicines in breast milk, and the effects of medicines including CMs on the quantity and quality of breast milk are also presented. This is followed by a review of the use of herbal medicines by the general population in Australia and other countries and the use of herbal medicines in lactation, with particular emphasis on herbal galactagogues. As the thesis focuses on the perspectives of breastfeeding women and pharmacists, a review of the perspectives of women and pharmacists towards the use of medicines including CMs in breastfeeding was conducted and presented in this chapter. Finally, the current role of pharmacists in the Australian context is presented.

2.1 Advantages of Breastfeeding

There have been numerous published studies over the years demonstrating the advantages of breastfeeding for newborn infants, postpartum women and society (35). Acknowledging these benefits, the Australian Breastfeeding Association, American Academy of Paediatrics and WHO all recommend exclusive breastfeeding during the first six months after birth (1, 36). In Australia, the percentage of women who choose breastfeeding instead of bottle-feeding immediately postpartum has increased from approximately 48% in the 1970s to over 90% in the recent decade (3). Breastfeeding provides tailored nourishment to the growing needs of infants, offering better nutrition, improved cognitive performance and neurological development (37), enhanced immunity (38), reduced mortality and incidence of Sudden Infant Death Syndrome (SIDS), reduced allergic/hypersensitivity diseases and Type 1 and Type 2 diabetes mellitus (36, 39-42).

Besides health benefits to the breastfed infants, initiation of breastfeeding immediately postpartum has been shown to reduce postpartum bleeding and assist

women in the recovery process after childbirth (43). As suggested by Baghurst et al. (44) and Baker et al. (45), breastfeeding may also accelerate weight loss in women in the postpartum period. Furthermore, breastfeeding also plays a significant role in decreasing post-partum depression, and the incidences of breast and ovarian cancers are lower in women who have breastfed (43, 46-54). A study conducted by Schnatz et al. (55, 56) demonstrated a benefit of breastfeeding in decreasing the risk of postmenopausal osteoporosis. Although lactational amenorrhoea is not considered a reliable contraceptive method, it may prolong the intervals between pregnancies, thereby allowing a longer time for maternal health to improve following birth (43, 57). Besides these noteworthy advantages, mothers and their babies are brought into closer contact through nursing itself (58). Immediate skin-to-skin contact after delivery and the act of breastfeeding may help to develop the mother-infant relationship, at the same time providing women and their breastfed infants with reassurance (59). Breastfeeding has an impact on society by reducing the overall burden on the health system and reducing the costs involved with healthcare and hospitalisations especially during the first year of an infant's life (60). Moreover, formula-feeding an infant would incur additional costs and time, specifically in the purchase and process involved in preparing the formula. In summary, breastfeeding is the most beneficial, economical, efficient, and the only natural way of feeding an infant. With our expanding knowledge in this field and increasing awareness of the advantages of breastfeeding, health professionals from all disciplines should work together to promote breastfeeding (61, 62).

2.2 Breastfeeding in Australia

In the nineteenth century, breastfeeding by a wet nurse and cross-nursing were considered common practices of infant feeding in Australia (63, 64). Although wet nursing and cross-nursing both refer to breastfeeding an infant by a woman other than his or her own mother, their definitions and involvement differ. Wet nursing is defined as breastfeeding an infant by a woman who normally receives payment by her employer to do so and is not a reciprocal practice, whereas cross-nursing refers to the informal practice of sharing breastfeeding between women of social equivalence,

and may sometimes be reciprocal but normally unpaid (65). Nevertheless, these feeding practices became less common in the late twentieth century, when the community perceived these practices unfavourably due to concerns regarding risk of transmitting infections (65, 66). In the 1920s, Nestle's Lactogen[®] was first introduced along with heavy marketing to promote the sales and use of infant formulas (67). Although it was reported that the breastfeeding rate was at its lowest in the 1960s, there were gradual improvements in the rates of breastfeeding during the 1970s when the advantages of breastfeeding became apparent amongst the Australian community (65-67). Lund-Adams and Heywood (68) analysed the results of the first 1989-1990 National Health Survey conducted by the Australian Bureau of Statistics (ABS) and reported that up to 48% of the infants were receiving breast milk at the age of one month. The authors commented that the data collected from this survey were less useful than expected and had suggested improvements for future surveys investigating the breastfeeding rates in Australia (68). Further health surveys on a national scale were in place to continually assess and monitor Australian breastfeeding rates.

2.2.1 Breastfeeding Rates in Australia

Many national surveys have been undertaken to monitor the rates of breastfeeding in Australia. Following the first National Health Survey in 1990, another Australian National Health Survey was conducted in 1995 and found that 81.8% of the respondents who had a child between the ages of zero and three, initiated breastfeeding, 57.1% continued predominant or full breastfeeding at three months, and 18.6% at six months postpartum (69). It was also reported that demographic factors and socio-economic status were influential in determining the rates of breastfeeding and had to be taken into account when implementing strategies to improve the rates of breastfeeding and to reach the national target of having at least 80% of babies receiving any breast milk at the age of six months, by the year 2000 (69, 70). The 1995 and 2001 National Health Surveys showed similar rates of breastfeeding where 86% and 87% of infants between the age of zero to three years had received breast milk at some stage of their lives, respectively (70). The initiation and breastfeeding rates at discharge reported by the two health surveys were also

comparable (70). Although a decline was observed in breastfeeding rates with the number of months postpartum, there seemed to be a slight improvement in the duration of breastfeeding in 2001 when 48% of babies were still receiving any breast milk by the age of six months (70).

In 2004 the Australian Government funded Longitudinal Study of Australian Children showed an outstanding 92% breastfeeding initiation rate, however the rates declined sharply each month postpartum. It was reported that 71% of infants were receiving full breastfeeding at the age of one month, 56% at three months, 46% at four months, and only 14% at six months (1, 2, 71). The breastfeeding initiation rate continued to rise so that by 2011, 96% of infants were reported as being breastfed immediately after birth. At two, four and six months old, 57.8%, 38.6% and 17.6% of infants were exclusively breastfed, respectively, with breast milk the only source of nutrition (72). Nevertheless, it is important to note that a review of the available statistics and surveys showed that interpretation and direct comparison of the breastfeeding rates in Australia throughout the years are challenging due to inconsistent survey methodologies and definitions of breastfeeding used in these studies (1, 72).

2.2.2 Australian Dietary Guidelines

The *Australian Dietary Guidelines* published by the Australian Government provide dietary and nutritional recommendations to promote the overall well-being and health of the Australian population (35). The *Eat for Health: Infant Feeding Guidelines, Information for Health Workers* was published by the NHMRC in 2012, providing advice on the recommended infant feeding practices (35, 73).

The NHMRC acknowledges the advantages of breastfeeding and the need for on-going strategies to promote, support and monitor breastfeeding in the Australian community (1, 73). It has been recommended that all infants should be exclusively breastfed until the age of six months, with breast milk being the only source of nutrition for the infant (73). After this time, solids may be introduced to an infant's diet, however mothers are encouraged to continue breastfeeding their babies until

twelve months of age. If preferred, mothers may also choose to continue breastfeeding in addition to complementary foods beyond this age (73). The recommendation by the NHMRC is in line with advice provided by the Australian Breastfeeding Association, American Academy of Paediatrics and World Health Organization (WHO) (36, 61).

2.2.3 Breastfeeding Strategies in Australia

In addition to clear guidelines and recommendations on best infant feeding practices, many strategies have been implemented in the last twenty years at both government and non-governmental levels to promote breastfeeding in Australia (1, 32). Some examples of these strategies include the Queensland's *Optimal Infant Nutrition: Evidence-based Guidelines 2003-2008*, *Breastfeeding in New South Wales: Promotion, Protection and Support (2006-2012)*, South Australia's *Breastfeeding Program Strategic and Action Plan 2007-2012*, *Australian Breastfeeding Association's Strategic Directions Plan for 2009-2012*, the *National Breastfeeding Strategy (1996-2001)* and the currently running *Australian National Breastfeeding Strategy 2010-2015* (1, 32). The objectives and goals of these state-based and national breastfeeding strategies were very similar. These included promoting and supporting breastfeeding as well as raising the Australian community's awareness of the advantages of breastfeeding. Despite adopting the national strategy, it is worth noting that there has been no specific state-based strategy in WA.

The *National Breastfeeding Strategy (1996-2001)* was an Australian Government funded program aimed to promote breastfeeding in Australia (32). As a result of this strategy, many resources have been created to assist the community in promoting breastfeeding, targeting all relevant stakeholders, from health professionals and hospitals to families (1, 32). Efforts of this strategy included the provision of relevant breastfeeding support training to health professionals involved in the care of Indigenous women and Aboriginal and Torres Strait Islander healthcare workers (1). Continuing education kits were produced and distributed to paediatricians, general practitioners, pharmacists and child health nurses, to assist these health professionals in providing practical and consistent advice to breastfeeding women and their

families in the community (1). A total of 3,500 obstetricians and antenatal educators were sent an education package consisting of a poster, video and an educator's manual, whilst about 50,000 employers in Australia were provided with booklets, flyers and posters with regards to balancing work and breastfeeding at workplaces (1). Efforts were also made to produce and distribute resources targeting families, such as posters, tip cards in different languages, comic booklets and booklets for individuals with low health literacy (1, 32). These resources served to increase the public's awareness of the benefits of breastfeeding, thereby increasing the chances of successful breastfeeding. Despite the above mentioned efforts and actions, this strategy was conducted without a nationally agreed framework, and information on the extent and impact of this strategy on local practices in the different states of Australia were also not available (1).

2.2.4 The Australian National Breastfeeding Strategy 2010-2015

The *Australian National Breastfeeding Strategy 2010-2015* that succeeded the *National Breastfeeding Strategy (1996-2001)* was endorsed by the Australian Health Ministers in March 2009 (1), and states "The Australian National Breastfeeding Strategy provides a framework for priorities and action for all governments to address the protection, promotion, support and monitoring of breastfeeding throughout Australia."(1)

The objective of this strategy is to increase the rates of exclusive breastfeeding in Australia from birth until six months, followed by complementary foods and continued breastfeeding the infant until twelve months of age and beyond (1). The three visions of this national breastfeeding strategy are:

- "Australia is a nation in which breastfeeding is protected, promoted, supported and valued by the whole of society."(1)
- "Breastfeeding is viewed as the biological and social norm for infant and young child feeding."(1)
- "Mothers, families, health professionals and other caregivers are fully informed about the value of breastfeeding."(1)

The principles of the current strategy are categorised as: i) “mother and child”, ii) “ecological context”, iii) “access”, iv) “diversity”, v) “collaborative care”, vi) “continuity of care”, vii) “evidence-based” and viii) “effective governance” (1). Of these eight principles, ‘collaborative care’ and ‘continuity of care’ are most relevant to the research objectives of this thesis. As suggested by the strategy, health professionals should work collaboratively in the provision of holistic care to women who are breastfeeding and their families. Since the endorsement of this strategy, there have been limited studies investigating the role of pharmacists in this context (74). Pharmacists should work collaboratively with other health professionals such as general practitioners, child health nurses and lactation consultants, to meet the healthcare needs of breastfeeding women. Furthermore, it is stated in the strategy that ‘continuity of support at key transition points between birthing and community services and into the broader community is seamless from the perspective of mothers and their families’ (1). The key research question here is what efforts could be made to ensure continuity of care for women during this transition period. Being at the front line of primary healthcare, community pharmacists are easily accessible and have been involved in the provision of continuing care and monitoring of patients living the Australian community (4). Pharmacists are also included in the current national breastfeeding strategy as one of the support staff (1). To date, no study has explored an expanded role for community pharmacists in providing breastfeeding support and continuity of care to women and their families during the postnatal period in the Australian context. Furthermore, there is no clear description of the roles and expectations of pharmacists as breastfeeding support staff in the community in the national documents.

2.3 Factors Affecting Breastfeeding

Despite the rise in breastfeeding initiation rates in the last decades, duration of breastfeeding remains an area to be improved in Australia (1, 72). Many studies have been conducted to investigate the factors affecting breastfeeding practices and reasons of early cessation of breastfeeding (2, 28). With an understanding of the

various factors affecting breastfeeding practices in Australia, the reasons and issues could be addressed to improve the duration of breastfeeding. Hector et al. (28) proposed a conceptual framework summarising the factors affecting breastfeeding practices. As shown in Figure 2.1, these factors may be classified as individual, group or society level factors. This framework may be used in generating hypotheses regarding the factors which affect breastfeeding practice and the interventions necessary to address these factors.

Factors at the individual level consist of attributes of the woman, her infant and the mother-infant relationship. A woman's awareness, experience, knowledge, skills, demographic and social variables can all directly influence her decision to initiate and to continue breastfeeding (3, 28, 66). On the other hand, the group level factors are associated with environmental factors, such as the hospital, community, work and home or family environment, as well as the availability of related health services or public policies (28). Creating a breastfeeding friendly environment for the mother and infant will encourage mothers to breastfeed their infants, provide reassurance and facilitate successful breastfeeding practices. Finally, attributes of the economy, cultural issues, and expectations as well as the perspectives of the society as a whole towards breastfeeding may also be influential towards breastfeeding practices in Australia (28). These factors are acknowledged by the Australian National Breastfeeding Strategy 2010-2015, which will inform subsequent interventions and strategies to promote and support breastfeeding in the Australian community (1).

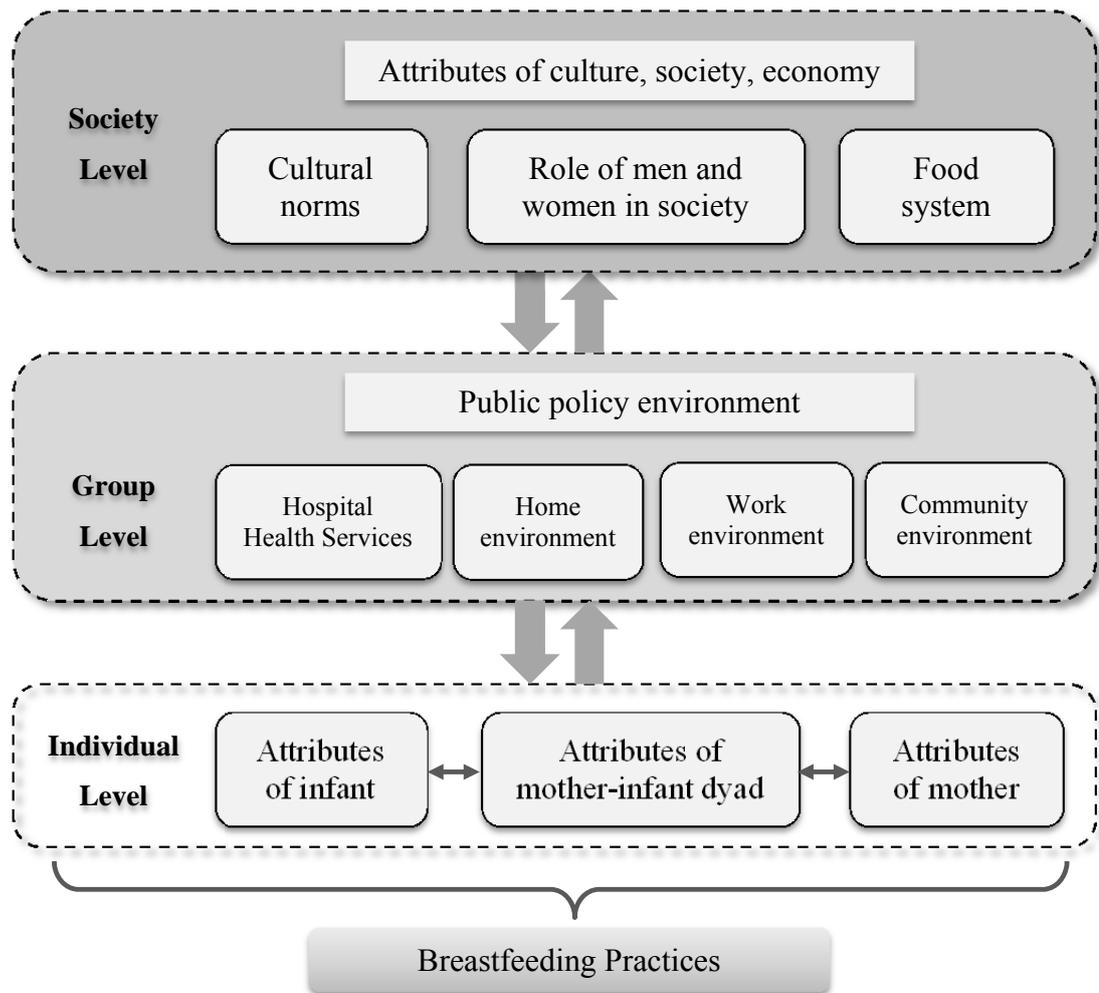


Figure 2.1: Factors affecting breastfeeding practices

2.3.1 Barriers to Successful Breastfeeding

There are many factors which could contribute to a new mother not initiating breastfeeding or early cessation of breastfeeding. Several studies have been conducted in Australia to identify women's reasons for not initiating breastfeeding or ceasing breastfeeding earlier than when is recommended by the Australian Dietary Guidelines (1, 73). The most common reported reason for unsuccessful breastfeeding and early weaning is milk supply that is perceived to be low or insufficient to meet the needs of nursing infants (30, 31, 61, 75-77). The National Health Survey conducted in 2001 by the Australian Bureau of Statistics (70) revealed that the most commonly self-reported reason for discontinuation of breastfeeding was inadequate breast milk supply (30%), followed by the feeling that it was the time to stop (23%),

breastfeeding-related problems, such as cracked nipples (10%), and having to return to work (8%). Women's socioeconomic backgrounds may also influence their breastfeeding practices. Results of a recent study in Chicago, USA, supported the literature in that women from a lower income or socioeconomic group were more likely to discontinue breastfeeding earlier and that the most common reported reasons for discontinuing breastfeeding included: the perception of insufficient milk supply (46%), maternal medical problems (13%), and having to return to school or work (13%) (78). While deficient mammary gland tissue, maternal hormone imbalance, poor breastfeeding technique or latching leading to ineffectual milk removal can all contribute to low supply of milk (30, 61), women's inaccurate perception of insufficient milk supply and the lack of confidence or reassurance have also been shown to affect the duration and success of breastfeeding (58).

According to the Queensland Health *Optimal Infant Nutrition: Evidence-based Guidelines 2003-2008* (79), breastfeeding initiation or duration may be hindered by demographic, physical, psychological, social, clinical and environmental factors. Mothers of younger age or being adolescent, of a low income or socio-economic group, having lower education background, high parity, and women with a linguistically and culturally diverse background are less likely to initiate and/or continue breastfeeding (3, 66, 70, 79). According to the 2001 National Health Survey, the percentage of women aged over 30 years who were breastfeeding their infants at six months old was higher (54%) than women between the ages of 18 and 29 (38%). The same survey also showed that 28% of women aged over 30 years were breastfeeding their babies at 12 months of age, compared with only 14% of those between the age of 18 and 29 years old (70). Women with higher education levels were also more likely to initiate breastfeeding and reported longer duration of breastfeeding compared to women with no higher qualifications since leaving school. This trend seems in line with other developed countries, for example the USA (80-82): a qualitative study was conducted with 17 teenage mothers living in the USA to explore factors contributing to adolescent mothers' breastfeeding practices and decisions (80). The study reported that adolescents' breastfeeding practices were influenced by their skills and knowledge, as well as experience with any previous child or younger siblings, expectations and attitudes towards breastfeeding.

Physical factors which act as barriers to breastfeeding include sore or cracked nipples, multiple births, maternal obesity and diabetes, infant physical or medical issues, and infant prematurity (79). Besides these physical factors, maternal psychological factors such as lack of confidence, maternal depression, and inaccurate perception of inadequate milk supply, as well as negative perspectives and attitudes towards breastfeeding have all been demonstrated to have an unfavourable impact on the success of breastfeeding (79). Mastitis has been reported as a common form of infection experienced by breastfeeding women, which may present a challenge to successful breastfeeding (83). Besides attributes of the mother and infant, healthcare workers' attitudes and knowledge may also affect women's experience and breastfeeding practices. These include the lack of support and adequate discharge plans, as well as poor or wrong diagnosis or management of breastfeeding-related health issues (79). Other reasons reported in studies include inconsistent advice provided by healthcare workers and the lack of community support (84). In order to address the issue of inconsistency and to ensure accurate advice is provided to women, it is important to understand the perspectives, attitudes, knowledge and competence levels of the relevant healthcare workers to identify areas requiring interventions. Western Australia (WA) is one of the Australian states where currently women are discharged from hospitals after giving birth before breastfeeding is established (3). The issue of inadequate community support should also be looked into to provide continuity of care to women, especially during the immediate postpartum period and specifically also if it is the first child.

Other cited barriers to successful breastfeeding include medical issues of the mother or infant, and the need to use medication whilst breastfeeding (43, 62). Several studies have described the risks and potential risks, as well as women's concerns over the use of medications in breastfeeding (85-87). Concerns over infants' safety may lead to unnecessary cessation of breastfeeding or may compromise women's ability to receive appropriate pharmacotherapy in the management of health conditions. Therefore, appropriate resources and education should be available to and be provided to women to increase their awareness of this issue and prompt them to seek the advice of a health professional such as general practitioners or pharmacists in order to make informed decisions. On-going training and continuing professional education are also indispensable to ensure that health professionals, especially those

who have regular contacts with breastfeeding women, are up-to-date with their professional knowledge and latest evidence-based resources.

2.4 Clinical Implication of Medicine Use in Breastfeeding: The dilemma

Considering the recommended duration of breastfeeding, it is likely that women may require medical treatment at some stage whilst breastfeeding for minor ailments, acute conditions or chronic diseases (73). Therefore, the dilemma of medication administration whilst breastfeeding, including medications for breastfeeding-related problems such as mastitis, is not uncommon in clinical practice (88).

Stultz et al. (27) conducted a survey in Pennsylvania, USA, investigating the extent and types of medications used by women during breastfeeding and found that 96% of the survey respondents had used at least one medicine during breastfeeding, either for chronic medical conditions or incidental and acute illnesses. The study also showed that women were significantly more likely to use prescription and non-prescription medicines during breastfeeding as compared to while they were pregnant (27). The Pharmaceutical Society of Australia (PSA) Professional Practice Standard clearly defines non-prescription medicines as “*all medicines available for purchase by the public that do not require a prescription. Non-prescription medicines include, but are not limited to, Pharmacist Only Medicines (S3), Pharmacy Medicines (S2), unscheduled medicines, complementary medicines, and nutritional supplements*” (89). The most commonly used medicines reported by the respondents were multivitamins, paracetamol, non-steroidal anti-inflammatory drugs, nasal decongestants, cough suppressants, antihistamines, progestogens and antibiotics (27). Most of these medicines are available OTC (without a prescription) in Australia except progestogens and antibiotics. These medicines are classified as either non-scheduled (available in pharmacies and supermarkets), Pharmacy Medicines (Schedule 2, available in pharmacies only) or Pharmacist Only Medicines (Schedule 3, available in pharmacies only under supervision of the pharmacist) where pharmacists working in the community pharmacies are responsible and

expected to ensure the safe and effective use of these medicines (34). Nevertheless, the authors suggested that many of the medicines reported by the participants had unknown safety profiles when used in breastfeeding (27).

A study was conducted in Brazil to investigate the effect of drug administration during the postnatal period on breastfeeding recommendations (90). Of the 2,161 participants who provided breastfeeding-related information, the majority (96.2%) reported using medicines during the immediate postpartum period. However, most of these medicines were considered safe and compatible with breastfeeding and did not seem to pose a negative influence on a woman's decision to breastfeed (90). The study concluded that whilst the use of medicines during the postpartum period is common, on-going efforts should be made to review these practices to ensure women are only prescribed and recommended the essential and safe medicines.

Another survey conducted in the Netherlands found that 65.9% of the 549 breastfeeding women who participated in the survey had used medicines. In contrast to the Brazilian study, the need to take medicines appeared to play a vital role in affecting women's perspectives and decisions to initiate or continue breastfeeding. As stated by Schirm et al. (91), "women frequently hesitated to use drugs during breastfeeding, stopped either breastfeeding or drug use to avoid combining the two, took a measure to minimise exposure to the child, did not use any drug because of breastfeeding, or did not breastfeed because of drug use", which may be summarised as the dilemma associated with the use of medicines during breastfeeding. The authors concluded that although using medicines during breastfeeding seemed to be a common practice, many women may be reluctant to do so (91).

Breastfeeding woman with a health issue requiring medical treatment often presents a conundrum for health professionals. Despite the increasing popularity of herbal medicines amongst the general population, a review of the available literature identified that only limited research studies have been conducted to determine the clinical efficacy and safety of herbal medicines and their constituents when used specifically during breastfeeding. Further studies to explore women's attitudes and perspectives towards the use of medicines during breastfeeding are also required to enhance our understanding of women's concerns and the factors affecting their

decision-making process. This will subsequently enable appropriate and practical interventions or strategies to be implemented to promote the safe and effective use of medicines including CMs in breastfeeding, whilst allowing mothers to continue breastfeeding.

2.4.1 Exposure of Breastfed Infants to Medicines via Breast Milk

The main concern for lactating women on medications is the transfer of medicines into breast milk. Medicines circulated in the maternal bloodstream can potentially be transferred into human breast milk, exposing breastfed infants to medicines that may be harmful. The mechanisms which govern the transfer of medicines into human milk include passive diffusion, exocytosis, transcytosis, secretion of milk fat, vesicular transport and via various active drug transporters (39, 92-99). Previous studies have shown that passive diffusion accounts for the transfer of most medicines into human milk, by means of either paracellular or transcellular diffusion (92, 100).

Lactation stage, physicochemical properties of medicines (size, lipophilicity, acid dissociation constant or pKa and ionization), pharmacokinetics of the drug or medicine in the mother and infant (absorption, plasma drug concentration, bioavailability, distribution, metabolism, protein binding, and excretion rates) and characteristics of milk can all influence the extent and rate of medicine transfer (92, 94, 101-103). Furthermore, the dosage forms and routes of administration of medicines may have substantial implications on the pharmacokinetics of the medicine and hence their safety in breastfeeding. Determining risk and extent of exposure as well as predicting effects in infants usually form the basis when considering safety of medicines use by mothers during breastfeeding, which involve consideration of all the above mentioned factors so that the milk-to-plasma ratio (M/P), and absolute and relative infant dose can be calculated (104-106). A summary of medicine transfer from the mother to her infant is provided in Figure 2.2.

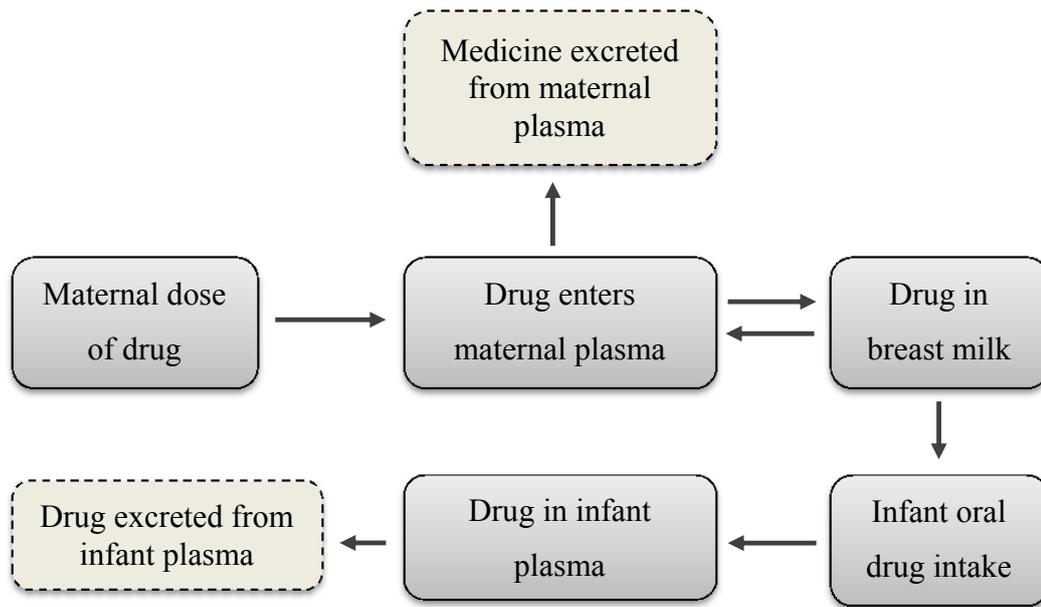


Figure 2.2: Factors influencing drug transfer from the mother to her infant

There have been many studies undertaken to determine the transfer and safety of conventional medication use during breastfeeding, as documented in *Medications and Mothers' Milk* by Thomas Hale (62) and *Drugs in Pregnancy and Lactation* by Briggs et al. (107). The USA Food and Drug Administration (FDA) has classified commonly used medicines into Lactation Categories (L1, L2, L3, L4 and L5) based on their safety in breastfed infants, with L1 representing the safest options (62). Nevertheless, only limited numbers of conventional medicines which are commonly used are assigned a Lactation Category (62). Although most medicines are considered safe during breastfeeding (in L1 and L2 categories), there have been incidents and reports of adverse events in infants after exposure to medicines or substances via breast milk (61, 62). Besides conventional medicines, alcohol, nicotine and caffeine have all been reported to adversely affect the infant's nervous system and mental alertness following maternal consumption (108-112). Certain food components present in human milk have also been reported to cause allergic responses in infants (113, 114).

In contrast to potentially causing harmful effects, infant exposure to xenobiotics via breast milk may sometimes confer therapeutic benefits and positive clinical sequelae in breastfed infants. For instance, studies have demonstrated the transfer and presence of antiviral agents including acyclovir, ganciclovir and zidovudine in the milk following maternal administration (97, 115, 116). Breastfed infants are exposed to viral infections through vertical transmission via breast milk if lactating mothers are infected (97, 117, 118). It has been suggested that maternal administration of aciclovir, ganciclovir or zidovudine reduce viral load in the maternal plasma and lead to the accumulation of these antivirals in the milk, thereby potentially lowering viral transmission rates by decreasing viral titers in the breast milk (97).

As previously mentioned, an authorised prescriber is not required to be involved in the sale and use of CMs, including herbal medicines, in breastfeeding, and their use is not recorded or monitored through the Pharmaceutical Benefits Scheme (PBS) or dispensing software in Australia. These products are often available from stores and supermarkets. Unlike conventional medicines, herbal medicines are mixtures that are chemically rich and complex, often comprising hundreds or more herbal constituents (20, 119). The full profile of chemical constituents in many herbal medicines and their pharmacological actions in the human body remain uncertain, and in some cases, unknown. Furthermore, the profile and distribution of constituents may vary throughout a plant or plant parts. As with all crude natural substances, the profiles of their constituents may vary not just in terms of quantity, but also their quality (20). As a result of this, it is not surprising that the therapeutic effects of herbal medicines may vary between different manufacturers or different batches of materials within the same manufacturer. This explains why herbal medicines, even those with well-evidenced efficacy, may not always demonstrate consistent therapeutic effects. In addition, the types of extraction and other methods of processing the herbal materials adopted by the manufacturers can impact on the herbal medicinal products' chemical composition and subsequent quality of their products. Many herbal medicinal products contain more than one herbal ingredient, and there is not always standardisation of herbal ingredients across the different brands of herbal medicinal products. Hence when considering the safety of a herbal medicine or products containing a combination of herbal ingredients in the context of breastfeeding, one has to consider not just a single, but rather many, components, mostly with limited or

unknown pharmacokinetics, pharmacodynamics and pharmacological information. To add to the complexity of the issue surrounding the use of herbal medicines in breastfeeding, many of these medicines are used traditionally in diverse cultures and are known in varying names in different countries, making direct comparison of herbal medical products challenging (120). As with conventional medicines, the packaging and labelling of all CMs, including the labels of herbal medicinal products, should have accurate and detailed information including a batch number, complete identification of the contents, dosage information and contact number of the manufacturer. Another concern with regard to using herbal medicinal products in breastfeeding is the risk of adulteration and contamination with potentially toxic substances, accidental or intentional species substitution, and there may be differences between the actual and labelled contents (20, 121, 122). Further information on the regulation of CMs in Australia is provided in Section 2.5.3.

The aforementioned factors and the characteristics of herbal medicines present challenges and issues for pharmacovigilance of herbal medicines in the general population, and more so in women who are breastfeeding. The potential and extent of transfer of all or any constituents of a herbal medicine to the infant, as well as its effects on quantity and quality of breast milk, should be taken into account when evaluating the safety and suitability of these medicines in breastfeeding. The health of an infant may be compromised if the infant is exposed to breast milk with potentially harmful or toxic components transferred from the maternal plasma to the breast milk. Hence, it makes sense that when determining the extent and rate of transfer of any medicine including herbal medicines into the breast milk, the physicochemical properties and pharmacokinetics of all the herbal constituents of a particular herbal medicine have to be given thorough consideration. The chemical complexity of herbal medicines makes the process of determining their clinical pharmacokinetics, pharmacodynamics and pharmacology extremely challenging and at times problematic, especially when they are used during breastfeeding.

2.4.2 Effect on Quantity of Human Breast Milk

Another concern is the effect of medication administration on the quantity and quality of breast milk produced, which may then impact on the exclusivity, duration and hence success of breastfeeding. Drugs that have been reported to compromise production of milk include cabergoline (123), bromocriptine (124), ergotamine (62), pseudoephedrine (125) and oestrogens (62, 126).

Cabergoline, bromocriptine and ergotamine have all been used in the management of hyperprolactinaemia due to their effects in terms of suppressing lactation (127). Interference with blood flow to the breasts and inhibition of prolactin secretion are two common mechanisms contributing to the decrease in breast milk production (127). Many studies have investigated the effects of pseudoephedrine use in breastfeeding (125, 128, 129). Aljazaf et al. (125) studied the effects of pseudoephedrine on human breast milk production (by test weighing the infants before and after each feed) in eight women and found that a single dose of 60 mg pseudoephedrine significantly decreased milk production by 24% from 784 to 623 mL per day and that there was a moderate reduction in the mean plasma prolactin level of 13.5% (125). In the same study, the calculated infant dose via exposure of the drug in the breast milk based on four-time dosing schedule of 60mg pseudoephedrine was less than 10% (4.3%), suggesting untoward effects on the infants' safety were unlikely (125). Despite the absence of evidence to indicate safety concerns in the infants, the results suggest that pseudoephedrine should be used with caution in lactating women to avoid unfavourable effects on their breastfeeding performance. Oral contraceptives containing oestrogen should also be avoided especially during the immediate postpartum period due to the risk of suppressing breast milk production (126, 127). There has also been speculation about diuretics decreasing breast milk supply (130). Isolated case reports published in the late 1900s suggested possible suppression of milk supply by oral diuretics such as spironolactone and hydrochlorothiazide, however no further research has been conducted to confirm these effects (131, 132).

Besides conventional medications, some CMs have also been associated with reduction of milk supply. It has been suggested that pyridoxine (vitamin B6), when

taken in excessive amounts, may suppress milk production (133). However, Andon et al. (134) demonstrated that neither nutritionally relevant nor therapeutic doses of pyridoxine suppressed plasma prolactin levels and did not appear to adversely affect lactation. Peppermint, sage, camphor, bilberry, and parsley have been used traditionally for weaning, however no studies have been published to support their clinical use (61, 133). Nevertheless, until more data are available, use of these herbal materials in large quantities should be avoided in lactating women who wish to continue breastfeeding or increase their milk supply.

2.4.3 Effect on Quality of Human Breast Milk

Maternal diet may affect the quality of milk by altering its taste, and hence may affect infant-feeding behaviour in breastfeeding (135). Infants may be sensitive to changes in the taste of breast milk (127, 136). For example, the use of aromatic substances like garlic during breastfeeding and its effect on the taste of milk remains controversial. While some studies suggested that maternal use of garlic may alter the taste of milk and render infant refusal to feed, another study has shown that garlic-flavoured milk causes infants to nurse longer, enhancing the breastfeeding performance (137).

2.4.4 Perspectives of Women towards Medicines Use in Breastfeeding

‘Perspective’ in the context of this study is defined as “a particular attitude towards or way of regarding something; a point of view” (138), whereas ‘attitude’ is further defined as “a settled way of thinking or feeling about something” (139).

A study published in 1990 conducted by Matheson et al. (140) in 885 participants found that women’s ‘doubts’ concerning the use of medicines in breastfeeding were associated with the number of medicines taken. It was also shown in a separate study published in 1993 that up to one in five women who were prescribed antibiotics either discontinued breastfeeding unnecessarily or decided not to initiate antibiotic therapy at all, despite being advised and reassured by their healthcare providers (141). Women’s concerns over breastfed infants’ safety and the

compatibility of medicine use with breastfeeding were also demonstrated in a Dutch survey published in 2004 (91) where 30% of women hesitated over the use of medicines while breastfeeding: twelve percent of the 549 survey respondents were not breastfeeding their infants due to the need to use medicines, whilst one in ten either stopped using the medicines or discontinued breastfeeding (91).

Despite the evidence cited above regarding antibiotic use, women who need to use medicines during breastfeeding often rely on their health professionals for accurate advice and recommendations (87). Nevertheless, a study by Jones and Brown (142) in 2000 which surveyed a group of 820 breastfeeding women identified that there was only a 28% satisfaction rate with the advice provided by their general practitioners and pharmacists. Six percent commented that conflicting advice was received and only approximately one in ten women who had purchased OTC medicines in the pharmacy was asked if she was breastfeeding by the pharmacy staff (88, 142).

Studies have shown that women who suffer from postnatal depression may be hesitant to commence treatment with antidepressants during breastfeeding (143, 144). In line with reasons expressed by other people who suffer from depression (145-147), it has been reported that women with postnatal depression, whether breastfeeding or not, are concerned about issues with side effects, dependency and stigma attached to the use of antidepressants (143). In addition to these findings, women who are breastfeeding have also expressed concerns over the use of antidepressants during breastfeeding. Women's negative perceptions towards the use of antidepressants during breastfeeding may contribute to compliance issues and subsequently compromise women's health outcomes (85, 143, 148). Poorly managed depression in a breastfeeding woman may also impact on her infant's wellbeing. Nevertheless, it was demonstrated in an in-depth qualitative study by Turner et al. (143) that women's perceptions of antidepressant use in breastfeeding may improve with appropriate counselling and advice from health professionals. Encouragement from their family and friends, as well as a positive experience with previous use of antidepressants may also assist in promoting treatment adherence and optimisation of therapy.

Most research has focused on exploring the perspectives of women towards the use of conventional medicines in breastfeeding, such as antidepressants and analgesics (87, 143). As discussed earlier, previous studies have shown that women may be reluctant to commence conventional pharmacotherapy whilst breastfeeding due to safety concerns and their desire to breastfeed (87, 91). As a consequence, some women may choose to self-medicate with OTC medicines or turn to natural remedies due to their perceived safety profile (7, 27, 87). However, the perspective of breastfeeding women towards the use of other OTC medicines and complementary and alternative therapies, specifically herbal medicines, during breastfeeding, is an area that has not been well studied.

2.4.5 Perspectives and Attitudes of Health Professionals towards Use of Medicines during Lactation

The attitudes and knowledge of health professionals often affect their decision-making, ultimately influencing the health outcomes of their patients. Therefore, it is important to explore and understand the perspectives of health professionals towards the use of medicines, including herbal medicines, when breastfeeding. This is especially important for those who have regular contacts with women and their families during the postpartum period, to promote the safe and effective use of medicines during breastfeeding.

Healthcare professionals and workers who have frequent contacts with breastfeeding women in the community include general practitioners (GPs), pharmacists, child health nurses and lactation consultants (87, 149). Although child health nurses play a valuable role in assisting women during the postpartum period, no published studies exist which have explored their perspectives towards the use of medicines in breastfeeding (87). On the other hand, many studies have been conducted over recent years to explore GPs' perspectives towards prescribing for breastfeeding women (83, 87, 88, 150-154).

In a study conducted by Jayawickrama et al. (83) in Melbourne, Australia, 76% of the 335 GPs who participated in the survey reported on their experiences of making

clinical decisions about prescribing for lactating women. Approximately half of the breastfeeding women who presented themselves to the GPs in this study had infections, with mastitis being the most common form of infection (24%). Examples of other infections included endometritis, tonsillitis, upper respiratory tract and urinary tract infections. Depressive disorders and requests to use analgesics were also common scenarios triggering women to present themselves to GPs (83). In this study, “complexity of managing risk” emerged as the over-arching theme, as participants described the uncertainty associated with making clinical recommendations and prescribing for the breastfeeding woman (83). Participants reported having to involve other health professionals such as specialists during the process of decision-making for more complex medical issues, as in postnatal depression. The availability of reliable and consistent information resources was also deemed indispensable to assist them in making recommendations as to what medicines should be used or avoided in lactation. In this study, the issue with pharmacists being over-conservative was also raised by some participants (83). The authors concluded that GPs indicated that prescribing during lactation was a complex and time-consuming task, often having to do research and weigh the risk and benefit on a case-by-case basis. It was also reported that in the absence of evidence-based information, GPs sometimes suggest unnecessary discontinuation of breastfeeding (83).

Jones and Brown (142) surveyed 590 GPs and 641 community pharmacists in the UK to investigate their attitudes and knowledge towards the use of medicines in breastfeeding, as well as their perceptions of the significance of breastfeeding. The majority of the participants in both groups agreed with the statement “breastfeeding is a health promotion issue” (142). Over 90% of the general practitioners would routinely ask questions to ascertain if women were breastfeeding if they were accompanied by a baby; however this was only the case for half of the pharmacists in this study. A few pharmacists (n = 9; 1.4%) expected women to initiate queries relating to the appropriateness of using medicines in breastfeeding. The frequency of queries received by pharmacists ranged from weekly to a monthly basis, with questions commonly concerning the safety of using medicines, such as cough and cold treatments, laxatives, oral contraceptives and sedatives during lactation. Both

groups of health professionals believed that they should provide information about the potential adverse effects should the woman continue to breastfeed (142).

Another study conducted by Long and Montouris (152) surveyed 202 attendees of the American College of Physicians' annual meeting in 2003, who were mostly (92%) physicians. Participants were asked their views and knowledge on the use of antiepileptic medications while breastfeeding. Less than half (47%) of the survey respondents provided the correct response ('true') to the statement "most women taking antiepileptic drugs can safely breastfeed" (152). The lack of physicians' knowledge in this area may lead to unnecessary recommendations to cease breastfeeding. The study also demonstrated that there was a need to provide further training especially to those health professionals who are involved in making clinical decisions about medications to be used by nursing mothers.

A few studies have also explored pharmacists' knowledge and perspectives on the use of conventional medicines in breastfeeding. Long and Montouris (152) conducted a study which involved surveying 109 registered pharmacists in Ohio. Of these 109 participants, 79% were practising in community pharmacies. Interestingly, only 34% of the pharmacists who took part in the survey responded correctly to the statement "most women taking antiepileptic drugs can safely breastfeed" (155). In a separate study published in 2009, 36 community pharmacists in Rhode Island, USA, were supplied with a reference text published by Hale, entitled *Medication and Mothers Milk* (156) and were asked to participate in a survey. Amongst the 33 pharmacists who responded to the survey, 45% said they received on average breastfeeding and medicines-related queries on a daily to weekly basis in their practice. Despite the majority of the participants feeling comfortable providing advice to nursing mothers, only 42% of them regularly asked women about the use of medications during breastfeeding. In line with the findings of the study previously conducted by Jones and Brown in the UK (142), about 60% of the pharmacists in this study thought that breastfeeding mothers should self-disclose to pharmacists if they were breastfeeding.

In the most recent study published, De Ponti et al. (5) in 2013, surveyed 176 Australian community pharmacists to investigate their perspectives on the use of

medicines in breastfeeding, using a structured questionnaire. The majority of the pharmacists (92%) agreed that they felt confident in counselling and supplying medicines to breastfeeding women. The participants' knowledge was determined based on five medications, namely ibuprofen, paracetamol, metronidazole, lithium and St John's wort (5). Ninety-four percent of the pharmacists were aware that paracetamol is safe to be used during breastfeeding. Only 8% and 37% of the participants were aware that metronidazole and ibuprofen are both compatible with breastfeeding, respectively. Participants were also conservative about the use of lithium in breastfeeding, with 43% raising concerns and 42% needing to look up information. The study further found that most of the participants (92%) had concerns or a lack of knowledge regarding the use of St John's wort in breastfeeding, despite this herbal medicine being considered as "relatively compatible" with breastfeeding, according to the authors (5). This recommendation was based on a separate observational, prospective cohort study conducted by Lee et al. (157) on 33 breastfeeding women receiving St John's wort in Group 1, who were compared with 101 disease-matched controls in Group 2 and 33 age- and parity-matched controls with no disease in Group 3. The study found no changes in breast milk production and infant weight gain in the first 12 months of life. There were only two cases of colic, two cases of drowsiness and one case of lethargy in Group 1, as compared to one case of colic each in Groups 2 ($p < 0.01$) and 3 ($p = 0.20$). Of the five cases reported from Group 1, three sought advice from their doctors but specific medical treatment was not needed (157). However, important information such as the details and descriptions of the St John's wort products used were not provided. Another study which involved analysis of four breast milk samples (both fore and hind milk) from one woman who took 300 mg of St John's wort extract (Jarsin[®]) three times daily found only low concentrations of hyperforin in the samples, and there was no reported side effects in the mother or infant (158). Although limited in numbers, the available studies did not identify serious adverse outcomes. Further research is warranted to investigate the pharmacokinetics of the constituents of this herbal medicine in the infants' and mothers' plasma and breast milk, to confirm the safety and justify the use of this herbal medicine in breastfeeding.

In the absence of evidence-based information from Randomised Controlled Trials (RCT) informing the safety aspects of medicines when used during breastfeeding,

many health professionals face a challenge when needing to provide advice to women and their families. A review article published in 2011 by Hussainy and Dermele (87) on the practices, knowledge and attitudes of health professionals (endocrinologists, GPs and pharmacists), towards the use of medications in breastfeeding. It was commented that despite health professionals possessing positive attitudes towards this topic, many showed poor knowledge in this field. To assist health professionals in making clinical recommendations to breastfeeding women, there is a need to review and update the available resources, as well as incorporating recent evidence and ensuring consistency between all these references.

2.5 Use of CMs in the General Population

The use of CMs is increasingly common worldwide. Over the years, much research has been undertaken to investigate the prevalence and pattern of use of these medicines in many countries (7, 159, 160). Despite the lack of evidence-based information confirming the efficacy of many CMs and alternative therapies in treating specific medical conditions, their use may potentially lead to other beneficial patient-centred health outcomes (161-163). Besides perceived physical health improvements, participants in a study conducted by Greene et al. (163) in Massachusetts and North Carolina, USA, described the favourable psychological benefits associated with the use of CAM, though the findings were related to CAM in the broader context, and not specific to CMs or herbal medicines. Although not directly related to their proposed indications, the authors reported that CAM use had facilitated users' positive changes in their health behaviours, empowering them to lead a healthy lifestyle, including improved diets, smoking cessation and increased levels of daily exercise (163). Many users of CAM believed such treatments assisted in coping with stress and anxiety, and provided them with a sense of empowerment and increased hope (161, 163). Similar findings were also found specifically with the use of herbal galactagogues amongst a group of breastfeeding women (30).

2.5.1 Trends in Australia

Results of surveys conducted in Australia have agreed with the findings from other countries (7, 25, 160, 164-167), with a prevalence study conducted in 2005 by Xue et al. (7) showing 68.9% of the participants recorded use of one or more forms of CAM in the previous 12 months. In addition to herbal medicines, CAM in this context also referred to other forms of alternative therapies such as general clinical nutrition, massage therapy and meditation. The study involved a total of 1067 adult participants from all states and territories of Australia (7). Women between the ages of 18 and 34, well-educated, employed with higher income levels and were covered by private health insurance were more likely to use CAM (7). Forty-four percent of the survey respondents reported visiting CAM practitioners, and the adult Australians were estimated to visit CAM practitioners 69.2 million times over a one year period (7). The authors commented that this frequency was not only comparable, but almost identical to the number of times conventional medical practitioners were visited (69.3 million), which further confirmed the popularity of CAM amongst the general adult Australian population (7). Despite the common use, regular users did not always inform their medical practitioners of their decision to use CAM. Approximately 23% of the survey respondents had used Western and Chinese herbal medicines in the previous 12 months, with 16.3% and 7% specifically using Western and Chinese herbal medicines respectively. Western herbal medicine was amongst the top four most popular forms of CAM, after clinical nutrition, Western massage therapy and meditation. Amongst the users of Western and Chinese herbal medicines, 29.1% and 32.9% visited a practitioner of that type of CMs in the previous 12 months, respectively. Females were also more likely to use Western herbal medicines than their male counterparts ($p < 0.001$).

A separate study investigated the prevalence and pattern of use of CAM in South Australia (160). This 2004 publication reported that 52.2% of the population in that state used CAM, with 20.6% specifically using herbal medicines. In line with the study mentioned above, this survey revealed that women between the ages of 25 and 34, with higher education and income levels showed greater use of CAM (160). There were also some data specific to the use of herbal medicines. The use of herbal medicine has risen from 9.9% in 1993 to 20.6% in 2004. The prevalence of herbal

medicine use was higher in 2004 than in 1993 and 2000 for both men and women, with women's use rising from 16.6% in 2000 to 24.9% in 2004 ($p < 0.01$) (160). In 2007, Zhang et al. (25) conducted a cross-sectional population-based survey of 2526 participants living in Victoria, and reported that approximately one in four survey respondents had used one or more herbs for medicinal purposes in the previous 12 months. The 24 most commonly used herbal medicines reported in the study were aloe vera, garlic, green tea, chamomile, echinacea, ginger, cranberry, peppermint, ginseng, ginkgo biloba, evening primrose, dandelion, valerian, liquorice, St John's wort, slippery elm, milk thistle, dong quai, black cohosh, bilberry, senna, hawthorn, saw palmetto and chasteberry (25). The majority of the survey respondents believed that their herbal medicine(s) of choice was effective and helpful (25).

A nationally representative cross-sectional postal survey conducted in Australia between June 2009 and February 2010 involving 1608 adults aged 50 years and older (response rate = 37.3%) found that 46.3% of respondents had used one or more complementary medicines in the previous 24 hours (168). The most commonly used complementary medicines reported in this study were omega-3 marine triglycerides such as fish oils (25.2%), glucosamine (16.8%), multivitamins and minerals (14.6%), calcium (11.6%) and vitamin D (10.8%). However, the prevalence of herbal medicines use specifically, was not reported. Women in this study used more complementary medicines in the previous 24 hours when compared to men ($p < 0.001$). Pharmacies were reported to be the main source of complementary medicines (53.2%), followed by health food shops (20.2%), supermarkets (17.6%), and the internet (2.7%). The study also showed that CMs were most likely to be recommended by family and friends ($p < 0.001$) or the media ($p < 0.001$), when compared to conventional medicines (168).

2.5.2 Trends in Other Countries

Research undertaken in the last couple of decades in many countries including the USA (169, 170), Canada (171-173), Brazil (174), the UK (175, 176) and the United Arab Emirates (177) have all demonstrated a substantial increase in the use of CAM, in particular CMs amongst the general population.

Herbal medicines are widely used in the USA (178, 179). A nationally representative cross-sectional study which involved telephone surveys demonstrated that the prevalence of herbal medicine use amongst the USA population increased significantly from 3% in 1990 to over 12% in 1997 ($p \leq 0.001$) (169). In 2001, a population-based survey was conducted in Michigan and found that the prevalence of herbal medicines use was 21% (180). In the 2002 National Health Interview Survey conducted in the USA, approximately 60% of the 31,044 adults who participated in the survey conducted through computer-assisted personal interviews had reported using some form of complementary and alternative therapies in the previous 12 months (181), of whom, 18.9% were specifically using natural or herbal products. Another population-based telephone survey conducted in Michigan, USA, in 2001 and involving 3764 adults found that 20.5% of respondents (95% CI 19.1-21.9) had used herbal supplements in the previous year (180).

Many previous studies have demonstrated that herbal medicines use is popular amongst consumers or patients living in the UK (182, 183). Posadzki et al. (183) conducted a systematic review of studies and surveys published between 2000 and 2011 which investigated the prevalence of herbal medicine use in the UK. The systematic review found that the prevalence of herbal medicines use amongst the general population varied, ranging from 4.8% to 92.4% (183). There was an average of 15.8% incidence of reported adverse effects experienced by users of herbal medicines. It was also reported that the majority of the herbal medicines users did not inform their conventional health professionals such as doctors about their decisions to use herbal preparations (183).

A cross-sectional survey published in 2008 by AlBraik et al. (177) showed that 76% of the 330 survey respondents in Abu Dhabi, United Arab Emirate, had used at least one herbal product. The study reported a total of 65 different herbal medicines being used in the treatment of 48 medical conditions. Adverse effects were experienced by 27 of the participants (8.2%), whilst the majority believed that herbal medicines were generally safe (177). It was also demonstrated that friends and family played an important role in influencing an individual's decision to use herbal medicines (177).

CAM and CMs are used by individuals worldwide, including in specific population types such as in the elderly, and are used for a myriad of conditions including in major chronic diseases. The use of herbal medicines, a type of CMs, has been reported to be increasingly common amongst the elderly population, with the two most commonly used being ginkgo and garlic (184). Other commonly used herbal medicines included chamomile, ginseng, aloe vera, spearmint and ginger (184). Herbal medicines have also gained their popularity amongst non-elderly patients with chronic diseases or conditions (185). A systematic review conducted by Liwa et al. (186) revealed that 25% to 65% of hypertensive patients living in the sub-Saharan Africa were using herbal medicines, and that herbal medicines were the most common form of CMs used.

The use of CAM is also common amongst people with diabetes mellitus (187-193). For example, a recent study conducted in Malaysia showed up to 62.5% of people with type 2 diabetes were frequent users of CAM (193). Amongst the types of CAM reported in this study, biological-based therapies such as herbal medicines were the most commonly used. Bitter melon (*Momordica charantia*) (30.4%), Misai Kucing (*Orthosiphon stamineus benth*) (24.2%), garlic (*Allium sativum*) (13.3%) and Sabah snake grass (*Clinacanthus nutans lindau*) (7.9%) were amongst the most commonly reported herbs used traditionally for their perceived medicinal benefits (193). The study also reported the use of other CAM therapies, including reflexology, Ayurveda, acupuncture, Reiki, massage, yoga and tai chi, albeit to a lesser extent than herbal medicines. Garlic, fenugreek, and bitter melon are also frequently used in India to aid the management of diabetes mellitus (194). According to Nahas and Moher, cinnamon (*Cinnamomum verum*) is also used in Canada and the USA for this purpose (195).

A review of the literature has revealed that the use of herbal medicines is likewise common amongst patients with other chronic health conditions, for example cancer, human immunodeficiency virus, rheumatological diseases, asthma and chronic renal disease (159, 196, 197). It was evident that the choice of herbal medicine is heavily influenced by tradition in the varying cultures, and the availability of these herbal medicines in different countries.

2.5.3 Regulation of Complementary Medicines in Australia

The TGA is responsible for the regulation of all medicines including CMs, as well as medical devices available in Australia (198). The regulation of complementary medicines in Australia is similar to the approach followed by the FDA in the USA (199).

In Australia, a two-tiered system is in place for the classification of all medicines. Depending on the associated risks, the TGA classifies medicines into either the ‘higher risk’ or ‘lower risk’ categories (198). Medicines classified as ‘higher risk’ are registered on the *Australian Register of Therapeutic Goods* (ARTG) and are subjected to stringent assessments evaluating their efficacy, safety and quality (200). All registered medicines are issued with a unique AUST R code, and include all prescription medicines (Schedules 4 and 8) and most of the OTC conventional medicines available from community pharmacies (mostly Schedule 2 or Schedule 3), for example treatments for cold and flu or cough, some analgesics and treatment for other primary healthcare conditions or minor ailments (34, 200).

On the other hand, medicines or products classified as ‘lower risk’ are listed on the ARTG by the TGA and are issued with AUST L numbers (198). These include only some of the OTC medicines, but the majority of the CMs including herbal medicines, vitamins and supplements (200). These medicines are subjected to less rigorous assessments as compared to registered medicines, and the products are only evaluated for safety and quality, but not their efficacy (200). This forms the basis of the argument that regulation concerning the use and marketing of herbal medicines should be strengthened, as these medicines may still be associated with medicine interactions and that adverse effects have also been reported (25, 201, 202).

Although most CMs are only listed on the ARTG, it is worth noting that there have been significant reforms by the TGA in the last two years (203). Following consultations with the public and key stakeholders, the reform aims to strengthen the regulation of CMs in Australia (203). A series of activities has been undertaken to improve the confidence of the Australian community towards the quality and safety of CMs. Recent efforts included updates and revision of the *Australian Regulatory*

Guidelines for Complementary Medicines (ARGCM) and enhanced post-marketing surveillance (203). Manufacturers and sponsors of CMs have also been advised of their obligations to hold evidence to support the marketed indications of their products, along with an updated electronic or online application system for these medicines (203). Nevertheless, this reform is only at its early stages, hence further efforts and on-going monitoring are required in the regulation of CMs to benefit the Australian community.

The marketing and supply of CMs is another aspect of the regulation of CM products in Australia that is relevant to the context of this research. The TGA through the Therapeutic Goods Advertising Code (TGAC) clearly indicates that the marketing of all therapeutic goods should not be against the “quality use of medicines” principles, and states that “the marketing and advertising of therapeutic goods, including CMs, is to be conducted in a manner that promotes the quality use of the product, is socially responsible and does not mislead or deceive the consumer” (16). Classified as AUST L medicines in Australia, the advertising and marketing of CMs are currently co-regulated between the TGAC, the Australian Self-Medication Industry and the Complementary Healthcare Council of Australia (CHC) (16, 204, 205).

As opposed to AUST R medicines, products classified as AUST L are subjected to less stringent advertising control. For example, direct-to-consumer advertising of all medicines classified as Schedule 3 (except those listed in Appendix H of the SUSMP), Schedule 4 and Schedule 8 (classed as AUST R) is not permitted (16, 206). However, as long as they comply with the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations 1990 as well as the requirements specified by the TGAC and CHC, direct-to-consumer advertising of CM products is permitted. Despite the lack of efficacy data for many CMs, the widespread advertising of these medicines through mainstream media for example television, radio stations, newspapers and magazines, may have an impact on the public’s perception of the safety and efficacy of these products.

2.5.4 Attitudes and Perspectives of Pharmacists towards CMs

In Australia, community pharmacies are one of the major suppliers of CMs including herbal medicines and nutritional supplements (6, 7, 207). Therefore, pharmacists practising in community pharmacies have regular contact with frequent users of these medicines. Studies have shown that the public perceive pharmacists as a reliable source of health and medicine-related information and most consumers in a study conducted by Tran et al. (208) were satisfied with pharmacists being CM providers. CMs stocked in pharmacies were also perceived to be superior in safety and efficacy compared to those sold in other places such as health food outlets and supermarkets (208).

A study published in 2010 by Braun et al. (207) investigated the attitudes and perceptions of 1,121 Australian pharmacy clients towards the use of CMs and their expectations of community pharmacists. The majority of the survey respondents expected pharmacists to provide accurate information about the safety aspects of CMs, whilst 90% believed that pharmacists should check for any interactions or contraindications with the use of these products as part of their routine practice. Over 90% of the pharmacy clients who participated in the survey expected pharmacists to be knowledgeable in the area of CMs (207). It is therefore important to explore community pharmacists' knowledge, attitude and perspectives towards these medicines to improve pharmacy practice (if required) and to meet the expectations of the public (209, 210).

In 2011 Culverhouse and Wohlmuth (201) conducted a qualitative study in Queensland, Australia, which involved 12 practising Australian community pharmacists, to explore the factors influencing their recommendation of CMs. The authors reported that "a desire to provide a health benefit to the customer" was the primary motivation of pharmacists recommending CMs (201). The pharmacists' knowledge, experience, clients' feedback and the presence of pharmacy protocols were also reported as factors influencing pharmacists' recommendations. Pharmacists who participated in the study raised their concerns over the lack of information or evidence supporting the efficacy and safety of many CM products.

The lack of clear benefits to their clients and time constraints were also seen as barriers to extended recommendation of CMs. This study has demonstrated that pharmacists acknowledge the common use of CMs in Australia, and that education on these medicines should be integrated into the pharmacy curriculum (201). Pharmacists' desire for greater CAM education in general, including CMs and other complementary therapies, was also demonstrated in previous studies published by Tiralongo and Wallis (211, 212) in 2008, who reported positive improvements with pharmacy students' knowledge as a result of integrating CAM education and training into the curriculum of the pharmacy degree. Nevertheless, students who participated in the study demonstrated greater interest in CMs than other complementary therapies.

Another survey was conducted in 2010 to explore the perspectives and information-seeking behaviour of 80 pharmacists practising in community pharmacies located in the rural regions of Victoria, Australia (202). Despite the authors using the terms "CAM" or "CAMs", the study only specifically investigated participants' views towards CMs and not other complementary therapies. Despite agreeing that they should routinely ask clients or patients if they were taking CMs, many pharmacists reported a lack of confidence in doing so most likely stemming from the low self-perceived knowledge level. It was also suggested that the lack of understanding and knowledge concerning CMs affected pharmacists' attitudes and perception of uncertainty. Participants in this study thought that CMs most in need of information were co-enzyme Q10, glucosamine, fish oil, ginkgo, echinacea, probiotics and saw palmetto. Pharmacists used a variety of resources and references in their daily practice, including CM textbooks and internet websites (202). Similar to studies conducted in the urban areas of Australia, pharmacists working in the rural community pharmacies expressed their desire for more evidence-based information about CMs and were willing to undertake further training opportunities (202).

Pharmacists practising in community pharmacies may have different exposure and experiences to pharmacists working in the hospital environment. In 2008 Brown et al. (213) investigated 81 hospital pharmacists' knowledge, attitude and information-seeking behaviour towards the use of CMs. The study revealed that whilst hospital pharmacists sought information about CMs on a monthly basis, many had limited

knowledge and were having difficulties accessing reliable information. A separate survey of 107 hospital pharmacists revealed that many were lacking in confidence and CAM-related knowledge, which included CMs and other alternative therapies (214). Eighty-seven percent of the survey respondents perceived CMs to be unsafe and thought that monitoring of the use of these medicines should be in place. Nevertheless, only 55% of pharmacists routinely asked if their patients were using any CMs and alternative therapies. It was identified that pharmacists were cautious with the use of CAM and related practices and had raised their concerns regarding the cost, effectiveness, safety and regulatory aspects of these products (214).

Although many published studies have investigated the perspectives and attitudes of pharmacists towards the use of CAM, and more specifically CMs in Australia, there is currently limited information reported on their perspectives towards the use of herbal medicines specifically in women during breastfeeding.

2.6 Use of Herbal Medicines in Lactation

Many women are self-medicating with various CMs and supplements, most commonly as a result of recommendations by friends or family, or as prescribed by their healthcare professionals (26, 215-219). A study published by Nordeng et al. (215) in 2004 surveyed a group of 400 postpartum Norwegian women which showed that 36% of the survey respondents had used at least one herbal medicine during pregnancy, with family and friends being the most common sources of recommendations. Amongst the commonly reported herbal medicines were echinacea, ginger, cranberry, chamomile and some iron-rich herbal ingredients (215). An interesting trend was observed in that there was an increase in the use of these medicines from the first through to the third trimester (215). The authors reported that 39% of the users were using herbal medicines that were either considered potentially harmful or that there was insufficient information to indicate their safety in pregnancy (215). In the same study, 43.3% of the women who had breastfed in the past reported the use of herbal galactagogues during breastfeeding (215).

Forster et al. (26) surveyed 588 pregnant women in Australia in 2003 and found that 36% of women had used one or more herbal medicines during pregnancy. The three most commonly used herbal medicines were raspberry leaf, ginger and chamomile (26). Stultz et al. (27) suggested that women use more prescription and non-prescription medications postpartum during lactation compared to pregnancy.

Another study published in 2010 investigated the prevalence and pattern of use of herbal remedies in Indiana and reported that 342 (74.2%) of the 461 Hispanic women who participated in the survey were users of herbal remedies (219). Of the 342 female users, 30.4% were either breastfeeding at the time of the survey or had breastfed in the past, with 14.8% indicating they commenced using herbal remedies when they initiated breastfeeding (219). The majority of the female participants were aware of the potential risks associated with the use of herbal medicines while breastfeeding and 36.6% of women who breastfed reported ceasing the use of these remedies when they initiated breastfeeding (219). In this study, the most commonly used herbal medicines for their medicinal purposes were chamomile, cinnamon, garlic, lemon, onion, grass syrup and oregano (219). In line with other studies, extended family members were the most common source of recommendation for the use of herbal remedies whilst breastfeeding (27, 215, 219).

A study published in 2012 by Lee et al. (24) reviewed the use of nutritional supplements amongst breastfeeding women in Perth, Western Australia. The review focused on the use of nutritional supplements, particularly folic acid, iron, iodine and calcium. It was reported that supplementation in the form of multivitamins or multiminerals were most frequently used as dietary supplements during breastfeeding (24). Approximately three-quarters (78%) of the 587 participants reported using folic acid and 21% used iron supplements during pregnancy, and between 30% to 40% of these women continued to take these supplements during the postpartum period (24). Although this study aimed to investigate the use of nutritional supplements as previously mentioned, a few mothers self-reported the use of herbal supplements for example garlic and ginger whilst breastfeeding (24). However, the purposes of using these herbal medicines were not recorded. Nevertheless, the authors concluded that further studies are warranted to investigate and document the use of these supplements during breastfeeding in women from different countries and of different

cultural backgrounds (24). Current herbal reference texts often suggest avoidance of certain herbal products based on what is known about the toxicity of the herbal medicine, case reports, or when there are little or no data available to support their use (61, 62, 107, 220-223). Such recommendations do not take into account the extent of transfer of herbal constituents into human breast milk. It will be useful to find out whether they are transferred into the breast milk, to examine any potential benefits or ill effects, at the same time provide scientific evidence to ensure the safety of breastfed infants while allowing mothers to receive appropriate therapy of their choice. Despite the increasing popularity of herbal medicines, there is currently limited information available on the extent of use and safety of these medicines during breastfeeding, at least in the Australian context (24, 26, 27, 224). Understanding the significance of breastfeeding and possible clinical implication of the use of medicines during breastfeeding on infants is important, and it makes sense that due attention should be paid to determine the prevalence of use and identify the herbal medicines most popular amongst breastfeeding women.

2.7 Use of Galactagogues in Breastfeeding

Galactagogues are a group of substances or medicines either proven or believed to aid lactation during the initiation and maintenance stages, thereby increasing human breast milk supply (30, 64, 225-228). In other words, galactagogues are substances which may be used by women to induce, increase or maintain milk production (228). As discussed in Section 2.3, the most common reported reason for unsuccessful breastfeeding and early weaning is milk supply that is perceived to be low or insufficient to meet the needs of nursing infants (30, 31, 61, 75). Besides that, deficient mammary gland tissue, maternal hormone imbalance, poor breastfeeding technique or latching, leading to ineffectual milk removal can all contribute to low milk supply (30, 61). Mental well-being of mothers is also an important factor to consider, as fatigue, emotional stress and anxiety may all inhibit milk supply (58, 228). If problems remain after addressing the above issues with proper education of techniques by lactation consultants or with psychological support or relaxation techniques, galactagogues may be trialled (229).

Breast milk production is regulated by the endocrine system (230). A peptide hormone, prolactin, is responsible for controlling milk production (230). The lactotroph cells in the anterior pituitary gland release prolactin into the maternal blood stream in response to infant suckling on the nipple (228, 230, 231). The release and binding of dopamine at the dopamine D₂ receptors in the tuberoinfundibular pathway of the brain decreases the synthesis of prolactin by the anterior pituitary gland, thereby inhibiting milk production (230). Therefore, it is thought that milk production may be increased by antagonising the effects of dopamine or inhibiting its binding at the dopamine D₂ receptors. For example, domperidone is a dopamine D₂ receptor antagonist which is used as an antiemetic, but also used in lactation due to its effect in enhancing milk supply. Many dopamine D₂ receptor antagonists have also been evaluated for their effectiveness as galactagogues, based on their mechanism of action (228).

Although increasing prolactin secretion is thought to be the main mechanism of action of most galactagogues, it is speculated that some galactagogues may also act via a different mode of action. A review of the literature has revealed that the mechanisms of action, efficacy and safety aspects of many commonly used galactagogues have not been thoroughly studied (226, 232-236). Besides their clinical efficacy, Zuppa et al. (228) emphasized that any medicines or substances used as galactagogues should be evaluated for their safety in breastfeeding. At the same time, any potential adverse effects on the mother and her infant should also be taken into consideration when making clinical recommendations on the use of galactagogues in breastfeeding (233).

2.7.1 Conventional and Herbal Galactagogues

Galactagogues are available in Australia in the form of either conventional medicines or of herbal origin. Dopamine D₂ receptor antagonists, metoclopramide (237-241) and domperidone (242, 243) are examples of conventional galactagogues that are most commonly used in clinical practice and best documented. These agents are thought to increase milk supply and production by increasing the levels of prolactin

in the maternal plasma (226, 239, 243). Other examples of galactagogues include sulphuride (244-246), chlorpromazine (247), human growth hormone (227, 248, 249) and thyrotrophin-releasing hormone (228, 250, 251). Many of these conventional medicines were initially marketed and are still currently prescribed for reasons other than to promote breast milk supply. For example, domperidone and metoclopramide are used as antiemetics, while chlorpromazine is used as an antipsychotic agent (252). Hence their use for this indication is off-label.

Throughout the world, women have used many alternative approaches including following special diets and the use of herbal or natural substances in an attempt to increase milk production. Mothers of different cultural and ethnic backgrounds may choose different approaches according to their tradition or experience (253-258). Herbal medicines commonly believed to aid lactation include fenugreek (*Trigonella foenum-gracum*) (61, 62, 259-262), blessed thistle (*Cnicus benedictus*) (30, 61, 228, 263), milk thistle (*Silybum marianum*) (264, 265), goat's rue (*Galega officinalis*) (61, 266, 267), marshmallow (*Althaea officinalis*) (61), fennel (*Foeniculum vulgare*) (30, 61), torbangun (*Coleus amboinicus* Lour) (261), nettle (*Urtica dioica*) (30, 61), black seed (*Nigella sativa*) (268) and many others. Despite their long history of use, scientific evaluation is lacking to confirm the clinical efficacy of most of these herbal medicines as galactagogues. No information exists describing the transfer or otherwise of these medicines into the breast milk and their effects on breastfed infants.

The Consolidated Standards of Reporting Trials (CONSORT) group develops the CONSORT Statement, which provides a checklist and recommendations for reporting of randomised trials (269). The purpose of the CONSORT Statement is to offer researchers and authors a standard way of preparing reports of their trial findings to facilitate transparent and complete reporting, as well as enabling interpretation and critical appraisal of their findings (269). Gagnier et al. (270, 271) elaborated on the CONSORT checklist and developed recommendations for reporting of RCTs specifically for herbal medicine interventions. Wolsko et al. (272) evaluated 81 RCTs published between 1st of January 2000 and 9th of February 2004, which involved single-herb products of five commonly used herbal medicines. The authors identified and reported an inadequacy in the documented characterisation of

herbal ingredients in these reports. This is also the case for many studies involving herbal galactagogues in that the recommendations provided by the CONSORT guidelines for reporting RCTs of herbal interventions were not followed. Detailed information on the herbal ingredients of the products tested, for example, the sources, types and concentrations of extracts and other detailed characteristics of the herbal products are lacking. In addition, the research methodology employed to determine the efficacy of herbal galactagogues, including the methods of milk volume or milk intake measurements, should be taken into consideration when interpreting the robustness of findings of the studies.

2.7.2 Milk Intake Measurements

There are several established methods to measure milk volume or transfer of milk from mothers to breastfed infants for the purpose of determining milk intake. Many early studies have used methods including direct milk expression using breast pumps or manual expression (273), deuterium dilution (274-276), measurement of fat droplets flow using a Doppler ultrasonic flow meter (277-279), and test-weighing either mothers or infants after feeding (280-283). Despite the advantages, many of these methods have their limitations and the choice of method is often determined specifically for each circumstance. Understanding that milk ejection and removal influence milk intake by infants, recent studies have supported the use of ultrasound imaging techniques to detect milk ejections (284) and use of Showmilk (by Medela AG), a continuous weighing balance to measure flow rate of milk (284, 285). Test-weighing remains the most commonly used method to date for determining the 24-hour milk intake in evaluating lactation performance. Maternal and infant test-weighing represent two different approaches to determine milk production (283). These two methods involve weighing the mother and infant using electronic balances separately immediately before and after a breastfeed, and the weight loss and weight gain calculated, respectively, represents milk intake (280-283). In both cases, the accuracy of this method depends on successful transfer of milk from mother to infant which may be influenced by infant's appetite, regurgitation and spillage of breast milk (283). Besides the technical and practical issues, Arthur et al. (283) also showed the significance of taking into consideration and correcting for evaporative water

losses (EWL) to avoid overestimation of milk intake by the maternal test-weighing method and underestimation of milk intake by the infant test-weighing method. To correct for EWL, subjects are reweighed approximately 20 minutes after the feed (that is after the post-feed weigh), during which subjects are advised not to eat, drink, change clothing, defecate or urinate. The change in the second period of weight measurement can be used to calculate the rate of EWL, using a method described by Arthur et al. (283). In the context of evaluating the efficacy of galactagogues, breast milk production, rather than intake, should be considered. Hence, to measure breast milk production, the mothers' rate of EWL should be taken into account.

2.7.3 Effectiveness and Safety of Conventional Galactagogues

2.7.3.1 Domperidone

Domperidone (trade name in Australia: Motilium[®]) is a dopamine D₂ receptor antagonist which stimulates the release of prolactin, thus increasing breast milk production (252). This drug is currently marketed for the treatment of nausea and vomiting in Australia, but also widely accepted as a galactagogue (252, 286). Despite its widespread use in Australia, domperidone is currently not available in the USA and its use in lactation has been banned by the FDA since 2004 on the basis of potential risks associated with its use, including cardiac arrhythmias or arrest, and sudden death (287). In 2003, this decision interrupted an RCT designed to recruit 44 participants to evaluate the effect of domperidone on breast milk quality and composition (288).

Few RCTs have been successfully conducted to evaluate the efficacy of domperidone as a galactagogue. Results of a double-blinded RCT was published in 1985 which involved a total of 32 women in Italy with issues of insufficient milk supply and found that those who received domperidone at a dose of 10 mg three times daily showed significantly higher milk production than those in the placebo group (n = 17) (289). The 24-hour milk production was determined by the infant test-weighing method (weighing infants before and after each breastfeeding session) using an electronic scale. No side effects were reported in either the mothers or their breastfed

infants. The authors concluded that domperidone may be useful to assist women who are experiencing difficulty breastfeeding (289).

Another RCT conducted in Ontario, Canada, involving 20 mothers of premature infants was published in 2001 by da Silva et al. (234). All participants mechanically expressed breast milk using a breast pump supplied by the researchers, and fed breast milk to their infants via a nasogastric tube. The expressed breast milk was collected in sterile containers which allowed measurement of the volume of milk production. Participants received either domperidone 10 mg three times a day or placebo for seven days. From day two to seven, women in the domperidone group reported a mean increase in milk volume of 49.5 mL (SD: 29.4mL, mean daily milk volume measured was 162.2 mL), significantly higher than those in the placebo group (234). Comparing to the basal values, the increase in milk volume was calculated at 44.5% in the domperidone group and only 16.6% in the placebo group. Prolactin levels in the maternal serum on day five were also reported to be significantly higher in the domperidone group (234). Whilst small amounts of this drug were identified in the milk samples, no known adverse effects were experienced by either mothers or infants.

An RCT, the “EMPOWER trial”, is currently registered to investigate the effects of domperidone and whether this medicine is safe and effective to be used as breast milk enhancer in mothers of preterm infants (286). The study involves between 20 to 25 centres located in Canada, Chile, Israel and Qatar. To be eligible for the study, mothers have to be recruited during the period seven to 21 days postpartum, with infants born in less than or equal to 29 weeks gestation, are mechanically expressing breast milk and are experiencing inadequate breast milk supply. Milk production will be determined by measuring the volume of breast milk expressed. Based on previous research, the authors hypothesized that domperidone may play an important role in assisting mothers with preterm neonates, to increase their milk supply and thus allow continued pumping during the period of hospitalization (286).

2.7.3.2 Metoclopramide

Metoclopramide is another dopamine D₂ receptor antagonist, marketed in Australia under the trade names, Maxolon[®] (252). Unlike domperidone, metoclopramide can cross the blood-brain-barrier and its use may be associated with side effects (230). In a study conducted by Kauppila et al. (238), women reported side effects with the use of metoclopramide, namely headache, tiredness, anxiety and intestinal problems. Another study also reported a similar adverse effect profile, in addition to insomnia and extrapyramidal or movement-related side effects (241). Information on the efficacy of metoclopramide in enhancing milk supply has been conflicting. Two RCT reported that no differences were observed between the treated and placebo groups (237, 290), whilst some others documented positive effects in increasing prolactin levels and mean milk volumes (228, 239, 241, 291, 292).

2.7.3.3 Other conventional galactagogues

Chlorpromazine is a dopamine D₂ receptor antagonist marketed as an antipsychotic agent in Australia (252). One study investigated the effects of chlorpromazine in four women with difficulty breastfeeding (247). Whilst the exact volumes of breast milk were not measured, women reported the feeling of breast fullness and weight gain was observed in the infants. Nevertheless, the use of chlorpromazine as a galactagogue is limited due to its side effect profile on the central nervous system. Sleepiness, lethargy and altered infant behaviours have been reported with the use of chlorpromazine in breastfeeding (228, 293, 294). No recent studies were found to further evaluate the appropriateness of using antipsychotic agents as galactagogues in breastfeeding. There are also currently insufficient data available to support the use of other agents such as growth hormones, somatotropin, medroxyprogesterone and thyrotrophin-releasing hormone in promoting breastfeeding performance (228). Based on the available information and adverse effect profiles, domperidone should be preferred as the galactagogue of choice in women who are breastfeeding.

2.7.4 Effectiveness and Safety of Herbal Galactagogues

2.7.4.1 Fenugreek (*Trigonella foenum-gracum*)

Originating from northern Africa and India, fenugreek, a member of the pea family, represents one of the many medicinal plants with a long history of use (259). The FDA has classified this herbal medicine as Generally Recognised As Safe (GRAS) when used in moderation (295). Fenugreek has been traditionally used worldwide, for instance in India as a spice for cooking (296), in Egypt as incense and in bread-making (297), in Rome to aid delivery and labour, as well as in China for oedema and weakness of legs (298). Other historical uses without sufficient evidence for benefit include the treatment of constipation, gastric ulcers, indigestion, inflammatory bowel disease, bronchitis, dermatitis, abscesses, cellulitis, and colic (259, 299). Recent studies have demonstrated some evidence of fenugreek in reducing plasma glucose (296, 299-302) and cholesterol concentrations (301, 303, 304).

The constituents of fenugreek seeds have been studied and it is reported to contain 0.1 to 0.9% diosgenin as the major saponin, other saponins, for example fenugrin B, smiligenin, sarsasapogenin and yuccagenin, coumarin compounds, betaines or alkaloids like carpaine, gentianine, trigonelline, flavones like vitexin, iso-orientin and 50% of mucilaginous fiber (220). The seeds also contain sotolone and a unique form of an amino acid, 4-hydroxy-isoleucine (61, 62). Several specific constituents of fenugreek have been studied and their effects examined. For instance, Aradhana et al. (305) investigated the effect of saponindiosgenin in ovariectomized mice and found that growth of mammary tissue was induced. Hypoglycemic and insulin-sensitizing properties of fenugreek are suggested to be attributed to 4-hydroxy-isoleucine (306-310), fenugreekine (311) and trigonelline (312).

Fenugreek should be used with caution in individuals with peanut allergy, asthma, hypoglycaemia, or patients taking warfarin (313) and who are pregnant, due to its possible effect on uterine stimulation (314, 315). Besides mild gastrointestinal adverse effects for example loose stools, stomach upset and bloating (when taken

orally in large doses), fenugreek is considered generally well tolerated (301, 314, 315).

Sotolone, also known as 3-hydroxy-4,5-dimethyl-2(5*H*)-furanone is a flavour compound present in fenugreek seeds. In 1975, Rijkens and Boelens (316) suggested sotolone to be the compound responsible for the characteristic odour of fenugreek. This finding was further confirmed by Girardon et al. (317) who detected the presence of sotolone in the aroma of fenugreek seeds using mass spectrometry (MS). Many studies have been undertaken to investigate this compound's unique sensory properties and its role in contributing to the odour and taste of various food products. Besides contributing to the aroma of fenugreek seeds and lovage (*Levisticum officinale*), sotolone has been identified also in wines, aged sake and cane sugar, and has been used in the manufacture of artificial maple syrup. Maple syrup-like odour which occurs in urine, sweat, and breast milk has been reported following the administration of fenugreek, possibly due to the sotolone component. Podebrad et al. (318) demonstrated the presence of sotolone in urine samples of patients with maple syrup urine disease and showed that this compound was accountable for the disease's characteristic odour. Sotolone has also been found to be excreted relatively unchanged in the urine.

Over the years, fenugreek has gained a reputation in the Western world as a galactagogue. Its use during breastfeeding has been listed as L3 (moderately safe) by Hale (62). It is the herbal remedy that is most commonly recommended for deficient milk supply. Many anecdotal reports suggest effectiveness of fenugreek in promoting lactation, including a survey of La Leche League (a breastfeeding organization) leaders and lactation consultants indicating positive effects in milk supply in approximately 75% of lactating women (319). Detailed protocols in regards to use of fenugreek were published by Huggins in 1998 (320) and later by Newman and Pitman in 2000 (321). According to the Academy of Breastfeeding Medicine's protocol #9 (322), the usual recommended dosage of fenugreek for stimulating lactation is one to four capsules three or four times daily. As there is currently no standardization of fenugreek content across various brands and sources, Hale and Hartmann (61) suggest that calculation of a total daily dose of 1.74 g to 4.9 g may be

more practical and useful. The German Commission E suggests a total dose of 6 g of fenugreek seeds daily in divided doses (323).

Despite its long history of use, objective investigation of the clinical efficacy of fenugreek as an effective galactagogue is limited. Hale (62) described the use of fenugreek as a galactagogue to be “widespread but undocumented”. A study was conducted by Swafford and Berens (262) who reported an increase in the average daily milk volumes from 207 mL to 464 mL, following two weeks’ use of six powdered fenugreek capsules daily. Participants used the mechanical pumping method to collect breast milk and the volume collected was subsequently measured. However, this small study was not placebo-controlled, and involved only ten women of whom characteristics and number of weeks post-partum were not stated (228, 262). The effect on milk volumes was also not studied following withdrawal of the stimulant (61, 262). The exact dosage and detailed information on the content or characteristics of the herbal product used were missing. The lack of this important information, in particular the content and composition of the herbal product used, creates difficulty for accurate evaluation of the study findings.

Another study was undertaken by Damanik et al. (261) who investigated the effect of torbangun (*Coleus amboinicus* Lour, a traditional Batakese remedy for lactation) versus fenugreek and vitamin B12 supplements. Twenty-three participants were given a daily dose of soup made with 150 g/day of torbangun leaves. Subjects of the fenugreek group (n = 22) were given capsules supplied by Bullivant Natural Product in New Zealand, which contained 600 mg of powdered fenugreek seeds and were advised to take one capsule three times daily. Participants in the other reference group (n = 22) took one Moloco+B12TM tablet (available from Kenrose, Indonesia) three times daily, each containing 20 µg of vitamin B12 and 15 mg of a placental extract. Milk volume was calculated by test weighing the infants before and after each feed over four 24-hour periods (days 14, 28, 42 and 56), then converting the weights into volumes by multiplying the grams with the breast milk density (0.983 mL/g). Despite using the test-weighing method to determine milk volume, the study did not take into account EWL as suggested by Arthur et al. (283). A 20% increase in production of milk was reported in the fenugreek group after two weeks compared to only 10% in the vitamin group (261). The authors also reported a 65% increase in

milk production in participants receiving torbangun supplementations, without affecting the mineral and macronutrient contents of the mothers' milk. Although the researchers conducted an analysis on the nutrient composition of the torbangun soup, the source and process involved in choosing and preparing the torbangun leaves were not mentioned.

The effects of fenugreek on milk production and its short term effects on infants' birth weight were investigated in a study by Turkyilmaz et al. (324). The study involved 66 mother-infant dyads who were randomly assigned to either the test (Still tea, Humana[®]), placebo (herbal tea containing apple) or control group (no herbal tea). It was reported that infants of mothers who received fenugreek-containing herbal teas showed significantly less weight loss immediately postpartum ($p < 0.05$) and had regained birth weight before the others ($p < 0.05$) (324). Breast milk was expressed by participants using electric breast pumps and milk volume was measured. The mean milk volume measured in women who were receiving galactagogue teas containing fenugreek was $73.2 \text{ mL} \pm 53.5 \text{ mL}$, which was significantly higher when compared to those in the placebo or control groups ($p < 0.05$) (324). Despite the findings suggesting promising effects of fenugreek, it was possible the galactagogue teas used in this study contained other herbal ingredients that could have influenced the findings. The presence of other herbal ingredients in galactagogue teas makes it difficult to conclude if the effects seen were solely due to fenugreek or the additive or synergistic effects from a combination of herbal ingredients.

The effects of fenugreek were also reported in a qualitative study conducted by Westfall (30). Of the 23 women interviewed, eleven used at least one herbal galactagogue and four specifically used fenugreek. All four women perceived fenugreek to be effective in increasing milk supply (method of milk volume measurement was not stated), however one was advised by a health nurse to stop using this herbal medicine due to it being contraindicated in breastfeeding (30). Better designed studies, for example, randomized placebo-controlled trials involving a larger sample size and the use of standardised products with fenugreek as the sole ingredient, are warranted to confirm the clinical efficacy of fenugreek as a herbal galactagogue. The transfer of fenugreek and its constituents into human breast milk

is currently unknown (62, 228). Considering its widespread use, the transfer of fenugreek and/or its constituents into the breast milk should be investigated to evaluate its safety and potential benefits to the breastfed infants.

2.7.4.2 Milk thistle (*Silybum marianum*)

In the recent decade, milk thistle has gained a reputation as a herbal galactagogue amongst breastfeeding women (30, 228, 265). Nonetheless, its efficacy as a galactagogue and its mechanism of action have not been established (133). This herbal medicine is considered as generally well tolerated, with very rare occurrences of gastrointestinal side effects like nausea, diarrhoea and flatulence (133). Silymarin, an extract from the seeds of milk thistle may be involved in drug interactions due to its inhibitory effects on the P-glycoprotein and cytochrome P450 liver enzymes, specifically CYP 3A4 and 2C9 enzymes (133).

To date, only one RCT has been conducted to evaluate the clinical efficacy and safety profile of this herbal medicine in enhancing milk production. Di Pierro et al. (265) in Peru evaluated the safety and efficacy of milk thistle in a group of 50 women and found that there was an 85.9% increase in daily volume of milk produced, compared to only 32.1% in the placebo group when milk volumes were measured on the last day of the trial (day 63). Breastfeeding women in the test group were given 600 mg of milk thistle orally three times daily in the form of micronized Silymarin (265). The length of the trial was 63 days and total daily milk volumes were measured at three time points (day 0, 30 and 63). The milk volume was determined by test-weighing the infants before and after each breastfeeding session, then adding this to the volume of milk expressed by a breast pump after each feeding session to empty the glands. The authors reported no adverse effects experienced in both the test and placebo groups and that silymarin was not detected in the expressed milk samples. The chemical composition and quality of milk was also not altered, suggesting its safety in breastfeeding (265). Nevertheless, this study was not double-blinded and detailed information about the mother-infant dyads' characteristics was not provided (228). Larger scale double-blinded RCTs are recommended to confirm the findings of this study and validate the clinical efficacy and safety of silymarin in breastfeeding.

2.7.4.3 Shatavari (*Asparagus racemosus*)

For many years, *Asparagus racemosus* or shatavari has been used in Ayurveda, the traditional medicine of India, as a galactagogue (133, 236). Sharma et al. (325) conducted a double-blinded, placebo-controlled RCT in 64 women with poor lactation to evaluate the effects of shatavari. Half of the participants were in the test group and received two teaspoons of mixture containing 15% by weight of shatavari twice a day for four weeks, however the actual dose of this herbal medicine was not stated. Detailed information on the characteristics of this herbal ingredient was also lacking. In this study, prolactin concentrations in the maternal serum, weight gain of the breastfed infants, and the use of other forms of milk as supplement feeds were used to assess the effects of shatavari. Nevertheless, this study did not use any specific methods to measure actual breast milk volumes. Whilst no adverse effect was recorded, the authors concluded that there were no significant changes on the above outcome measures between the two groups (325).

A separate double-blinded, placebo-controlled RCT was conducted in India to evaluate the effectiveness of shatavari in promoting breastfeeding performance (326). The study involved 60 breastfeeding women with infants younger than six months old. Participants had to be experiencing some symptoms of difficulty in lactation to be eligible for the trial. Similar to the study mentioned previously, prolactin concentrations in the maternal serum and weight gain of the infants were measured. Prolactin concentrations were significantly increased in the test group receiving powdered shatavari at a dose of 60mg/kg/day given three times daily for 30 days (33% versus 10% in the placebo group) (326). Infants' weights were also significantly increased by 16% and 6% in the test and placebo groups, respectively (326). Findings from the two RCTs which evaluated the galactogenic effects of shatavari were conflicting. Direct comparison between these two studies was also impossible as the actual dose of shatavari used in the first RCT was not provided. Further controlled studies are needed to confirm the clinical efficacy and safety of shatavari in breastfeeding.

2.7.4.4 Other herbal galactagogues

Another common herbal medicine used as a galactagogue to promote breastfeeding performance is *Galega officinalis*, also known as goat's rue (133, 327). Other herbal galactagogues with anecdotal evidence include fennel (*Foeniculum vulgare*), chasteberry (*Vitex agnus-castus*), blessed thistle (*Cnicus benedictus*), stinging nettle (*Urtica dioica*) and raspberry leaf (*Rubus idaeus*) (30, 133, 236). To date, no clinical trials exist to evaluate the use, safety and the galactogenic efficacy of these herbal medicines in breastfeeding. Westfall (30) conducted a qualitative study of herbal galactagogues use in British Columbia to explore breastfeeding women's experiences and perceived effectiveness of five herbal medicines: fenugreek, blessed thistle, fennel, stinging nettle and raspberry leaf. Despite the absence of actual milk volume measurements, participants of this study appreciated the psychological benefits and reassurance that these herbal medicines had provided throughout their breastfeeding journey. There is also the possibility of the "Hawthorn effect". Despite the long history and widespread use of herbal galactagogues, studies are still lacking to confirm their safety and effectiveness in enhancing breast milk production. It appears that there is a lack of a standardized approach or method in determining breast milk production. In the available studies, researchers have employed various methods to measure milk volumes and evaluate breastfeeding performance. The different methodologies used in these studies may have contributed to variation in the results. Although test-weighing infants before and after each breastfeeding session was considered most appropriate to avoid interruption to normal feeding practices, many studies did not take into account the potential of EWL as described by Arthur et al. (283). Further double-blinded RCT with carefully planned methodologies are required to confirm their clinical efficacy and toxicological studies to evaluate safety of these galactagogues in breastfeeding mothers and their infants.

2.8 Role of the Pharmacists

Breastfeeding women need up-to-date and accurate information on the benefits and risks of taking medicines during breastfeeding (328). In Australia, this pivotal role is

generally undertaken by GPs and pharmacists (87, 154). Due to their accessibility, community pharmacists are likely to have regular contact with nursing mothers living in the community who may require advice and assistance. Breastfeeding women and the public in general also regard pharmacists as medication advisors and expect pharmacists to provide advice and recommendations regarding queries relating to all medications, including CMs (87, 201, 207, 328).

2.8.1 Over-the-counter and Non-prescription Medicines

In Australia, the TGA administers the Therapeutic Goods Act and Regulations and controls the availability of all medicines and poisons to the Australian public using a ‘scheduling’ or classification system (329). In the context of pharmacy practice, medicines are either not subjected to scheduling (those considered having minimal harm or risk) or classified as Schedule 2 (Pharmacy Medicine), Schedule 3 (Pharmacist Only Medicine), Schedule 4 (Prescription Only Medicine) or Schedule 8 (Controlled Drug). Besides Schedule 4 and Schedule 8 medicines, all medicines or products classified as Schedule 2, Schedule 3 or non-scheduled are available in the community pharmacy OTC, without prescriptions from authorised prescribers (206, 329, 330). Furthermore, pharmacists must be responsible and be involved in the sale of all Schedule 3 products, whilst adequate advice should also be provided by either pharmacists or trained pharmacy assistants when a Schedule 2 medicine is requested (329, 330). Some common examples of OTC medicines include cough and cold remedies, some analgesics, antifungals, herbal medicines and nutritional supplements.

2.8.2 Public Health Services in the Australian Community Pharmacies

According to the Pharmaceutical Society of Australia (PSA), promotion of the community’s health awareness is considered one of the roles of pharmacists (331). Besides the supply of medicines and provision of medicine-related advice, pharmacists are also encouraged and expected to be involved in the provision of general healthcare advice as well as providing health promotion education to the public. In the PSA’s Position Statement on ‘Pharmacist Involvement in Preventative

Health Care Services', it is stated that "*PSA regards pharmacists as a key, but underutilised, member of the primary care team and strongly supports an expanded and appropriately funded role for pharmacists*" (332). The public also perceive pharmacists as relevant public health providers, with those who had previously received public health services or advice from a pharmacy reporting high satisfaction (4).

Over the years, the roles of pharmacists have greatly expanded. Community pharmacy facilitated public health promotion or services have been increasingly common worldwide (4). Many community pharmacies in Australia have extended trading hours and the no appointment policy makes pharmacists one of the most accessible healthcare professionals. Public health and professional services available in community pharmacies range from bone mineral density checks, weight loss and smoking cessation programs, to monitoring of chronic medical conditions such as hypertension and diabetes. To enhance the consumers' experience and satisfaction in the pharmacy, some have employed Western herbal medicine practitioners and naturopaths, as one of the efforts to expand the range of services available within the community pharmacy (333). To the proprietors, it also makes sense that these efforts may play a role in improving the sales and business of the pharmacy.

A systematic review conducted by Eades et al. (4) published in 2011 identified that most pharmacists included in the studies perceived public health services an integral part of their professional role. Nevertheless, pharmacists' confidence in the provision of public health services was considered only low to average. Common barriers included time constraints, lack of adequate space within the pharmacy, lack of consumer demand and their perception of potential negative reaction from pharmacy clients. Further training was identified to enhance the knowledge and skills of pharmacists in the specific types of professional services (4).

In Australia, some pharmacies also employ nurses on private contracts to provide postnatal child and maternal healthcare within the community pharmacy setting (74). Zadoroznyj et al. (74) conducted a qualitative study in Queensland to investigate the practice of a pharmacy-based child health nurse in the provision of postnatal care. It was acknowledged that the practice of pharmacy based postnatal or child health

clinics was a response driven by the market and demand in filling the gaps in the public health system. No study has been conducted to explore the potential role of pharmacists in promoting breastfeeding and their perspectives on providing breastfeeding-related health services within the community pharmacy. Taking into consideration the available information on the perspectives of pharmacists and consumers on pharmacy-based public health services, expanding the professional roles of pharmacists in the provision of high quality breastfeeding and postnatal-related healthcare services within the Australian community pharmacy setting seems relevant and justifiable. Nevertheless, the need for training and continuing education is essential to ensure this health professional is capable of meeting the needs and thereby promoting the overall health outcomes of their clients. Appropriate training in the area of medicines use in breastfeeding will also enhance pharmacists' confidence in providing advice to breastfeeding women and their families (334).

2.9 Overall Aims of this Thesis

The review of the literature has highlighted a gap in current research, in particular a paucity of data with regard to the use of herbal and other non-prescription medicines during breastfeeding and the potential role of community pharmacists in the support of breastfeeding women. This research therefore aimed to evaluate the perspectives of breastfeeding women with respect to the use of herbal medicines and factors that influenced their decision to use non-prescription medicines, with particular emphasis on herbal medicines including herbal galactagogues. In addition, the study aimed to investigate the role of Australian community pharmacists in supporting breastfeeding women in the community, including the provision of advice and information on herbal and other non-prescription medicines.

Specific objectives of each of the three stages are presented in separate chapter sections: the objectives of Stage 1 are located in Section 3.2, while the objectives of Stages 2 and 3 are covered in Sections 4.2 and 5.2 respectively.

Chapter 3
**A Population-based Survey on the Use of Herbal
Medicines during Breastfeeding**



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This Chapter reports on Stage 1 of the research. This stage involved a population-based survey of women living in Western Australia on the use of herbal medicines during breastfeeding. This stage explored the prevalence and pattern of use of herbal medicines during breastfeeding, the women's sources of recommendation, supply and information-seeking behaviour, as well as their attitudes and beliefs. In this chapter, an introduction specific to the study is provided, followed by the study objectives and research methods including study design, questionnaire, data collection and analysis procedure. Data collected from the Stage 1 study are presented, followed by a discussion of the findings.

3.1 Introduction

Literature data have highlighted findings that lactating women who are taking medications are often concerned about the transfer of medicines into breast milk. Medicines circulating in the maternal bloodstream can potentially partition into human breast milk, exposing breastfed infants to medicines that may be harmful. Another concern is the effect of medication on the quantity and quality of breast milk produced, which may impact on the exclusivity, duration and success of breastfeeding. While medicines include conventional and complementary medicines, most studies to date have focused on evaluating the safety aspects of conventional medicines. Despite the increasing popularity of herbal medicines, there are currently limited data available on the pattern of use and safety of these medicines during breastfeeding.

As previously discussed in Chapter 2, the use of CAM is increasingly common worldwide. Research undertaken in the last couple of decades in many countries including the USA (169, 170), Canada (171), the UK (175, 176), and the United

Arab Emirates (177) has demonstrated a substantial increase in the use of CAM, including CMs and other alternative therapies, amongst the general population. Research conducted in Australia has shown results consistent with the above findings (7, 24, 25, 160, 164-166). A prevalence study conducted in 2005 by Xue et al. (7) showed that 68.9% of the participants recorded use of one or more forms of CAM in the previous 12 months, with 16.3% and 7% specifically using Western and Chinese herbal medicines, respectively. Western herbal medicine was amongst the top four most popular forms of CAM, after clinical nutrition, Western massage therapy and meditation. Amongst the users of Western and Chinese herbal medicines, 29.1% and 32.9% visited a practitioner of that type of CMs in the previous 12 months, respectively. Females were also more likely to use Western herbal medicines than their male counterparts ($p < 0.001$) (7). Zhang et al. in 2008 (25) further reported the prevalence and pattern of use by the general population of Victoria, Australia, of the top 24 most commonly used herbal medicines. These were aloe vera, garlic, green tea, chamomile, echinacea, ginger, cranberry, peppermint, ginseng, ginkgo biloba, evening primrose, dandelion, valerian, liquorice, St John's wort, slippery elm, milk thistle, dong quai, black cohosh, bilberry, senna, hawthorn, saw palmetto and chasteberry, in decreasing order of popularity amongst the survey respondents (25).

Many women have self-medicated with complementary medicines and supplements, most commonly on the recommendation of friends or family, or as prescribed by their healthcare professionals (26, 215-219, 336). Studies conducted by Nordeng et al. (215) in a group of 400 Norwegian women and by Forster et al. (26) among 588 Australian women both showed that 36% of subjects had taken one or more herbal medicines during pregnancy. We anticipated that some use of herbal medicines was likely to occur during breastfeeding as Stultz et al. (27) suggested that women generally use more medications post-partum compared to during pregnancy. Despite the increasing popularity of herbal medicines, there is currently limited information available on the extent of use and safety of these medicines amongst breastfeeding women.

3.2 Objectives

The objectives of Stage 1 were guided by the initial literature review which identified gaps in the research. This study aimed to provide current information on the prevalence and pattern of herbal medicines used by women whilst breastfeeding in Western Australia, and to identify commonly used herbal medicines.

This information will inform and direct Stages 2 and 3 of the research. The study also explored the attitudes of breastfeeding women towards herbal medicines and the perceptions of breastfeeding women regarding safety and effectiveness of herbal medicines used during breastfeeding, and their information-seeking behaviour. The specific objectives were to:

- i) Estimate the percentage of women who have used one or more herbal medicines during breastfeeding.
- ii) Identify the types of herbal medicines commonly used by breastfeeding women.
- iii) Explore reasons for use, sources of the recommendation, their sources of supply and information for use of herbal medicines.
- iv) Investigate factors that may affect the decision and choice of herbal medicines use during breastfeeding, including demographic factors such as age, parity, ethnic background, occupation, level of education and other socioeconomic contributors.
- v) Determine the attitudes and perceptions of breastfeeding women regarding the safety and effectiveness of herbal medicines use during breastfeeding.

3.3 Research Methods

This section describes the methodology used for Stage 1 of the study. An overview of the study design is presented, followed by the procedures employed for participant recruitment, the study questionnaire and finally the analysis of data. Data were collected between February and December 2012.

3.3.1 Study Design

This study was conducted using a self-administered structured questionnaire. The questionnaire was constructed based on information from the literature search and other published surveys (7, 25, 26, 183, 215, 219, 337). The questionnaire was validated following the steps described by Portney and Watkins (338). Firstly, the questionnaire was circulated for face validation amongst five academic colleagues, three lactation consultants and two pharmacists employed at a large maternity hospital, seeking feedback on questions and format and suggestions for improvement. Secondly, the questionnaire was then construct validated by administering face-to-face to a group of 16 breastfeeding women recruited through two mothers' groups, to seek feedback on the language, comprehension and the types of questions asked, as well as their views on the overall format of the questionnaire. The questionnaire was subsequently amended following an evaluation of the responses and a discussion with the research team. Minor changes were made to the questionnaire, including the removal of 'prompts' of which herbal medicines were used to avoid bias, and some formatting changes to improve the overall presentation of the questionnaire. No issue with understanding of the questionnaire and the participant information sheet was identified during the validation process. These responses were not used further in the analysis. The study was approved by the Human Research Ethics Committee of Curtin University (Approval number: PH-03-11, see Appendix B). A Participant Information Sheet was developed according to the guidelines as specified by the Curtin University HREC (see Appendix C).

3.3.2 Study Population and Recruitment Strategies

The target population was women who were 18 years or older, currently breastfeeding or who had breastfed in the 12 months prior to the time of the survey. To achieve the study objectives, there were no restrictions as to whether the participant was on any medications or had any medical conditions. Women from all cultural or ethnic backgrounds were eligible for the study. Balancing the need to minimise selection bias and maximise response rate, the decision was made to recruit participants through four main avenues to enable a wide range of participant characteristic types to be recruited:

- i) *Mothers and parenting groups.* With written approval from the Australian Breastfeeding Association (ABA), breastfeeding women were recruited from local mothers and parenting groups where the primary investigator (TFS) attended the group meetings.
- ii) *Community pharmacies.* A list of 557 WA community pharmacies was provided by the Pharmacy Registration Board of Western Australia (339). A stratified sampling technique was used to obtain sets of pharmacies within three defined geographical areas: North metropolitan, South metropolitan or regionally based according to postcodes. The lists of pharmacies were arranged in a random order by attaching a computer generated random number to each record and sorting each list by the number. Permission was sought from a total of 30 randomly selected pharmacies, 10 from each region, to place 10 sets of recruitment forms in each pharmacy (an example of the cover letter is provided in Appendix D). The pharmacists in-charge were requested to hand out the sets of forms to any women who visited their pharmacy whom they believed could have been eligible for the study, regardless of whether they were using any medicines.
- iii) *Immunisation clinics and child health centres.* Written site authorisation was obtained from the Child and Adolescent Community Health Executive (CACH), Health Department of Western Australia, to display posters advertising the study at all immunisation clinics and child health centres

registered with the CACH in the Perth metropolitan area. Examples of the cover letter to CACH and poster are provided in Appendices E and F, respectively.

- iv) *Advertisement in newspapers and local parenting papers.* This strategy was implemented to advertise the study to the general public.

3.3.3 Data Collection

All participants who had expressed interest in participating in the study were provided, either face-to-face or via postal mail, a set of forms consisting of the participant information sheet (Appendix C), the survey questionnaire (Appendix G) and a reply paid envelope (Appendix H). The participant information sheet explained that responses would be treated in confidence. Consent was assumed upon return of the completed questionnaire.

3.3.4 Study Questionnaire

The questionnaire comprised four sections (see Appendix G). Sections 1 and 2 collected participants' demographic profile and their family background characteristics including their country of origin and ethnicity. This information was collected to explore the association between these factors and the pattern of use of herbal medicines during breastfeeding.

Section 3 requested information on the prevalence and pattern of use of herbal medicines during breastfeeding. This section explored the reasons for use, sources of recommendation, users' perceived effectiveness and side effects experienced. Section 4 explored the participants' information-seeking behaviour as well as their attitudes and beliefs towards the use of herbal medicines during breastfeeding. The types of questions in the questionnaire determined the response options, which were a mix of open-ended and closed-ended questions using Likert-style scaled responses.

3.3.5 Data Analysis

The survey responses were analysed using the Statistical Package for Social Sciences (SPSS[®]) version 20 software for Windows. Responses obtained from close-ended questions and questions using Likert-style scaled responses were coded numerically and entered into SPSS[®] under 'Value Labels' (for example: 1 = Yes, 2 = No). Qualitative responses obtained from open-ended questions were identified and coded. Reasons for use were categorised and coded concurrently with data entry. Upon completion of data entry, all categories were reviewed, checked and reclassified if necessary to ensure consistency in coding and that there was no duplication. These coded responses were then analysed in the same manner as the quantitative responses. Data were summarised using standard descriptive statistics (frequencies and percentages for categorical variables; means and standard deviations for variables measured on a continuous scale). The prevalence of use of herbal medicines during breastfeeding was calculated, along with its 95% confidence interval. Univariate associations between demographic data and use of herbal medicines were assessed using Chi-square statistics or t-tests, as appropriate. Logistic regression model and cross-tabulation were used to identify any association between the prevalence of use and any of the demographic data collected. The optimal model was obtained using a 'backwards elimination' strategy, whereby all demographic variables were initially included in the model, and then excluded, one at a time, until all variables remaining in the model were significantly associated with the use of herbal medicines. Respondents were classed as 'users' or 'non-users' for the purpose of analysis depending on whether or not they had reported the use of any herbal medicines during breastfeeding. Participants were classified as 'users' if they had specified the use of any herbal medicines for the purpose or intention of treating or managing any medical condition or to improve their health, whereas participants were treated as 'non-users' if they had used the herbs for non-medicinal purposes, such as in cooking or as a beverage. Responses that included non-herbal complementary medicines or other products not classified as herbal medicines, such as fish oils and multivitamins, were initially entered into SPSS[®]. During analysis of the data, a separate SPSS[®] file was created and labelled 'only herbs' which excluded non-herbal complementary medicines in the analysis.

3.4 Results

Data collected from the Stage 1 study were divided into five parts and presented in this section: i) respondents, ii) prevalence and pattern of use, iii) sources of recommendation, supply and information-seeking behaviour, iv) alternative methods to increase milk supply, and v) attitudes and beliefs of women towards the use of herbal medicines during breastfeeding.

3.4.1 Respondents

A total of 1118 questionnaires were distributed: 560 were distributed to prospective participants during mothers and parenting group meetings, 300 distributed through community pharmacies, and the remainder distributed to prospective participants who expressed interests in response to posters at immunisation clinics and child health centres or advertisement in newspapers and local parenting papers. No unused questionnaires were returned, despite a request to the distribution centres to do so. A total of 304 questionnaires from eligible participants were returned, with an estimated response rate of 27%. The mean (SD) age of respondents was 32.8 ± 4.2 years for 'users' and 32.3 ± 5.0 years for 'non-users' ($p = 0.300$). The majority of respondents resided in the Perth metropolitan area, were born in Australia or New Zealand, had completed secondary school education, had a relatively high total annual household income (\geq AUD\$ 80, 000), had only one child and were not living with their parents. The characteristics of respondents related to breastfeeding are summarised in Table 3.1. A comparison of the characteristics of the Stage 1 respondents and the respondents of the 2010 Australian National Infant Feeding Survey (340) is provided in Table 3.2.

Table 3.1: Demographic profile of respondents

Variable	Proportion of users (n/N, %)	p-value
Total number of participants	304	
Proportion of respondents using herbal medicines	182/304 (59.9)	
Age, years (mean, SD)		0.300
Users	32.8 (SD 4.2)	
Non-users	32.3 (SD 5.0)	
Residential area, determined by postcode (n = 303)		0.51
Perth metropolitan	171/284 (60.2)	
Other WA region	10/19 (52.6)	
Country of birth (n = 304)		
Australia/New Zealand	97/180 (53.9)	0.0180
Asia/Africa	58/80 (72.5)	
Europe/USA/Canada	27/44 (61.4)	
If not born in Australia, years residing in Australia (mean, SD)		0.39
Users	14.1 (SD 8.9)	
Non-users	15.7 (SD 10.8)	
Ethnic background (n = 301)		0.0328
Caucasian	55/105 (52.4)	
Asian	57/80 (71.3)	
Others	68/116 (58.6)	
Level of education (n = 302)		0.56
Secondary education	12/24 (50.0)	
Secondary school certificate of education	13/24 (54.2)	
Diploma or advanced diploma	12/16 (75.0)	
Trade certificates I, II, III or IV	15/27 (55.6)	
Bachelor degree	88/137 (64.2)	
Graduate diploma or graduate certificate	19/33 (57.6)	
Master degree	19/31 (61.3)	
Doctoral degree	4/10 (40.0)	
Total annual household income last year (n = 302)		0.0219
Low (< AUD\$ 37K)	7/17 (41.2)	
Middle (AUD\$ 37K – AUD\$ 80K)	61/86 (70.9)	
High (AUD\$ 80K+)	113/199 (56.8)	
Parity (n = 304)		0.54
1 child	102/176 (58.0)	
2 children	58/94 (61.7)	
3 children	16/27 (59.3)	
4 children	6/7 (85.7)	
Living with parents (n = 304)		0.68
Yes	19/30 (63.3)	
No	163/274 (59.5)	

Table 3.2 Comparison of Stage 1 respondent characteristics with respondents of the 2010 Australian National Infant Feeding Survey (340)

Characteristics	Percentage (%) of respondents in the 2010 Australian National Infant Feeding Survey (N = 28, 759) (340)	Percentage (%) of respondents in Stage 1 (N = 304)
Age		
24 or younger	8.8	3.9
25 – 29	23.9	22.4
30 – 34	35.6	35.5
35 – older	30.7	38.2
Missing	1.1	0.0
Parity		
Primiparous	41.0	57.9
Multiparous	55.3	42.1
Missing	3.7	0.0
Education		
Bachelor degree or higher	41.2	69.4
Diploma/certificate	35.9	14.1
Year 12 or equivalent	13.5	7.9
Year 11 or below	9.2	7.9
Missing	0.2	0.7
Country of birth		
Australia	73.2	55.9
Overseas	26.8	44.1

As shown in Table 3.2, the characteristics of the respondents of Stage 1 were similar to respondents of the 2010 Australian National Infant Feeding Survey (340) in that the majority of the respondents were women over the age of 30. In addition, the majority of the respondents in these two surveys were women with post-secondary educational qualifications and were born in Australia. Nevertheless, there was a higher proportion of respondents from the Stage 1 group with tertiary education (Bachelor degree or higher) than those of the national survey. The Stage 1 study also involved a larger proportion of women born overseas (44.1%) than respondents of the national survey (26.8%). However, no sampling frame is available for Western Australia or the metropolitan area of Perth.

3.4.2 Prevalence and Pattern of Use

Amongst the 304 respondents, 182 (59.9%) indicated that they had used one or more herbal preparations for various medicinal purposes during breastfeeding (CI 54.4-65.4%). The number of herbal products used by respondents ranged from zero to six, with a median value of one product per respondent. Of the 182 respondents who took at least one herbal medicine during breastfeeding, 70 (38.5%) reported the use of only one herbal medicine, 51 (28.0%) used two herbal medicines, 37 (20.3%) used three herbal medicines, 16 (8.8%) used four herbal medicines, five (2.7%) used five herbal medicines, and three (1.6%) used six herbal medicines. Over half (60.4%) of users indicated that the reasons for use of these herbal medicines were breastfeeding-related. Approximately one in four of all the respondents (74/304; 24.3%; 95% CI: 19.5% - 29.1%) took one or more herbal medicines specifically to help increase milk production or supply during breastfeeding. A logistic regression model was used to investigate if any respondent characteristics or demographic factors were associated with the decision to use herbal medicines during breastfeeding, with the results shown in Table 3.3. The multivariate model showed that respondents with an Asian birthplace were significantly more likely to use herbal medicines, as well as were those from middle income families (total annual household income of AUD\$ 37, 000 – AUD\$ 80, 000). These factors were the only two that remained after the backwards-elimination model-fitting strategy. Other variables which were initially included in the model were excluded since they appeared to be not significantly associated with the outcome.

Table 3.3: Logistic regression model: Factors associated with the use of herbal medicines during breastfeeding using a multivariate model

Variable	Odds Ratio	95% Confidence Interval	<i>p</i> -value
Country of Birth			
Asia	2.20	1.25 to 3.88	0.0061
Other	1 (reference)		
Family income			
Low (<AUD\$ 37K)	0.29	0.10 to 0.84	0.0234
Mod (AUD\$ 37K to 80K)	1 (reference)		
High (>AUD\$ 80K)	0.53	0.31 to 0.91	0.0214

A total of 51 different herbal medicines was named by respondents. Amongst the survey respondents, the top ten most commonly used herbal medicines during breastfeeding in the descending order of popularity, along with the percentages of respondents who have used the herbal medicines, were fenugreek (18.4%), ginger (11.8%), dong quai (7.9%), chamomile (7.2%), garlic (6.6%), blessed thistle (5.9%), cranberry (4.9%), fennel (4.9%), aloe vera (3.3%) and peppermint (3.3%). It was possible that some respondents may have not recollected every herbal medicinal component giving rise to the possibility of under-reporting. Women were asked to indicate the reasons for use, who recommended the use, and their perceived effectiveness of whether the herbal medicine was helpful to address their intended indication. Of the users of the top ten herbal medicines, the proportion of women who perceived the herbal medicine as helpful varied from 20.0% to 83.3%. These findings along with their prevalence are shown in Table 3.4. There were 18 different herbal medicines or ingredients indicated by the respondents specifically as galactagogues, used to increase breast milk supply and breastfeeding performance. Table 3.5 reports on the top seven most commonly used herbal galactagogues along with their perceived effectiveness, in descending order of priority.

Table 3.4: Top ten most commonly used herbal medicines during breastfeeding (in descending order of popularity), N = 304

Common name of herbal medicine	Binomial/ Scientific name	n (%) reporting use of this herbal medicine	n (% of herbal medicine users) who believed it helped	Reported indications (% of specific herbal medicine users)
Fenugreek	<i>Trigonella foenum-graecum</i>	56 (18.4)	44 (78.6)	Increase breast milk supply (98.2) Boost immune system during a cold (1.8)
Ginger	<i>Zingiber officinale</i>	36 (11.8)	17 (47.2)	General health enhancement, tradition (65.7) Relief of “wind” and “air” (22.9), Others (11.4)
Dong quai	<i>Angelica sinensis</i>	24 (7.9)	10 (41.7)	General health enhancement (90.9) Others (9.1)
Chamomile	<i>Matricaria chamomilla</i>	22 (7.2)	13 (59.1)	Calming and relaxation, stress (86.4) Others (13.6)
Garlic	<i>Allium sativum</i>	20 (6.6)	7 (35.0)	Boost immune system during a cold (38.9) General health enhancement, tradition (50.0) Antifungal (5.6) Improve blood circulation (5.6)
Blessed thistle	<i>Cnicus benedictus</i>	18 (5.9)	15 (83.3)	Increase breast milk supply (100.0)
Cranberry	<i>Vaccinium macrocarpon</i>	15 (4.9)	6 (40.0)	Urinary tract infections/bladder health (76.9) Others (23.1)
Fennel	<i>Foeniculum vulgare</i>	15 (4.9)	10 (66.7)	Increase breast milk supply (80.0) Relieve colic (13.3) Energy, restore iron levels from blood loss (6.7)
Aloe vera	<i>Aloe vera</i>	10 (3.3)	2 (20.0)	Detox (62.5) Aids digestion, intestinal health (12.5) General health enhancement (12.5) Sunburn, cooling effect (12.5)
Peppermint	<i>Mentha piperita</i>	10 (3.3)	7 (70.0)	Calming and relaxation (60.0) Relief of bloating (20.0), Others (20.0)

Table 3.5: Top seven most commonly reported herbal galactagogues (in descending order of popularity)

Common name of herbal galactagogue	Binomial/ Scientific name	n (%) reporting use of this herbal medicine	n (% of specific users) who believed the herbal medicine helped
Fenugreek	<i>Trigonella foenum-graecum</i>	56 (18.4)	44 (78.6)
Blessed thistle	<i>Cnicus benedictus</i>	18 (5.9)	15 (83.3)
Fennel	<i>Foeniculum vulgare</i>	15 (4.9)	10 (66.7)
Goat's rue	<i>Galega officinalis</i>	7 (2.3)	7 (100.0)
Nettle/ Stinging nettle	<i>Urtica dioica</i>	5 (1.6)	4 (80.0)
Blackthorn berry	<i>Prunus spinosa</i>	5 (1.6)	4 (80.0)
Shatavari	<i>Asparagus racemosus</i>	4 (1.3)	4 (100.0)

3.4.3 Recommendation, Supply and Information-Seeking Behaviour

Participants were asked to state who had recommended the use of each of the specified herbal medicines. Responses were tabulated separately, and grouped into seven main categories as presented in Table 3.6. Approximately two-thirds of the users (n = 112, 61.5% of herbal medicines users) had chosen to use herbal medicines during breastfeeding based on recommendations from their family members. Prescribers and specialists, including general practitioners, gynaecologists and obstetricians were least likely to recommend the use of herbal medicines during breastfeeding, as the results have shown that only four participants (2.2% of herbal medicines users) were recommended to use herbal medicines by this group of health professionals. Table 3.6 also summarises the sources of supply based on the users' responses. The majority of the users (n = 105, 57.7%) had obtained or purchased their herbal medicines or products from community pharmacies. Health food stores and supermarkets were two other common sources of supply, followed by naturopathic clinics, family and friends and the internet.

Table 3.6: Sources of recommendation, supply and information

Survey Questions	n (% of user/ respondents)*
<i>Who has recommended the use of herbal medicines? (n = 182 number of users)</i>	
Family members	112 (61.5)
Naturopaths, herbal or health food stores	86 (47.3)
Friends	57 (31.3)
Self (including self-reading of magazine, internet)	56 (30.8)
Health professionals (including clinic/ child health nurses, midwives, lactation consultants)	26 (14.3)
Pharmacists and pharmacy staff	24 (13.2)
Prescribers and specialists (including doctors/ general practitioners, gynaecologists, obstetricians)	4 (2.2)
<i>Sources of supply: Where have they obtained or purchased their herbal medicines? (n = 182 number of users)</i>	
Community pharmacies	105 (57.7)
Herbal or health food stores	88 (48.4)
Supermarkets	73 (40.1)
Naturopathic clinics	27 (14.8)
Family or friends	26 (14.3)
Internet	4 (2.2)
<i>Sources of information: Where to seek information concerning use of herbal medicines during breastfeeding? (N = 303)</i>	
Pharmacists	154 (50.8)
Doctors	146 (48.2)
Family or friends	139 (45.9)
Internet	133 (43.9)
Lactation consultants	89 (29.4)
Naturopaths or homeopathic practitioners	87 (28.7)
Child health nurses	83 (27.4)
Herbal or health food stores	71 (23.4)
Books, literature or journal articles	59 (19.5)
Others	11 (3.6)

* Does not total 100% as more than one response had been indicated by some participants

All respondents to the survey (users and non-users) were asked where they did get information or could get information concerning the use of herbal medicines during breastfeeding. The results indicated that respondents were most likely to seek information and advice from pharmacists and doctors. Of the 105 respondents who had purchased herbal medicines from community pharmacies, 76 respondents (72.4%) indicated that they would seek information from a pharmacist if necessary. Family and friends as well as internet resources were also common reported sources of information, followed by lactation consultants, naturopaths or homeopathic practitioners, child health nurses, health food stores, and books, literature or journal articles. Despite doctors being identified as one of the common sources of information, only 52 (28.6%) of the users in this study had made their doctors aware of their decision to use herbal medicines whilst breastfeeding.

3.4.4 Alternative Methods to Increase Milk Supply

Approximately one-third of the participants (n = 100) had indicated the use of other products or alternative methods including special diets or techniques to increase breast milk supply during breastfeeding. The most commonly used method reported from this study was frequent milk expression with the use of an electric breast pump, followed by the use of domperidone (Motilium[®]) and increased fluid intake. Table 3.7 presents the list of products or alternative methods indicated by the participants.

3.4.5 Attitudes and Beliefs towards the Use of Herbal Medicines

Over 70% of respondents (n = 211) strongly agreed or agreed that there was a lack of information resources available to them regarding the use of herbal medicines during breastfeeding, whilst 23.6% selected the option “no idea” and 6.3% strongly disagreed or disagreed.

Many of the respondents (43.4%) believed that herbal medicines are generally safer when compared to conventional medicines used during breastfeeding. Most (71.6%) had indicated a previous refusal or avoidance of medicine treatments during breastfeeding due to concerns regarding the safety of their breastfed infants. When

given a choice, the majority of the women (75.9% of respondents) preferred more information to be available regarding the safety and efficacy of herbal medicines specifically when used during breastfeeding.

Table 3.7: Other products or alternative methods used by participants to increase breast milk supply

Methods of increasing milk supply (other than the use of herbal medicines)	n (% of respondents)
Frequent milk expression with electric breast pump	23 (7.6)
Use of domperidone (Motilium [®])	22 (7.2)
Increased fluid intake	21 (6.9)
Eating rolled oats/ oat milk	12 (3.9)
Fish soup boiled with green papaya	8 (2.6)
Multivitamin/ iron/ folic acid	5 (1.6)
Seafood diet	2 (0.7)
Increase intake of brewer's yeast	2 (0.7)
Peanuts	2 (0.7)
Low fat diet	1 (0.3)
Limited caffeine and alcohol intake	1 (0.3)
Increased protein in diet	1 (0.3)
Plenty of rest	1 (0.3)

3.5 Discussion

In this section, the results of Stage 1 study presented above are discussed in relation to the objectives as described in Section 3.2. The findings are discussed in five parts: i) prevalence and pattern of use, ii) recommendation, supply and information-seeking behaviour, iii) attitudes and beliefs, iv) limitations of the Stage 1 study and v) the next stage linking to Stages 2 and 3 of this research.

3.5.1 Prevalence and Pattern of Use

As previously presented in Table 3.2, the characteristics of the Stage 1 respondents were compared with the characteristics of the 2010 Australian National Infant Feeding Survey respondents. The 2010 Australian National Infant Feeding Survey was funded by the Australian Government Department of Health and Ageing and executed by members of the Australian Institute of Health and Welfare (340). The project was the first specialised, large-scale, nationally representative survey of Australian infant feeding practices, attitudes and behaviours (340). According to the findings of the 2010 Australian National Infant Feeding Survey, women aged 35 and over and those with tertiary education were associated with higher rates of initiating breastfeeding and were more likely to breastfeed for longer periods at higher intensity (340). The characteristics of the respondents of Stage 1 were similar to respondents of the 2010 Australian National Infant Feeding Survey in that the majority of the respondents were women over the age of 30. Specifically, a larger proportion of the Stage 1 respondents were women aged 35 and older. The majority of the Stage 1 respondents were also women with tertiary education. These findings is of relevance to this study as women who breastfeed for longer may be likely to have experienced an incidental illness and to face the dilemma of needing to use a medicine whilst breastfeeding. The fact that Stage 1 involved a larger proportion of women born overseas having a higher level of herbal medicines use reflects cultural differences in the sample used in the study.

Although many studies have been conducted to investigate the prevalence and pattern of use of CMs in Australia in the general population, few have focused

specifically on the use of herbal medicines by women during breastfeeding. In this study, 59.9% of the women used at least one herbal medicine during breastfeeding for various medicinal purposes. This estimated prevalence (59.9%) appeared to be higher than results from a similar study conducted in a group of Australian women (588 participants; median age 32; 57% born in Australia/New Zealand; 17% born in Asia; 26% born in other countries) published in 2006, which found that 36% of participants took one or more herbal medicines during pregnancy (26). The demographic profiles of respondents of the study mentioned previously differ slightly in that the Stage 1 study involved a higher percentage of women born in Asian countries. Many studies conducted in Australia and other countries have demonstrated the popularity of herbal medicines in the general population (7, 169, 177) and also amongst pregnant (26, 215) and breastfeeding women (24, 336, 341), most likely due to the increased awareness and availability or accessibility of herbal products. The 2011 Census indicated that 27% of the Australian population were born overseas, with the majority of migrants from European and Asian countries (342). An association was identified between the respondents' birthplace or their ethnic background and the decision to use herbal medicines. Women with an Asian background in this study were significantly more likely to use herbal medicines during breastfeeding. A study conducted in Taiwan explored the use of Chinese herbal medicines by women during both pregnancy and the postpartum period (341). The authors not only reported a relatively high prevalence of herbal medicines use in the cohort, but also demonstrated a marked escalation of prevalence from 33.6% during pregnancy to 87.7% during the postpartum period. Our results suggested a higher prevalence of herbal medicine use by women from the middle-income families, supporting the argument that cost and affordability may be a factor to consider when selecting the type of therapy (7, 160, 165). The relationship between women from the middle-income families and the higher prevalence of herbal medicine use should be further explored.

The most commonly used herbal medicines found in this study were consistent with previously published reports. Herbal medicines which were not used specifically as galactagogues including ginger, dong quai, chamomile, garlic, cranberry, aloe vera and peppermint, were all included in the 24 common medicinal herbs used by the general Victorian population as reported by Zhang et al. (25). Furthermore, the

reported indications for use of these herbal ingredients were consistent with the traditional uses in many of the previous studies (7, 25, 26, 215).

Over 24% of respondents took at least one herbal medicine for the purpose of increasing breast milk supply or promoting breastfeeding performance. Amongst the top ten herbal medicines used by the women in this study, fenugreek, blessed thistle and fennel emerged as the top three herbal medicines used as galactagogues. Other herbal galactagogues included goat's rue, nettle, blackthorn berry and shatavari. The *ABM Clinical Protocol #9: Use of Galactagogues in Initiating or Augmenting the Rate of Maternal Milk Secretion* published by The Academy of Breastfeeding Medicine Protocol Committee in 2011 (343) recognised the widespread use of herbal remedies including fenugreek, blessed thistle, fennel seeds, goat's rue, milk thistle, oats, dandelion and other herbal ingredients as galactagogues to enhance breast milk supply. Reviews conducted in the area of herbal galactagogues by Abascal and Yarnell in 2008 (327) and Zapantis et al. (133) in 2012 both identified fenugreek, blessed thistle and fennel seeds as commonly used herbal galactagogues. All these herbal medicines have gained their reputation as galactagogues over the years, however mostly based on anecdotal evidence (133, 334, 336). Limited clinical trials or large-scale studies are available to ascertain their efficacy as galactagogues. Nevertheless, the present study identified the common herbal galactagogues used by women living in WA and that the users' perceptions of the effectiveness of these herbal galactagogues were in general favourable. The above mentioned factors and the findings of this study have highlighted the need to conduct clinical research to confirm their efficacy and safety in breastfeeding. A qualitative study conducted through interviews exploring herbal galactagogue users' perspectives would also enhance our depth of knowledge on this topic of interest.

Identification of the recruitment avenues or location of surveys that were returned was not possible. As the survey involved a range of recruitment strategies, it should be noted that the source of recruitment may have had an impact on the responses of survey respondents. For example, participants recruited through community pharmacies may have been more likely to have purchased their herbal medicines or products from a pharmacy and may have been more likely to have sought advice

from a pharmacist. However, only 300 of the 1118 forms (26.8%) were distributed through this avenue.

3.5.2 Recommendation, Supply and Information-Seeking Behaviour

This study investigated the sources of recommendation and supply, and explored breastfeeding women's information-seeking behaviour. Family and friends were the most common source of recommendation, yet approximately half of this cohort of breastfeeding women (57.7% of reported users) obtained or purchased their herbal medicines from a community pharmacy. A similar trend was reported in an Australian study conducted by Morgan et al. (168) which found that family and friends were the most common source of recommendation for the use of CMs, and that pharmacies were the most common source of supply of CM products. This finding indicates a potential role for community pharmacists and pharmacy staff in influencing breastfeeding women's decisions regarding the use of herbal medicines during breastfeeding.

When given a choice, breastfeeding women were most likely to recognise pharmacists and doctors as sources of information and advice regarding the use of herbal medicines. As previously stated, over 70% of the respondents who had previously purchased herbal medicines from pharmacies indicated that they would seek information from a pharmacist if necessary. Internet resources, family and friends were also commonly reported sources of information. Interestingly, only 52 (28.6%) of the 182 users of herbal medicines in this study had made their doctor aware of their decision and choice of therapy. Other studies have also revealed a lack of communication between users of CAM in general and their doctors in terms of their use of herbal medicines and other alternative therapies (219, 344). This finding contradicts the previous results which found that participants were most likely to seek advice from pharmacists and doctors, indicating that participants' perceptions or views may not necessarily reflect their actions. Although it may be possible that participants could have perceived that herbal medicines were safe and hence did not feel the need to consult their doctors, further investigation into the reasons and breastfeeding women's behaviour would provide more insight into this issue.

Nevertheless, all healthcare professionals, including doctors and pharmacists should take the initiative to ask and provide evidence-based advice, if available, regarding the appropriateness of using herbal medicines during breastfeeding. Considering the high prevalence of herbal medicines used during breastfeeding and the risk of potential interactions and adverse outcomes, all healthcare providers, including community pharmacists and pharmacy staff, should routinely ask appropriate female clients if they are breastfeeding and if they are using any medicines including CMs. Although other studies have investigated the role of community pharmacists in providing advice regarding the use of CMs in the general population (201, 202, 345-348) and the role of community pharmacists in counselling breastfeeding women (87, 156), there is a paucity of studies that have examined the role of community pharmacists in providing advice regarding the use of herbal medicines specifically to breastfeeding women and their families.

3.5.3 Attitudes and Beliefs

Forster et al. (26) have suggested the reason for the high prevalence of women not informing their doctors regarding their decision to use herbal medicines during pregnancy was the assumption that herbal medicines are 'natural' and hence safety would not be an issue. It is likely that this factor may also be contributing to the high prevalence of use identified in this study as the majority of the women who participated (43.4%) perceived herbal medicines as safer options compared to conventional medicines during breastfeeding. Although most herbal medicines are readily available without a prescription, it is important to take into consideration the potential risk of drug-disease interactions and interactions between herbal medicines of their choice and medicines prescribed by doctors or available OTC. Approximately 70% of the 304 respondents indicated that they either strongly agree or agree that there was a lack of resources available to them regarding the use of herbal medicines during breastfeeding. Nevertheless, some women continued to use their herbal medicines of choice based on limited readily available evidence-based information. Over 70% of respondents indicated that they had previously refused or avoided medicine treatments during breastfeeding due to concerns regarding safety of their breastfed infants. The study has demonstrated the urgent need for further

research into this area as both untimely cessation of breastfeeding and mother denial of medicine treatments to meet their medical needs may lead to unwanted consequences.

3.5.4 Limitations

This study has some limitations. As the research involved a voluntary self-administered questionnaire, this study may overestimate the use of herbal medicines during breastfeeding as a result of voluntary response bias (202, 338). Women who had a personal interest or were taking herbal medicines may have been more likely to participate in the study. According to the Australian Bureau of Statistics (ABS), a total of 31, 820 babies were born in Western Australia in 2011 (349). Assuming approximately 90% of women initiated breastfeeding (3), the sample size of this study is small relative to this population. However, sample size calculation showed that the sample size of 304 breastfeeding women was adequate and provided an estimation of an absolute precision of 5.5%. There was also a low response from women from lower income families and thus the views expressed by the study participants may not accurately reflect those of the entire breastfeeding population. Although the study suggested an association between the use of herbal medicines and users' country of birth and ethnic background, all questionnaires were administered in English. Further studies conducted in other languages could provide a broader representation. As the surveys were self-administered, participants may not have had the opportunity to seek clarification if they were confused with the questions or terminologies used in the questionnaire. Nevertheless, the research team validated the questionnaire and the participant information sheet was in plain English. Feedback from colleagues and validation of the questionnaire did not identify any issues with participants' understanding of the questionnaire and the participant information sheet. When analysing the results of a survey, it is important to consider the style of questions and how the questions were worded in the questionnaire. On reflection, questions 4.3 and 4.4 were potentially leading questions, which could have influenced the responses of participants. While the majority of the participants indicated agreement to these two questions, it is unclear whether this was an artefact of the questions as worded. The study also collected information on other products or

alternative methods women had followed during breastfeeding to increase their breast milk supply. Future studies involving a larger sample size will be useful to further explore this aspect and their effects during breastfeeding.

3.5.5 The Next Stage

The use of herbal medicines, including herbal galactagogues is likely to be common amongst women during breastfeeding, at least amongst the survey respondents in this study. It was clear from Stage 1 that breastfeeding women indicated high levels of confidence in the safety of herbal medicines, compared to conventional medicines. This important presumption requires in-depth investigation to elicit the reasons that are informing the confidence and behaviour of breastfeeding women towards the use of herbal medicines. The Stage 1 study did not collect information on dosage forms, routes of administration and doses of herbal medicines used by participants. Although these factors may have substantial effects on the pharmacokinetics of these medicines and hence their safety in breastfeeding, they were beyond the scope of the Stage 1 study. Future studies investigating the doses and dosage forms of commonly used herbal medicines would provide useful information when determining the safety of herbal medicines in breastfeeding. These findings have therefore informed the objectives of the Stage 2 study, investigating breastfeeding women's experience of using herbal medicines, especially herbal galactagogues and documenting their perceived effectiveness and safety of these medicines. Stage 1 of the study has also identified the potential role expansion of community pharmacists and pharmacy staff, however did not explore the women's perspectives and reasons for their choice to utilise community pharmacies. The next stage of the research study, Stage 2 (Chapter 4), involved qualitative interviews which enabled in-depth investigation of women's perspectives and expectations and whether their needs were met, at the same time identifying areas for improvement in the healthcare system.

Health professionals and healthcare providers should be aware of the latest information regarding safety and efficacy of the commonly used herbal medicines in lactation and provide appropriate advice to breastfeeding women. Hence, the research questions proceeding from the Stage 1 study included whether there is

sufficient and reliable information and resources available to health professionals, and if they are confident in advising women on the use of herbal medicines during breastfeeding. Stage 1 of the study identified community pharmacies as the most common source of herbal medicines in Western Australia amongst the survey respondents, thus demonstrating the potential for increasing the involvement of community pharmacists. Stage 3 (Chapter 5) of this study was designed to address the findings from Stages 1 and 2 from the community pharmacists' perspectives.

Chapter 4
The Use of Herbal Galactagogues in Lactation:
Breastfeeding Women's Perspectives and Views
including the Involvement of Community
Pharmacists



Sections of this chapter were published in: *Sim TF, Hattingh HL, Sherriff J, Tee LBG. Perspectives and attitudes of breastfeeding women using herbal galactagogues during breastfeeding: a qualitative study. BMC Complement Altern Med. 2014; 14:216. (350).* A copy of the published paper is attached in Appendix I.

Sections of this chapter submitted for publication in: *Sim TF, Hattingh HL, Sherriff J, Tee LBG. Exploring the role of community pharmacists in promoting safe and effective use of herbal medicines during breastfeeding: breastfeeding women's perspectives. Submitted to International Journal of Pharmacy Practice. 2014.* A copy of the submitted paper is attached in Appendix J.

This chapter reports on Stage 2 of the research. This stage involved an exploratory study of breastfeeding women's perspectives on the use of herbal galactagogues during breastfeeding and their views on the role of community pharmacists in meeting their breastfeeding needs. Both descriptive and qualitative approaches were used to obtain and analyse the data. An introduction specific to the Stage 2 study is provided, followed by the significance and rationale of the study, specific objectives, the research methodology including the study design, the data collection and analysis procedure, the results and a discussion of the findings.

4.1 Introduction

Guideline 4 of the Australian Dietary Guidelines 2013 published by the National Health and Medical Research Council entitled "*Encourage, support and promote breastfeeding*"(35) acknowledges the physical and mental health outcomes of breastfeeding for both infants and mothers. According to the guidelines, exclusive breastfeeding is recommended for infants until the age of six months. When solid foods are introduced to the infants' diet at approximately six months of age, breastfeeding should be continued in conjunction with solid foods until 12 months of age and beyond as complementary feeding if desired. Many efforts, including the initial development of the *National Breastfeeding Strategy (1996-2001)* (32) and subsequently the *Australian National Breastfeeding Strategy 2010-2015 (1)*, have

been initiated to support and promote successful breastfeeding in Australia. Despite the many efforts to promote breastfeeding, some women may still experience difficulty breastfeeding due to numerous factors. One of the commonly reported reasons for unsuccessful breastfeeding and early weaning is perceived low or insufficient breast milk supply (75). Deficient mammary gland tissue, maternal hormonal imbalances, poor breastfeeding technique or latching leading to ineffectual milk removal can all contribute to insufficient supply of milk (30, 61). If these issues have been addressed and other strategies followed such as education about techniques by lactation consultants and milk flow is still insufficient, galactagogues may be trialled by some mothers (229).

Many herbal medicines have gained recognition and positive reputation by the public and health professionals as alternative approaches to enhancing breastfeeding performance (133, 226, 259). Herbal galactagogues are available in Australia in various dosage forms, from capsules and tablets to liquid tinctures (25). Considering that the choice of dosage forms may directly affect their safety and efficacy, efforts should be made to investigate and document the dosage forms and usage directions that breastfeeding women have followed. However, despite the increasing popularity of herbal galactagogues, very little is currently known about the pattern of use in Australia, as well as the safety and efficacy of these medicines during breastfeeding. Results from Stage 1 of the research study show that approximately one in four of the respondents in that study ($74/304 = 24.3\%$; 95% CI: 19.5% - 29.1%) had used one or more herbal medicines during breastfeeding to help increase milk production or supply, regardless of whether they had been diagnosed with insufficient milk supply. Fenugreek (*Trigonella foenum-graecum*) was the most commonly used herbal galactagogue during breastfeeding amongst the survey respondents. Other commonly reported herbal galactagogues included blessed thistle (*Cnicus benedictus*), fennel (*Foeniculum vulgare*), goat's rue (*Galega officinalis*), nettle (*Urtica dioica*), blackthorn berry (*Prunus spinosa*), and shatavari (*Asparagus racemosus*).

In spite of their long history of use, there is a lack of scientific evaluation to verify the safety and clinical efficacy of most of these herbs as a galactagogue (133). However, many women continue to use herbal galactagogues based on anecdotal evidence (133, 226). In line with data presented in the literature review, an

interesting trend was observed through Stage 1 of the study in that many breastfeeding women had decided to use herbal galactagogues despite agreeing that there was a lack of information and resources available to them regarding the quality, safety and efficacy of these herbal medicines (87, 133). Research into the impact on successful breastfeeding and potential effectiveness or psychological benefits of herbal galactagogues would provide insights into the perceived clinical effectiveness of these galactagogues as alternative options for breastfeeding women who wish to increase their breast milk supply.

Besides evaluating the perceived benefit, use of any medicine or substance during breastfeeding may have safety risks for breastfed infants (334). Limited published research was found with regards to the transfer of herbal galactagogues or their derivatives into breast milk and their potential effects on breastfed infants. Current herbal reference texts often suggest avoidance of certain herbal products based on what is known about the toxicity of the herbal ingredients, from case reports, and when there are little or no data available to support their use (61, 62, 107, 220-223). These recommendations may not have taken into account the extent of transfer of herbal constituents into human breast milk or the impact on infant feeding behaviour. In a review by Bingel and Farnsworth (263), over 400 plants have been recorded as galactagogues in the literature. Scientific evidence is lacking for the vast majority of these plants in terms of their mechanisms, effectiveness as galactagogues and safety when taken during breastfeeding. Whilst herbal medicines may be considered by the public as 'natural' and 'safe' when compared to conventional medicines, it needs to be pointed out that there are currently limited toxicological data available to support their use in breastfeeding. Some herbal medicines may contain constituents which are intrinsically toxic, even when present in low concentrations. Some examples of intrinsically toxic constituents may include, but are not limited to: aristolochic acids, which have been associated with nephrotoxic and carcinogenic effects (351, 352); and pyrrolizidine alkaloids, which have been shown to be hepatotoxic and photogenotoxic (353, 354). Despite limited information on the transfer of constituents of herbal medicines into the breast milk, it should be noted that some herbal constituents may still pose a risk, especially when transferred in toxicologically significant amounts into the breast milk. Investigation on the chemical constituents of commonly used herbal medicines, and whether they are

transferred into the breast milk, would allow examination of the potential benefits or ill effects and at the same time provide evidence to ensure the safety of breastfed infants while allowing mothers to receive therapy of their choice.

The Stage 2 study endeavoured to document the pattern of use, safety and effectiveness of herbal galactagogues during breastfeeding based on breastfeeding women's personal experience and observations. Gaining an understanding of their perspectives, why and how they have chosen to use herbal galactagogues over conventional options, their experiences and the factors or indicators that influenced their breastfeeding performance, will provide insight into the potential value of herbal galactagogues and identify research gaps to inform direction of future studies.

The initial focus of Stage 2, to investigate the use of herbal galactagogues during breastfeeding based on breastfeeding women's perspectives and experiences, was expanded to include the role of community pharmacists in meeting the breastfeeding needs of breastfeeding women in a community pharmacy setting. This decision was informed by findings from Stage 1 of the research which demonstrated that approximately half of the participating breastfeeding women had obtained or purchased their herbal medicines from a community pharmacy. Data from Stage 1 also show that breastfeeding women were most likely to seek information and advice regarding the use of herbal medicines during breastfeeding from pharmacists and doctors, with more than half of the respondents indicating that they would seek advice from a pharmacist. This finding indicated a potential role community pharmacists and pharmacy staff could play in influencing breastfeeding women's decisions to use herbal medicines during breastfeeding, and subsequently the impact on breastfeeding performance. There is limited information on the perceived role of community pharmacists from the perspective of breastfeeding women. Understanding the perspectives of breastfeeding women, their views and experiences with community pharmacists and whether they believe there is a role for community pharmacists to play in this area will provide valuable insight into the current and future potential role of pharmacists. At the same time, this may also facilitate positive breastfeeding outcomes in the community by evaluating how pharmacists can better assist breastfeeding women with their needs. Identifying the facilitators and barriers of breastfeeding women in utilising the expertise of community

pharmacists in providing high quality breastfeeding-related healthcare in a community pharmacy setting will also assist with identification of the areas of pharmacy practice which need to be improved. A better understanding of their unique needs and perspectives will enrich our knowledge in the area of CMs and pharmacy practice, in turn benefiting women who may require assistance whilst breastfeeding.

4.2 Objectives

The objectives of Stage 2 were guided by the initial literature review which identified research gaps, and was later directed by the findings from Stage 1 of the study in accordance with exploratory research processes.

The aim of Stage 2 was to obtain an in-depth understanding of the perspectives and experiences of women who have used herbal galactagogues during breastfeeding. The specific objectives were to:

- i) Evaluate the use and perceived benefits, effectiveness and safety of herbal galactagogues during breastfeeding based on participants' personal experience and observations.
- ii) Investigate the types of herbal galactagogues used, the dosage forms, their administration (whether they were tablets or capsules, tea, seed or other dosage forms), the dosages or amount and frequency of consumption, as well as the period and duration of administration since immediately post-partum.
- iii) Explore the perspectives and attitudes towards the use of herbal medicines whilst breastfeeding.
- iv) Explore the perceptions with regards to the role of community pharmacists in meeting women's breastfeeding-related healthcare needs in community pharmacies.
- v) Identify facilitators and barriers in utilising community pharmacists to provide breastfeeding-related healthcare in the community pharmacy setting.

4.3 Research Methods

This section describes the research methods employed for Stage 2 of the study. It begins with an overview of the study design, followed by ethical considerations related to the study, eligibility criteria of participants, recruitment strategies, the development of the interview guide and procedure, and methods for analysis of data. The interviews were conducted between October 2012 and April 2013.

4.3.1 Study Design

Exploratory research was conducted through in-depth semi-structured interviews with breastfeeding women who were using one or more herbal medicines during breastfeeding to increase breast milk supply. An interview guide was developed with a mix of closed and open-ended questions to gather information about the use of herbal galactagogues, participants' perspectives and attitudes and their perceptions towards the role of community pharmacists in meeting their breastfeeding-related healthcare needs.

4.3.2 Ethics Approval

Human research ethics approval was obtained from the Curtin University Human Research Ethics Committee (HREC) on 6th September 2012 (Approval number: HR85/2012, see Appendix K). A participant information sheet (Appendix L) and consent form (Appendix M) were developed according to the guidelines provided by the Curtin University HREC, which clearly stated the rights of participants and the procedure of the study.

As the nature of the study could potentially have involved issues with cultural sensitivities, the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (355) was consulted. Throughout

the study, the researcher and supervisors respected all rights, welfare, perceptions, customs and beliefs of participants. The researcher rigorously adhered to an open style of communication. To avoid distress to participants, all participants were reassured at the start of the interviews that the study was not to advocate or discourage the use of any medicines or choice of therapy, but rather to obtain insight into the participants' experiences and perception. The researcher did not make any comments on the participants' choice of therapy. Participants were reassured that their participation was completely voluntary and anonymous and they could withdraw at any time during the interview.

No ethical issue was raised throughout the study period. Audio-recordings of the interviews were erased after the transcription process was finalised.

4.3.3 Participants

Eligibility and Inclusion Criteria

Breastfeeding women living in the Perth Metropolitan area, who expressed interest, were invited to participate. All participants had to be: i) 18 years or older, ii) breastfeeding or have breastfed in the previous 12 months at the time of interview, and iii) have used or were using one or more herbal medicines as a galactagogue during breastfeeding to increase breast milk supply or to improve breastfeeding performance at the time of interview. Participants were not required to have been diagnosed with insufficient milk supply, nor had to be from a certain cultural or ethnic background.

Recruitment Strategies

To achieve the study objectives, purposeful sampling was used to recruit participants for the study, targeting breastfeeding women who visited naturopaths or who had an interest in herbal medicines. According to Patton (356), "The logic and power of purposeful sampling lies in selecting information-rich cases for study in depth." Hence, careful selection of participants with a specific interest in the topic was

considered appropriate to enable relevant and quality data to be collected, which in turn improves reliability and credibility of the findings. There are various purposeful sampling methods as described by Patton (356), and of these, the chain or snowball sampling method was considered most appropriate for this study and thus adopted. This process involved asking a participant recruited from a naturopathic clinic or community pharmacy to provide details of the study and contact details of the researcher to her friends or family members who were eligible for this study, and this chain was continued. Unlike other studies where a specific participant type may be identified or recruited from an organisation or setting, the use or purchase of herbal medicines in Australia are not required to be reported nor recorded, hence there was not a specific setting or location to recruit participants. Therefore, the purposeful chain sampling method fitted the scope of this study.

To reduce bias due to the sampling method, the study was advertised to the wider public through a media release prepared by the Public Relations Consultant from Curtin University Corporate Relations and Development. The study was advertised in the *Curtin Health Innovation Research Institute (CHIRI)* newsletter, *The Parent's Paper*, *Western Nurse Magazine*, the *Southern Gazette*, and was also announced via the Curtin FM 100.1 Perth radio station, where contact details of the researcher were provided if women were interested to participate in the study.

As the main objective of the study revolved around the use of herbal galactagogues during breastfeeding, a decision was made to also advertise the study at naturopathic clinics and community pharmacies with a focus on breastfeeding and CMs use. Posters with details of the study (Appendix N) were placed at a health centre whose Clinical Director had agreed to collaborate in the recruitment of participants. This health centre was located in the metropolitan area of Western Australia and had a strong focus on naturopathy and supported the registration of Western herbal medicine for public safety through the TGA.

Through the snowballing effect, participants suggested community pharmacies where more participants were likely to be recruited. Two community pharmacies were subsequently identified for the recruitment of participants. Both of these community pharmacies had a strong focus on customer service, naturopathy and provided a

range of breastfeeding-related services. Participants were then recruited from these pharmacies through expression of interest in response to the participant information sheets (Appendix L) and posters (Appendix N).

Justification of Sample Size

Portney and Watkins (338) commented that sample size determination in qualitative research is based on experience, judgment and the research purpose. According to these authors (338), ‘samples that are too small will not support claims of having reached a point of data saturation. Samples that are too large will not permit the in-depth analysis that is the essence of qualitative inquiry.’ Based on a similar galactagogue study conducted in British Columbia (30) which involved 23 participants, a decision was made to initially recruit up to 20 women for this part of the study and through the data analysis determine whether a point of saturation had been reached, when there was no emergence of new themes. According to a study published in 2005 by Guest et al. (357) on “*How many interviews are enough*”?: *an experiment with data saturation and variability* which studied the variability and data saturation degree, researchers have found that data saturation was present within the first twelve in-depth interviews. An initial number of 20 participants was therefore considered sufficient to reach data saturation whilst also enabling in-depth analysis.

4.3.4 Interview Guide

The initial literature review identified a need for more research in the area of herbal galactagogue use during breastfeeding, in particularly the perceptions of the effectiveness and safety in the Australian context. Taking into account findings of Stage 1 and the available literature, the interview guide was therefore developed to explore the perspectives and experiences of breastfeeding women towards the use of herbal galactagogues. To confirm and further evaluate the findings from Stage 1 of the research with regards to community pharmacy, the guide also included questions to explore the views of breastfeeding women on the role of community pharmacists in meeting their breastfeeding needs in the Australian healthcare system. The first step involved in developing the interview guide was emanated from the aims and

objectives of the study, and to identify exactly what information was needed to answer the research objectives. The research team then developed the interview questions required to obtain the relevant information. For example: one of the objectives of the study was to evaluate the use of herbal galactagogues and that it was considered useful to explore participants' reasons for use of these medicines, hence the interview question was developed: "*Can you tell me why you have used/are using a herbal galactagogue?*".

To address the study objectives, a semi-structured interview guide (Appendix O) consisting of a mix of closed-ended and open-ended trigger questions was developed. This interview guide was pilot tested on two breastfeeding women to ensure that the research objectives were addressed and the questions were clear. As part of the validation process, subsequent amendments were made following suggestions made by the two participants and discussions amongst members of the research team. Amendments to the interview guide included the addition of 'probes' when considered necessary to allow more in-depth information to be elicited around a particular issue, for example, "*Can you tell me more about that?*" Another amendment made following pilot testing was the inclusion of sub-questions for Question 9, when exploring participants' experiences and perceived effectiveness of herbal galactagogue(s) of their choice. The interview guide was used to provide guidance to the interview sessions. An overview of the interview guide is as follows:

- Questions 1 to 12 (including sub-questions) involved closed-ended and open-ended questions to provide both descriptive and qualitative data related to the pattern of use, effectiveness and safety of the particular type(s) of herbal galactagogue(s) used based on personal experiences and perceptions of the participants.
- Questions 13 and 14 (including sub-questions) consisted of open-ended questions that explored the perspectives and attitudes of breastfeeding women, their experiences and perceptions of the available resources and support from the healthcare system and the role of community pharmacists.

Data Collection

Prior to conducting all face-to-face interviews, the purpose of the research and what the interview would cover were explained to participants verbally as well as with the provision of a participant information sheet. For the face-to-face interviews, copies of the participant information sheets (Appendix L) were provided and all participants were requested to sign a consent form (Appendix M) prior to conducting the interviews. An electronic copy of the participant information sheet was sent via email to participants who had provided their email contact and requested a telephone interview. In cases where email contact was not available, the content of the participant information sheet was read to the participant over the telephone and verbal consent was obtained before the interview. Participants were given ample opportunity to ask questions and were reminded that the study was completely voluntary and that they could withdraw at any stage without prejudice. Taking into consideration the variability between participants and at the same time ensuring that the topic of discussion could be thoroughly covered, the interviewer (TFS) adhered to a discrete and flexible approach throughout the interview process. Deviation from the interview guide was necessary in some instances, for example, when the interviewee mentioned an issue not necessarily addressing the questions in the guide, but still considered relevant to the topic. The use of 'probes' was also slightly different for each participant depending on their responses. The interviewer followed the same interview schedule to guide all interviews, however was flexible in the conduct of the interviews, in keeping with the flexible and emergent nature of qualitative research design (358, 359). All interviews were audio-recorded, rather than videotaping to maintain anonymity of participants, and subsequently manually transcribed verbatim.

4.3.5 Data analysis

The transcripts were analysed using descriptive and qualitative approaches. Participants were de-identified and codes were used in the analysis. For example: the first interviewee was given a code "BW1", indicating "Breastfeeding Woman 1", and numbers in the numerical series were allocated to subsequent interviewees.

Descriptive analysis

Participants' responses to closed-ended questions in the interview guide were analysed using descriptive analysis to summarise the findings. Data collected on the type(s) of herbal galactagogue(s) used, reasons for use, recommendations and information resources, methods, routes and dosage administered, commencement and duration of administration were summarised. Data were systematically separated into categories based on the name or type of the herbal galactagogue(s) discussed.

Qualitative analysis

The opened-ended questions in the interview guide that explored the experiences and perspectives of participants were analysed using thematic analysis as described by Boyatzis (360). The transcription process was undertaken by the candidate and provided an opportunity for the candidate to become immersed in the interview data (361). Firstly, contents of the transcripts were read repeatedly to attain a thorough understanding of topics that emerged from the interviews, at the same time paying attention to the 'patterns' that occurred throughout the interviews. After familiarisation, the candidate then carefully read the transcripts line-by-line, while highlighting phrases or sentences and generating initial 'codes'. At this stage, the candidate then collapsed the data to create categories to aid analysis. Notes were made alongside the codes to describe the meaning of the codes where relevant. These codes were then grouped into categories, to form a working analytical framework. The codes were reviewed and emerged "ideas" or themes were recorded and supporting quotations documented under each theme category. Different "units of ideas" were then reclassified as subthemes under a specific "collective idea" or theme. These themes were then regrouped under distinctive headings addressing the research questions. The analytical framework was finalised when no new codes emerged after coding of the last transcript. The candidate subsequently again reviewed all transcripts, to ensure accurate coding and that no new "ideas" had emerged in addition to the existing codes and categories. To ensure reliability of the process of analysis, project supervisors (LH, LT) reviewed the analysis throughout the process, and provided input before the analysis was finalised.

4.4 Results

Results from the interviews are reported using descriptive analysis for closed-ended questions and qualitative thematic analysis for open-ended questions. Supporting quotations which reflected each key theme are provided to illustrate the dimensions of each theme.

A total of 20 in-depth semi-structured interviews were undertaken with breastfeeding women living in the Perth Metropolitan area. Saturation of data was reached after approximately 15 interviews but a decision was made to continue until all 20 participants were interviewed. After 20 interviews, the research team was confident that no new themes were emerged.

All prospective participants who expressed interest were contacted and invited to participate in an interview if they met the inclusion criteria. All interviews were conducted on a one-to-one basis to ensure privacy and confidentiality of participants. Ten interviews were conducted face-to-face at a place convenient to the participant and 10 were conducted via telephone. Of the 20 participants, 17 were of Caucasian descent, two were of Asian descent and one of Middle-Eastern descent.

The interviews lasted between 18 and 78 minutes. As participants were mothers with a young child, all participants were reassured that priority would be given to their infant or child if they needed to be attended to, and interviews were stopped and resumed at another time convenient for the participant. Qualitative narrative data were collected through recordings of the dialogues between the researcher and the individual participant.

Sections 4.4.1 to 4.4.3 report on findings of the descriptive analysis; while sections 4.4.4 to 4.4.8 focus on the qualitative thematic analysis and exploratory data.

4.4.1 Pattern of Use

Data about herbal medicines used were categorised based on the name or type of the herbal galactagogue(s) discussed: i) fenugreek as a sole ingredient, ii) fenugreek and blessed thistle as a combination product, and iii) naturopaths' own "lactation tincture" with a combination of herbal ingredients. Summaries of the pattern of use are provided in Table 4.1, Table 4.2 and Table 4.3, respectively. All 20 participants had used fenugreek either as a sole ingredient or in combination with other herbal ingredients. This finding correlates with the Stage 1 results, which indicated that fenugreek was the most popular herbal galactagogue amongst breastfeeding women. Ten participants had used fenugreek as a sole ingredient to promote breastfeeding (Table 4.1), whilst three had used fenugreek and blessed thistle as a combination product (Table 4.2), and seven used a naturopath's own 'lactation tincture' with a combination of herbal ingredients (Table 4.3), respectively. The most popular formulation or brand of fenugreek was Nature's Own[®] Fenugreek 1000mg, which nine participants had used. Participants commenced herbal galactagogue therapy at various times since delivery of the baby, with one participant commencing as early as three days and one as late as seven months postpartum. Duration of administration also varied from one week to nine months.

4.4.2 Reasons for Use of Herbal Galactagogue

Participants were using herbal galactagogues during breastfeeding for various reasons, including perceived insufficient milk supply (n = 9), diagnosed insufficient milk supply (n = 8), as a supplement in the absence of perceived or diagnosed insufficient milk supply (n = 2), or as part of tradition (n = 1). Participants classified as "perceived insufficient milk supply" were women who had not previously been diagnosed with breastfeeding supply issues by a health professional, however they "perceived" or "considered" themselves as having low milk supply. Participants who had been previously diagnosed with clinical insufficient milk supply by a health professional were classified under "diagnosed insufficient milk supply".

Table 4.1: Summary of the pattern of use: fenugreek as a sole ingredient (n = 10)

Participants	Product/ dosage form	Dosage of administration	Commencement of therapy	Duration of therapy
BW 1	Crude seeds cooked with rice as a sweet dessert	Approximately 60g of seeds cooked with one cup of rice and sugar in pressure cooker, taken twice daily	2 weeks postpartum	5.5 months (since 2 weeks postpartum till 6 months – still using)
BW 3	Nature's Own® Fenugreek capsules (Each capsule contains 1000mg fenugreek dry seed powder)	1 capsule twice daily, then 6 capsules when required as one off dose to boost supply	3 months postpartum	9 months (since 3 months postpartum till one year)
BW 6	Nature's Own® Fenugreek capsules (Each capsule contains 1000mg fenugreek dry seed powder)	Initially 1 capsule daily, then increase to 2 capsules daily when required	3.5 months postpartum	1 month (since 3.5 months postpartum till 4.5 months – still using)
BW 10	Nature's Own® Fenugreek capsules (Each capsule contains 1000mg fenugreek dry seed powder)	2 capsules three times daily	2 weeks postpartum	8.5 months (since 2 weeks postpartum till 9 months)
BW 12	Nature's Own® Fenugreek capsules (Each capsule contains 1000mg fenugreek dry seed powder)	2 capsules in the morning and 2 capsules at night, was aware of the possibility to increase dosage to 6g daily, however 2 capsules twice daily was sufficient to product an effect.	6 weeks postpartum	3.5 months (since 6 weeks postpartum till 5 months – still using)
BW 13	Nature's Own® Fenugreek capsules (Each capsule contains 1000mg fenugreek dry seed powder)	2 capsules three times daily	10 weeks postpartum	8 weeks (since 10 weeks postpartum till 18 weeks – still using)
BW 14	Nature's Own® Fenugreek capsules (Each capsule contains 1000mg fenugreek dry seed powder)	Initially 1 capsule daily, then increase to 5 to 6 capsules daily	2 weeks postpartum	4.5 months (since 2 weeks postpartum till 5 months – still using)
BW 15	Nature's Own® Fenugreek capsules (Each capsule contains 1000mg fenugreek dry seed powder)	1 capsule three times daily	12 weeks postpartum	3 months continuously (since 12 weeks to 6 months), then use when required
BW 18	Nature's Own® Fenugreek capsules (Each capsule contains 1000mg fenugreek dry seed powder)	Initially 1 capsule three times a day for one week, then 2 capsules three times a day	2 months postpartum	1 week (ceased therapy due to adverse effect –diarrhoea)
BW 19	Nature's Own® Fenugreek capsules (Each capsule contains 1000mg fenugreek dry seed powder)	2 capsules three times a day	3 months postpartum	3 months (since 3 months postpartum till 6 months – still using)

Table 4.2: Summary of the pattern of use: fenugreek and blessed thistle combination products (n = 3)

Participants	Product/ dosage form	Dosage of administration	Commencement of therapy	Duration of therapy
BW 2	Nature's Sunshine [®] Breast Feeding Support <i>(Each capsule contains 300mg fenugreek seed powder and 150mg blessed thistle herb powder)</i>	2 capsules twice daily	3 days postpartum	8 months (ceased therapy when stopped breastfeeding)
BW 7	Herbs of Gold [®] Breast-feeding Support <i>(Each tablet contains 1.5g fenugreek seed extract and 500mg blessed thistle herb)</i>	1 tablet twice daily	7 months postpartum	3.5 months (since 7 months postpartum till 10.5 months – still using)
BW 11	Herbs of Gold [®] Breast-feeding Support <i>(Each tablet contains 1.5g fenugreek seed extract and 500mg blessed thistle herb)</i>	Initially 5 to 6 tablets daily, then reduce when required	3-4 weeks postpartum	18 months (since 3-4 weeks postpartum till 19 months)

Table 4.3: Summary of the pattern of use: naturopaths' own 'lactation tincture' with a combination of herbal ingredients (n = 7)

Participants	Product/ dosage form	Dosage of administration	Commencement of therapy	Duration of therapy
BW 4	"Lactation tincture" from naturopath, containing fenugreek and other herbal ingredients which were unknown to participant	1 cup tincture taken four times a day everyday	5 weeks postpartum	5 months (since 5 weeks postpartum till 6 months – still using)
BW 5	"Lactation tincture" from naturopath, containing fenugreek and other herbal ingredients which were unknown to participant	5mL tincture taken six times daily (up to a total daily dose of 30mL)	9 weeks postpartum	7 months (since 9 weeks postpartum till 9 months – still using)
BW 8	"Lactation tincture" from naturopath, containing fenugreek and other herbal ingredients which were unknown to participant	5mL tincture taken three times daily alternating with twice daily	7 weeks postpartum	3 weeks (since 7 weeks postpartum, then ceased, then restarted at 4 months for 1 week)
BW 9	Weleda® Nursing Tea (Each tea bag contains dry powder of fenugreek seed 500mg, fennel bitter seed 400mg, anise seed 400mg, caraway seed 400mg and lemon verbena leaves 300mg)	1 tea bag steep in hot water, taken once or twice daily	10 weeks postpartum	3 months (since 10 weeks till 22 weeks)
BW 16	"Lactation tincture" from naturopath, containing fenugreek and other herbal ingredients which were unknown to participant	5mL tincture taken once in the morning	3 weeks postpartum	14 weeks (since 3 weeks till 17 weeks – still using)
BW 17	"Lactation tincture" from naturopath, containing fenugreek and other herbal ingredients which were unknown to participant	5mL tincture taken three times daily when required when breast milk supply was low	3 months postpartum	1 month continuously, then use when required until the time of interview
BW 20	"Lactation tincture" from naturopath, containing fenugreek and other herbal ingredients which were unknown to participant	5mL tincture taken three times daily or twice daily if missed a dose	6 weeks postpartum	2.5 months (since 6 weeks postpartum till 4 months – still using)

4.4.3 Sources of Recommendation and Supply

Many of the participants had chosen to use herbal galactagogues based on a recommendation, and in most cases more than one resource was utilised to reinforce the decision. These included advice obtained from friends, family members or other mothers with breastfeeding experience (n=11), midwives (n=5), lactation consultants (n=4), naturopaths (n=4), self-reading and researching (n=4), a child health nurse (n=1), and the Ngala helpline* (n=1).

Participants were more likely to believe and seek advice from their peers, who were mothers with breastfeeding experience, as illustrated by the following comment:

“...talking to people on the mothers group page and the breastfeeding support groups, they have all walked through the journey, they understand, and tried different things and suggested different options.” (BW 4)

Although friends and family being the most common source recommending the use of herbal galactagogues, the majority of women (n = 17) obtained their herbal galactagogues from local community pharmacies. Other sources included health food stores (n = 6), naturopathic clinics (n = 4) and the local grocery store (n = 1), as summarised in Table 4.4. This finding indicates a potential vital role community pharmacists and pharmacy staff could play in influencing breastfeeding women’s decisions regarding use of herbal medicines during breastfeeding. This potential role and involvement of community pharmacists from breastfeeding women’s perspectives will be further explored in Section 4.4.8.

* Ngala is a not-for-profit organisation based in Western Australia that provides Early Parenting and Early Childhood services to support and guide families with young children.

Table 4.4: Sources of recommendation and supply

	Number of participants (n)*
<i>Who recommended the use?</i>	
Friends and family members	11
Midwives	5
Lactation consultants	4
Naturopaths	4
Self-reading and researching	4
Child health nurse	1
Ngala helpline	1
<i>Where did they obtain the herbal galactagogues?</i>	
Community pharmacies	17
Health food stores	6
Naturopathic clinics	4
Local grocery store	1

**Note "n" does not equal 20 as more than one responses were provided by some participants*

4.4.4 Perceived Effectiveness and Safety of Herbal Galactagogue

Summaries of the perceived effectiveness and safety of herbal galactagogues based on the participants' personal experience and observation are provided in Tables 4.5, 4.6 and 4.7. Most of the participants (n = 16) had "perceived" or "observed" that these herbal galactagogues were effective in promoting breastfeeding performance. Some participants commented that they were unable to judge (n = 4) due to the simultaneous use of other approaches to increase breast milk supply including use of Motilium[®] (domperidone) and the "pumping method" by using electronic breast pumps. Overall, most participants reported a positive experience on milk supply with the use of herbal galactagogues during breastfeeding. Several breastfeeding performance indicators were mentioned as participants were asked to describe their experience with the use of herbal galactagogues. These included breast engorgement (feeling of "fullness") and increased milk supply. The most commonly reported side effects were body odour from the use of fenugreek (n = 9), followed by headache (n = 2), diarrhoea (n = 2), delayed return of menstrual cycle (n = 1) and an increase in the number of wet nappies in the infant (n = 1), while the other eight participants stated that no side effect or adverse outcome was observed. The most common indicator which participants used to evaluate their breastfeeding performance and whether there was an increase in milk supply was the physical engorgement of the breasts, some described this as the feeling of "fullness". Other indicators mentioned by participants included changes to the duration of feeding sessions, changes in the infant's perceived satisfaction and feeding behaviour, the infant's growth rate and changes in body weight, as well as an increase in the volume of expressed milk. When participants described their positive experiences with the use of herbal galactagogues using descriptions of breastfeeding performance indicators, confidence and self-empowerment emerged as an over-arching theme. Despite the lack of clinical trial data on the actual increase in volume of breast milk production, the breastfeeding performance indicators boosted participants' confidence level and aided in the delivery of psychological benefits. This enabled participants to experience self-empowerment, which in turn may facilitate exclusive and successful breastfeeding. Further information on this is presented in Section 4.4.5, along with the relevant supporting quotes.

Table 4.5: Perceived effectiveness and safety: fenugreek as a sole ingredient (n = 10)

Participants	Perceived effectiveness by user	Adverse effects observed
BW 1	<p>Effective</p> <p>Onset of effect: Within one day</p> <p>Indicator: Breast engorgement</p> <p><i>“So if I have fenugreek tonight, tomorrow morning then I will have very very , what’s the term, engorged breast, a lot of milk, and I found that it was quite instantaneous. Sometimes I even had to express the milk to relieve [the engorgement].The effect was that obvious and instantaneous.”</i></p>	Body odour in mother and infant
BW 3	<p>Effective</p> <p>Onset of effect: Within 4 – 6 hours</p> <p>Indicator: Breast engorgement, infant’s perceived satisfaction, increased volume of expressed milk</p> <p><i>“...I can feel I am full and uncomfortable which normally doesn’t happen till 6am in the morning. Even before feeding, I could feel my breasts so full...it’s just fuller and just quicker feed, the let down is just quicker, there’s more there... I will express 240mL [before using fenugreek], after using the herb, it will be around 270mL. At night normally would be 40mL, but I can express 80 to 90mL at night after using fenugreek.” “...the duration was shorter, quicker, because at night, it will be 15 minutes each breast for newborn. Otherwise, it will take 30 minutes each breast.... When I had it [fenugreek] will just be 15 minutes each side and she will be quite happy, obviously shorter feeding made her less grumpy. It’s just easier feeding, I think she is fulfilled quicker, the flow was obviously quicker, so it was just like drink, drink, drink, bang!”</i></p>	Sweet-smelling body odour which seemed to be dose-dependent. Odour was absent at 1 or 2 capsules (1-2g) daily, but present at 6 capsules (6g) daily.
BW 6	<p>Effective, Onset of effect: Within one day or less than 24 hours</p> <p>Indicator: Breast engorgement, infant’s perceived satisfaction and feeding behaviour, infant is putting on weight</p> <p><i>“When my milk comes down, I can see he is really swallowing like a lot, and it will come down more quickly, so it will take less time for all to happen, he feed probably a bit longer sometimes, and that really gulping sort of feeling, seems like a large volume he is getting, compared to before.”</i></p>	None observed
BW 10	<p>Unable to judge, was using Motilium[®], and top-up with infant’s formula</p> <p><i>“I have no idea. Only because I have limited supply to start with, so I don’t know if it is better or worse since being on it. Same as for Motilium, I have been on it since day dot, but I don’t know. They tell me that I have a good supply considering the surgery that I had, but I really don’t know.”</i></p>	Slight headache

BW 12	<p>Effective</p> <p>Onset of effect: 6-8 hours</p> <p>Indicator: Breast engorgement, quicker and more active feeding session, infant's perceived satisfaction and feeding behaviour, longer interval between each feed</p> <p><i>"I could feel that my breasts were very full, and I had to feed her immediately to relief the swelling."</i></p> <p><i>"Like if she has had a feed around 4pm, before that she would cry for a feed about 3 hours later, but after taking the tablet, sometimes she can wait till around 8 or 9 before needing to have another feed. I suppose that could be related to her growing up too, you know, when little they tend to feed more, every 2 or 3 hours, then slowly become 3 or 4 hours."</i></p>	Slight body odour underarm
BW 13	<p>Effective, Onset of effect: 12 hours</p> <p>Indicator: Breast engorgement, decreased number of feeds per day</p> <p><i>"I have found that since using it myself, that I do feel like my milk supply has been kept quite high because of that."</i></p> <p><i>"It has decreased the number of times I feed a day, probably initially because he was getting as much as what was there but it wasn't enough, so he would be hungry after one or two hours. Whereas now, because he might be getting more at the first feed, he might not feed to feed again after 3 or 4 hours."</i></p>	None observed
BW 14	<p>Effective (with higher dose of 6g daily)</p> <p>Onset of effect: 4-5 hours</p> <p>Indicator: Breast engorgement, ability to express further 50mL after feeding, quicker and smoother feeding session</p> <p><i>"I remember increasing the dosage in the afternoon after lunch and immediately that night I felt that my breasts were so full, they were about to leak I think."</i></p>	None at low dose (1 capsule daily), body odour after taking 6 capsules daily

BW 15	<p>Effective</p> <p>Onset of effect: 2-3 days</p> <p>Indicator: Breast engorgement, increased in volume of expressed milk by 50-100mL, leaking milk</p> <p><i>"I was leaking milk during the night. I would wake up with a wet bra in the morning."</i></p>	None observed
BW 18	<p>Slightly Effective at low dosage (1 tds), however unable to judge for high dosage (6 d) due to adverse effect</p> <p>Onset of effect: One day</p> <p>Indicator: Breast engorgement</p> <p><i>"Initially with taking three a day, I think it did make some difference, but I would say it still wasn't enough or ideal. I decided to increase the dosage to six a day. I can't really tell if taking six a day made any difference because I stopped using it immediately after a day because of diarrhoea and I was too scared to go back to it because now I know that my body doesn't agree with it. Maybe if my body could tolerate the high dose, it would have helped."</i></p>	Persistent diarrhoea, therefore ceased usage
BW 19	<p>Effective</p> <p>Onset of effect: 1-2 days</p> <p>Indicator: Breast engorgement, infant's perceived satisfaction and feeding behaviour</p> <p><i>"I just felt that my breasts were a lot fuller and feeding was quicker and smooth because she isn't crying. That's why I am thinking, maybe it is because I have more milk, and she's getting enough, that's why she is more satisfied."</i></p>	None observed

Table 4.6: Perceived effectiveness and safety: fenugreek and blessed thistle combination products (n = 3)

Participants	Perceived effectiveness by user	Adverse effects observed
BW 2	<p>Effective (in maintaining milk supply, not really increasing)</p> <p>Onset of effect: 1 day</p> <p>Indicator: Breast engorgement, infant's perceived satisfaction</p> <p><i>"You could really tell when your breasts are full. Before I kind of always felt, not deflated but you know, if she were longer than usual between feed I wouldn't really notice it, but then after being on fenugreek, if she went long than say 2 or 2.5 hours between feed, it was very obvious, my breast will look very engorged and it will start leaking, which has never happened before."</i></p>	None observed
BW 7	<p>Effective</p> <p>Onset of effect: 2 hours</p> <p>Indicator: Breast engorgement, infant's perceived satisfaction and feeding behaviour, shorter feeding session</p> <p><i>"I can see more effective sucking and slurping. After taking fenugreek, it was like suck, swallow, suck, swallow, so she was getting more. It was like proper sucking rather than just getting a bit of milk then just suck for the rest of it. Before that, she would only have proper feed for 10 minutes then just sucking afterwards, not really swallowing. But after fenugreek, it was like 20 minutes of constant feeding and swallowing... she seems sort of happier and fuller after feeding. She just appeared to be getting lots of milk and I feel good about that. She appeared more settled."</i></p>	Sweet-smelling body odour and in urine
BW 11	<p>Unable to Judge</p> <p>Onset of effect: 1-2 days</p> <p>Indicator: Breast engorgement, infant's perceived satisfaction and feeding behaviour</p> <p><i>"So sometimes the little one will wake up constantly all night just wanting more milk and in the morning still wants more, but whereas from drinking the tea, I kind of feeling my breasts was filled up quicker."</i></p>	None observed

Table 4.7: Perceived effectiveness and safety: naturopaths’ own ‘lactation tincture’ with a combination of herbal ingredients (n = 7)

Participants	Perceived effectiveness by user	Adverse effects observed
BW 4	<p>Effective</p> <p>Onset of effect: 4-5 days</p> <p>Indicator: Infant’s perceived satisfaction and feeding behaviour, increased milk ingested based on baby-weighing method before and after each feed, shorter feeding session</p> <p><i>“I still don’t have huge milk supply, but at least I have a milk supply.” “We weighed her, initially the weight was something like 20g difference, and then after that it got to about 40, 50, 60g difference. The screaming stopped! She wasn’t getting enough food before, I was getting trouble before sleep, lots of crying and screaming before that. As soon as I started this course of action, my milk increased, she slept better, less screaming, she was getting enough food. Yes, so I wasn’t up until 6am in the morning trying to get her to sleep, put it that way!”</i></p>	Maple-syrupy smell on the body
BW 5	<p>Effective</p> <p>Onset of effect: 1-2 days</p> <p>Indicator: Infant’s perceived satisfaction and feeding behaviour, increased volume of milk supply through supply line</p> <p><i>“So for example she might be getting, you know, 5 or 10 ml from me, and 120 ml from the supplement, and then 2 weeks later when I did the milk studies again, she was getting 60 mL from me. Yes. 2 weeks later, and it was 60 mL and sometimes it was up to 90 mL from the breast!”</i></p> <p><i>“That definitely helped. I don’t think I would still be able to be breastfeeding if it wasn’t for the herbs. Or, actually, I probably will still be breastfeeding because XXX won’t take a bottle, ever, has never ever taken a bottle. But I haven’t used... I haven’t had to supplement any milk since she was 7 months old. And I think if I wasn’t using the herbs, I would still have to be supplementing.”</i></p>	Delayed return of menstrual cycle, woman believed that it is due to goat’s rue based on her reading
BW 8	<p>Effective</p> <p>Onset of effect: Within 24 hours</p> <p>Indicator: Breast engorgement, infant’s perceived satisfaction and feeding behaviour, shorter feeding session</p>	Liquorice-like smell from pores on body, sweat and urine

	<p><i>"I remember the next morning I woke up, I could just feel immediately that my breasts were really hard and full, and that was like that for a few days, so definitely increase very quickly. I could feel engorged. I know initially the first time I took it I was leaking milk and it was like that for a couple of days. I would say easily 25% increase."</i> <i>"It made the feeding smoother. Definitely did have an effect on how she is feeding, she was feeding better. Duration of feeding would have been shorter because she was getting milk, more actively feeding throughout the whole time."</i></p>	
BW 9	<p>Effectiveness observed or perceived by user: Unable to judge Onset of effect: Only slight effect after at least 1 week <i>"To tell the truth with my supply it didn't make a huge amount of difference, but I think it did support it slightly."</i></p>	None observed
BW 16	<p>Effective Onset of effect: 1-2 days Indicator: Breast engorgement, infant's perceived satisfaction and feeding behaviour, increased volume of milk <i>"I just feel that third time round feeding, my baby is four months old and normally your breasts have settled down and you can't tell unless it is right before a feed at that four hour mark or whatever, you have a very full breasts, and at the end of the day, they tend to be less full, they felt less full. To me, this time they feel full, there's something always in there. So I don't know how to explain that, just feel that there's always got milk..."</i></p>	"Sweeter" breast milk
BW 17	<p>Unable to judge, believed there's benefit, so will continue to use Onset of effect: 3 days Indicator: Breast engorgement, infant's perceived satisfaction, modest increase in volume of milk expressed <i>"I can feel my breasts are fuller first of all, and when I express I get a lot more milk. I can see that the baby, because normally before taking it, when I know my milk supply is a bit low, she might need both breasts on a feed. And with this, she would only take one breast for a feed. So there's definitely sufficient milk in one breast. So that's how I know my milk supply has gone up again."</i> <i>"I just feel that the breasts are fuller before a feed..."</i></p>	Occasional headaches, mild diarrhoea, slight maple-syrupy smell on body and in breast milk

BW 20	<p>Effective</p> <p>Onset of effect: Immediate effect, after 1 or 2 days</p> <p>Indicator: Breast engorgement, perceived infant's satisfaction and feeding behaviour</p> <p><i>"I could tell because I could feel that they were so full, and I had to breastfeed to relieve the feeling. Also, I think baby was going through a growth spurt at that time, and I was surprise that I had enough milk to feed her, so I was very happy, and I think she is happy too."</i></p>	<p>Slight body odour, increase in number of wet nappies in infant</p>
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4.4.5 Perspectives and Attitudes towards the Use of Herbal Medicines during Breastfeeding

Five main themes emerged from the thematic analysis of the qualitative data collected during interviews when participants were asked to describe their experiences and general perspectives towards the use of herbal medicines during breastfeeding: i) perseverance and determination to breastfeed, ii) confidence, self-empowerment and reassurance, iii) concerns over breastfed infants' safety, iv) role and expectations of health professionals, and v) peer and parental influence. Embedded within the five themes were the users' attitudes and perspectives. Throughout all these themes, the views of users and why they had chosen to use alternative options over conventional therapies to promote breastfeeding performance were explored and addressed.

4.4.5.1 Perseverance and determination to breastfeed

Many participants seemed to have adopted the 'breast is best' philosophy. These women acknowledged and appreciated the health, physical and psychological benefits of breastfeeding to both mothers and infants.

"...how much it helped my bonding with my baby and even just a general satisfaction from it, not only satisfaction but also I would say the benefits were much higher." (BW 1)

Recognition of the importance and significance of breastfeeding was identified as the main facilitator to develop perseverance and a determined attitude to breastfeed:

"... basically I was just trying to get him back to the breasts and don't want to stop breastfeeding him, so it's to try and increase the supply because there is a need there." (BW 11)

“I can see a difference and it made me feel a lot better to be able to feed my baby in the right way. I was also less sleep deprived!” (BW 14)

All women who participated in this study were aware of the Australian Dietary Guidelines 2013 (35) with the recommendation to breastfeed exclusively for the first six months of an infant’s life. Taking into consideration the advantages of breastfeeding along with endorsement from their health professionals, perseverance and determination played a vital role in promoting successful breastfeeding as women were prepared to take all actions required to ensure exclusivity and the avoidance of infants’ formula as much as possible.

“I was expressing. So it [ensuring sufficient milk supply] was hard, and I didn’t want to use formula. I was expressing the whole year, I was always worried about my supply. For the whole year, it was crazy, I persevere, keep trying and trying.” (BW 3)

“You have to try different things, until you find one that works for your body. I think the key thing is to let people know that you need to persevere and just stick with it.” (BW 4)

“Yes, there was definitely some perseverance.” (BW 11)

“I, myself, was very determined to breastfeed.” (BW 12)

“Breastfeeding is not easy, definitely not. You need to persevere and you need to be absolutely patient with everything that you do. You need to have very high patience level and you need to feel comfortable and confident doing it.” (BW 20)

An underlying theme was observed when women described their strong mental will to breastfeed. Participants were prepared and willing to attempt all options available to safeguard breastfeeding and promote their breastfeeding performance.

“I mean honestly, if drinking snake oil would make me have more breast milk I would have done it, anything that helps!” (BW 3)

“I would be willing to try anything if I know that it would be safe for my baby and that it would help keep my milk supply up.” (BW 7)

“I would try anything really, anything that would help to increase my milk supply because the last thing I want is for my baby to not get enough milk and be forced to give formula.” (BW 12)

“For me, I personally would try anything, anything as long as it helps to keep my baby on breast milk and to keep her full and healthy.” (BW 14)

“I am willing to give anything a go if it works and if it helps.” (BW 15)

“I certainly am not opposed to the idea of using herbs to support breastfeeding. Really, I don’t care what it is, as long as I can tolerate it and it helps, I am willing to try anything.” (BW 18)

As described above, participants reported four main reasons for use of herbal galactagogues, including perceived insufficient milk supply, diagnosed insufficient milk supply, as a supplement and as part of the tradition. Besides those who had been diagnosed with insufficient milk supply, all other participants embraced the “just-in-case” approach to use herbal galactagogues prophylactically in order to avoid breast milk supply issues.

“[I use fenugreek] even though I did not have problems producing milk, but just to keep up the milk supply.” (BW 1)

“I was just concerned that my milk was going down, because it went down with my first child at three or four months.” (BW 6)

“My husband is 6-foot and I am only 5-foot. I know that my son has got my husband’s gene, he has the potential to grow quite quickly, but I was feeling

like he feels hungry even after he has emptied both breasts, so I thought if there was more milk there, it can filled him quicker and he can grow quicker.” (BW 13)

“I want to make sure that I have enough supply, now having to look after two other children... it was just as a top up when he was eight months old, I just think he’s a little unsettled and a friend suggested it and I used it for a month or so and was just to boost the supply I guess before it gets worse.” (BW 16)

“...when I expressed, I realized I didn’t have sufficient milk and my baby wasn’t satisfied after a feed and so I sort of better get the milk supply up before it is gone completely.” (BW 17)

“I was under all the stress, and the fact that I was planning to go back to work in a couple of months’ time, I didn’t want my milk to be compromised, I wanted to do something and take some actions right away.” (BW 18)

4.4.5.2 Confidence, self-empowerment and reassurance

Confidence and self-empowerment was previously discussed in Section 4.4.4 when participants described the perceived effectiveness and safety of herbal galactagogues based on their personal experiences. Interestingly, these elements reappeared throughout the interview conversations and continued to emerge as an over-arching theme. There seemed to be a relationship between the women’s breastfeeding confidence level and duration of exclusive breastfeeding. Even in the absence of milk volume measurement, one participant described how the use of herbal galactagogues promoted her confidence and fostered self-empowerment to breastfeed.

“...because this [fenugreek] works so quickly and it just gave me that confidence straight away. It took away that anxiety and stress.” (BW 6)

Many participants also mentioned the feeling of reassurance through the use of herbal supplements during breastfeeding, which was especially important for first-time mothers. Hence, the use of herbal galactagogues was thought of as one of the

methods of reassurance in the context of their own perceptions. These positive emotional impacts contributed to the success of breastfeeding practices amongst the participants.

“I think it’s [fenugreek] worth trying. And as for me, I certainly find that useful and reassuring that I have found something effective to increase my milk supply. As a new mum, you just never know, you never know what is coming, what problems you will encounter and I certainly did not anticipate that milk supply will be an issue. I have always thought that breastfeeding is easy and will come naturally because everyone else does it, and I wasn’t told about it being an issue.” (BW 12)

“I can see a difference and it made me feel a lot better to be able to feed my baby in the right way. I was also less sleep deprived!” (BW 14)

“Breastfeeding is not easy, definitely not. You need to persevere and you need to be absolutely patient with everything that you do. You need to have very high patience level and you need to feel comfortable and confident doing it. To me, I think using the liquid is a good idea because I feel that at least it has helped, and I am doing the right thing.” (BW 20)

4.4.5.3 Concerns over breastfed infants’ safety

A number of participants voiced their concerns over breastfed infants’ safety whenever any medicine is warranted. These participants were cautious and apprehensive over their decision on what to take or what to avoid whilst breastfeeding, expressing their fear of it affecting their infants’ health.

“I’ve been apprehensive about it, whenever I need to take something, I will always consider if that is safe for my baby or if it might affect breastfeeding.” (BW 6)

“People need to know what is available, and what are the evidences, before they can make decisions, especially when you are pregnant or breastfeeding,

you are just always cautious about what you eat, what you can or cannot take.” (BW 14)

“I really didn’t want to take anything harsh that could affect my baby’s health, so I was more cautious over what I take. I would say that because I was breastfeeding, I was more cautious over what I take and what I eat, and I think that using natural herbs would be safer than using chemicals.” (BW 18)

“I don’t know a lot of herbs but I would tend to use natural remedies first before using other chemicals. I am more concerned about how these products will affect my baby and the last thing I want is to put my baby at risk.” (BW 20)

Some participants associated the use of conventional or “Western” medicines as dangerous or harmful to take during breastfeeding. Limited awareness of potential side effects and medicine knowledge had for some women led to the refusal of conventional recommendations for treatment of insufficient breast milk supply, for instance with the prescription medicine domperidone (Motilium®).

“I don’t really want to take anything pharmaceutical at this stage, when she was only 6 weeks old at the time, she was so tiny, so definitely I was very reluctant to take anything. I was concerned about what was in it [Motilium®], and how it will affect both of us. I thought it was too harsh of a treatment.” (BW 8)

“To me, it [herbal galactagogue] seems a lot safer, because when I was on Motilium®, the way how that works changes dopamine levels in the brain which then increases milk supply and prolactin. That to me has always felt like “Frankenstein” sort of thing. It [fenugreek] just seems more natural. I don’t get concern about any transfer to my milk, because it’s natural and it has been used for hundreds or thousands of years, really, I think over time it would have been tested and proven.” (BW 7)

An underlying theme emerged as participants described their concerns over the use of conventional medicine while breastfeeding. The general perception of “herbal is natural, and natural is safe” was identified. Many participants in this study displayed a tendency to use herbal alternatives during breastfeeding with the general assumption that herbal galactagogues were safer alternatives compared to other options.

“It’s a herb, so it can’t be bad for you. It makes me feel happier that a herb can do that for me. It doesn’t have to be pharmaceutical or a drug, you know. I don’t take any other herbs really, but it’s amazing what it can do.” (BW 6)

“I think if you can avoid taking chemical pharmaceutical drugs, then I would exhaust every single herbal option before I go near any pharmaceutical. Because the herbal options are usually much safer, they usually don’t cause any issues in the baby. For me, in any situation I would exhaust any homeopathic or herbal remedy before I went to pharmaceuticals.” (BW 11)

“I would try fenugreek first. I would try the herbal options. I don’t know, but if he is getting it from me, then there is a chance that it can go to him, so I rather go with a natural option first.” (BW 15)

“I guess I just thought that using a herb would be safer compared to using some chemicals to increase my milk supply.” (BW 18)

“I don’t oppose of the idea of using herbs during breastfeeding. I think it is usually safer, that is usually what I choose if I am breastfeeding.” (BW 19)

Nevertheless, some women commented that natural remedies may not always be safe and that they would still be mindful and vigilant when choosing their therapy of choice. As one participant commented:

“Given that it comes from nature, even though you can’t quantify how much the active ingredient is in there, I believe that it may be enough to cause any problems. So in my opinion, if a herb or substance is used whilst

breastfeeding, as long as there is no or significant adverse effect, or it can be incorporated to part of your diet, then it should be okay, but I am not too keen on tablets and capsules, even though it may be herbal or complementary.” (BW 1)

The decision and likelihood to use herbal options to promote breastfeeding performance was at times linked to women’s personal preference. Some of the participants appeared to have previously used herbal medicines in managing other health issues separate to the pregnancy and lactation phases of their lives. In conjunction with the perception of herbal galactagogues being “safer”, women preferred to use the herbal alternatives during breastfeeding.

“I’ve always use herbal. I didn’t want to rely on taking a drug to get my milk supply up.” (BW 2)

“I will try and avoid and try alternatives, my last resort will be to take the drug. I will try natural versions if that was available.” (BW 3)

“...so definitely doesn’t matter if it was for breastfeeding, I would prefer to go the herbal path, as long as I understand that it will be safe for my baby. I think because I believe in the use of natural remedies, it was all my choice to walk that path first anyway.” (BW 4)

“Even before I was breastfeeding, I tend to choose herbal, during pregnancy I tend to use herbal and that carried through till I was breastfeeding, so that was definitely my first choice.” (BW 8)

“I do think that if there is a herbal option available, and if that is effective and if I know that it won’t cause any problems to me and my baby, I would prefer to use it.” (BW 12)

“In any situation, I would exhaust any homeopathic or herbal remedy before I go to pharmaceuticals.” (BW 14)

4.4.5.4 Role of and expectations towards healthcare workers

Breastfeeding women's expectations of healthcare workers emerged as a prevailing topic of discussion in these interviews. In the context of this discussion, healthcare workers included doctors and specialists, midwives, child health nurses, lactation consultants, naturopaths and community pharmacists. Besides health information, expectations of participants centred on drug or product knowledge, including options of alternative therapies, at the same time respecting women's decision or choice. Participants expected all healthcare workers to have an adequate level of awareness and knowledge on the availability of all different treatment options. Some of the participants indicated a need for healthcare workers to be more open-minded, supportive and prepared to provide alternative options should women wish to be able to choose. Participants preferred to receive suggestions or options with information on their effectiveness in order to make an informed decision.

"I think it's the attitude of people. So you know you go and see the lactation consultant, and they don't tend to, in my experience they don't tend to believe that herbs do very much. Even other health professionals like doctors and pharmacists should be aware or should know about the alternative options, so we can make our own decision, that would have been very helpful." (BW 5)

"...or sometimes to make sure medical professionals see the benefit of alternative therapies. But obviously more support from them would be fantastic." (BW 7)

"I think that having the health professionals being more aware of it. A lot of doctors and even midwives and things just don't know enough about it. So they would automatically go to a pharmaceutical rather than trying something herbal first because they don't know enough about the safe and the knowledge that it is okay to do that." (BW 11)

"I think health nurses need to be informed whether they agree with it or not, just to, if somebody is having issues with feeding, and they don't want to take

any other sort of medicines, then this [herbal galactagogue] could be an option for them.” (BW 16)

One participant who showed preference to the use of herbal remedies described her experience with healthcare workers and discontentment after being diagnosed with milk supply issue:

“It [using herbal galactagogue] is not talked about. Not to boost subject, but no one takes these sorts of things seriously I suppose. I think hospitals need to be more open-minded and willing to talk about other things other than just manufactured drugs.” (BW 2)

It was also noticeable from the interviews that involving breastfeeding women in decision-making regarding their own healthcare will enable a sense of autonomy and therefore increase the likelihood of adherence to therapy regardless of whether it is conventional or alternative therapies. Many participants believed that information regarding herbal medicines to support breastfeeding should be provided in the “mother’s information pack” during visits to pre-natal clinics.

There was also a perception that many healthcare workers were not supportive of the use of herbal medicines during breastfeeding, and were not seen as having full awareness of the range of herbal products available and their evidence in terms of safety and effectiveness. Noticeably, regular users of herbal medicines believed that alternative options should be made available to women by their healthcare workers and wished that all breastfeeding women would be counselled on the appropriate use of medicines and be made aware of the availability of alternative options at some point before lactation. Some participants further commented on the potential value of awareness in reducing distress and anxiety during early days postpartum.

“I think it [fenugreek] is an amazing herb. I wish I had known that with my first child. I think that every breastfeeding mother should know about it, because you get so stressed when you feel like your milk is starting to decrease...” (BW 6)

“I think people need to know that it does actually work, not just some crazy hippy thing. Because actually that was what I thought, I initially thought that the herbs were for people who didn’t want to use conventional medicines because they have issues with big “pharma” or whatever, but honestly for me, it has worked wonders, like far better than anything that any doctors have ever recommended it to use. So I just wish that more women actually are aware of it.” (BW 7)

“I just wish more people knew about it because I know, especially during the early days, a lot of people really worry about supply. I think there’s a lot of misinformation about people not having enough milk and a lot of people that I’ve heard of said they have stopped breastfeeding because they didn’t have enough milk or have a very hungry baby.” (BW 8)

“For me, I think it would have been a lot easier if I had known about taking fenugreek earlier.” (BW 12)

“I think that these options should be made available to all breastfeeding mums out there if they do experience any trouble with breastfeeding... I think more people need to know about it [herbal galactagogues], and it’s not just about knowing that it exists, but also knowing what is the right dose and right way of taking it to ensure you get the effect you want.” (BW 14)

“... so I just don’t think people know about it, that’s why they fear away from it, unless someone they trust has recommended it to them.” (BW 16)

In the absence of adequate information from their health professionals regarding therapy of their choice, in this case herbal or alternative therapies, participants disclosed that internet was a common source of information.

“I think more women should know about this, because no one told me until I read it online myself.” (BW 19)

Despite the criticism about the lack of information about herbal remedies by most healthcare providers, some of the participants reported receiving information and recommendations relating to the use of herbal medicines by some providers. A need for reassurance by healthcare providers emerged as an underlying theme as some participants elucidated their experiences and relationships with their trusted healthcare providers. Participants appeared to be more inclined to follow and feel comfortable with recommendations as advised by their healthcare providers.

“I was extremely grateful that NGALA mentioned it to me.” (BW 6)

“I trust my naturopath in terms of what she prescribes, that it would be safe for myself and the baby while breastfeeding.” (BW 9)

“I am certainly not opposed to the idea of using herbs during breastfeeding, as long as I know and have checked with my child health nurses and doctors or even ringing up a pharmacist.” (BW 12)

“When I heard from my doctor that there were other options, I immediately thought that I would give it a go first.” (BW 18)

“ I need to know about it, I guess be informed by someone I trust or know quite a lot about what I am taking and in this case, I don’t particularly know what’s in it, but someone that I trust [the midwife] has recommended it.” (BW 16)

“I never even thought twice about taking it, I never had any hesitation in it, because of the people who have recommended it to me, like the lactation consultants and the naturopaths. I know a naturopath who is very cautious over what she prescribes when you are breastfeeding, so I never thought twice. I don’t know much of it or how much benefit it had, but I have no problems taking it, I suppose it is a natural herb.” (BW 10)

The need for research and evidence-based information on the use of herbal medicines during breastfeeding was identified by several participants. They expected health

professionals to be up-to-date with the latest research data and be able to translate the information into their daily practice.

“I guess the supplements out there just need more studies. There’s lots of research that goes into glucosamine and fish oil and all these that we think is going to help us, but not for breastfeeding, it will be nice to have that knowledge to know that it works and it is safe.” (BW 3)

“I think more research would be needed, stuff like that to tell women what to expect from taking a product [whilst breastfeeding].” (BW 8)

4.4.5.5 Peer and parental influence

The impact of peer and parental influence on breastfeeding women’s decision and choice of therapy was discussed from the perspectives of sources of recommendation and supply. It was evident that some participants were more likely to believe and follow certain recommendations if the recommendations were made by parents or peers whom they could relate their experience to or women who had breastfeeding experience.

“ [The best thing is] talking to people on the mothers group page and the breastfeeding support groups, they have all walked thought the journey, they understand, and tried different thing and suggested different options.” (BW 4)

“I just heard from my other girl friends who have taken it, that it made a big difference to them. One of them even said that don’t take it, because it gives you so much milk that it gives you mastitis and all that. I mean I don’t have that problem, but heard lots of positive things from other people.” (BW 10)

“I have now recommended it [fenugreek] to a couple of friends who have just had a baby, even though they are not having problems with milk supply, I mentioned it to them anyway, just in case they need it.” (BW 12)

“...because my friend who is the midwife is very cautious, but she recommended it, and she is a great advocate for breastfeeding, that’s why I thought well I’ll give it a try...” (BW 16)

“The first port of call if you are a breastfeeding mum, you would probably go and talk to other mums.” (BW 17)

“My best friend has used them in the past, so I trusted it.” (BW 18)

Some participants described stress from parents and peer pressure to breastfeed as the drive to the trial of all methods available to ensure successful breastfeeding. In these instances, potential psychological or emotional benefits of using herbal galactagogues had further benefits in terms of confidence and reassurance as discussed in Section 4.4.4.

“For me, it was probably pressure from my mum to breastfeed.” (BW 3)

“I was also under a lot of stress from my mother and mother-in-law to breastfeed...” (BW 12)

One participant further described how her family member influenced her decision to use herbal galactagogues:

“I recommended it to my sister-in-law, but she didn’t find that useful, when I told her she has to take six, she found that expensive. Buying formula would have been much cheaper, so she didn’t bother with taking the herb any longer.” (BW 3)

4.4.6 Views on Available Herbal Medicines Resources

Four main themes were apparent in the interviews as participants described their views on the resources available to them as breastfeeding women regarding the effectiveness and safety of herbal medicines used during breastfeeding. These four themes were: i) information needs ii) credibility and reliability of information iii) expectations of health professionals, and iv) role of community pharmacy.

4.4.6.1 Information needs

Despite their decision to use herbal galactagogues during breastfeeding, the majority of the participants (17 of 20) commented that there was a lack of resources available regarding the use of herbal medicines during breastfeeding. Although these herbal medicines were widely available OTC in Australia, information regarding their efficacy and safety during breastfeeding was perceived as not being well established, or at least not made readily available to them.

“It’s a lot of word of mouth, you cannot rely on the internet, but you can do some research online, but in terms of, the average woman who doesn’t have any contact with people who deals with herbs, they will find it difficult because they won’t know where to look. So there’s little out there, unless you know what you are looking for.” (BW 4)

“There’s not much information available out there. Well, I supposed there might be, but most of the time I don’t know where to look for these information.” (BW 6)

“I don’t think there is much out there, at least they weren’t easily available. If it wasn’t for my friend at mothers’ group, I wouldn’t have known to take fenugreek.” (BW 12)

“No one mentioned it to me, I basically read it on the internet myself, online. So I won’t say there is much out there, at least not available to me readily.” (BW19)

Although the lack of readily available information was perceived as an inconvenience for most, two of the participants indicated that there was adequate information available provided that the source of information could be identified:

“It’s probably not a lack. But you do need to know where to look for information.” (BW 3)

“I don’t think it’s too bad, I think the resources related to herbal medicine I think we can do with a lot more information and make it more widely available so that people who are in need of it can use them.” (BW 8)

Nevertheless, the majority of participants expressed a need for accessible evidence-based information and more research to be conducted to facilitate safe and effective use of medicines during breastfeeding. This is vital in promoting successful breastfeeding and avoiding unnecessary early cessation of breastfeeding.

“If it was proven medically and endorsed, more people would be able to use that [herbal galactagogue], instead of just giving up breastfeeding when they feel the supply is low or grabbing the first bottle of formula.” (BW 18)

In addition to the general need for further research, a need for research specifically conducted locally was also identified to facilitate the application of findings to the Australian healthcare context. As herbal preparations exist in various brands and dosage formulations throughout the world, some participants found it impractical to relate to information or studies conducted overseas.

“I think it’s better if we have our own, because obviously all countries the culture is different. And obviously you can’t do research in every single country, but I think I will be more incline to believe it if it was from Australia rather than from overseas. Also different countries have different brands, which to me in my case, different brands gave me a different effect. So like for example if you see a brand from an American website, but then you may not get it in Australia. I think it is really important to have an Australia sort of research around it.” (BW 7)

4.4.6.2 Credibility and reliability of information

Many participants relied on the internet or their friends and family for information, advice and recommendations. Credibility and reliability of information accessed from the internet was highlighted during the interviews. Although many participants questioned the trustworthiness of information obtained from non-accredited sources, they were left with no other option but to use the internet.

“Most of the stuff you get from the internet, I am just always worried about reliability, and the more you read, you tend to trust it more, which may not necessarily be a good thing sometimes.” (BW 5)

“I don’t think there is a lot of information out there about the use of herbs. Even the one that I was taking [Nature’s Own[®] Fenugreek 1000mg capsules], on the label it only says it is for healthy gut or something along that line. Nothing was mentioned about breastfeeding on the label. I went online and people are talking about fenugreek online, but I don’t know if this information can be trusted.” (BW 18)

Participants further cited the need for reliable information endorsed by accredited organisations for example the Australian Breastfeeding Association (ABA) or medical board.

“I had to rely on [internet] forum discussions and word of mouth to make up my mind whether a herbal product is suitable for me or not. So if it was endorsed by a medical or I know the Australian Breastfeeding Association is not a medical, but if it was endorsed more medically in some way or another, it might be more helpful, people might be able to use it more.” (BW 17)

Along with the general perception of the lack of easily accessible reliable information, one participant who was both a health professional and a mother of an eight-month old at the time of the interview, described her views on the information

resources. Inconclusive information was seen as confusing and further posed a dilemma:

“If there is something available, I find that it is usually inconclusive. There is just not enough data and they [the resources] leave the ball to the mothers’ court to decide whether they want to take it. I feel like there is no conclusive information as much regarding herbal medicines during breastfeeding.” (BW 1)

From the perspective of some participants, reliance on parents or close family members and friends for breastfeeding-related information was considered sufficient. This raises questions about the credibility of information obtained from these sources, which will be discussed in greater detail in Section 4.5.

“I only went to where my mum told me, so I personally never looked into safety and efficacy of herbal medicines during breastfeeding.” (BW 1)

“If it wasn’t for my friend at mothers’ group, I wouldn’t have known to take fenugreek. I have now recommended it to a couple of friends who have just had a baby, even though they are not having problems with milk supply, I mentioned it to them anyway, just in case they need it.” (BW 12)

4.4.6.3 Expectations towards health professionals

In general, health professionals were viewed as reliable sources of information. Besides voicing their need for additional research studies, participants also demonstrated a desire for written and verbal information from their healthcare professionals with regards to the use, safety and efficacy of herbal medicines during breastfeeding. It appeared that some participants perceived that there was a lack of health professionals’ awareness about the availability and evidence-based information regarding use of herbal medicines during breastfeeding. Participants expected information related to the use of herbal medicines to be provided in a leaflet or pamphlet format by their health professionals.

“The info packs that you get from the hospitals and pamphlets from nurses don’t have much information about herbal remedies for use during breastfeeding. Like I mentioned earlier, if I had known the presence of fenugreek for example, I would have tried that with my first child and may have a better or easier time with breastfeeding.” (BW 6)

Acknowledging that there is a lack of available information, participants believed that health professionals should endeavour to provide guidance. Information on herbal options during breastfeeding should be made readily available to all breastfeeding women as suggested by some participants.

“At least on what’s available, I mean there might not be a lot of information available, but at least to guide us on where to look out for information.” (BW 5)

Despite expecting health professionals to have adequate levels of knowledge, participants had varying expectations of different health professionals. One participant commented on how she felt that healthcare workers working in the mainstream health system may have different perspectives than those from the field of naturopathy:

“Most of the naturopaths I have spoken to are fairly comfortable recommending things even when I was pregnant or breastfeeding. I find people who are working in natural health are more comfortable than people who are working in mainstream health, they are more hesitant to recommend stuff, they have a more complex... I mean they couldn’t really say whether something was safe or not.” (BW 8)

In the context of reliable information resources, community pharmacy was perceived as an easily accessible health destination and pharmacists were recognised by participants as overall medicine experts. The role of community pharmacy will be covered in greater detail in Section 4.4.8.

4.4.7 Perspectives on the Current Healthcare System and Level of Breastfeeding Support Provided

Although none of the questions in the interview guide was specifically designed to address this topic, breastfeeding women's perspectives on the current healthcare system and the level of breastfeeding support provided emerged as a common focus of discussion by some participants as they described their experiences before, during and after delivery. A mix of positive and negative feedback were noted from the narrative conversation during the interviews.

A multidisciplinary team consisting of a diverse group of healthcare professionals including doctors, pharmacists, child health nurses, midwives and lactation consultants was seen by participants as contributors to the current healthcare system. Many of the healthcare workers were mentioned throughout the interviews when participants described their experiences and understanding with "healthcare" and "breastfeeding support". Despite her perception of insufficient information available regarding the use of herbal medicines during breastfeeding, one participant acknowledged the level of assistance and support provided:

"I would say there is certainly a lot of help out there, I mean a lot of breastfeeding help. You have the child health nurses, midwives, lactation consultants, chemists, doctors and all to help and ask questions if you need to, but I don't think there is enough information out there about use of herbal medicines." (BW 15)

Despite the overall positive experiences, participants highlighted several areas for improvement. Immediate postpartum and early parenthood were viewed as challenging and may be associated with anxiety, stress and confusion in some women, which may impact on their ability to absorb and internalise information. According to some participants, in-depth practical information regarding breastfeeding were not provided until immediate postpartum. Although some pre-natal classes may have touched on the subject, the level of breastfeeding-related information was viewed as insufficient to enable full understanding and anticipation of the potential breastfeeding-related issues which women may encounter. Hence,

participants suggested for breastfeeding and related-information to be part of the focus during pre-natal classes or information sessions to avoid confusion during the lactation stage.

“Before birth, because that’s when you want to learn as much as possible about what’s going to happen when the baby comes because you have no idea. But after baby arrives, you are so consumed and you don’t pay attention to what’s happening around you. Especially, I didn’t really remember anything during the first week. So doctors and nurses could have told me things but I wouldn’t remember, but information should be available before birth.” (BW 2)

All participants from this study had used one or more herbal galactagogues to support breastfeeding. Nonetheless, many of them were not aware of insufficient breast milk supply being a potential issue before the baby was born. Besides the provision of breastfeeding-related information during pre-natal classes, participants further suggested that potential issues with insufficient breast milk supply and information on options available to boost supply, including herbal galactagogues and non-pharmacological therapies should be made available prior to delivery. Pre-natal classes and visits to healthcare professionals were proposed as the most appropriate avenues. This valuable information was perceived as potentially useful and expedient when discussed before the birth of their infants, especially for first-time new parents.

“You know breastfeeding is going to be hard, but you are not told anything about your milk will dry out or drop or supply issue. You are not told any of that, not until you go through it, then you go, “Oh okay, milk supply issue!” So I guess women should be warned about milk supply issues, what to do and what are the options including alternative therapies so women can make their decision.” (BW 2)

“...even if there were brochures that you can pick up, or read through, as there wasn’t much available regarding alternative therapies or ways that you can try to boost your milk supply.” (BW 7)

“I only found out that [fenugreek] after it [low milk supply] became an issue, but if, say maybe within the maternity ward, or during the pre-natal education, that could be introduced at that stage. We are told the importance of breastfeeding and all that, but not really about being aware that supply could be an issue. So, if this was discussed earlier on before delivery, we can prepare and start taking some supplements, rather than addressing it way down the track when you realized that you have a supply issue.” (BW 9)

“More information on what problems you may encounter during breastfeeding and what you can do about it, all these information should be discussed and given before the baby comes. Many women would have attended the pre-natal classes and all that which is where you learn about giving birth, parenting and breastfeeding. I think that is the best time and place to give out information about what are the possible breastfeeding issues you may or may not face, for example insufficient milk supply, and what you can do about it.” (BW 10)

“I attended several pre-natal classes and breastfeeding classes. They were really helpful and relevant, but nothing was mentioned about the possibility of supply issue and what you can do about it or how can you tell if baby is not getting enough. So maybe something along that line would be helpful to other breastfeeding mums.” (BW 12)

“Most mothers will be going to prenatal classes before the baby is born. They do explain breastfeeding but they don’t go through the different things that you can do to help the situation. They sort of tell you this is how you should breastfeed to get the attachment right and things like that, but not really like the issues that could come with it. Well, I just think that if people sort of think that breastfeeding is given, it’s just going to come naturally, it’s just going to be easy. But in reality, it is not, and there are all these issues that come with it, so if you can kind of give everyone a heads up of things that could be coming your way, so at least it gives them some understanding and they can prepare themselves if it didn’t happen the way it was meant to.” (BW 15)

“Sometimes it is so, you are so sleep deprived, when the baby arrived, you are thinking, I am just trying to keep my head above water, so it’s great to have information out there before the baby arrives, or particularly with your first baby. I think maybe they should have given you a little bit more information on breastfeeding and other options out there if you have problems with supply, as well.” (BW 16)

To avoid confusion, it is also crucial that all healthcare providers across the multidisciplinary team are up-to-date with recommended guidelines to ensure consistent and dependable information be delivered.

“I don’t think that there’s, this is my opinion, there isn’t a massive amount of support or in hospital for my first baby. I was told different things in regards to breastfeeding, different ways, it was just confusing, so I had to work out how it would work for me, and that’s very common in first time mum. They are told different things and ended up feeling very confused.” (BW 16)

In addition to the above, participants also put forward their thoughts on what information and which services would be beneficial to breastfeeding women, as below:

i) Need for clinical studies and evidence on the use of herbal medicines during breastfeeding, including the safety and efficacy of herbal galactagogues:

“Definitely clinical studies, about what you are doing is the right thing, if it is going to affect your breast milk in a positive way and that it won’t affect the child in a negative way.” (BW 3)

“...for women who are really struggling for supply, they need to see how much which product can increase your milk supply. I mean for normal women, what percentage of it it increases, stuff like that.” (BW 8)

ii) Availability of information on different brands or dosage formulations of herbal galactagogues in Australia:

“...how can you use this thing more accessible to yourself, how can you buy them, is fenugreek in seed or can you take tablet, and is it going to work for you as well, is there a difference with different form of fenugreek. Sometimes it could be that you have not taken enough, so that’s interesting.” (BW 4)

iii) Pamphlets or information on the different options and use of herbal and alternative therapies to support breastfeeding should be made available in the information packs prior to delivery:

“I just think that in the information pack that you get in the hospital, I think there should be a pamphlet on the use of herbal medicines for breastfeeding. New mothers read the information that is in the packs, and every mother gets one, so it should be in there.” (BW 6)

“Many women would have attended the prenatal classes and all that which is where you learn about giving birth, parenting and breastfeeding. I think that is the best time and place to give out information about what are the possible breastfeeding issues you may or may not face, for example insufficient milk supply, and what you can do about it.” (BW 10)

iv) Information on monitoring breastfeeding performance, for example signs of insufficient milk supply and signs of a settled baby:

“...signs of a settled baby, signs that maybe you don’t have enough milk , obviously if your baby is not putting on weight or unsettled...” (BW 16)

4.4.8 Perception on the Role of Community Pharmacists in Promoting Safe and Effective Use of Herbal Medicines during Breastfeeding

A number of themes and subthemes emerged as the participants described their views and perception on the role of community pharmacists in providing breastfeeding support. Although their views varied widely, participants perceived community pharmacy in general as a convenient source of information which can be trusted. When asked whether they believed that there was a role for community pharmacists to play in the area of herbal medicines and breastfeeding, common facilitating themes and inhibitors or barriers were identified, as summarised in Table 4.8. Throughout the interviews, participants identified several breastfeeding support services deemed to be useful and beneficial in the community pharmacy setting.

Table 4.8: Facilitators and inhibitors/ barriers to an increased role of community pharmacist

Facilitators	Inhibitors/ Barriers
<ul style="list-style-type: none"> ▪ Convenience and accessibility <ul style="list-style-type: none"> ▪ Locality ▪ Availability ▪ Image as a one-stop health destination ▪ Layout ▪ Client-pharmacist relationship ▪ Staff knowledge and credibility ▪ Cost factors 	<ul style="list-style-type: none"> ▪ Lack of advertisement, publicity and promotions ▪ Inconsistent approach ▪ Breastfeeding-related inexperience and low awareness ▪ Pharmacists' pre-conceived perception towards herbal medicines ▪ Overlap of role with other health professionals ▪ Privacy issues/ pharmacy layout

4.4.8.1 Facilitators

The facilitators including convenience and accessibility, client-pharmacist relationship, staff knowledge and credibility, and cost factors emerged as subthemes and are discussed in this section.

Convenience and accessibility

Participants highlighted the convenience and accessibility of community pharmacy as a facilitator to expand the role of community pharmacists in supporting breastfeeding in the community, at the same time promoting safe and effective use of medicines (mainly non-prescription medicines including herbal and alternative therapies) during breastfeeding. Participants perceived community pharmacy as a convenient and easily accessible source of information and supply of a wide range of products.

Locality

In the context of convenience and accessibility, locality emerged as an underlying theme. Community pharmacies are spread out in the Perth metropolitan area and were perceived as “everywhere” and “local” by participants.

“I think that community pharmacies are everywhere.” (BW 1)

“My local chemist is very near my house, it is literally just behind us, I can walk there. I think that is the case for most people as there are so many pharmacies around. You don’t have to make appointment, and you can ask to speak to a pharmacist.” (BW 18)

It was noticeable from the interviews that the term “local” was commonly associated with “trusting relationships”. Participants often felt at ease and comfortable to discuss issues relating to breastfeeding with their local trusted community pharmacists.

“There is a gap for people who don’t have easy access to information. If there was somebody that was local who can talk to them about it, that will make it far easier.” (BW 4)

“It is just another avenue that new mothers can use. As a new mum, we are so confused and so bombarded with information that we do look for recommendations and if there was some community pharmacists, if I knew of one that was close to me that is easy for me to get to, I think I would use them the same as how I would use my child health nurses to answer my questions for me. The fact that they [community pharmacies] are near and local, they are definitely very easy to access.” (BW 13)

Availability

In addition to locality, availability was recognised as a facilitator by some participants. The opening hours and the “no appointments required” practice of community pharmacies were valued, especially for those who labelled themselves as “busy mums”.

“You do not need a booking and usually there isn’t a long wait for you to see a pharmacist to get some proper advice.” (BW 1)

“...you don’t need to make appointment. Definitely easier to go to a pharmacist for advice, it’s the location and accessibility.” (BW 4)

“I know I can go anytime, they are open quite late, and you can get the support and advice when needed. Because often when you are breastfeeding with the young child it is very difficult to get doctors’ appointment or another appointment. So it’s not easy having that accessibility.” (BW 9)

Image as a one-stop health destination

As participants talked about convenience and accessibility, another underlying theme apparent in the interviews was the image of community pharmacy as a one-stop

health destination. Participants labelled community pharmacy as a one-stop destination involved in many aspects of their health, from a source of information, to a source of supply and to monitoring of medical conditions in the community or an “alternative to doctors”. Some participants had utilised community pharmacies as the source of breastfeeding-related information, source of herbal galactagogues supply and source of advice regarding breastfeeding performance and infants’ health. This feature was a main contributor to the overall convenient and accessible perception of community pharmacies.

“And this is when pharmacy can help because you don’t need to go to a doctor to ask a question when you have settled down at home.” (BW 2)

“It would be fantastic if you could go to one place for all the information rather than having to go here and there, you know, one place for the medical information, and another place for the herbal information. It will be like a one-stop for busy mums to get all the information they needed.” (BW 5)

“...you can almost always get quick answers and it is convenient because you can just buy the products or whatever they recommend at the same place, you don’t have to go and see someone, and then drive to another shop to buy the products. It’s just easier to go to one place, especially when you know you can get most of the things from one place when you are so busy with baby and other stuff.” (BW 14)

“You can just get the product from the store and not have to go to a different place just to buy or get the product. It is easy for busy mums like me.” (BW 18)

“It will be convenient and easy. I mean I won’t want to drive all the way with my baby to a specific place just to get some advice or to buy something. I think it is just easier to go down to your local chemist.” (BW 19)

Layout

Participants experienced community pharmacy as a provider of a vast range of health-related products and facilities. Pharmacists were expected to play the role of health/medicine-related information provision and product supply. There was an expectation that community pharmacists should set aside their personal opinions and follow ethical obligations and have an adequate knowledge of all the products available at their workplace.

*“If pharmacy has them in the store, they should know about their products.”
(BW 8)*

“I suppose I would ask more questions at the place where I get my products. For example, if I go to the chemist and get my fenugreek, I would ask the pharmacist or the staff questions about the product, because I would assume they would know best because they have it in their store. I would trust the information because they are trained in that area and from my past experience, they have always been quite helpful.” (BW 12)

“Nowadays most pharmacies sell all kinds of products, including baby-related or natural medicines, if they can provide information based on their knowledge and are willing to help us, I think it would be very valuable. I think especially with busy new mums, you really need someone you can trust to give you information.” (BW 18)

Client-pharmacist relationship

Participants who managed to build a trusting relationship with their local community pharmacists were more likely to perceive community pharmacy as a valuable resource avenue based on their positive feedback.

“Because you get to know your little pharmacy, like I mostly go to one pharmacy down in [a pharmacy located in the North metropolitan region of Perth] and they know me now. When I go in, they ask how is the baby going.

So if they have the information, that would be much easier to just talk to them.” (BW 5)

“I suppose pharmacists are very trusted in the community to a lot of people. So if someone can go to a pharmacy, and they say we do recommend you can use these herbs to increase supply, people will be more incline to believe and try it. Whereas if it is just from word of mouth, or if you see something on TV or hear about it, there’s not actually any credibility behind the claim perhaps.” (BW 7)

Staff knowledge and credibility

Information attained from pharmacists or pharmacy staff were often seen as trustworthy and credible. Community pharmacists and their support staff were assumed to meet the expectations of the public by acquiring adequate levels of knowledge. As some participants were concerned about the reliability of information obtained from non-reputable sources such as the internet, participants appreciated the value of information given by the pharmacists.

“We or the public would generally trust community pharmacists as good source of information.” (BW 1)

“I can just walk in and ask the question and trust that answer.” (BW 2)

“...the few times when I had questions about medications during breastfeeding, I called up the pharmacies and they were fantastic.” (BW 9)

“I just notice that my local chemist is very good with all the over-the-counter medicines. Asking about what I am taking and you know, any contraindications with other medicines and things.” (BW 10)

“It would be so much easier for new mums to just walk in [to a community pharmacy] and get some reliable answers to their queries.” (BW 12)

“I think getting information or recommendation from a pharmacist would be more reputable than your own internet search, because you don’t know how reliable that website is, it may be leading you down the wrong path, so I think a pharmacist might have the advantage of that part, plus they know what they are talking about, because they are trained in that field.” (BW 13)

“Services like baby-weighing services, breastfeeding information sessions with lactation consultants and nurses. These services are important and although they are available now, I think it will be more convenient for mums if they can get these services from their local chemists. That’s just an idea. I think when you are breastfeeding and when you are a new mum, you just need someone reputable that you can trust to tell you if you are doing things right, and if no, how should things be done, like if the baby is getting enough milk and putting on weight, signs of poor sleeping etc.” (BW 18)

Cost factors

Cost factors were quoted as a reason for the role of community pharmacists to be expanded. Visits to a doctor or other health professionals were seen as costly to some participants, while many believed that similar information could be obtained from a pharmacist without a charge.

“It’ll be great to have someone with medical knowledge , not having to go to the doctor and spend 80 dollars just for a question and not having to rely on the internet for basic questions to make sure I get the right information.” (BW 2)

“I think it would be more convenient if new, or busy mums can just go in and get some advice, plus it would be less expensive this way, knowing that starting a family would cost some money, pharmacists are there all the time, you can just ask and get some answers you trust.” (BW 16)

4.4.8.2 Inhibitors/ barriers

A number of inhibitors or barriers were identified by participants, which included the lack of advertisement, publicity and promotions, inconsistent approach, breastfeeding-related inexperience and low awareness, pharmacists' pre-conceived perception towards herbal medicines, overlap of role with other health professionals, and privacy issues relating to pharmacy layout.

Lack of advertisement, publicity and promotions

Although many community pharmacies may be involved in expanding their services to the public, the lack of advertisement, publicity and promotions were identified by participants as a barrier. Participants from this study commented that many women were unaware of the available services and facilities nowadays available in community pharmacies. As the conventional operation of a community pharmacy was predominantly dispensing and the supply of medicinal products, in the absence of adequate publicity, breastfeeding women were not fully utilising the services and facilities provided by the community pharmacies.

“It needs to be more advertised, or maybe mothers are told while at the hospital stay. A lot of women actually don't know about the services available [at community pharmacies].” (BW 2)

Inconsistent approach

Some participants had identified an inconsistent approach from staff at various community pharmacies. One participant commented:

“Depends if I am shopping with the kids. If I am, they will ask [if I am breastfeeding], if not, they won't. Most never ask me if I don't have kids with me. Just the assumption that someone is not with a child, doesn't mean they are not breastfeeding. You look okay, not messy, just doing shopping in nice clothes, they obviously made the assumption that you are not breastfeeding. Without kids, very rarely they ask.” (BW 3)

The lack of a consistent approach with some queries handled by pharmacy assistants during busy times was also seen as a hindrance to building a trusting relationship between the breastfeeding woman and pharmacist.

Breastfeeding-related inexperience, knowledge and low awareness

A lack of some pharmacists' personal breastfeeding-related experience, knowledge and awareness was identified as prohibitive in providing convincing advice to breastfeeding women.

“I am not sure how much they know or whether they have experience with breastfeeding and all, but if they do, I think it would be beneficial.” (BW 18)

There was a clear need for all practising community pharmacists to increase their awareness and knowledge in this field, which was comprehended as beneficial according to participants.

“I think community pharmacists are accessible, except during busy times, if community pharmacists are better educated and have better awareness in this area or focus a lot more about safety and efficacy of medicines including herbal options during breastfeeding, that will be helpful.” (BW 3)

Pharmacists' pre-conceived perception towards herbal medicines

Some participants appeared to believe that pharmacists in general as a pharmaceutical or medicine expert had pre-conceived negative perception towards herbal medicines and alternative therapies. Participants who believed that there was a limited role for pharmacists to be involved in natural or herbal remedies perceived pharmacists as “over-cautious” and their fear to recommend herbal medicines with little or no scientific evidence to support their efficacy and safety during breastfeeding, which was seen by regular users of herbal remedies as a lack of willingness and knowledge in the area of herbal medicines.

“If they can obviously be open-minded about it. It will be better if they don’t just push products with medical based one, I think if you can get pharmacists on board I think that will be fantastic, that will help the community to make a difference.” (BW 7)

“I think maybe checking with the pharmacist would be a good idea but I am not too sure how much they know about herbal medicines. I am very convinced that they know about their pharmaceutical products, so maybe they would be able to offer help regarding herbal medicines, since they sell it all the time.” (BW 14)

“I know that there are a few people out there who just don’t believe in natural medicines. I know my original GP I went to said that it was a load of crap, don’t bother trying it.” (BW 15)

“It obviously depends how much they know about alternative ways to increase milk supply and how much they want to be involved.” (BW 16)

“I think if all health professionals, not just community pharmacists, if they can be more aware of and be more open to discussion about the use of alternative therapies during breastfeeding, this would definitely help breastfeeding women. And I am saying this not because I am being an advocate, it’s about giving women the choice and option that they are comfortable with. It is also important to understand that natural is not always good, but you still need to be vigilant and careful about getting the facts right.” (BW 18)

Despite the lack of confidence in some participants, many of them continued to believe that it would be promising and favourable if community pharmacists could be better educated in the area of herbal medicines and breastfeeding.

Overlap of role with other health professionals

Some participants appeared to be concerned with the overlap of the pharmacists' role with other health professionals. One participant further commented that different health professionals have their distinctive role in healthcare:

“[If] it was about herbal stuff, maybe the naturopaths and friends who are naturopaths. But if it was to do with Motilium[®] or medical or drugs, I will be talking to a lactation consultant, a GP or district nurse or pharmacists.” (BW 4)

Privacy issues and pharmacy layout

Participants expressed their concerns with regards to privacy when discussing breastfeeding-related issues with their pharmacists in the pharmacy. The layout of some pharmacies was not only seen as contributing to the lack of privacy issues, but also the amount of breastfeeding related information or products. Despite the availability of a vast range of products and brands across pharmacies, some participants expressed their frustrations in terms of purchasing herbal galactagogues.

“When I went to the pharmacy, there was only one bottle of fenugreek, they were nearly out of it, it should be stocked, and there should be a breastfeeding section!” (BW 6)

“There wasn't much information available to me regarding the use of herbal or alternative therapies. For example, there was only one brand, one bottle of fenugreek available on the shelf, and the product information wasn't even in relation to breastfeeding or anything related. When I tried to look online, I could see tons of information and forums, but the thing is, whether these can be trusted.” (BW 18)

4.4.8.3 Breastfeeding Support Services in the Community Pharmacy Setting

Participants provided several suggestions and recommendations of breastfeeding support services in the community pharmacy setting which they believed would be an advantage.

“These services are important and although they are available now, I think it will be more convenient for mums if they can get these services from their local chemists. That’s just an idea. I think when you are breastfeeding and when you are a new mum, you just need someone reputable that you can trust to tell you if you are doing things right, and if no, how should things be done, like if the baby is getting enough milk and putting on weight, signs of poor sleeping etc. Maybe not all of them, but I think it may benefit some mums, especially if transport is an issue and if they can just walk to their chemists.”
(BW 18)

In addition to providing expert advice on medicines use during breastfeeding, it was suggested by participants of the study that the following be implemented in community pharmacies:

- Lactation booth;
- Liaise with Australian Breastfeeding Association (ABA) to provide and distribute pamphlets and educational materials in the pharmacy;
- Baby weigh-in service or station;
- Breastfeeding information sessions in-store with lactation consultants and nurses;
- One-on-one counselling service in a specified consultation room or corner of the pharmacy to ensure privacy and confidentiality.

4.5 Discussion

The key findings of Stage 2 of this research are presented and discussed in four sections: i) use of herbal medicines as galactagogues, ii) perceived effectiveness and safety of herbal galactagogues, iii) perspectives and attitudes of breastfeeding women towards the use of herbal medicines whilst breastfeeding, and iv) role of community pharmacists in providing medicines and breastfeeding-related advice to breastfeeding women. A workflow diagram illustrating the flow of Stage 2 data collection and thematic analysis is provided in Figure 4.1. The figure serves to aid visualisation of the process and discussion of Stage 2 findings.

4.5.1 Use of Herbal Medicines as Galactagogues

This section discusses the results previously presented in Sections 4.4.1, 4.4.2 and 4.4.3. To explore their use, the initial recruitment strategy did not specify the name(s) or type(s) of the herbal galactagogue(s) to be used. Women were not required to be on a particular herbal galactagogue to be eligible for this study. Nevertheless, fenugreek was used by all of the 20 participants either as a sole ingredient or in combination with other herbal ingredients. This finding correlates with the Stage 1 results, which indicated that fenugreek was the most popular herbal galactagogue amongst breastfeeding women studied in Western Australia. Herbal medicines used as galactagogues by participants of the Stage 2 study were fenugreek, blessed thistle, fennel bitter seeds, anise seeds, caraway seeds, lemon verbena leaves and possibly other herbal or even non-herbal ingredients used in naturopaths' own 'lactation tincture' unknown to participants. Herbal galactagogues identified and used by participants of this study were consistent with findings from Stage 1 study which indicated that fenugreek, blessed thistle and fennel were the top three most commonly used herbal medicines during breastfeeding for the purpose of enhancing breast milk supply amongst the survey respondents.

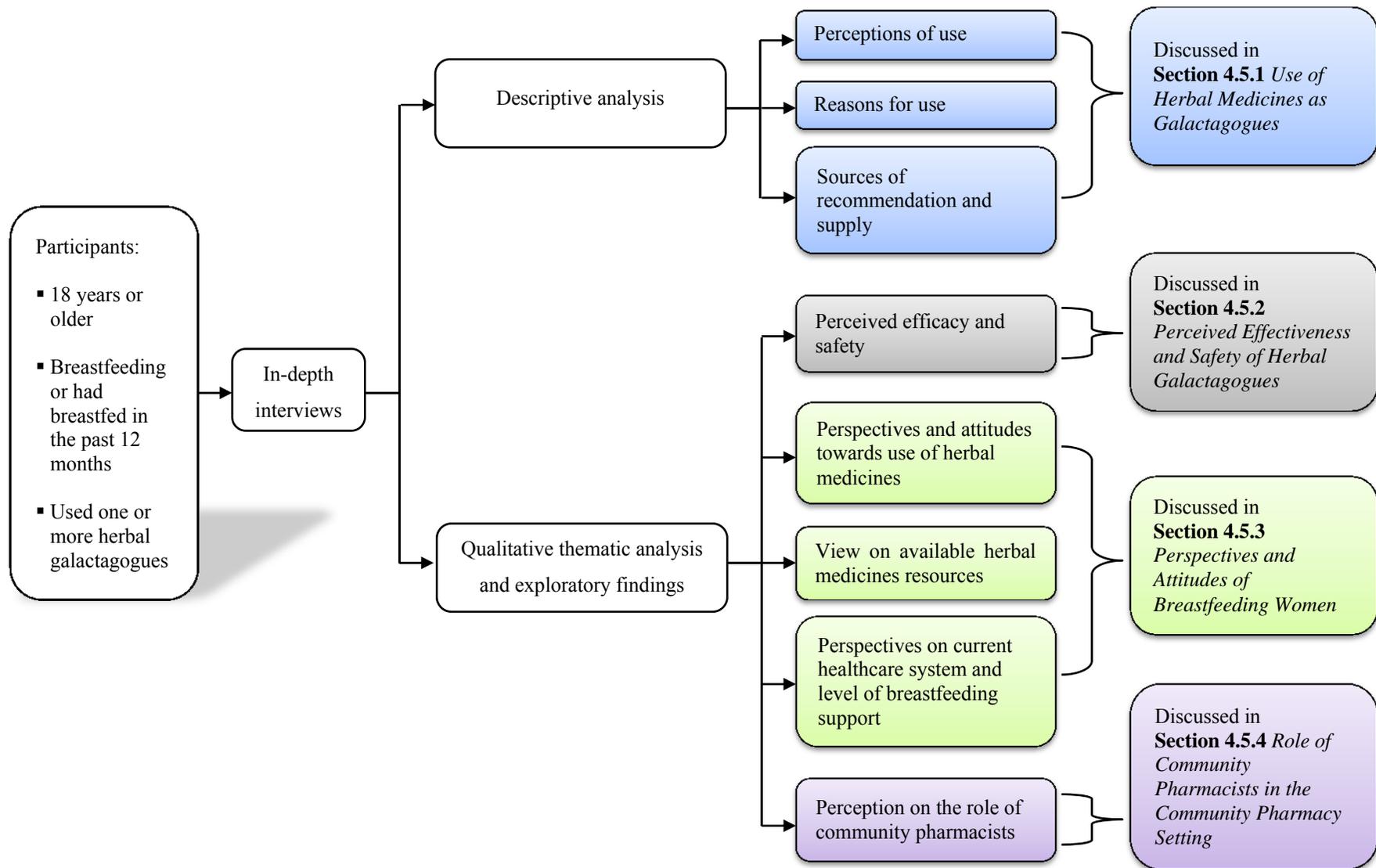


Figure 4.1: Schematic representation of the Stage 2 process

This finding was also in keeping with the literature reports. A qualitative study conducted in British Columbia in 2002 which involved 23 women identified fenugreek, blessed thistle, fennel, stinging nettle and raspberry leaf as the five most reputed herbal galactagogues (30). The majority of the participants were born in Canada, while others were born in Germany, USA and Asia. Caucasians represented the majority of the participants (70%), followed by Asian, Metis, and mixed racial backgrounds. In this study, 17 out of 20 participants in Stage 2 were Caucasians, followed by two Asians and one of Middle-eastern descent.

As evident in this study, herbal galactagogues exist in various dosage forms and preparations. Although fenugreek was identified as the most commonly used herbal galactagogue in this study, the dosage forms of administration by participants varied. These included crude seeds, capsules containing dried seed powder, extract tincture and nursing tea. Potency and doses of herbal preparations across different brands were also not standardized, making comparison of clinical effect challenging (343). In addition, many participants were using relatively low doses of fenugreek, lower than the 6 g daily doses (in various forms or preparations of the herbal ingredient) as recommended by the German Commission E (323). Seven participants were also taking a combination of herbal ingredients as galactagogues in the form of a 'lactation tincture' prepared by their naturopaths with unknown ingredients, strength or potency, making it impossible to compare between products in relation to the effects of specific herbs. Taking into consideration that dosages and length of treatment may influence the efficacy and adverse effect profile, all contents of the products including tinctures prepared extemporaneously should be clearly listed and made available to all users. This is important if an emergency health crisis arises.

This study also indicated that fenugreek exists in many commercially available products in combination with other herbal ingredients in Australia, in a similar trend to other countries (133, 259). Many commercially available herbal products as seen in this study combined various herbal ingredients in an attempt to maximise galactagogenic effects, which further presents ambiguity when trying to identify the effects of a specific individual herbal galactagogue (133). Besides the variability of dosage of administration, there was also no consistent approach in recommendation in regards to the commencement and duration of therapy. As evident in this study,

women appeared to administer herbal galactagogues at various times since postpartum and for different durations.

Reasons for Use

There were various reasons for use of herbal galactagogues amongst the study population. Women were using herbal galactagogues in the presence and absence of milk supply issues. Only eight out of the 20 participants were diagnosed with insufficient milk supply by their health professionals. On the other hand, more than half (n = 12) of the participants were using the herbal galactagogues of choice due to perceived insufficient milk supply, as a supplement prophylactically and as part of the tradition. Although there are many physiological or medical reasons for insufficient milk supply, other social and psychological factors may also play an imperative role in affecting the mothers' milk production (2, 133). The perception of inadequacy is common amongst breastfeeding women, and may lead to subsequent anxiety which may affect breastfeeding performance and well-being of the women (30). This indicates a potential psychological role of any methods or products used to enhance breastfeeding performance. Use of herbal galactagogues as part of the elements of self-care during the postpartum period was also observed for some women in this study. As perceived insufficient milk supply especially during early stages postpartum had been shown as one of the main reasons for commencing herbal galactagogues in this study, the importance of other non-pharmacological measures including education on breastfeeding techniques, encouragement and perseverance should not be neglected. Initiatives to increase women's awareness of the possibility of various breastfeeding issues that they may encounter including perceived insufficiency and methods to address the issues may help to avoid early cessation of breastfeeding. From these data, however only a minority of these participants sought advice from a lactation consultant or a child health nurse. Increasing their awareness of the potential issues and the availability of these resources prior to delivery or during the perinatal period may serve to better prepare breastfeeding women for the challenges ahead.

Sources of Recommendation and Supply

This study reveals that the users of herbal galactagogues were likely to receive advice and believed their friends and family members who were mothers with previous breastfeeding experience. Women could relate their personal experience and emotion to other mothers, hence friends and family members were the most common source of recommendations. Consistent with the results obtained from Stage 1, community pharmacies remained one of the main sources of herbal medicines supply including herbal galactagogues for breastfeeding women. At the present time, community pharmacies represent one of the major provider of CMs in the Australian community (201). Although community pharmacists are not the main source of recommendation to use herbal galactagogues during breastfeeding, being the major provider of CMs signals opportunity for pharmacists and pharmacy staff to intervene and promote safe and effective use of CMs during breastfeeding. However, the paucity of scientific data may present a challenge for pharmacists when it comes to decision-making and the provision of recommendations and advice to their clients. The role of community pharmacists from the pharmacists' perspectives will be further explored in Stage 3 of this research. This finding also further reinforces the results of Stage 1, which demonstrated a potential role of community pharmacists and pharmacy assistants in the topic of discussion. Further studies to explore the perspectives of community pharmacy staff will enable better understanding of the topic and identify any research gaps and interventions necessary to improve pharmacy practice.

4.5.2 Perceived Effectiveness and Safety of Herbal Galactagogues

This section of the discussion refers to data presented in Section 4.4.4.

The study acknowledged the users' experience and perceived effectiveness of the herbal galactagogues of their choice on a case-by-case basis. In addition, the safety aspects of herbal medicines were also documented in the form of adverse effects experienced or observed by the users personally and their breastfed infants. The majority of the participants (16 of 20) had indicated that they felt the herbal

galactagogues of choice were effective in terms of enhancing their breastfeeding performance, with fenugreek and blessed thistle being the two most commonly used herbal galactagogues. Consistent with published literature, fenugreek and blessed thistle are the two commonly used herbal galactagogues (133, 236, 343). A study conducted by Turkyilmaz et al. (324) demonstrated that the use of a brand of herbal tea (Still tea, Humana[®]) which contains fenugreek and other herbal ingredients significantly increased breast milk production when consumed during the early postpartum period, as discussed in Chapter 2 of this thesis. No adverse effects were reported (324). As the herbal product contained a combination of fenugreek and other herbal ingredients, it was difficult to assess if the demonstrated effectiveness was attributed solely to fenugreek or included the effect of other ingredients. A study conducted by Di Pierro et al. (265) demonstrated effectiveness of milk thistle as a galactagogue with no reports of adverse effects in either mothers or infants. The adverse effects reported by participants in the Stage 2 study included a maple syrup-like body odour (which was dose-dependent), headache and diarrhoea, which were all consistent with published literature (133, 228, 235, 236). One participant reported delayed menstrual cycle from the use of a 'lactation tincture' supplied by her local naturopath. This 'lactation tincture' contained a combination of herbal ingredients including fenugreek and goat's rue, which she believed to be the cause of this adverse effect. A search of the literature revealed that the hormonal effect experienced by this participant was more likely to be due to fenugreek, as this herbal medicine has been shown to have oestrogenic activity in an *in vitro* study (362).

Besides the measurement of milk volume after expression, many women used various ways to judge or evaluate if a herbal galactagogue was effective or useful in the domestic environment. These were considered 'breastfeeding performance indicators' for the purpose of this study. As discussed earlier, the psychological or emotional impact of the use of herbal galactagogues during breastfeeding should not be underestimated. As evident in this study, confidence and self-empowerment emerged as an over-arching theme throughout the interviews, especially when participants described their positive experiences. This finding was also observed in similar study conducted by Westfall (30), who commented that the psychological benefits of herbal galactagogues should not be neglected. This theme was also mentioned in a review article published by Ayers (29) who commented, "Because the

most commonly cited reason for the premature discontinuation of breastfeeding is the mother's perception (usually inaccurate) of insufficient milk supply, offering women a sense of self-efficacy and empowerment through alternative therapy may help to combat this sense of inadequacy".

Despite their long history of use, there are currently limited efficacy and safety data with regards to the use of herbal galactagogues during breastfeeding (133, 235). Most available studies which have examined the clinical efficacy and safety of herbal galactagogues appeared to have small sample sizes and a lack of consistent approach in terms of standardizing the protocol and process of studies (343). Although the qualitative nature and sample size of this Stage 2 study does not allow for a definitive conclusion to be made as to which type(s) of herbal galactagogue(s) were effective or safe, the exploratory nature of the study delivered better understanding of the topic in the Australian context and provided direction to subsequent research in the field. The findings of this study, along with a review of the relevant literature, identified a need for scientific evaluation of the commonly used herbal galactagogues in Australia, namely fenugreek and blessed thistle.

4.5.3 Perspectives and Attitudes of Breastfeeding Women

This section discusses the data presented in Sections 4.4.5, 4.4.6 and 4.4.7, which aimed to explore women's perspectives towards the use of herbal medicines, the views of users as to why they had chosen to use alternative options over conventional therapies to promote breastfeeding performance, their views on the available herbal medicines resources and the current healthcare system.

Although many previous studies have examined the perspectives and attitudes of women towards the use of medications during breastfeeding, most had focused on the use of conventional medications (87). As suggested by findings of Stage 1, the prevalence and popularity of CMs, specifically herbal medicines amongst breastfeeding women, should not be neglected.

All participants of this study appreciated and valued the benefits of breastfeeding. The perseverance and determination to breastfeed as observed in the participants were thought to be an outcome of the acceptance of the 'breast is best' philosophy. Participants of this study showed a positive attitude towards breastfeeding and were willing to take any efforts necessary to ensure the success of breastfeeding, including the use of herbal medicines to promote breastfeeding performance. For most participants, the strong will to breastfeed along with recommendation from family and friends had led to the use of herbal galactagogues during breastfeeding. As discussed previously, the potential psychological or emotional impact of using herbal galactagogues prophylactically during breastfeeding should not be neglected.

Women who had used herbal galactagogues during breastfeeding may have accepted and adopted the integrative and holistic approach into their own healthcare. Previous studies have demonstrated the acceptance of CM integration in healthcare amongst the general population in Australia (207) and Canada (363). These two studies explored consumers' views on CMs (in Australia) or NHPs (in Canada) and pharmacy practice. Some women who had used herbal galactagogues during breastfeeding were also users of herbal medicines prior to pregnancy and lactation. Consistent with previous research on perspectives of alternative healthcare users, this finding demonstrated that some women chose alternative options over conventional medicines as they offer personal autonomy and a sense of control over their own health, and that the decisions aligned with their values and beliefs (364-368). The sense of empowerment when a breastfeeding woman actively seeks out and adheres to an alternative regimen plays a positive role in her breastfeeding journey (30). As perceived insufficient milk supply is one of the major cause of premature cessation of breastfeeding, offering women a sense of empowerment and self-efficacy through herbal galactagogues may aid in contending this inadequacy (29). Nevertheless, qualitative studies involving interviews of herbal galactagogue users or case studies alone are not sufficient to provide evidence to support the clinical efficacy of these medicines. A double-blinded RCT will be necessary to determine the clinical efficacy of these herbal medicines as galactagogues. The main outcome measures of such studies should include measurements of daily milk volume, maternal serum prolactin concentrations and reported adverse effects in mother or infant, before and after taking the herbal galactagogues. The potential effect of herbal galactagogues in

providing women with a sense of self-efficacy and their subsequent effect on breastfeeding performance could also be assessed using the Breastfeeding Self-Efficacy Scale (BSES). The BSES is an instrument developed to measure the confidence in breastfeeding women (369). As women's breastfeeding self-efficacy has been shown to be a predictor of breastfeeding duration and patterns of infant feeding (369, 370), such a study could also assess the effects of herbal galactagogues on the BSES scores and their effects on breastfeeding duration.

Given the fear of adverse effects and risk of harming their infants with the use of conventional medicines and the popularity and acceptance of integrative or holistic healthcare in the general population, women may be likely to opt for alternative options for example herbal medicines for promoting breastfeeding performance. Previous dissatisfied experience with conventional treatments may also encourage the use of alternative therapies whilst breastfeeding (364). Of the seven participants who had used combination products, six were using 'lactation tinctures' obtained from their naturopaths containing a combination of herbal ingredients that were unknown to the participants. Of these, three participants (BW 4, BW 8 and BW 20) also specifically raised concerns over safety of breastfed infants with regards to using medicines whilst breastfeeding and that they believed herbal medicines would be a safer option. Despite expressing concerns over safety issues, some women continued to use products recommended by their naturopaths, even without any knowledge of the ingredients. This in itself is of concern, as participants' decision to use these products conflicted with their views with regard to safety. It was apparent that these women had inaccurately perceived all herbal medicines in the context as being 'natural' and therefore will always be 'safe' to be used whilst breastfeeding. It is also possible that these women may have built rapport with their naturopaths and that they had trusted their advice and recommendation. It needs to be acknowledged that herbal medicines are not always 'safe' and there is a risk that some herbal medicines may cause side effects or potentially toxic effects in both the mothers and their infants if their constituents are transferred into the breast milk. Furthermore, many herbal medicines lack scientific information to support their efficacy and safety when taken in breastfeeding, as compared to conventional medicines. Some breastfeeding women may have limited knowledge on the risk and benefit profiles of herbal medicines, and the misconceptions surrounding the safety of herbal medicines are of

concern. This finding highlights a need for intervention to raise the level of public awareness and to provide available information on safety aspects of using herbal medicines, at least amongst breastfeeding women. The scope for improving information dissemination and communication with breastfeeding women on herbal safety issues is limited by the lack of detailed high level data on this topic.

Consistent with the literature and previous findings, breastfeeding women identified the need for more in-depth information, including scientific evaluation of the efficacy and safety of herbal galactagogues and other herbal medicines during breastfeeding (87, 208, 365). Women expect health professionals to have adequate knowledge and to be willing to offer advice and discussion over alternative therapies to promote breastfeeding performance. An interesting finding of the study was that women may have varying expectations towards different healthcare workers, where one participant specifically commenting that naturopaths and healthcare workers working in the field of naturopathy were more comfortable in recommending herbal medicines during breastfeeding, than those working in the mainstream health system. It could be argued that naturopaths and those working in the field of naturopathy may have more knowledge or experience in the area of herbal medicines and hence may be more comfortable in recommending their use in breastfeeding. Nevertheless, it should be noted that there is limited high level information available regarding the safety of herbal medicines taken during breastfeeding. Healthcare workers from the mainstream health system, such as doctors, nurses and pharmacists, may be more cautious in their recommendations due to concerns regarding the lack of scientifically-based information to support the use of these medicines during breastfeeding. In the absence of evidence-based information or when the benefit to the mother does not clearly outweigh any potential risk to the breastfed infant, these health professionals may be hesitant to recommend and choose to avoid the use of these medicines.

4.5.4 Role of Community Pharmacists

Finally, this section discusses the findings as presented in Section 4.4.8, which explored breastfeeding women's perspectives on the role of community pharmacists

in promoting safe and effective use of herbal medicines during breastfeeding and providing breastfeeding support.

A review paper has indicated that many studies exist to examine the perspectives and attitudes of health professionals as well as breastfeeding women towards the use of medications during breastfeeding (87). Nevertheless, there have been limited studies that have explored the perspectives of women towards the role of community pharmacists in this topic. The current study has illustrated an opportunity for community pharmacists to expand their role in the community pharmacy setting, based on breastfeeding women's perspectives. Most participants identified a role for pharmacists in the area of providing easily accessed, trust-worthy advice and information about medicines including CMs use during breastfeeding. This study has highlighted the role of community pharmacists in the community pharmacy setting through increased provision of information and advice on the efficacy and safety aspects of CMs during breastfeeding. Besides information on conventional medicines and CMs, breastfeeding women also expect pharmacists to have basic knowledge on breastfeeding and the various issues related to breastfeeding.

In general, breastfeeding women regard pharmacists as a trusted health professional, a drug expert, and the first port of call for questions relating to use of medicines during breastfeeding. Whilst pharmacists were not actively recommending the use of herbal galactagogues during breastfeeding, being one of the major supplier of CMs in the Australian community, women expect pharmacists to play a substantial role in providing advice and recommendation regarding CMs use. However, the paucity of data specifically in the area of herbal medicines and their safety in breastfeeding may create a challenge for pharmacists. The advice pharmacists can provide may be limited due to the lack of evidence-based information, which may not fulfil the requirements or meet the expectations of some breastfeeding women.

4.5.4.1 Facilitators

As evident in this study, convenience and accessibility of community pharmacies, client-pharmacist relationship, knowledge and credibility of pharmacists, as well as cost all represent important factors when women decide the source of advice. In

other words, the characteristics and values of both the community pharmacies and the staff, which include pharmacists and assistants, are factors which drive breastfeeding women to utilising this avenue.

Women in the study appreciated the convenience and accessibility of community pharmacies, which had enabled them to obtain advice in a timely manner. This factor, in contrast to the appointment-based services provided by other health professionals, consolidated the role of community pharmacies in providing free healthcare services to breastfeeding women. Women perceived community pharmacies as a convenient one-stop health destination, from obtaining health and medicine-related advice to purchasing products. In addition, some participants from this study also see a role for pharmacists to play in providing monitoring services in the community and as an alternative to visiting their local general practitioners. This finding demonstrated a switch from the traditional ‘shopkeeper’ image of pharmacists to now the ‘healthcare provider’ image (371). Besides contributing to the expansion of pharmacists’ role in the community, this will also help to reduce burden to the healthcare system and reduce appointment waiting times for general practitioners.

Most community pharmacies, being local, may also help develop trusting relationships with breastfeeding women and their family members. As observed from this study, client-pharmacists relationship plays an integral role in enabling breastfeeding women to discuss freely and comfortably regarding issues related to breastfeeding. Building rapport between client and pharmacist is fundamental in many aspects of healthcare promotion in the community pharmacy healthcare setting, especially in this case, building trust between breastfeeding women and community pharmacists will enable the former to feel comfortable in discussing any breastfeeding-related issues.

In many previous studies, pharmacists’ knowledge and credibility were mentioned as one of the facilitating factors driving consumers or clients to community pharmacies (4, 87, 371-373). In this study, the knowledge and credibility of both pharmacists and pharmacy staff were cited by some participants. However, the context of discussion was directed more towards pharmacists’ knowledge on general health conditions and

the use of conventional medicines, and less so for the use of CMs including herbal galactagogues during breastfeeding.

Ideally, pharmacists and pharmacy staff should actively enquire and identify women if they are breastfeeding at every occasion prior to providing advice to ensure appropriate recommendations can be provided to breastfeeding women. However, this may present as a challenge unless pharmacists and relevant pharmacy support staff are adequately trained, especially in terms of their knowledge in this field and communication skills to ensure women do not react negatively when approached. Unlike some conventional medicines, herbal galactagogues and other CMs are readily available OTC. Breastfeeding women who are buying CMs from the pharmacies are more likely to have regular interactions with pharmacy assistants. Hence, the role of pharmacy assistants in this context and their impact on building relationships with clients should not be neglected.

This study identified the various factors which facilitated breastfeeding women to utilise community pharmacies. From the breastfeeding women's perspectives, this study has also identified a clear need for pharmacists and pharmacy assistants to continuously undergo training to upgrade their knowledge and communication skills when dealing with breastfeeding women. Besides improving the knowledge in the area of CMs, training on basic knowledge of various aspects of breastfeeding will also help to foster relationships and promote breastfeeding in the community.

4.5.4.2 Barriers

Several barriers to expanding the community pharmacists' role were identified by participants of this study and needed to be addressed in order to improve pharmacy practice in the topic of discussion. These barriers were a perceived inconsistent approach, lack of knowledge and awareness, lack of personal or close-contact breastfeeding-related experience, pharmacists' pre-conceived perception towards herbal medicines, concerns regarding overlap of role with other health professionals, privacy issues and pharmacy layout. The lack of advertisement, publicity and promotions were also identified as barriers to some women.

Some participants expressed their desire for community pharmacists to be more 'open' to discuss various issues related to breastfeeding and to offer more discussion on CMs and alternative therapies during breastfeeding. Consistent with the literature, the consumers expected community pharmacists to be more knowledgeable in the area of CMs and to have a greater level of engagement and interaction with their pharmacists (374). However, taking into consideration the scope of practice and skills of pharmacists, it is vital that pharmacists are clear with their role and be able to identify the need to refer breastfeeding women to other health professionals for example child health nurses or lactation consultants for further breastfeeding-related advice when necessary. Increasing the awareness of pharmacists and the appropriate referrals would also help foster inter-professional collaboration and relationships.

The perceived lack of a consistent approach as described by one participant in this study was considered a barrier or hindrance to building a trusting relationship between the breastfeeding woman and the pharmacist. These included inconsistent questioning to identify whether the client was breastfeeding and the lack of referral to pharmacists by the pharmacy staff especially during busy times in the pharmacy. Hence, time constraint was seen by some as one of the contributing barriers to appropriate pharmacists' advice. In a study conducted by Jones and Brown (142), only 11% of the surveyed breastfeeding women who had purchased OTC medications from pharmacies were asked their breastfeeding status by the pharmacists and pharmacy staff. Hussainy and Dermele (87) further commented that this issue should be addressed to enable accurate information and advice be provided to breastfeeding women in the community. All pharmacists and pharmacy staff have an ethical obligation to provide relevant as well as accurate advice to all clients, including breastfeeding women. This may be facilitated by actively enquiring, as part of their process and competent pharmacy practice, all women of childbearing age, to identify whether they are breastfeeding or pregnant. Nevertheless, care needs to be taken in a way these questions are presented to avoid potentially embarrassing the patients.

Taking into consideration the potential sensitivity issues related to breastfeeding, the lack of pharmacists' personal breastfeeding-related experience was identified as one of the contributing barrier from the breastfeeding women's point of view. It also

appeared that the layout or design of some pharmacies may be contributing to some degree of lack of privacy. Nevertheless, the gender of pharmacists was not one of the issues raised by participants of this study. To overcome the above barrier, all pharmacists and pharmacy staff are expected to have a basic knowledge about breastfeeding in order to communicate effectively with breastfeeding women, and that all pharmacy support staff should be able to identify cases which require referral to the pharmacist. As a primary care provider in the community, effective communication is essential to enable holistic care and to appreciate and recognise the breastfeeding women's needs (375). Despite the lack of personal experience with breastfeeding, good communication skills possessed by a pharmacist may aid to foster a trusting relationship with any clients, and certainly in this case, with breastfeeding women.

Some women believed that pharmacists may have a pre-conceived negative perception towards herbal medicines and alternative therapies, and would prefer if the pharmacists were more willing to discuss and recommend the use of herbal medicines during breastfeeding. Some saw herbal medicines and breastfeeding as outside the scope of pharmacy practice, which may form one of the barriers to obtaining pharmacists' advice. Increasing the awareness and knowledge of pharmacists in this field was identified as the key to developing confidence when dealing with breastfeeding women. A study conducted by Bushett et al. (202) in 2010 which investigated rural Australian community pharmacists' perspectives towards CMs had found that despite the varied views on CMs, most pharmacists acknowledged the popularity of these medicines amongst consumers in the community, and that community pharmacists play an important role in promoting the safe and effective use of these medicines. One of the challenges to providing conclusive advice to consumers regarding the use of CMs is the lack of awareness or access to high quality resources and information (202, 348). To address this issue, further studies are warranted to explore the pharmacists' perspectives regarding the resources and information available to them as well as further training needed in the form of either continuing professional development (CPD) modules or continuing education (CE) lectures. Stage 3 of this study will explore the community pharmacists' perspectives to enhancing understanding and to identify initiatives or strategies required to address the above research gap. As Stage 1 of this research has

begun the process of estimating the prevalence in WA of herbal medicines use during breastfeeding, the current stage of study suggested that community pharmacists may have the potential to play a greater role in promoting the safe and effective use of herbal medicines during breastfeeding from the breastfeeding women's perspectives.

4.5.4.3 Services and Strategies

Several strategies and services suggested by participants of this study such as baby weigh-in service or station, lactation booth and private consultation room may be seen as challenges to some community pharmacies. These strategies involve space allocation and may require considerable financial investment. Hence, demographic profiles of residents around the pharmacy should be considered to establish the need, and ensure cost effectiveness, at the same time viability of the business model. Nevertheless, other strategies for example distribution of breastfeeding-related pamphlets and educational materials from the PSA or ABA in the pharmacy may prove to be beneficial to women, at the same time increase awareness and involvement of pharmacy staff in promoting breastfeeding in the community.

From the perspectives of breastfeeding women, the findings of this study have enhanced our understanding of the current and potential future roles of pharmacists and pharmacy staff in the community pharmacy setting. While many studies have investigated the role of other health professionals in promoting breastfeeding in the community, few studies and initiatives exist to examine and expand the role of community pharmacists (87, 376-379). Taking into account the facilitators and the views of breastfeeding women, this study has identified opportunities to enhance community pharmacists' involvement. Nevertheless, the barriers and challenges should be addressed. The perspectives of breastfeeding women and community pharmacists will be compared and discussed in Chapter 6.

The importance of breastfeeding women's perspectives should not be neglected. The issues raised by breastfeeding women through the interviews in this study identified areas of pharmacy practice which require improvement and revealed opportunities for expansion of the community pharmacists' role to better support breastfeeding women and promoting breastfeeding in the community.

4.5.5 Limitations

Taking into consideration the process and method of recruitment which involved naturopathic clinics, there is a likelihood of selection bias which will have increased the likelihood of recruiting women with similar attitudes and perspectives towards these medicines. However, this method was considered most appropriate to identify and reach out to prospective participants. Women who could have been eligible for the study might not have fully understood the word ‘galactagogue’ in the poster, and hence might not have volunteered to participate in the study. Nevertheless, all participants of the study met the inclusion criteria and issues with understanding of the questions or topic were not identified during the interviews. It should also be noted that two questions (Question 13c and 13d) were worded in a way that could potentially influence participants to respond in agreement to the questions asked. This could explain the finding of this study that most participants agreed there was a lack of available resources. Open-ended questions would have provided better opportunity to explore participants’ views. For example: Question 13c could be rephrased as “*What is your opinion on the information resources available to you regarding the use of herbal medicines during breastfeeding?*”, and Question 13d as “*What are your views on the safety of herbal medicines and conventional medicines when used during breastfeeding?*” Although these were closed-ended questions the responses provided a range of insights into these issues. Participants were self-selected through expression of interest and hence do not represent all breastfeeding women in Australia who are regular users of herbal medicines. A known limitation with all qualitative studies, however, is the challenge to attempt generalisation of findings to the wider population (380). The interviewer (TFS) is a pharmacist, which may have influenced the interviews and affected the analysis. Participants were also aware that the researchers were from the School of Pharmacy at Curtin University, and that could have led to participants aware of a pharmacy background to provide more emphasis in relation to their views of pharmacists and the pharmacy profession. Nonetheless, this study has enhanced our understanding of women’s perspectives and factors which may influence their choice of therapy whilst breastfeeding in the Australian context.

4.5.6 The Next Stage

The Stage 2 study provided insight into the perspectives and attitudes of breastfeeding women towards the use of herbal galactagogues. The positive attitudes of these herbal galactagogue users should prompt health professionals and researchers to further explore this topic whilst the negative views regarding timing of education on breastfeeding and inconsistency of information should be taken into consideration to improve services for breastfeeding women. Themes that emerged in this study also pointed towards an opportunity for community pharmacists to expand their role through the provision of breastfeeding specific advice and services, based on the responses of a number of participants of the study. Nevertheless, further studies exploring the perspectives of other stakeholders are necessary to confirm the feasibility, practicality and usefulness of such services within the community pharmacy setting. Unlike some conventional medicines, herbal galactagogues and other CMs are readily available OTC. Pharmacists and staff should therefore enquire women if they are breastfeeding prior to providing advice or supply products to ensure appropriate recommendations can be provided. Further research into CMs use in breastfeeding, specifically herbal medicines, will allow health professionals like pharmacists and clinic nurses to provide evidence-based advice on the efficacy and safety of these medicines to their clients.

As the themes from Stage 2 indicated an opportunity for community pharmacists to expand their scope of practice and provide breastfeeding support (including advice about herbal medicines), the logical next step was to explore the perspectives of pharmacists and whether pharmacists were willing and equipped to expand their services. The next stage of the study would also provide insight into whether there is an agreement or a misalignment between the perspectives of breastfeeding women and pharmacists in terms of the role of pharmacists and what this profession can offer to better support breastfeeding women. Although Stage 2 focused on the perceptions of herbal medicines in breastfeeding, a theme emerging from the responses of some participants suggested a potential greater involvement of pharmacists in the provision of breastfeeding-related services within the community. As previously mentioned in Section 2.1.4, community pharmacists are well placed to provide continuing care and support to breastfeeding women and their families. In

the 2012 *Consumer Needs* project funded by the Australian Government Department of Health and Ageing, pharmacies were identified as the primary point of access for consumers in the community seeking non-prescription medicines (381). Considering the available literature and the fundamental role of community pharmacists in Australia in the provision of advice and supply of medicines that do not require prescriptions from authorised prescribers, it is likely that they would be approached on a regular basis by the public including breastfeeding women and their families with queries in relation to not just herbal medicines, but also other non-prescription medicines. In contemporary pharmacy practice, there has been growing interest for pharmacists to provide holistic, patient-centred care and for community pharmacies to be health hub destinations in Australia (382, 383). Taking into consideration the aforementioned points, Stage 3 of the study (Chapter 5) has taken the broader approach in exploring the perspectives and attitudes of community pharmacists towards promoting the safe and effective use of herbal medicines and other non-prescription medicines during breastfeeding, their confidence and knowledge, the factors influencing the extent of their involvement, and their perception of the current and potential roles in supporting breastfeeding in the community.

Chapter 5

**Promoting Safe and Effective Use of Herbal and
Non-prescription Medicines during Breastfeeding
and Supporting Breastfeeding in the Community:
The Pharmacists' Perspectives**



This chapter reports on Stage 3 of the research. This stage involved an exploratory study of Western Australian community pharmacists' perspectives on their role in promoting safe and effective use of non-prescription medicines during breastfeeding. This stage also further explored the potential for role expansion and greater involvement of pharmacists in supporting breastfeeding in the community. The chapter begins with an introduction to the Stage 3 study, followed by the study objectives and research methods employed. The results from Stage 3 study are then presented, followed by a discussion of the findings.

5.1 Introduction

Breastfeeding is the preferred nutritional option to ensure a good start to an infant's life. Breast milk provides good nutrition tailored to their growing needs, while offering passive immunity and various growth hormones to breastfed infants (1, 384). However, studies have shown that the majority of lactating women need to take at least one medicine whilst breastfeeding, either for acute or chronic medical conditions (27, 88, 91). Lamounier et al. (90) reported up to 96% of the 2,173 women included in their cross-sectional study received some form of medication therapy during the period immediately postpartum. A survey conducted by Stultz et al. (27) reported that women who participated in the study took more prescription as well as non-prescription medications during breastfeeding compared to when they were pregnant. Furthermore, there is also evidence that women have a tendency to self-medicate and use OTC and/or CMs during pregnancy and lactation (26, 335, 341). Although most CMs are available without prescriptions from authorised prescribers, there is still potential for their constituents to be transferred into the breast milk, which could pose safety concerns in the infants (385). Some herbal medicines may also affect breastfeeding performance by decreasing the breast milk supply (61, 62, 220). Breastfeeding women expect pharmacists to provide accurate and up-to-date information on whether a medicine should be used in breastfeeding (87). A study conducted by Braun et al. (374) which surveyed Australian pharmacy users has demonstrated a high expectation of the public for pharmacists to provide them with reliable information on the safety and efficacy of CMs.

Considering the recommended duration of breastfeeding, it is likely that women will experience minor ailments at some stage during lactation, such as a cough and cold, headache, or musculoskeletal pain or inflammation, which are all OTC treatable conditions (83). With the appropriate advice from pharmacists, some non-prescription medicines may assist in the management of these conditions, facilitating the well-being of the mother without unnecessary interruption to breastfeeding. Although there are several reference texts and numerous studies on the use and safety of medicines in breastfeeding, many of these references have inconclusive data on a large number of medicines due to the lack of studies and research (62, 87, 154). Furthermore, there is a lack of documented information about the safety of CMs, especially herbal medicines, in breastfeeding. This often places health professionals and breastfeeding women who request advice in a difficult situation as the decision on whether to use the medicine is based on the available information. This could compromise treatment of the mother or the infant's health, or may lead to unnecessary cessation of breastfeeding.

Community pharmacists are at the front line of healthcare. As primary healthcare professionals, pharmacists have frequent contact with breastfeeding women and their family. A study conducted on the Gold Coast, Australia, by Hughes et al. (149), showed that 78% of pharmacists reported seeing women with infants on a daily basis. Being regarded as medication experts and primary care health professionals, the public relies on community pharmacists for reliable and accurate information on the safety aspects of medicines (5). In addition, pharmacists are viewed as appropriate providers of advice and services related to public health in the community (4). Previous surveys of consumers and findings from Stages 1 and 2 of this research have all demonstrated that the public trust community pharmacists (87, 386).

To date, limited information exists regarding Australian health professionals' practices and knowledge of medicine use during breastfeeding (5, 87). In 2013, De Ponti et al. (5) published the first Australian study investigating the perspectives of 176 community pharmacists on the use and safety of medicines in breastfeeding. The study was conducted using self-administered postal surveys and it had a greater focus

on prescribed and conventional medicines, with only one CM, St John's wort, mentioned in the questionnaire (5). Ninety-two percent of the participants felt they were confident to supply and counsel breastfeeding women on the use of medicines. The outcome of this study suggested that despite pharmacists felt confident and willing to discuss medicines use with breastfeeding women, their knowledge in this area was variable (5). Appropriate training and continuing education is warranted to ensure pharmacists are well-equipped with knowledge regarding medicines use in breastfeeding, including non-prescription conventional medicines and CMs.

There has been no published study investigating community pharmacists' attitudes and perspectives towards their role in promoting safe and effective use of CMs and other non-prescription medicines during breastfeeding in the Australian context. There are also no data exploring their views regarding breastfeeding and other related activities in the community as part of being a public health service provider.

Exploring the perspectives and attitudes of pharmacists through a qualitative approach using semi-structured interviews will allow for more detailed and in-depth understanding of their opinions about the role of pharmacists in supporting breastfeeding women. As Stage 1 and Stage 2 of the research study have demonstrated that the use of herbal medicines is common amongst women during breastfeeding and community pharmacies are a common source of CMs supply and information in Australia, it is important to expand the research in this area to investigate the perspectives and attitudes of community pharmacists as service providers. Exploring pharmacists' opinions will also enhance our understanding of the factors influencing their decision-making processes and explore educational needs or strategies to assist pharmacists in their practice.

5.2 Objectives

The objectives of the Stage 3 study were to explore community pharmacists' perspectives and opinions on their role in promoting safe and effective use of non-prescription medicines, including herbal medicines, during breastfeeding. In addition, the study would evaluate the potential for role expansion in the support of breastfeeding and provision of related services in Australian community pharmacies. The Stage 3 objectives were guided by a review of the literature and informed by findings of Stages 1 and 2. In-depth semi-structured interviews with practising Western Australian community pharmacists were undertaken to:

- i) Identify and document the commonly requested medicines or products by breastfeeding women and the kind of information commonly asked.
- ii) Evaluate pharmacists' views on the major findings of Stages 1 and 2.
- iii) Investigate pharmacists' information-seeking behaviour, the common resources or references used in their practices for information related to the safety of non-prescription medicines (including conventional medicines and CMs) in breastfeeding, and information related to other aspects of breastfeeding.
- iv) Explore pharmacists' personal attitudes and perceptions towards the use of non-prescription medicines during breastfeeding, including conventional medicines and CMs, their confidence and self-awareness of knowledge level.
- v) Investigate the factors facilitating or inhibiting the provision of high-quality professional advice to breastfeeding women in a community pharmacy setting.

- vi) Explore pharmacists' views on providing advice and support to breastfeeding women, and provision of breastfeeding-related services in the community pharmacies.
- vii) Identify whether there is a need for continuing professional development (CPD) in this area and the topics deemed to be useful and practical for pharmacists.
- viii) Evaluate pharmacists' views on the potential for role expansion and specialisation in the area of women and newborns' health.

5.3 Research Methods

This section describes the research methods employed for Stage 3 of the study, which begins with an overview of the study design, followed by participant selection and recruitment strategies. Information is also provided on the development of the interview guide used in this study, and the procedure of data collection and analysis. The interviews were conducted between July and September 2013.

5.3.1 Study Design

This exploratory study was conducted through semi-structured interviews with pharmacists practising in community pharmacies in Western Australia. An interview guide with a mix of closed and open-ended questions was used to gather information about pharmacists' perspectives and attitudes towards their role in: i) promoting the safe and effective use of non-prescription medicines including CMs during breastfeeding, and ii) supporting breastfeeding in the community. In accordance to the exploratory nature of this research, the design of Stage 3 and the interview guide were informed by findings of Stages 1 and 2. Hence, a new human ethics application was prepared and approved for the Stage 3 study. This stage of the study had ethics approval from Curtin University (Approval number: PH-24-12, see Appendix P).

5.3.2 Participants

Eligibility Criteria and Recruitment Strategies

To be eligible for the study, participants had to be registered pharmacists practising in community pharmacies at the time of interviews. The recruitment strategy involved recruiting pharmacists from community pharmacies registered with the Pharmacy Registration Board of Western Australia (339). The 557 community pharmacies in Western Australia were separated into three categories with defined geographical areas (North metropolitan, South metropolitan and regional), based on

postcodes, and then sorted into random orders. Note that this list was also utilised in Stage 1 of the research study.

According to Patton (359), it is recommended that a “maximum variation sampling” approach to participant recruitment be employed in qualitative studies to enable in-depth inquiry into the topic of discussion. Hence, attempts were made to recruit participants from different banner groups and a variety of practice settings to obtain representation of a wide variety of working environments and banner policies, which could have influenced the pharmacists’ practices, attitudes and perspectives. The pharmacies were contacted via telephone to invite the pharmacist on duty or the proprietor to participate in the research study. To maximise variation in the sample, only one pharmacist from each pharmacy was allowed to participate.

Justification of Sample Size

As stated in Section 4.3.3, sample size determination in qualitative studies is based on the research purpose, researcher’s experience and judgment (338). The number of participants should be sufficient for the data to reach a point of saturation, where no emergence of new themes is identified, whilst also enabling in-depth analysis. Guest et al. (357) conducted an experiment to investigate the number of interviews required to reach data saturation and variability and reported that 12 in-depth interviews were sufficient to reach a point of saturation. Taking into account similar studies in the area of pharmacy practice and public health which employed qualitative research methods, a decision was made to recruit between 25 to 30 community pharmacists (4, 87, 201, 212).

5.3.3 Interview Guide

A semi-structured interview guide was used to provide guidance to all interview sessions. The interview guide (Appendix Q) was developed considering the relevant literature and in accordance with exploratory research findings of Stages 1 and 2 of the research. The interview guide was initially circulated amongst colleagues within the School of Pharmacy to obtain feedback. Advice and suggestions from colleagues

were taken into consideration and the interview guide was amended following discussion with the research team. The amended interview guide was then pilot tested on three community pharmacists to ensure the questions were clear and that the research objectives were met.

The interview guide comprised eight sections, each with a mix of closed and open-ended questions:

- Section A: Details and experience of pharmacist. Eight questions gathering background information and experience of the participants.
- Section B: Principal place of practice. Eight questions collecting information about participants' place of practice, which included location, demographics, type of pharmacy (independent or banner group), business model and pharmacy layout.
- Section C: Identifying needs. Eight questions addressing needs, for example: how often participants get enquiries related to the topic, the types of enquiries and products requested by breastfeeding women, the process of dealing with enquiries in the pharmacy that were related to breastfeeding, and their views on breastfeeding women's source of CMs supply and information.
- Section D: Education and information-seeking behaviour. Seven questions assessing participants' behaviour when seeking information, what resources or references were preferred, and their opinion on the availability and credibility of resources.
- Section E: Attitudes and confidence level. Six questions exploring participants': i) personal confidence level in providing advice to breastfeeding women with regards to the use of conventional medicines and CMs including herbal medicines, ii) perception of their roles, and iii) the factors facilitating or inhibiting the provision of advice and support to breastfeeding women.

- Section F: Knowledge. One of the three questions in this section assessed self-awareness of knowledge level where participants were asked to choose from “strongly agree”, “agree”, “neither agree nor disagree”, “disagree” and “strongly disagree” to six statements related to medicine use and safety while breastfeeding. This section also explored participants’ perspectives of the Australian National Breastfeeding Strategy 2010-2015.
- Section G: Implementation of strategies. Three questions exploring participants’ attitudes towards greater involvement in national health strategies and their views on what strategies could or could not be implemented in the community pharmacies to support breastfeeding.
- Section H: Continuing Professional Education (CPE). Questions one and two in this section explored the topics of CPE which they felt useful and practical. Questions three and four explored participant’s perspectives on pharmacists specialising in women and newborn’s health and role expansion into lactation consultancy.
- Four of the open-ended questions in the interview guide specifically explored participants’ views on the major findings of Stages 1 and 2 which were relevant to pharmacists and pharmacy practice. Questions seven and eight of Section C explored participants’ views on findings of Stage 1; whereas question six of Section E and question three of Section G explored participants’ views on findings of Stage 2.

5.3.4 Data Collection and Analysis

Data Collection

The Stage 3 study employed a similar data collection approach to Stage 2, as described in Section 4.3. Interviews were conducted either face-to-face or via telephone at a mutually agreed place and time. For all face-to-face interviews, the

purpose and process of the interview were explained verbally and in written form to the participant, with the provision of a participant information sheet (Appendix R). Ample opportunities were given to participants to ask questions if they required further information about the study. All participants were requested to sign a consent form (Appendix S) before the commencement of the interviews. Where face-to-face interviews were not feasible (due to logistical difficulties or the location of pharmacists), interviews were conducted via telephone. With the participants' verbal consent, copies of the participant information sheet and consent form were mailed to their postal addresses, along with a reply paid envelope to return the signed consent form. Upon receiving the signed consent form, arrangements were then made to conduct the telephone interviews. All participants were provided with an AUD\$50 Coles Group gift voucher, as a token of appreciation and reimbursement for their time and expenses such as travel costs (with Curtin University low risk ethics approval). With written consent from all participants, the dialogue between each participant and the student researcher were recorded to collect the narrative data for the purpose of analysis. All interviews of the Stage 3 study were audio-recorded, then manually transcribed verbatim for the purpose of analysis.

Data Analysis

Participants were de-identified and identification replaced with codes, to ensure anonymity. For example: the first interviewee was given the code "CP1", indicating "Community Pharmacist 1".

A computer software package (NVivo[®] Version 10.0, QSR International) was used to organise qualitative data and quotations to facilitate the thematic analysis. The transcribed data were analysed using descriptive and qualitative approaches. Data collected from Sections A and B of the interview guide were summarised using descriptive analysis, which included the details and experience of the participants, and information on their principal place of practice. Participants' responses to the closed-ended questions were summarised, whilst a similar approach of thematic analysis and development of the coding framework as described for the Stage 2 study (see Section 4.3.5) was followed to analyse the qualitative data collected from the other sections.

5.4 Results

Closed-ended questions were analysed and presented using a descriptive approach, while data collected from the open-ended questions were subjected to qualitative thematic analysis. Supporting quotes are provided to explicate the themes where relevant.

A total of 30 in-depth semi-structured interviews were conducted with pharmacists practising in community pharmacies in Western Australia. All participants were registered with AHPRA at the time the interviews were conducted. The point of saturation was reached after about 25 interviews however a decision was made to conduct five more interviews to ensure no new themes emerged from the data. After the completion of 30 interview sessions, the research team was confident that the data had reached saturation.

Twenty-eight interviews were conducted face-to-face at a place and time mutually agreed by the interviewer and interviewee. Two interviews were conducted via telephone due to the location of the participants and the logistics or feasibility of sending an interviewer. The duration of interviews ranged between 26.2 minutes and 70 minutes, with a mean interview duration of 39.4 minutes (n = 30).

Section 5.4.1 will report on demographic characteristics of the participants and their pharmacies; while Sections 5.4.2 to 5.4.6 will concentrate on exploratory data and results of the thematic analysis. The results are presented according to the sections in the interview guide. Although the section headings reflect the interview guide sections, subthemes that had emerged will also be reported under the respective headings. An overview of this section is provided in Figure 5.1.

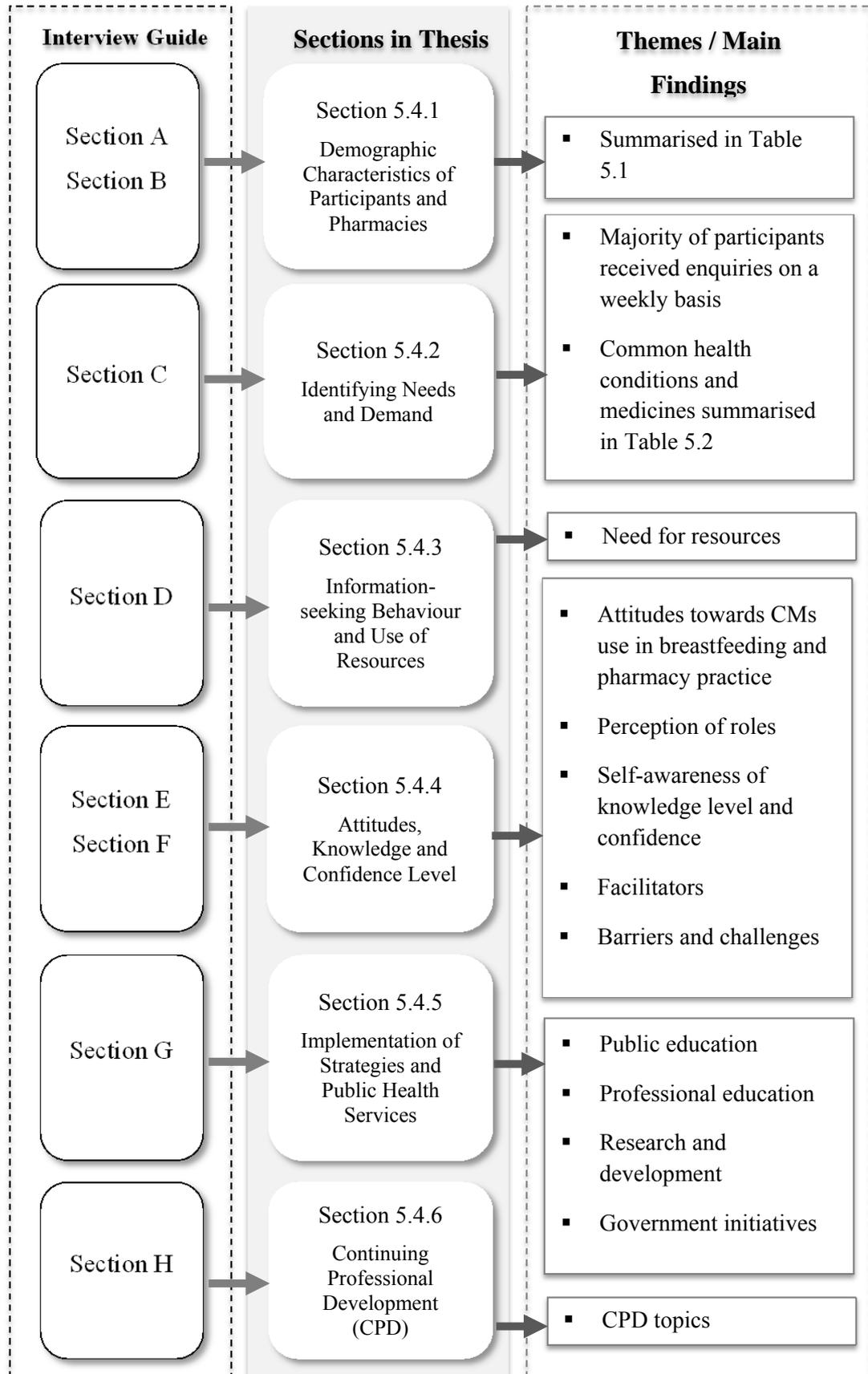


Figure 5.1: An overview of the Stage 3 results

5.4.1 Demographic Characteristics of Participants and Pharmacies

Table 5.1 summarises the demographic characteristics of participants and their principal place of practice. Most participants received their university qualification in Australia, and three participants had postgraduate qualifications which included the Australian Association of Consultant Pharmacy (AACP) accreditation and Postgraduate Diploma in Clinical Pharmacy. Their experience in community pharmacy practice as registered pharmacists ranged from one month to 42 years. Participants represented a range of positions or roles in the pharmacy, which are reported in Table 5.1.

Seven participants worked in independent pharmacies, while 23 worked in pharmacies of varying banner groups, which included Chemmart Pharmacy, Superchem Discount Pharmacy, Guardian Pharmacy, Friendlies Chemist, Soul Pattinson Chemist, Terry White Chemists, Optimal Pharmacy Plus, Pharmacy 777 Chemists, Priceline Pharmacy, Pharmacist Advice and Greg's Discount Chemist. Information about participants' role in the pharmacy and business model or orientation was also collected, as shown in Table 5.1.

Twelve male and 18 female pharmacists, aged between 23 and 63, participated in the study. Eight worked in pharmacies located in the North metropolitan region; seven from regional areas and 15 from South metropolitan regions. Nine pharmacies were located in areas with mostly young families; eight were in areas with mostly older people; while the rest reported a mix of age groups. Amongst the 30 pharmacies, only five had employed a child health nurse and none employed a lactation consultant within the practice. Most pharmacies (24 of 30) had a counselling area suitable for providing private counselling to breastfeeding women and two had plans for pharmacy refits in the near future to accommodate the growing demand for an effective counselling area within the pharmacies.

Table 5.1: Demographic characteristics of participants and their pharmacies

Participant	Age	Gender	Community pharmacy work/ week (hours)	Years of practice (years)	Role in pharmacy/ job description	Pharmacy type	Pharmacy business model	Breastfeeding experience
CP1	30	Female	38	7.5	Dispensary pharmacist and patient care-focused	Banner	Discount, volume and sales-focused	Close family and friends
CP2	27	Female	44	3	Dispensary pharmacist	Independent	Compounding pharmacy and newsagency	None
CP3	35	Female	12	12	Dispensary pharmacist	Banner	Nursing home-focused	Personal or partner
CP4	63	Female	18.5	42	Dispensary pharmacist and patient care-focused	Banner	Mixed sales and professional services-focused	Personal or partner
CP5	29	Female	34	6	Dispensary pharmacist and patient-care focused	Banner	Professional services-focused	None
CP6	29	Male	50	2.5	Pharmacy manager	Banner	Mixed sales and professional services-focused	None
CP7	33	Female	25	10	Professional services pharmacist and patient care-focused	Banner	Professional services-focused	Close family and friends
CP8	57	Female	50	31	Proprietor	Independent	Mixed sales and professional services-focused	Personal or partner
CP9	38	Female	20	17	Proprietor	Banner	Professional services-focused	Personal or partner
CP10	24	Male	45	2	Dispensary pharmacist and patient care-focused	Banner	Discount, volume and sales-focused	None

CP11	28	Male	65	4	Pharmacy manager	Independent	Discount, volume and sales-focused	None
CP12	31	Female	25	7	Proprietor	Banner	Professional services-focused	Personal or partner
CP13	31	Male	45	6	Proprietor	Banner	Professional services-focused	Personal or partner
CP14	28	Male	40	3	Dispensary pharmacist and patient care-focused	Banner	Professional services-focused	None
CP15	27	Male	46	0.5	Pharmacy manager	Banner	Discount, volume and sales-focused	Close family and friends
CP16	31	Male	55	7	Dispensary pharmacist and patient care-focused	Independent	Professional services-focused	None
CP17	25	Female	40	0.5	Dispensary pharmacist	Banner	Professional services-focused	None
CP18	23	Female	42	2.5	Dispensary pharmacist and patient care-focused	Banner	Professional services-focused	None
CP19	28	Female	45	2	Pharmacy manager	Banner	Discount, volume and sales-focused	None
CP20	39	Male	45	15	Proprietor	Banner	Professional services-focused	Personal or partner
CP21	50	Male	20	27	Dispensary pharmacist	Banner	Discount, volume and sales-focused	Personal or partner
CP22	27	Female	50	2	Pharmacy manager	Independent	Mixed sales and professional services-focused	None
CP23	28	Male	50	1 month	Pharmacy manager	Independent	Mixed sales and professional services-focused	None
CP24	24	Female	45	0.5	Professional services pharmacist and patient care-focused	Banner	Discount, volume and sales-focused	None

CP25	33	Female	10	11	Dispensary pharmacist	Banner	Professional services-focused	Personal or partner
CP26	37	Female	60	16	Proprietor	Independent	Professional services-focused	None
CP27	30	Male	45	6	Pharmacy manager	Banner	Mixed sales and professional services-focused	None
CP28	29	Female	35	0.5	Dispensary pharmacist	Banner	Discount, volume and sales-focused	None
CP29	29	Female	38	8	Pharmacy manager	Banner	Professional services-focused	Close family and friends
CP30	28	Male	50	4	Professional services pharmacist and patient care-focused	Banner	Professional services-focused	Close family and friends

5.4.2 Identifying Needs and Demand

The majority of the participants received regular enquiries from the public about the use of various medicines during breastfeeding on a weekly basis. Most pharmacies had procedures in place for pharmacy assistants to refer enquiries related to the use of medicines while breastfeeding to a pharmacist. These enquiries were mostly related to the use of OTC conventional medicines, which included products classified as Schedule 2, Schedule 3 and other non-scheduled conventional medicines. To a lesser extent, participants also received requests for advice regarding the use of CMs and prescribed (Schedule 4) medicines. Nevertheless, most participants reported a growing demand for CMs. As stated by CP 7:

“It is an area that is becoming more and more popular and a lot more people are going down the path of complementary medicines and vitamins.” (CP 7)

All of the conditions or health issues presented by breastfeeding women, along with the requested medicines as reported by the participants of this study, are presented in Table 5.2.

Participants indicated that women were mostly concerned over the safety of their breastfed infants as a result of using medicines while breastfeeding. Another concern was the impact of medicine on breastfeeding performance and breast milk supply. Other commonly sought information included directions for use and efficacy of the recommended medicines or products and ways to minimise the transfer of medicines into breast milk.

Table 5.2: All health issues and medicines requested by breastfeeding women reported by participants of the study

Ailments or health issues	Medicines/products requested
Allergies	Antihistamines
Cough and cold	Cough suppressant Expectorant/mucolytic agent Nasal decongestant
Enhancement of breast milk supply	Domperidone Fenugreek
General health using CMs	Echinacea Fish/krill oil Peri-natal multivitamins Vitamin C Weight loss product
Inflammation and pain	Analgesic Non-steroidal anti-inflammatory agent
Other miscellaneous	Antibiotics Eye drops and ointments Hypnotics for insomnia Topical corticosteroid Treatment for mastitis Treatment for postnatal depression

When participants were presented with one of the findings from Stage 1 which indicated that approximately 60% of the survey respondents had used one or more herbal preparations during breastfeeding, participants expressed their concerns over safety and the lack of stringent regulations over the sales of CM preparations and products:

“It concerns me as well that it is saying that people are getting them from the pharmacy, but nearly everything that we sell in the pharmacy can be sold in the supermarket or health food store, so there is not going to be any intervention in those places.” (CP 3)

Participants were also asked to present their views on another finding of the Stage 1 study, which indicated that 48.6% of the survey respondents regarded pharmacists as the main source of information, with the internet, family and friends also being reported as common sources of information. Most participants expressed their

concerns over the reliability of information accessible by women from the internet; some indicated a need for greater pharmacists' involvement:

"I feel that pharmacists should play a larger role in this sort of area, as a healthcare professional providing these sorts of information, rather than them sort of just jumping onto google and hoping that the piece of information they find is legitimate." (CP 11)

"We have more access to information than what you can find from the internet, because you don't know, the resources from internet, they might not be true all the time and they might not be evidence-based." (CP 18)

5.4.3 Information-seeking Behaviour and Use of Resources

Participants reported they had acquired most of their knowledge regarding the use of non-prescription conventional medicines and CMs in breastfeeding from their day-to-day work experience, self-directed continuing professional development, personal or close-contact breastfeeding experience, and university training as part of their pharmacy degree. In line with the growing demand, participants identified that universities should include more content and provide greater exposure to pharmacy students, covering: basic breastfeeding knowledge and postnatal care, the safety and use of medicines during breastfeeding, and reliable references or resources. One participant specifically commented on the need for pharmacists to show empathy and careful attention when communicating with women who may have decided to cease breastfeeding:

"You just have to be really careful and really empathetic and take each case by a case-by-case basis, because you don't want to offend people and make them feel intimidated or feel guilty because they are not breastfeeding." (CP 29)

A few participants also raised their opinion on the need for communication and motivational counselling skills to be able to provide advice to breastfeeding women:

“I think the university should train pharmacy students or future pharmacists on how to deal with breastfeeding mothers... it is the empathy side, the emotional side that it is hard for us to gauge... university should have one or two lectures on how to communicate with mothers, because personally I have seen mothers who would get really really really emotional when they get diarrhoea, because they will get dehydrated and they have got no milk... they are already emotional... I don't think the universities have prepared the students enough to handle the emotional side of things, and how mothers deal with babies.” (CP 1)

“It was very limited in terms of herbal medicines and I had to do a lot of extra learning, and still continue to do a lot of extra learning in terms of herbal medicines and alternative medicines.” (CP 3)

Participants used a variety of references and resources to assist them in their daily practice to advise breastfeeding women on the use of non-prescription medicines and CMs during breastfeeding. These included:

- *Australian Medicines Handbook (AMH),*
- Electronic version of the *Monthly Index of Medical Specialities (MIMS),*
- *Australian Pharmaceutical and Formulary Handbook (APF),*
- *Royal Women's Hospital Pregnancy and Breastfeeding Medicines Guide,*
- *Therapeutic Guidelines,*
- Product companies or manufacturers,
- Drug information centres at maternity hospitals and
- Other internet databases or websites.

Referral to other health professionals such as general practitioners, child health nurses and lactation consultants were at times considered necessary when pharmacists deemed the queries as beyond their scope of practice or expertise. There was also an overwhelming concern raised by all participants regarding the lack of

evidence-based reliable clinical studies about the use of CMs and their safety in breastfeeding:

“We can only go by or give the information that is available to us, and a lot of the times there isn’t a lot of information available on breastfeeding, there is quite a lot on pregnant women at the moment, but not a lot in breastfeeding.” (CP 2)

“I don’t think we have enough up-to-date and thorough information to provide. I think we have just sort of a limited amount of information that we can provide in our setting.” (CP 7)

“Particularly the complementary, because that is where people get caught up... particularly the complementary because that is what we don’t have hard evidence on.” (CP 21)

“I just don’t think there have been enough studies done on the herbal and complementary medication that provides sufficient data.” (CP 25)

Only one of the participants was aware of and fully utilising the *Medicines Information Centre, Women and Newborn Health Service in WA*, as recommended by the APF 22 (387). Mixed responses were observed when participants were asked their views on the need and feasibility of setting up a lactation resource centre in WA, which would be a potential source of information for women and health professionals. From the participants’ perspective, the main issue was to consider the cost-effectiveness of resource centres:

“I don’t know what is the cost. I guess you need to weigh out the cost and benefit, but I think it would definitely be beneficial, but whether or not it is cost effective...” (CP 26)

Most participants discussed the advantages of setting up a state-based lactation resource centre such as local and accessible face-to-face interactions and assistance

to women experiencing issues with breastfeeding, and that it would serve as a strategy for continuation of care and support in the community during the postnatal period. Another benefit mentioned was provision of information to health professionals:

“Because there’s a lot of enquiries regarding breastfeeding, in terms of either the technique, or how to use devices and all those things, and obviously that will relieve the burden of midwives.” (CP 11)

“Given that breastfeeding is always promoted as being the best, and that so many women have trouble with it, I think it would be really useful and also just to have that continuation of care. Because you have your baby, and you go home and a lot of women struggle, and just give up breastfeeding because it’s too hard or they think that they don’t produce enough milk, and there is a lot of misinformation out there as well. So I think it would be really useful, and also not just for like the actual patients but also for health professionals as well. So we can go to them for information or refer people on, because often you don’t really know what to do when someone is having problems.” (CP 29)

5.4.4 Attitudes, Knowledge and Confidence Level

Five major themes emerged regarding participants' attitudes, knowledge and confidence level towards promoting the safe and effective use of non-prescription medicines and other OTC products during breastfeeding and their role in supporting breastfeeding in the community: i) attitudes towards CMs use in breastfeeding and pharmacy practice, ii) perception of roles, iii) self-awareness of knowledge level and confidence, iv) facilitators and v) barriers and challenges to achieving effective support for breastfeeding women in the Australian community pharmacy context.

5.4.4.1 Attitudes towards CMs use in breastfeeding and pharmacy practice

Five subthemes or issues were apparent in terms of participants' attitudes towards the use of CMs in breastfeeding and pharmacists' responsibilities (Figure 5.2):

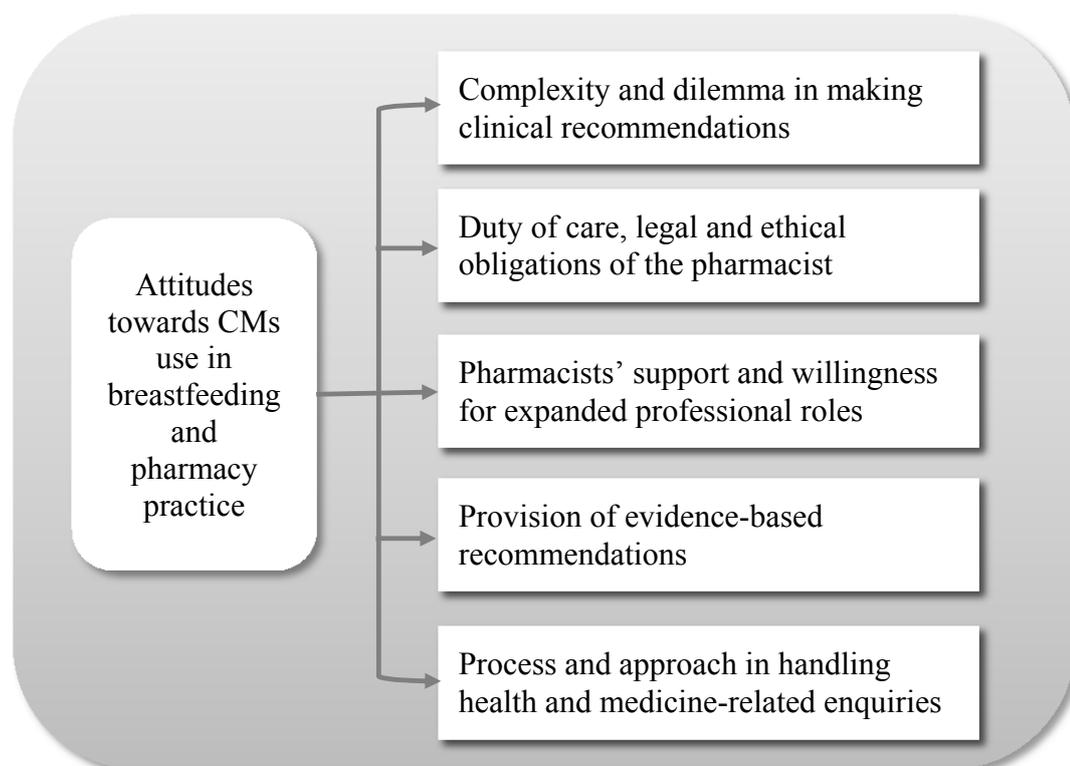


Figure 5.2: Pharmacists' attitudes towards CMs use in breastfeeding and pharmacy practice

5.4.4.1.1 Complexity and dilemma in making clinical recommendations

A common theme was the complexities that need to be considered and the dilemma in making clinical recommendations involving the use of non-prescription medicines and other OTC products, in particular CMs, during breastfeeding due to the lack of studies and safety data. Many participants expressed uncertainty and frustration when required to provide recommendations to breastfeeding women presenting to pharmacies:

“Sometimes we’ve been out in this dilemma. And the patient will say the doctor didn’t say anything or the doctor says its fine. So sometimes we do get that sort of dilemma. So at that stage we can only use our professional judgement and say, look, this is what is stated in the literature. I would just say if I were in your position that’s what I would do. And I think that’s the advice that we can offer, and it’s up to the patient...” (CP 12)

“It’s frustrating and more so it’s confusing because you would like to know if it is or is it not [safe].” (CP 21)

“I think that has impacted on a lot, it can make it quite difficult to say, you know, when there is not enough evidence to sort of give that information to the customer. So I do find that quite difficult...” (CP 28)

“...you feel like you can’t give people a definite answer. So it’s like there is no information, so you don’t really know, so you kind of just err on the side of caution because of the lack of information you have got on hand.” (CP 29)

The lack of conclusive, evidence-based information on the use of CMs and safety in breastfeeding was seen as a major dilemma when having to make clinical decisions and recommendations, as well as posing a negative impact on pharmacists’ confidence.

“...there is no evidence and I am not comfortable recommending...” (CP 1)

“I think that they are inconclusive. Often, it makes it hard for you to recommend anything, because the chances are they might be safe, but I wouldn't like to refer them on the 'might', you know. I would rather refer them onto the drugs that we know are safe... it seems to me that there is less choices for breastfeeding mum than there is for pregnant mum, because we know more about drugs in pregnancy than drugs in breastfeeding.” (CP 3)

“...because the evidence isn't there, I don't have the confidence to say you can or you can't use this... sometimes they can be a little bit vague like with the insufficient evidence, or they can be a little too brief, sometimes I would like a little bit more information.” (CP 28)

The safety of mothers and their breastfed infants was considered priority as it was consistently mentioned by all participants that they would not recommend any medicines, including CMs, in the absence of evidence demonstrating their safety in breastfeeding:

“I won't take the chance, if there is a lack of information.” (CP 6)

“I usually find that the case with complementary medication... when I can't find it that's when I would go on the side of caution and don't recommend it and tell them there hasn't been enough studies done about it.” (CP 10)

“Usually if the reference says they don't have enough evidence to support it, I wouldn't recommend it to the patients, and the breastfeeding mums as well, because I wouldn't be comfortable selling it them.” (CP 17)

“I would look into it a bit more and just with peace of mind, to make sure it's really really safe in breastfeeding.” (CP 27)

In the absence of evidence-based information, many participants also tend to err on the side of caution and be conservative over their recommendation:

“what I feel is that it makes me more conservative in my recommendation of products, because everything is not recommended... essentially what I do is I look through all the resources to find the one that says safe to use, and unless I can find one that say safe to use, I won't recommend that product. So, that makes me more conservative in my recommendation and that compromises the mum's ability to, you know, help with whatever she is experiencing at the moment...” (CP 2)

“I would err on the side of caution. Let the patient know and I wouldn't recommend that particular product and look for an alternative.” (CP 8)

Nevertheless, being over-cautious or conservative in their recommendations may compromise breastfeeding women's health, as one participant commented:

“I still feel like I could be helping them more, they often walk away without a good solution to their problems because I can't be sure that what I recommend to them would be safe, so to be safe you would recommend less, and then probably the mum goes through a bit more suffering than she might need to, because we are on the side of safety.” (CP 3)

5.4.4.1.2 Duty of care, legal and ethical obligation of the pharmacist

From the participants' perspectives, it was their duty of care as pharmacists to ensure the safe and effective use of all products and medicines, including OTC products sold in their pharmacies. Participants felt that they had the responsibility to ensure the safety of breastfeeding women and their breastfed infants:

“We need to make sure that the medicines we give out needs to be safe, and because we stock it... we still need to ensure. This is part of our job, to make sure that we give something that is safe and effective for the patient.” (CP 5)

“I feel that it’s part of your job as pharmacist if you are to sell that in your store, you should be able to make recommendations on it based on whether the patient is breastfeeding or not breastfeeding.” (CP 10)

“I think if we sell it then we are responsible for that sale.” (CP 29)

It was acknowledged that pharmacists had a legal and ethical obligation to acquire adequate knowledge of all products sold in the pharmacy, regardless of whether they were conventional or CMs. Participants also felt that it was part of their professional role to ensure the safe and effective use of these products in lactation and be able to make appropriate recommendations to women who may require treatment while breastfeeding.

“I would think that anything that we sell it in the pharmacy, if we choose to sell or to recommend that sort of products to the public, we need to have some general knowledge about the product itself...” (CP 20)

Clients’ well-being and health were identified as the main focus of pharmacists, as many commented that they would be reluctant to recommend or sell a product on the basis of promoting the business or increasing profit in the absence of clear client benefits:

“It is not a matter of having one less sale, it is a matter of what is good for the baby.” (CP 1)

“I think we need to be responsible when we are selling vitamins and it’s just not a business that, you know, you are getting an extra sale. I think we need to have some responsibility on our part to make sure that it is okay and that we do ask appropriate questions.” (CP 9)

5.4.4.1.3 Pharmacists’ support and willingness for expanded professional roles

When participants were asked their opinions on whether there was potential for pharmacists to expand their role and scope of practice to promote breastfeeding and other related professional services in community pharmacies, many showed support and willingness for expanding their professional roles:

“I think pharmacists are well placed to help with breastfeeding support... I would like to see that perhaps pharmacists are promoted more, maybe through... like child health nurses. Maybe child health nurses need to be saying to the mums, make sure you are checking all your medicines with your pharmacist, before you start taking anything...” (CP 3)

“I feel that pharmacists should play a larger role in this sort of area, as a healthcare professional providing these sorts of information.” (CP 11)

“...as a pharmacy profession, we are highly respected in the field, in terms of knowledge and definitely the willingness to provide the information at a convenient time to customers.” (CP 20)

It was also described that the pharmacists’ role should not be limited to merely dispensing and the supply of medicines, but to play a greater role in the provision of professional healthcare related services in the community:

“I stand for about pharmacists being more service and healthcare-orientated.” (CP 10)

“...pharmacists can do something else other than just dispensing medicines.” (CP 16)

One participant further commented that the provision of breastfeeding advice and related services should be considered as equally important to other professional services:

“In the pharmacy we teach people how to use the blood pressure monitors, we teach people how to use the diabetes monitor, we teach people how to use the pedometer, why can’t we teach people how to use the breast pump?... I think if we have time to teach people how to use the blood pressure monitors, [then] I think we will have time to teach people how to use the breast pumps.” (CP 1)

5.4.4.1.4 Provision of evidence-based recommendations

In their daily practice, participants strived to provide evidence-based recommendations to women in relation to the use and safety of medicines in breastfeeding. Consultation and advice were made based on the resources and evidence available:

“I consulted the reference. I showed the customer the information in the reference and explained the logic behind.” (CP 1)

5.4.4.1.5 Process and approach in handling health and medicine-related queries

It was evident that pharmacists followed a step-wise process and approach when handling health and medicine-related queries to breastfeeding women, as participants described the process involved in making clinical recommendations:

“So I checked the little breastfeeding book we had, I checked the eMIMS to find the appropriate product for her and recommended a couple of things to her depending on which symptoms were the most severe or what she wanted to treat and explained to her and recommended the products.” (CP 7)

“Now obviously the first thing we do is we have to check the patient, whether she’s on other medication, how old is the baby, and we have to go through, check the breastfeeding reference book, and then we go from there.” (CP 16)

“I try to get everyone to at least ask who is it for, this type of WHAMM² questions to ascertain if somebody is breastfeeding, then they can refer it to the pharmacists and...” (CP 27)

5.4.4.2 Perception of roles

Participants’ perceptions towards accepting the role of promoting safe and effective use of non-prescription medicines during breastfeeding and supporting breastfeeding in the community were generally favourable. The majority of the participants perceived pharmacists’ main role as the medication experts, providing advice on whether to use or not to use certain medicines whilst breastfeeding. Participants also commented that they were responsible for medicine advice and information, in particular non-prescription medicines, that are available in pharmacies without prescriptions or consultation with doctors.

“I think our role is to ask the questions and to ensure the medicine that we delivered to the patient or customer is safe to use and minimise the risk even for complementary products, we still need to make sure it is really safe to use.” (CP 6)

“Provide advice, counselling, as well as information on the medications that breastfeeding mothers may be seeking...” (CP 10)

“Simple questions like how do you help, what kind of medication we should recommend, what they can take, what they can’t take when they are breastfeeding.” (CP 15)

“Providing information on the use of medication, safe use of medications, from complementary to prescription medications... I think it’s advising

² WHAMM is an acronym representing a list of questions used by pharmacists and pharmacy staff to acquire information from their clients, including: who is the patient, what are the symptoms, how long has the symptoms been present, any action taken, current medications and medical conditions.

whether it is safe to take medicines... I think pharmacists should be doing that regardless.” (CP 26)

“...mainly proving advice, and ensuring that the infant and the mother are using medications safely... we are supposed to be very knowledgeable about medication in general, so we will be one of the port of call for breastfeeding mothers.” (CP 27)

Many felt that their roles and expertise were clearly defined from workers at supermarkets or shopping centres, as one participant stated:

“That’s the difference between a pharmacy and a shopping centre like Coles. We try to provide our advice.” (CP 13)

With knowledge of safe medicine use during breastfeeding, one participant felt that pharmacists could play a role in promoting breastfeeding continuation and avoiding unnecessary early cessation of breastfeeding:

“I think that pharmacists can help mothers who might be wanting to cease breastfeeding. Perhaps they might want to cease breastfeeding for something as simple as them wanting to use a certain medication and they don’t feel safe in doing so, and they might find a way around it, either a different medication, or perhaps pumping and discarding and just do a complementary feed in the meantime. I think pharmacists can help with that.” (CP 3)

The majority of the participants agreed that pharmacists represent a reliable source of medicine and health-related information for the public, at the community level.

“...we get a lot of queries independent of the sales. We are the information givers and advice and they take it... and it’s genuinely the trust in us.” (CP 8)

“I think pharmacists still play a very important role in terms of providing very useful information.” (CP 16)

“...it’s showing that pharmacists have got the biggest role and consumers are recognising this, and if they want the correct information, pharmacists are the way to go.” (CP 26)

Perceptions about the potential for greater involvement and role expansion of pharmacists in supporting breastfeeding and various related health promotions in the community pharmacy setting were generally positive. Many felt that they were in a position where unique opportunities were present to raise the awareness of the public with regard to the benefits of breastfeeding and related health topics.

“We are there to give advice on health issues and breastfeeding is a health issue as well.” (CP 6)

“I think being in the community setting, definitely as we are seeing mothers before and after their pregnancy, I think definitely pharmacists can help encourage women who have difficulty or are having second thoughts about breastfeeding, particularly about the benefits of breastfeeding.” (CP 9)

“We are one of the first port of calls, when people have healthcare-related questions or when people are sick, so I think you do have the opportunity to promote breastfeeding when people do come in.” (CP 10)

“I think we can help promote women to breastfeed for longer if they know that we are an educated resource that they can come and approach if they have any difficulty on top of their lactation consultants.” (CP 25)

Participants also discussed their role in the provision of postnatal care and support to women at primary healthcare level, at the same time recognising women who could be at risk of postnatal depression and other aspects of women’s mental well-being:

“...be able to learn how to communicate effectively with them, calm them down...” (CP 1)

“if they find that once they leave the hospital and they forget, they are sure that they can go somewhere where they can get information again, or just a reinforcement, because sometimes some mothers don’t stay in hospital for one or two days if you have natural birth unless you have caesarean, obviously you have to wait six days before your stitches come out. I mean you can’t always remember everything, and you are tired as well, you know, you haven’t had much sleep, so you are not always getting all the information thrown at you.” (CP 9)

Nevertheless, some participants felt that they had a limited role in the area of prescribed medicines:

“Very very very rare on prescription medicines because their doctor would have already spoken to them about it.” (CP 1)

Few participants commented that the provision of advice regarding techniques and other physical aspects of breastfeeding, such as feeding position and issues with infant latching, were beyond their defined roles and capabilities:

“...we do sell pumps, so we need to be able to support and recommend the correct use, but I think the whole actual natural feeding is probably a bit beyond our normal role.” (CP 21)

“Maybe not in regards to difficulty with latching and insufficient milk supply, that’s a bit beyond our capabilities.” (CP 24)

“In terms of difficulty with latching, I don’t know, I mean that is a very personal area, I don’t know if, I mean I don’t think it’s the pharmacist’s role to sit there and help them. I think that’s probably crossing boundaries. I think that is something that a mum is more comfortable with a lactation consultant, but at least we could refer them onto a lactation consultant.” (CP 25)

Forming an interdisciplinary collaboration with other healthcare professionals such as doctors, child health nurses and lactation consultants, was perceived as beneficial in terms of improving the overall health outcome of breastfeeding women and their infants:

“...you could also maybe liaise and work with... a child care nurse close to the area, put some pamphlets there or put some pamphlets at the local doctor’s surgery.” (CP 7)

“All of us do need to know bits and pieces of how each profession works. If we can drag nurse, doctor and pharmacist to a group of health professions that can discuss things, that will be even easier or better.” (CP 13)

“[If it is] not our area then we get someone more professional on it... we have few other professionals working together, so we all are good at what we know, at the end it will be good.” (CP 19)

Pharmacists could potentially also play a greater role as acting as a contact point and referring women to other health professionals where appropriate:

“...just being an access point to say, right, yes, you need to now talk to...for a reference, being a first point of contact, and an easy point of contact, rather than actually executing a strategy.” (CP 21)

“I think that the basic should be pharmacists giving free advice to the consumer, with a point of referral to someone who is being reimbursed by a government or a private industry, not by a small business.” (CP 26)

Other perceived roles discussed by the participants included the provision and demonstration of breastfeeding-related needs or equipment for example: how to operate a breast pump, how to express and store breast milk and other issues related to infant feeding. In addition to the previously mentioned roles, participants also felt that it was their role to provide women with advice in relation to common conditions

in breastfeeding and other primary healthcare issues related to breastfeeding, such as mastitis, sore nipples and insufficient milk supply.

5.4.4.3 Self-awareness of knowledge level and confidence

To explore pharmacists' self-awareness of knowledge level, all participants were asked to indicate their responses to six statements related to topics associated with breastfeeding and the use of medicines. Responses are summarised in Table 5.3.

Table 5.3: Participants' responses to statements in relation to their knowledge level (n = 30)

Statements	Strongly agree/ Agree	Neither agree nor disagree	Strongly disagree/ disagree
I am confident in discussing the safety and efficacy of non-prescription medicines use with breastfeeding women.	23	2	5
I am confident in recommending non-prescription medicines to breastfeeding women.	19	7	4
I feel comfortable in discussing any aspects and issues related to breastfeeding.	22	4	4
I understand how medications and nutrients are transferred into the breast milk.	19	5	6
I am aware of the factors determining infants' exposure to medicines in the breast milk.	23	3	4
I know how to advise women who require to use medicines during breastfeeding on how to minimise the transfer of medicines to their infants.	24	2	4

Participants were also asked to assess their confidence levels in providing advice to breastfeeding women on the use of both conventional medications (including prescribed and OTC) and CMs (including herbal medicines). All participants stated that they were more confident in providing advice on conventional medicines over CMs. It appeared that participants recognised the limited knowledge about the use of herbal galactagogues while breastfeeding. An over-arching theme emerged as participants discussed the availability of evidence and resources for CMs. The perceived lack of knowledge and evidence-based studies or research in the area of CMs use, including herbal medicines, in breastfeeding was seen to negatively impact on pharmacists' confidence to recommend them.

“We don't have the data to support the use of herbal preparations in breastfeeding, to know if they are going to be safe.” (CP 3)

“I think because we have more literature on prescribed and OTC medicine. Whereas with complementary is one of those areas that we don't have a book that says okay or not okay.” (CP 12)

“Unfortunately there isn't much evidence behind to support whether it [CM] is safe, that is the drawback, it becomes like a grey area where I am not comfortable recommending it.” (CP 15)

Many participants also reported they had greater experience and knowledge with regard to the use of conventional medicines over CMs in breastfeeding. *“...because of the experience I suppose. Because of the use or practice and the study that we have gone through...” (CP 20)* The issue with the lack of standardisation of herbal medicinal products was also raised by few participants, as one commented:

“I think because there is more trials and research done with prescribed and over the counter medicines, whereas with herbal medicines, especially if they are not standardised as well, that, and there's not as much evidence, so that sort of reduces my confidence.” (CP 28)

5.4.4.4 Facilitators

A number of subthemes emerged as participants described the factors that serve to facilitate the promotion of breastfeeding by community pharmacists and the provision of professional advice to breastfeeding women regarding the use of non-prescription medicines and other OTC products including CMs. These included: convenience, accessibility and affordability, respect, trust and the pharmacist-client relationship, knowledge and professionalism, expanding role of the profession and creating job opportunities, promoting better health in the community, facilitate complementary sales and promote business of the pharmacy, promote image of pharmacy and the profession in the community, ease burden on the health system.

Participants felt that their profession represents a convenient, accessible and affordable source of health and medicine related information to the public. The importance of trust, professionalism and favourable pharmacist-client relationships were also acknowledged by the participants. It was also reported that expanding the professional roles of pharmacists will facilitate greater job opportunities, at the same time contributing to better health in the community. Expanding the role of pharmacists in this context will also aid in the reduction of waiting periods at general practitioners, overall easing the burden on the Australian healthcare system.

Figure 5.3 shows a summary of the facilitators and barriers of expanding the role of pharmacists. The subthemes of facilitators and barriers, along with the supporting quotes are summarised in Table 5.4 and Table 5.5, respectively.

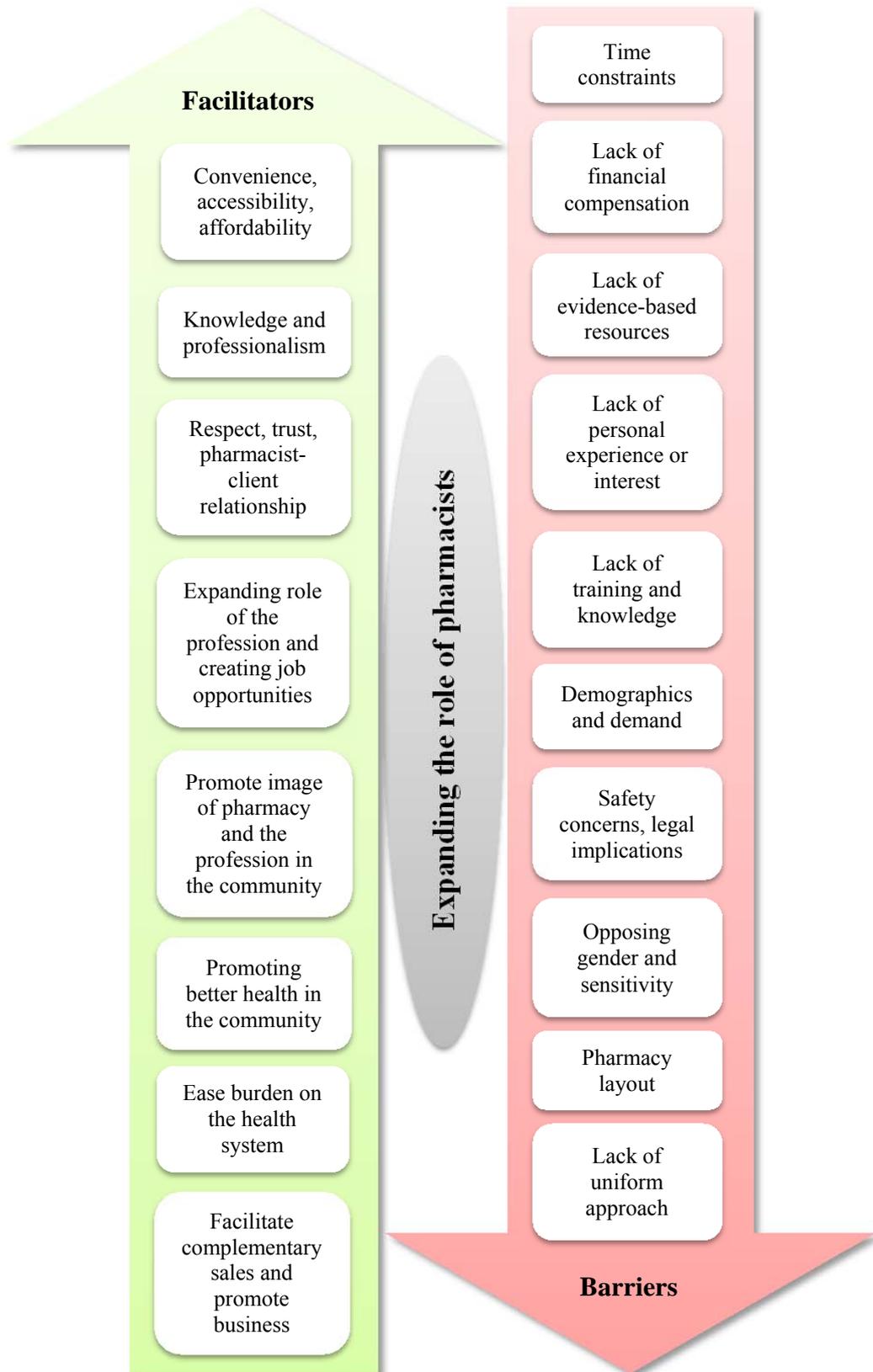


Figure 5.3: The facilitators and barriers of expanding the pharmacist's role

Table 5.4: Facilitators identified by participants

Subthemes	Supporting Quotes
Convenience, accessibility and affordability	<p data-bbox="547 297 1410 689"><i>“I think that pharmacies are available so easily and so readily in every community and that it might be somewhere that the mums feel comfortable as well because they are in there so often, and that they are known, and it is somewhere that they can go into without a specific appointment time, because some babies are not on-time or have routines necessarily, and some mums might find it hard to stick to it, whereas in the pharmacy, they can just drop in or out when it suits them.” (CP 3)</i></p> <p data-bbox="547 757 1410 898"><i>“I think we are convenient because we are there, and we can provide advice free of charge, they don’t need to make appointment, they can come in and see us anytime.” (CP 7)</i></p>
Respect, trust and pharmacist-client relationship	<p data-bbox="547 958 1410 1099"><i>“...we already have that relationship with the customers. So pharmacist-client relationship, we have already known the customers for six seven years, and we know them by their first name.” (CP 1)</i></p> <p data-bbox="547 1160 1410 1301"><i>“Many of the time, these women are all already clientele before they are even a breastfeeding mother and that makes us having a really good rapport with them, especially if they live locally.” (CP 15)</i></p>
Knowledge and professionalism	<p data-bbox="547 1361 1410 1458"><i>“Pharmacists are knowledgeable in the area certainly in regards to medicines.” (CP 3)</i></p> <p data-bbox="547 1518 1410 1603"><i>“Our professionalism... and our training and knowledge and also the trust that the public have in us as health professionals.” (CP 29)</i></p>
Expanding role of the profession and creating job opportunities	<p data-bbox="547 1664 1410 1805"><i>“...we are trying to increase our professionalism, and to do different things in our profession, so why not take on something like that that hasn’t really been a focus for pharmacists.” (CP 7)</i></p> <p data-bbox="547 1865 1410 2007"><i>“Nowadays we’ve got more and more pharmacists on the market and a lot of them can’t even look for a job. I guess if let’s say we create more job opportunities for them to be in the pharmacy...” (CP 13)</i></p>

Promoting better health in the community	<i>“...we are not just selling them a breast pump, but also telling them about their general health and well-being...” (CP 2)</i>
Facilitate complementary sales and promote business	<p><i>“...that would drive the sales up for any baby products because they know that you have these kind of services.” (CP 6)</i></p> <p><i>“I mean you will hope to get the follow-on, you will get the customer, they will become your customer, so then they would come in for anything else that they need.” (CP 7)</i></p> <p><i>“It is a good strategy for pharmacies to boost their sales and at the same time, it also makes them aware that the pharmacy also carries this service.” (CP 15)</i></p>
Promote image of pharmacy and the profession in the community	<p><i>“...it would increase the image of the pharmacy in their perception in their minds...” (CP 1)</i></p> <p><i>“Any type of service that we can offer, above and beyond is always good for the image of the pharmacy.” (CP 9)</i></p> <p><i>“It pushes pharmacy back to being more of a healthcare professional.” (CP 10)</i></p>
Easing burden on the health system	<p><i>“...ease the pressure on the health system, the GPs... that will ease the pressure on the whole health system, doctors can focus on things that you can’t focus on in a community pharmacy setting.” (CP 10)</i></p> <p><i>“...reduce the burden of GPs when we can provide them with the assistance.” (CP 30)</i></p>

5.4.4.5 Barriers and challenges

There were a number of barriers identified by the participants, as summarised in Table 5.5. These included: the lack of evidence-based information and resources, safety concerns and legal implications, time constraints, lack of training or knowledge and confidence, lack of funding or financial compensation, lack of needs or demand due to demographics, the issue with opposite gender, lack of pharmacist's personal experience or interest, inappropriate pharmacy layout and the lack of uniform approach by all pharmacists.

The majority of the participants expressed their concern in relation to the lack of funding or financial remuneration for providing professional services. Lack of financial compensation was also seen as a contributing factor to time constraints as a barrier and the increase in pharmacists' workload. Interestingly, one participant provided an opposing opinion, and stated:

"I think traditionally this should be part of our service, I don't think it needs to be compensated. From my point of view, it is part of our job, it should not be like wanting to get some benefits from that." (CP 6)

Despite agreeing that professional services provided in pharmacies should be remunerated, one participant also acknowledged that providing professional services would assist in building of relationships, and in turn improve the sales and business of the pharmacy:

"...you are building that rapport with them so they will come back and buy things from you, so you are being remunerated indirectly." (CP 26)

Breastfeeding was perceived as a potentially sensitive issue, especially for the opposing gender, an issue raised by some male and female participants. Interestingly, when male participants were asked to share their views about gender, over half of them felt that they were comfortable discussing breastfeeding issues, provided breastfeeding women were willing to discuss it with them and that they had positive relationships with their clients:

“I can see why some people think it would be, but to me it also depends on how willing the breastfeeding mum is willing to talk to a male pharmacist about it. Me personally, I don’t have any issue with it.” (CP 10)

“For myself, I don’t think so. I think it’s the trust that you have and how professional you are to present yourself in the area. Now I guess the trust doesn’t come overnight. For me, to work there for seven years, and I’ve seen some of the mum before that they are couple, they got married, and they come to me and they just tell me everything... It’s definitely not a barrier.” (CP 16)

One of the male participants further commented it was considered his responsibility and role to provide advice and professional services to clients regardless of their gender, and hence opposite gender should not be seen as a barrier:

“I did think about it, but I don’t think it should be a barrier.” (CP 11)

Table 5.5: Barriers and challenges identified by participants

Subthemes	Supporting Quotes
Lack of evidence-based information and resources	<i>“You really don’t have a clear decision on what is best for the patient as such. It would be better if we say no don’t use it or yes it’s safe use it. Obviously with a lot of clinical studies, there isn’t enough data or there aren’t enough people in the actual test study to come to a, you know, a proper conclusion.” (CP 9)</i>
Safety concerns and legal implications	<i>“I know people who will not do it, and that’s fair enough because they don’t want to put their license at risk.” (CP 6)</i> <i>“I suppose the litigation reasons as well, you don’t want to be stuck in a law suit if something happens.” (CP 9)</i>
Time constraints	<i>“I think that it is a time-consuming area. I doubt that most pharmacists would be able to sit down long enough to give the mums the time they would need...” (CP 3)</i> <i>“...in the pharmacy time is always an issue with everything, whether it is script, or counselling, doing blood pressure, or putting the order away, or dealing with something that has happened in the pharmacy.” (CP 9)</i>
Lack of training, knowledge and confidence	<i>“...not enough knowledge in the area, not enough training, so that we can’t give out the information confidently.” (CP 5)</i> <i>“I find it is a barrier for most pharmacists because we are not trained and there is not enough focus for time being put in to educate pharmacists on how to educate breastfeeding mothers.” (CP 15)</i>
Lack of funding or financial compensation	<i>“My view is that the above is not possible without funding. Because it’s going to be a lot of, a big investment, and is certainly not viable to do the above investment if there’s no return. And of course there are a lot of factors that attribute to what are you going to do in the pharmacy but without government funding, it is not possible.” (CP 11)</i> <i>“...obviously all these exercises require spending, this becomes expenses for the pharmacies. Like I said the return for the money that you put in is very very minimal. So the only barrier that stopping this</i>

	<p><i>to happen is because of the cost of running the program.” (CP 16)</i></p> <p><i>“We can’t keep providing this sort of service, and the resource, the staff resources, the pharmacy’s resources to care and giving advice for free.” (CP 20)</i></p> <p><i>“It’s all great, but who is going to pay. Community pharmacies are not in the position to pay for these services, and funds these services anymore, particularly with all the price reductions...” (CP 26)</i></p>
Lack of needs or demand due to demographics	<p><i>“...depending on where your pharmacy is. I mean not one shoe fits all. Each pharmacy is different, each pharmacy has different cliental so definitely demographics would play a role.” (CP 9)</i></p> <p><i>“Depends on demographics for sure. In a town with older population, I think it might be a waste of energy and time to set up for this.” (CP 14)</i></p>
Opposite gender and sensitivity issues	<p><i>“It is a very sensitive issue for male pharmacists to handle.”(CP 1)</i></p> <p><i>“...sometimes it can be an awkward situation, so the staff don’t always ask if you are pregnant or breastfeeding because you know, some people may take offence to it.” (CP 2)</i></p> <p><i>“It also depends on how willing the breastfeeding mum is willing to talk to a male pharmacist about it...” (CP 10)</i></p>
Lack of personal experience or interest	<p><i>“Not everyone is up to doing it...” (CP 9)</i></p> <p><i>“I’ve never experienced it myself. I’m afraid I would upset them because I don’t know what they are going through.” (CP 24)</i></p>
Inappropriate pharmacy layout	<p><i>“...we don’t really have quiet place, secure place or private area” (CP 4)</i></p> <p><i>“I think breastfeeding might be a sensitive issue, like more private issue. So a pharmacy without proper layout, I don’t think people will ask that much.” (CP 14)</i></p>
Lack of uniform approach	<p><i>“I think [there’s] actually a gap in community pharmacies. I think we perhaps should be asking all women are you breastfeeding.” (CP 26)</i></p>

5.4.5 Implementation of Strategies and Public Health Services in Pharmacy

Participants' perceptions about their role in providing breastfeeding-related health services in community pharmacies were generally favourable. They acknowledged the benefits of health services which could provide women with postnatal care and support at the community level. These included baby weigh-in stations and lactation clinics in the pharmacy. The employment of lactation consultants and child health nurses in the pharmacy was considered advantageous and feasible provided appropriate funding was available. The majority of the participants also considered the distribution of pregnancy and breastfeeding-related educational materials practicable within the context of pharmacy practice. This could be achieved through liaison with organisations such as the Australian Breastfeeding Association (ABA) and Pharmaceutical Society of Australia (PSA).

“That is easy enough to put pamphlets and stuff in and around the baby section or have some behind the counter.” (CP 2)

With appropriate training, some participants also felt that they would be capable of providing motivational counselling to breastfeeding women with health issues for example: insufficient breast milk supply and postnatal depression. Nevertheless, promotion of services should take place to advise the public should the pharmacy decide to implement any new services, as one participant commented:

“You could have people in the area that just don't come to you because they don't know that you have the service, or don't think you would...” (CP 7)

Only one participant was fully aware of the Australian National Breastfeeding Strategy 2010-2015, which included pharmacists as one of the breastfeeding support staff. Participants commented on the need for pharmacists to be informed of national health strategies in order to enhance community pharmacists' involvement, and ultimately improving client health outcomes. Many participants highlighted the importance of further training and education for pharmacists and pharmacy assistants in order to provide services in the community pharmacy setting.

One of the questions from the interview guide explored participants' perspectives of what could be done to improve or promote the practice of safe and effective use of non-prescription medicines including CMs during breastfeeding. Strategies identified by participants were multifaceted and included efforts from different areas: i) public education, ii) professional education, iii) research and development, and iv) government initiatives, as summarised in Figure 5.4.

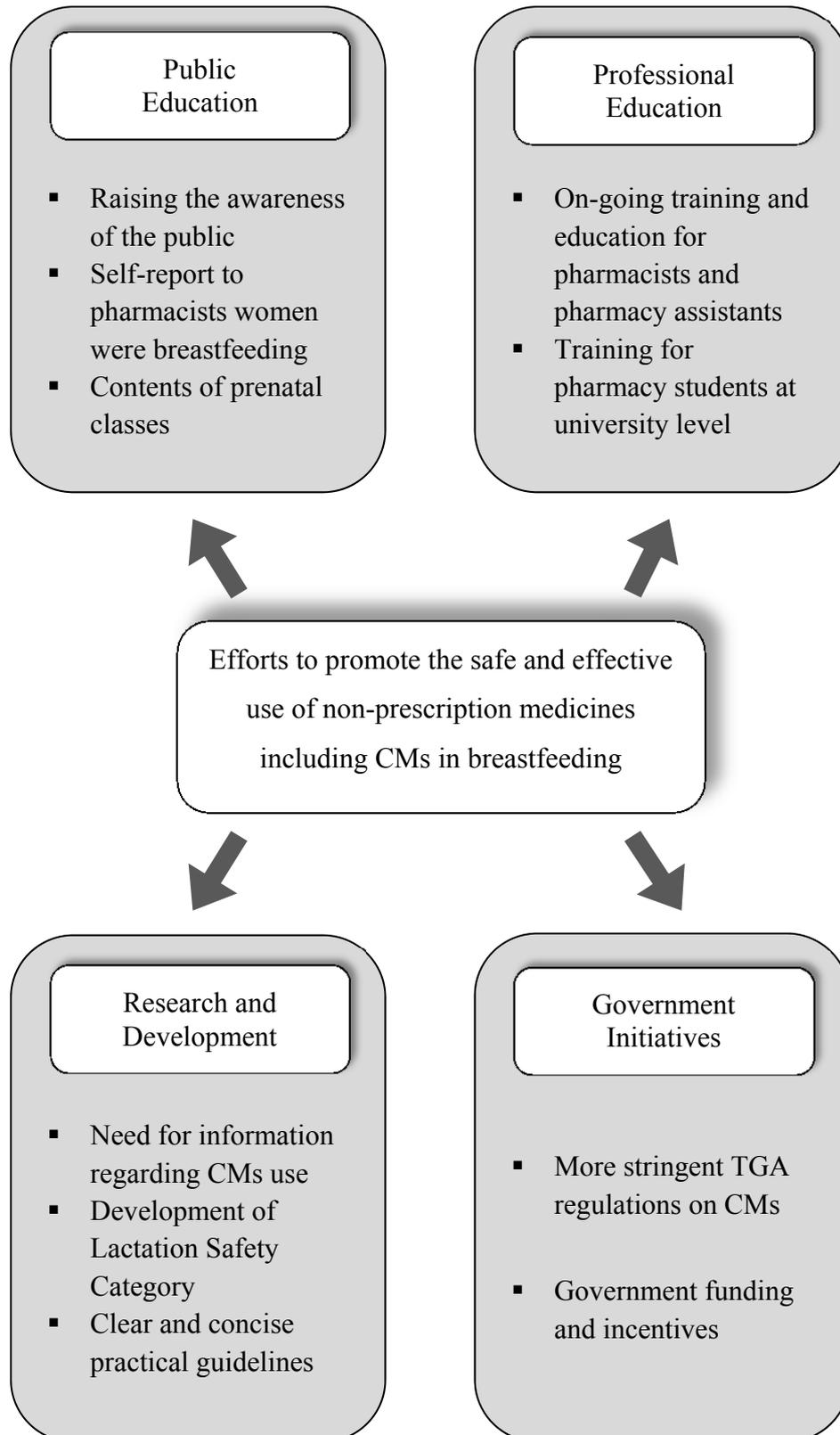


Figure 5.4: Multifaceted efforts to promote the safe and effective use of non-prescription medicines including CMs in breastfeeding

Educating and raising the awareness of the public was seen as key to promoting the safe and effective use of non-prescription medicines while breastfeeding.

“Maybe we should have more campaigns for breastfeeding women I’d say, like to increase the awareness, like not every product can be used when breastfeeding. For instance, if they are breastfeeding, make sure they ask the questions or refer to the pharmacists whenever it’s possible.” (CP 23)

It was consistently mentioned by participants that the public should be educated on the potential risks associated with the use of any medicines, including herbal medicines and natural products, when breastfeeding:

“A lot of the times I find that mums they don’t realise that if they are breastfeeding they need to be careful with what medications they are taking... they don’t think that breastfeeding is an issue and they don’t realise that the medicines that they take can get transferred to the baby...” (CP 2)

“A lot of people assume that they are natural products and assume that they are not going to do any harm.” (CP 3)

“I think when it comes to complementary medicines, they didn’t seek advice from the pharmacists, it seems like they commonly have a concept that it is just a herbal product, it is very unlikely to cause harm...” (CP 6)

“People just need to be careful, you know, don’t just assume that because it is natural, it is safe.” (CP 9)

One participant further commented on the importance of women informing pharmacists if they were breastfeeding:

“Customers also need to make us aware that they are breastfeeding, not withhold information from us, if that’s relevant. So if someone asked if they have any other medical condition, if they don’t say breastfeeding or if they

don't count breastfeeding as a medical condition, then really that's not our fault..." (CP 29)

Some participants suggested the awareness of the public could be increased through promotion and during prenatal classes:

"For example, the hospital should tell the mothers that when you are breastfeeding if you want to take any complementary supplements, you have to always ask pharmacists." (CP 6)

"I would say let the public know more, maybe TV advertisement, or paper and radios." (CP 14)

"Get people to ask the pharmacists. Push to ask the pharmacists message." (CP 21)

One of the common issues raised was to do with training and education. On-going training for pharmacists and pharmacy assistants was raised as important as well as training for pharmacy students at the university level. Nevertheless, focus should be placed on the safety aspects of medicines used in breastfeeding, especially CMs:

"...we work in the community pharmacy, and there's a big portion of vitamin and herbal supplements sale, and what we learn in Uni is about 90% on S2, S3, [and] S4 medicines, and 10% of herbal and vitamins. Whereas when you go out to a real community pharmacy, it's almost fifty-fifty. So it's definitely not adequate." (CP 6)

The need for greater information and research especially into the area of CMs use in breastfeeding was identified by many participants of this study. To that extent, the development of a Lactation Safety Category and the availability of clear and practical guidelines with evidence-based recommendations would better inform and guide health professionals in making clinical recommendations.

Some participants also discussed their expectations of drug companies and the need for more stringent TGA regulations on all CMs:

“I think first of all what needs to happen is from the legislation point of view. If the current legislation stays in place then the companies that make the complementary medication will not obviously spend more money on study of safety and efficacy of the medication in breastfeeding... If they are not spending anymore effort, you pretty much is going to be restricted on information and is not going to have more studies done. So I think if the government can do something to encourage the manufacturer to do more studies...” (CP 11)

“...the government has to be quite stringent on the drug company, and the labelling has to be quite up-to-date.” (CP 16)

It was recognised that government funding and incentives were necessary to assist with the implementation of the above mentioned strategies and services:

“I think they could provide more funding so pharmacists can have more programs or provide more services to increase the awareness.” (CP 18)

“Remuneration could help to motivate employers to allow the pharmacists to do so...” (CP 24)

“...put in money for research, so funding from somewhere for more research so that our references can be more up-to-date...” (CP 26)

5.4.6 Continuing Professional Development

A need for on-going CPD and training was highlighted in this study, for both pharmacists and pharmacy assistants. The majority of the participants agreed that additional training in the area of breastfeeding and medicine use should be a priority to increase confidence of pharmacists and to meet the growing demand and expectations of the public. Most participants preferred the contents to be delivered either face-to-face in events such as a CPD session, hardcopies in booklet format or CPD modules available via the internet. Participants were also asked to indicate topics of CPD which they thought would be practical and useful to their practice, which are summarised in Figure 5.5.

In addition to the topics summarised, participants also cited the need for training on motivational and effective counselling skills to assist them with communicating and understanding the emotional needs of breastfeeding women experiencing health issues.

Participants' views on whether there was scope for pharmacists to specialise in women and newborns' health and to qualify as lactation consultants were mixed. Whilst the majority of the participants supported the expansion of pharmacists' roles into these areas, a few believed they were beyond the scope of practice and capabilities of pharmacists.

Participants identified that the topics of CPD should include:

1. How to look for evidence-based information with regards to use of medicines, especially CMs in breastfeeding,
2. How medicines are transferred into the breast milk,
3. How to minimise the transfer of medicines into the breast milk,
4. What are the factors determining the exposure of infants to medicines in the breast milk,
5. What are the signs of a healthy breastfed infant and breastfeeding mother,
6. What are the common issues or ailments seen in lactation and how to manage them, for example: signs and management of insufficient milk supply and mastitis,
7. What are the non-prescription medicines or evidence-based alternative options available and recommended to treat breastfeeding women requiring treatment for common conditions seen in the pharmacy, for example: cough and cold, allergies, pain and inflammation,
8. Basic knowledge with regards to breastfeeding, for example: how to operate a breast pump, how to express and store breast milk, and
9. Signs and symptoms which warrant referrals and who their clients should be referred to.

Figure 5.5: Suggested topics of Continuing Professional Development

5.5 Discussion

The key findings of the Stage 3 study are discussed in five sections: i) attitudes and knowledge, ii) lack of resources for CMs use in breastfeeding iii) professional judgement and dilemmas, iv) ethical and legal obligations, and v) need for on-going professional education and training.

5.5.1 Attitudes and Knowledge

Limited published studies exist in the Australian context exploring community pharmacists' perspectives towards their role in promoting the safe and effective use of non-prescription medicines in breastfeeding, and supporting breastfeeding as well as other related professional health services in the community pharmacy setting (4, 5).

The role of pharmacists in this context is further defined in the PSA's Competency Standards Domain 6 *Deliver primary and preventative healthcare* (388). The only published study is a 2013 publication by De Ponti et al. (5) that investigated community pharmacists' perspectives on the use and safety of medicines in breastfeeding, and highlighted a need for further research in this area. It involved administration of postal surveys using a questionnaire form similar to that used by Amir and Pirotta (150) in their study of GP's perspectives. The study explored community pharmacists' perspectives and their knowledge of using paracetamol, ibuprofen, lithium, metronidazole and St John's wort in breastfeeding. The authors concluded that whilst pharmacists felt confident in counselling breastfeeding women, their knowledge was variable. This Stage 3 study differed from the former study in terms of the specific objectives, the overall focus, medicines investigated and the research methodology. With a qualitative approach using semi-structured in-depth interviews, the Stage 3 study has enhanced our understanding of community pharmacists' perspectives of their role in promoting the safe and effective use of non-prescription medicines, including both conventional and CMs, in breastfeeding. Furthermore, this study has also explored the potential for the expansion of the pharmacists' role into providing women and breastfeeding-related health services in the community pharmacy.

The most common health issues presented by breastfeeding women at the participating community pharmacies agreed with the results of a Melbourne, Victoria survey conducted in 2008. The survey results indicated that the common conditions breastfeeding women presented to general practitioners included mastitis and other infections requiring the use of antibiotics, depressive disorders, use of analgesics, contraception, insufficient milk supply and other atopic conditions (83, 150, 389).

In this study, the overall attitudes of pharmacists towards their role in promoting safe and effective use of medicines in breastfeeding and promoting breastfeeding in the community were favourable. Throughout the interviews, pharmacists showed care and willingness to expand their professional roles in supporting breastfeeding women. The facilitators and barriers identified were in accordance with the literature (4, 5, 87, 201, 390, 391). Eades et al. (4) commented that community pharmacists are regarded as one of the most accessible health professionals due to their extended trading hours and that no appointment is needed to obtain their advice. Convenience and accessibility of community pharmacists were acknowledged as main facilitators by participants of this study. As stated by Hughes et al. (149), “Pharmacy-based personnel reported more frequent exposure to women across the perinatal life-stages compared with GPs and nurses”. Consistent with the literature, the Stage 3 study demonstrated pharmacists’ frequent and regular contact with breastfeeding women in the community. This presents an invaluable opportunity for pharmacists and pharmacy staff to provide on-going support to women during the postnatal period, at primary healthcare level. Pharmacy support staff form approximately two-thirds of the Australian pharmacy workforce (392). Considering the regular interactions between women and the pharmacy staff, appropriate training should also be offered to support staff in order to meet the needs and expectations of women, at the same time ensuring they are able to recognise symptoms or cases which warrant referral to the pharmacist.

It was consistently reported by participants that pharmacists lack knowledge and confidence in discussing the use of CMs in breastfeeding. Despite the popularity of herbal galactagogues as indicated in Stages 1 and 2 of the study, pharmacists who participated in the Stage 3 study had limited experience and knowledge with regards

to their efficacy and safety in breastfeeding. Pharmacists' lack of knowledge and confidence in recommending and providing advice regarding the use of CMs to the general population have also been reported in various published studies (201, 214, 345, 390, 393-395). Taking into consideration the prevalence of herbal medicine use amongst breastfeeding women in Western Australia and to meet their expectations, the perceived lack of knowledge and confidence of pharmacists should be addressed (335, 350).

Pharmacists' attitudes in this context may be influenced by previous successful or positive experiences (201). Participants who had previous experience with the use of CMs and personal experience with breastfeeding showed great interest in supporting breastfeeding women. However in terms of herbal medicines, it was unclear whether they would choose to provide recommendations beyond the limited evidence-based information. Despite their interest and willingness to participate in public health services in the community, only one participant was fully aware of the implementation of the Australian National Breastfeeding Strategy 2010-2015. As pharmacists are listed as support professionals (1), this finding indicated that all stakeholders should be better informed of their roles and expectations in order to meet the objectives of such strategies.

The majority of the participants in this study agreed with the six statements addressing pharmacists' self-awareness of knowledge and confidence level. Despite the favourable perceived knowledge level, previous studies have demonstrated pharmacists' variable and poor knowledge in the area of medicines use in breastfeeding (5, 87, 88, 156). Nevertheless, the current study did not assess participants' knowledge of specific medicines, hence direct comparison to the literature is not possible. A review of the literature also suggested that a pharmacist's self-perceived confidence level does not always equate to knowledge adequacy (5, 88, 156, 396). It was suggested that raising the awareness and knowledge of pharmacists in regard to the commonly used medicines and their safety in breastfeeding would prevent health professionals from giving conservative recommendations unnecessarily and improve the quality use of medicines during breastfeeding (5).

5.5.2 Lack of Resources for CMs use in Breastfeeding

Participants identified a lack of available resources about non-prescription medicines, in particular high level information on CMs use in breastfeeding. This finding was in line with the published literature (5, 201). Despite findings from Stages 1 and 2 demonstrating the popularity of herbal medicines amongst breastfeeding women, to date, no published study has focused on investigating community pharmacists' perspectives towards CMs use in breastfeeding. Stage 3 provides useful information on the perspectives of community pharmacists with regard to the available resources and references in the context of CMs (including herbal medicines) and other non-prescription medicines in breastfeeding. Many previous studies have highlighted the lack of resources available with regards to the use, efficacy and safety of CMs in the general population (202, 210, 348, 394, 395, 397-399). Insufficient information and research into the use and safety of medicines in breastfeeding had also been identified by both women and health professionals as a challenge (83, 87, 142, 150, 156, 328, 396, 400, 401). As previously reported in Section 5.4.3, participants used a variety of references and resources to assist them with their daily practice in the provision of advice to breastfeeding women with regard to the use of non-prescription medicines, including CMs. Although these references and resources may provide useful information on conventional medicines, there is limited information on CMs, especially herbal medicines. The Pharmacy Board of Australia provides a list of recommended essential references and states "Pharmacists must be able to readily access contemporary works of professional reference in either conventional or electronic forms. The information is to be immediately available to the pharmacist during the clinical assessment, reviewing, dispensing and counselling processes" (402). According to the Pharmacy Board of Australia's *Guidelines on practice-specific issues – Guideline 1 (List of References)* (402), current editions of "an evidence-based reference work on complementary and alternative medicines" (402) must be readily accessible to pharmacists. Under this category, pharmacies in Australia should have at least one of the following: i) Herbs and Natural Supplements: An evidence based guide. Braun and Cohen (220); or ii) Herbal Medicines. Barnes, Anderson and Phillipson (403); or iii) e-MIMS; or iv) AusDI Advanced. Nevertheless, the Pharmacy Board of Australia does not have jurisdiction over pharmacy premises. The *Pharmacy Regulations 2010* (404) states

that it is mandatory for pharmacy premises to have specific documents and references, but none of them are references specific to CMs. Interestingly, in the interviews with Stage 3 participants, there was no mention of resources specific to CMs or herbal medicines, including textbooks (220, 403) and relevant CMs database for example Natural Medicines (formerly Natural Standard and Natural Medicines Comprehensive Database) (405). The fact that e-MIMS provides information on both conventional medicines and CMs and that it is available in electronic version and also contains other features such as “Drug Alert Interactions”, these factors may explain why some pharmacies would opt for e-MIMS as an option rather than textbooks. It may also be possible that participants were not aware of resources specific to CMs or it may be interpreted as pharmacists demonstrating their focus on conventional medicines. Nevertheless, this finding highlights the importance of ensuring that pharmacists are aware of the available resources, specifically not just where to find them, but also how to interpret the available information.

LactMed[®] (406) is a peer reviewed TOXNET database which contains information on safety of drugs in breastfeeding, including conventional medicines and some herbal medicines for example fenugreek. In the study conducted by De Ponti et al. (5), up to 25% of the survey respondents who were pharmacists (n = 175) reported using the LactMed[®] database as one of the resources for information with regard to the safety of medicines in breastfeeding. However, there was no mention of the use of this database from participants of Stage 3. Although this database is based in the USA and uses North American drug names, the database does provide useful information which could assist Australian pharmacists in making clinical recommendations since there is no similar database specific for drugs use in lactation available in Australia.

In addition to the need for further research into CMs use in breastfeeding, participants also raised the need for a more stringent approach by the Australian TGA to regulate the marketing of CMs. Currently, most CMs, including herbal medicines and supplements, are regulated under the specifications of ‘AUST L’ or ‘listed’ medicines (16). Although there have been many debates over the years around whether CMs should be subjected to the same regulations as conventional medicines (16, 160, 165, 391, 407), participants were of the opinion that improved

Australian regulation may encourage pharmaceutical companies to undertake further research regarding the safety and efficacy of their products in the different population groups, including pregnant and lactating women. As discussed previously in Section 2.5.3, the marketing and supply of AUST L medicines in Australia is currently co-regulated between the TGA through the TGAC and the CHC's Code of Practice (16, 204). As opposed to AUST R medicines, products classified as AUST L are subjected to less stringent advertising regulation. Despite the lack of efficacy data for many CMs, the advertising of these medicines through mainstream media may positively but inaccurately affect the public's perception of the safety and efficacy of these products. Considering the purpose of marketing is to promote the sales, loose controls over marketing of CMs will impact on the public's decision to purchase.

A range of information sources was used by participants of this study, reflecting their familiarity with seeking information particularly in relation to conventional medicines. The common information resources and references reported were similar to those described by De Ponti et al. (5), who stated that 79% of their survey respondents thought the available information regarding use and safety of medicines in breastfeeding was adequate, including St John's wort, which was the only herbal medicine included in the study. In a review written by Ilett and Kristensen (127) which was cited by De Ponti et al. (5), St John's wort was also the only herbal medicine evaluated for partition into breast milk. Despite agreeing that these resources and references provided guidance to pharmacists when making clinical recommendations, most participants of the Stage 3 study indicated that information specifically with regards to CMs including herbal medicines and their safety in breastfeeding was lacking. Insufficient coverage of data related to CMs and the safety of medicines in breastfeeding in commonly used resources and reference texts was identified as a barrier in this and previous studies (87, 156, 390) This area was perceived by the participants as a practice gap and had a negative impact on pharmacists' confidence. Participants preferred an easily accessible website or reference text which provides topic-based information on various OTC treatable conditions and options available for treatment of those conditions while breastfeeding.

In Australia, most conventional medicines have been classified under categories that indicate their safety in pregnancy (408). Many drugs have been assigned an Australian category, namely Category A (safest in pregnancy), B1, B2, B3, C, D or X (should be avoided in pregnancy due to high risk of permanent damage to the foetus), demonstrating their safety in pregnancy based on the available literature (252). Similar categories do not exist about the safety of medicines in lactation (83). The United States' Food and Drug Administration (FDA) has previously made attempts to classify commonly used medicines into Lactation Categories based on available evidence and the safety in lactation (61, 62, 409). Nevertheless, due to the lack of available evidence and research, not many medicines have been assigned a category. The lack of resources and research in this area had been acknowledged by the FDA and major revisions to the labelling of medicines in the US with regards to their effects in both pregnancy and in lactation were recommended (409). It should be highlighted that there were no comments about these lactation safety categories by the Stage 3 participants, suggesting that this classification has not been adopted into the daily practice of pharmacists in the Australian context. Until this point, the TGA has not introduced classification of medicines and their safety in breastfeeding. This in itself is of interest as there are currently no similar lactation safety categories in the Australian guidelines to assist health professionals in making clinical decisions and providing recommendations to breastfeeding women.

5.5.3 Professional Judgement Dilemmas

Concern over breastfed infants' safety was regarded as one of the crucial factors guiding pharmacists' decision-making process. This over-arching theme emerged as participants described their dilemma when making clinical recommendations with regards to the use of non-prescription medicines in breastfeeding. Pharmacists often face challenges to recommend non-prescription medicines which are safe and effective to breastfeeding women when they present themselves to the pharmacy requesting treatment for OTC treatable conditions. Based on the limited available information and resources, pharmacists based their recommendations on professional judgement and personal experience, weighing benefits of using a medicine for the breastfeeding mother and the potential risks to the infant's safety. In order to

minimise the level of uncertainty, participants tend to adopt a conservative attitude and recommend a product that they were familiar with. This finding was in line with the literature which also demonstrated the challenges and concerns of health professionals, including general practitioners and pharmacists, when they were required to provide clinical recommendations to breastfeeding women who present themselves to their practice for treatment (5, 83, 150, 389). In the absence of available evidence-based information, health professionals in many cases were required to consider the “risk to baby versus benefit to mother”, as described by Amir and Pirotta (150).

It appeared in this study that making clinical recommendations to breastfeeding women was regarded as a complex and potentially complicated task. A study conducted by Jayawickrama et al. (83) in Melbourne, Australia, explored general practitioners’ experience and perspectives towards prescribing for breastfeeding women. The researchers reported the “complexity of managing risk in prescribing for breastfeeding women” as the global theme of the study. Although this study was conducted with general practitioners, it provided insight into the challenges which all clinicians may face when making clinical recommendations to lactating women. Findings of the Stage 3 study complement the literature, by exploring pharmacists’ perspectives and attitudes towards promoting the safe and effective use of non-prescription medicines in breastfeeding.

5.5.4 Ethical and Legal Obligations

In order to practice in Australia, it is a requirement for all pharmacists to register with the AHPRA (22). Health professionals registered with AHPRA need to comply with the Code of Conduct for Health Professionals as well as a number of practice standards. Pharmacists practising in Australia are guided by the PSA’s Professional Practice Standards and Code of Ethics, where expectations of the pharmacists and pharmacy profession are summarised (33, 89). Regardless of the practice setting, all pharmacists should be competent with the PSA’s Professional Practice Standard 1: Fundamental Pharmacy Practice, which states: “The pharmacist displays accepted professional and ethical behaviour, maintains the consumer’s right to privacy and

confidentiality, and aims to achieve the quality use of medicines, health and wellbeing” (89).

The PSA’s Professional Practice Standard 12: Provision of Non-prescription Medicines and Therapeutic Devices states that: “The pharmacist is responsible for the safe and judicious provision of non-prescription medicines and therapeutic devices appropriate to the needs of the consumer” (89). The standard further defines non-prescription medicines as “all medicines available for purchase by the public that do not require a prescription. Non-prescription medicines include, but are not limited to, Pharmacist Only Medicines (S3), Pharmacy Medicines (S2), unscheduled medicines, complementary medicines, and nutritional supplements” (89). As non-prescription medicines are available to the public without a prescription from a prescriber, pharmacists have the professional obligation over their sales, to ensure quality use of these medicines.

Notably, aspects of the pharmacy profession’s ethical and legal obligations were recognised by all participants of the Stage 3 study. It was evident that those pharmacists constantly reflect on their ethical obligation to the public when providing professional advice, and that all recommendations were centred on their clients’ health and safety. This was in accordance to the first principle of the PSA’s Code of Ethics, which states: “A pharmacist recognises the health and wellbeing of the consumer as their first priority” (33).

Participants felt responsible for ensuring the safe and effective use of all medicines and products sold in their pharmacies, regardless of whether they were prescription or OTC medicines. This finding emphasised the participants’ awareness and compliance with the fourth principle of the Code of Ethics, which states: “A pharmacist acknowledges the professional roles and responsibilities to the wider community: A pharmacist will ensure responsible and accountable control and supply of therapeutic goods and contribute to public health and enhancing the quality use of medicines” (33). This was also in accordance with the PSA’s Position Statement on ‘Complementary Medicines’, which states: “The provision of complementary medicines is at the discretion of individual pharmacists who must exercise their professional judgement. However, pharmacists involved in the supply

of such products have the same obligation to provide information and advice, consistent with consumer needs, as they do with registered prescription and proprietary medicines” (410).

The PSA’s fifth principle of the Code of Ethics states: “A pharmacist demonstrates a commitment to the development and enhancement of the profession: A pharmacist will commit to advancing the profession through involvement in activities including training staff; engaging in teaching; acting as a preceptor; mentoring students, interns and colleagues; engaging in discussions and participating in initiatives to develop the profession; and showing professional leadership” (33). Furthermore, the sixth principle states: “A pharmacist maintains a contemporary knowledge of pharmacy practice and ensures health and competence to practise: A pharmacist will recognise the importance of lifelong learning and self-development and their impact on professional competence. Further, a pharmacist is responsible for ensuring personal health to practise and supporting health professional colleagues in this regard” (33). Compliance to the fifth and sixth principles of the Code of Ethics was also evident from participants’ commitment to CPD and desire for on-going training in the area of medicines use in breastfeeding and the other aspects of breastfeeding.

5.5.5 Need for Continuing Professional Education and Training

For on-going AHPRA registration, pharmacists in Australia are required to comply with the annual CPD requirements (22). For example, it is a requirement for all pharmacists to obtain 40 CPD credits between 1st October 2013 and 30 September 2014 in order to be eligible for renewal of AHPRA registration. As discussed in Stage 1 of the study, the increasing number of women using herbal medicines whilst breastfeeding pose a great challenge to community pharmacists. Findings of the Stage 3 study were in accordance with the literature, demonstrating pharmacists’ desire for further education and training in the area of CMs use and breastfeeding, as well as the need for modification of the university pharmacy degree’s curriculum to incorporate a greater component on CMs and various aspects of breastfeeding to meet the growing demand (87, 201, 390). Results have also showed that pharmacists, especially those who have regular contacts with breastfeeding clients in

the community need further training and education in order to provide appropriate guidance to the increasing number of women who are using CMs whilst breastfeeding and who regularly utilise community pharmacies as sources of advice and information. A need for continuing professional education and training for pharmacists was established, taking into account the demand and expectations of clients and the pharmacists' interests in further learning (163, 208, 390, 411). There seems to be an opportunity and urgent need for professional organisations and universities to provide CPD on CMs and various aspects of breastfeeding to pharmacists and pharmacy students. There is also a need for on-going and regular revisions of reference texts to make sure they incorporate the latest studies and evidence, so that these resources assist health professionals in providing up-to-date evidence-based recommendations.

5.5.6 Limitations

Every study has its limitations. As participation was voluntary, it is likely that pharmacists who were more interested in the topic had participated in the interviews, which could potentially underestimate the challenges or barriers to the expansion of pharmacists' role. Despite collecting information on pharmacists' self-awareness of knowledge and confidence level, the study did not assess pharmacists' actual knowledge on the commonly used medicines in breastfeeding and their approach to managing common OTC treatable conditions. As all participants of the study were community pharmacists from Western Australia, findings of the study may only be limited to the pharmacists group previously mentioned, and it is acknowledged that pharmacists working in different sectors, such as hospitals, or in other states or internationally, may have different experiences, perspectives and attitudes influencing their practices. The student researcher, who was the interviewer in this research study, is a practising pharmacist which may have influenced the interviews and affected the analysis. In an attempt to counterbalance any potential bias, the student had regular meetings throughout the period of data collection and analysis with the supervisors, all of whom have different disciplinary backgrounds and had no affiliations with any of the community pharmacies and pharmacists who participated in the study.

Chapter 6
General Discussion, Future Directions and
Conclusions



This chapter provides a summary and a general discussion of the significance of the overall findings of this research, followed by the overall conclusions from the research and the recommendations and directions for future studies.

6.1 Summary of the Thesis

This research explored breastfeeding women and community pharmacists' perspectives on herbal medicines use in breastfeeding. In summary, there were three stages to this study:

- **Stage 1** investigated the prevalence and pattern of use of herbal medicines amongst breastfeeding women living in Western Australia using a population-based survey.
- **Stage 2** explored breastfeeding women's experience on the use of herbal galactagogues and their attitudes towards the use of herbal medicines in general whilst breastfeeding. This stage also provided insight into women's perspectives on the pharmacists' involvement and potential roles in meeting their healthcare needs in the community pharmacy setting.
- **Stage 3** explored community pharmacists' perspectives of their role in promoting the safe and effective use of non-prescription medicines, including CMs in breastfeeding. This stage also explored community pharmacists' attitudes towards expansion of their roles in the provision of women and breastfeeding-related professional services in the community.

A flow chart summarising the process and findings is shown in Figure 6.1.

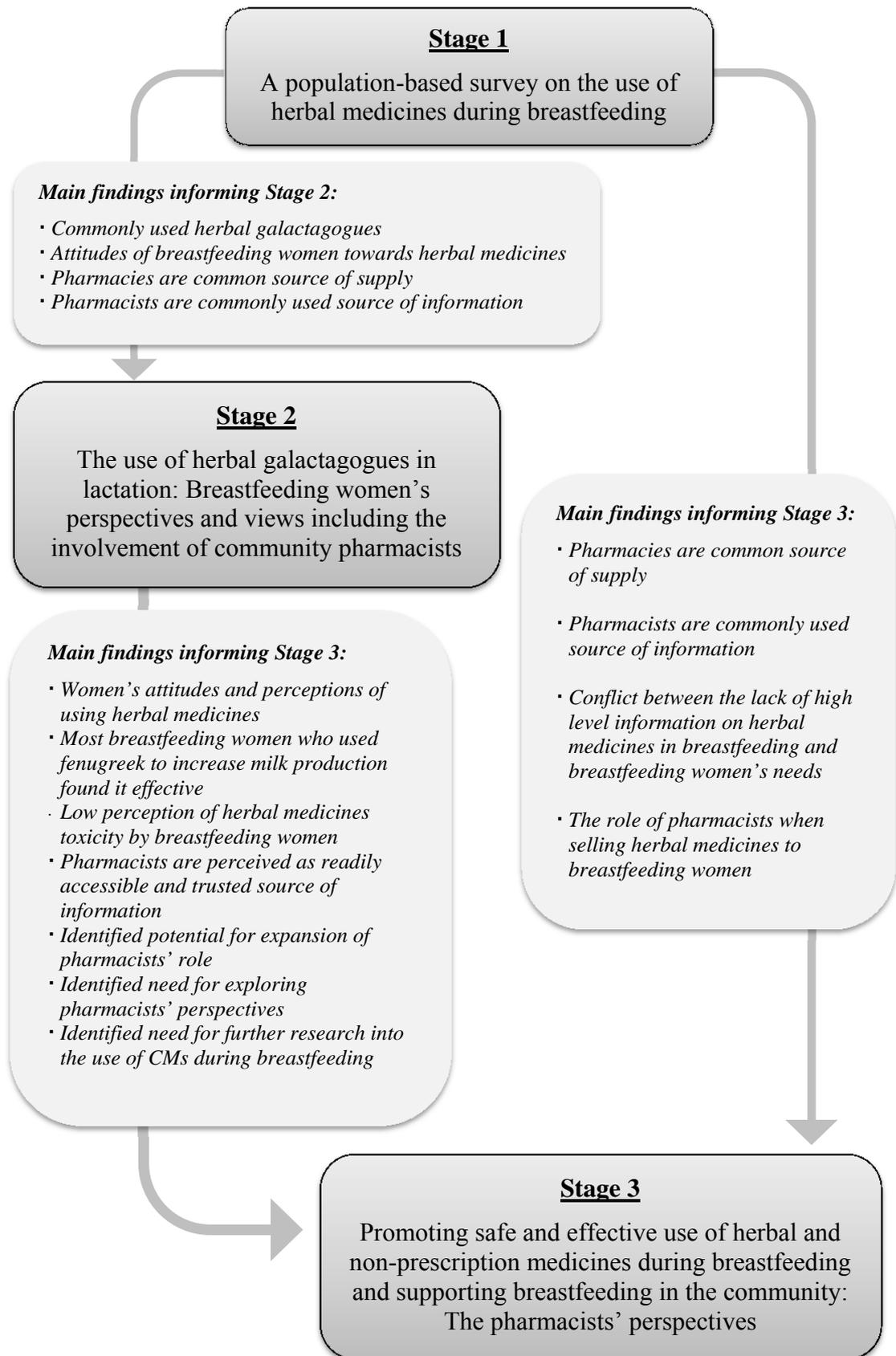


Figure 6.1: Flow chart summarising the process and findings of the research study

6.2 General Discussion

Detailed justification of the methodology employed in this research, the limitations and discussion of the key findings are presented in this section. The results and findings of Stages 1, 2 and 3 are discussed in relation to the overall aims of the thesis, which were to evaluate the perspectives and influencing factors of breastfeeding women with respect to the use of herbal medicines (especially galactagogues) and to investigate the role of Australian community pharmacists in supporting breastfeeding women, in relation to the provision of advice and information on herbal and other non-prescription medicines.

6.2.1 A Review on the Research Methodology of these Studies

To achieve the overall aims, a mixed-methods approach was adopted to gather data, opinions and experiences necessary to evaluate the perspectives of breastfeeding women and community pharmacists. Over the last decade, mixed-methods research has become increasingly popular amongst researchers in the fields of healthcare, pharmacy practice and health services (412-414). Mixed-methods research is also often been regarded as the third research paradigm, after quantitative and qualitative research (415). According to Creswell and Plano Clark (416),

Mixed methods research is a research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis and the mixture of qualitative and quantitative approaches in many phases of the research process. As a method, it focuses on collecting, analysing, and mixing both quantitative and qualitative data in a single study or series of studies. Its central premise is that the use of quantitative and qualitative approaches, in combination, provides a better understanding of research problems than either approach alone (416).

The overall approach followed to achieve the research aims was to use both quantitative and qualitative methodology with the goal of providing an in-depth understanding of the research topic of interest. Hadi et al. (412) state that this methodology “can potentially resolve this ‘indecisive battle’ between the two types

of methodology as it recognizes and appreciates the strengths and weaknesses of both qualitative and quantitative research designs”. Mixed methodology is also viewed as “practical” by Creswell and Plano Clark (417) as it allows researchers to develop the optimum method by choosing and merging different methodologies in order to gather comprehensive data to address the research problems.

According to Smith (414), the choice of research methodology in pharmacy practice and health services is “generally governed by data requirements for fulfilling research objectives and practical considerations in conducting research” (414). Considering the aforementioned points and the overall aims of this research, mixed methodology was considered the most suitable approach and best fitted the scope and purpose of the overall thesis. This research comprised three stages to collect comprehensive and relevant quantitative and qualitative data to evaluate the perspectives of breastfeeding women and community pharmacists on the use of non-prescription medicines, in particular herbal medicines in breastfeeding. As this thesis was an original work in Western Australia to evaluate the perspectives of breastfeeding women and pharmacists in the context of herbal medicines in breastfeeding, the design of the research had to be exploratory in nature, in that the findings of the various stages would inform and shape subsequent stages of the research, as shown in Figure 6.1.

The review of the literature identified that there was a lack of data with regards to the pattern of use of herbal medicines during breastfeeding and the potential role of community pharmacists in supporting breastfeeding women in relation to the appropriateness of their use. Although many studies have explored the pattern of use of herbal medicines amongst the general population, the use of these medicines specifically by breastfeeding women had not been well studied. The essential first step of this research was to investigate the prevalence of herbal medicines usage amongst breastfeeding women, the commonly used herbal medicines, women’s attitudes towards the use of these medicines as well as their information-seeking behaviour. To fulfil the research objectives of Stage 1 (as specified in Section 3.2), a survey of breastfeeding women living in Western Australia was considered an appropriate method to gather the required data. Using a quantitative approach, the survey was conducted using a structured questionnaire as the survey instrument,

designed for self-administration by respondents. This research method was chosen for Stage 1 as it allowed quantification of the data and enabled exploration of the associations, if any, between the responses of respondent subgroups and their patterns of herbal medicines use in breastfeeding. This quantitative approach also allowed the candidate to gather information on the commonly used herbal medicines and provided guidance to subsequent stages of the research.

Findings of the Stage 1 study, along with the literature review, guided and justified the development of Stage 2. Although Stage 1 identified that herbal galactagogues were commonly used amongst the survey respondents, detailed information on the routes of administration and dosages were not collected. Other aspects identified through Stage 1 that required further exploration were presumptions of the safety of herbal medicines compared to conventional medicines and the role of the pharmacy profession as pharmacies were identified as a common source of herbal medicines supply and pharmacists indicated to be the most common source of information. A need was therefore identified to obtain an in-depth understanding of the perspectives and perceptions of breastfeeding women and the factors affecting their choices. Hence, the aforementioned points justified the need to conduct Stage 2 with a qualitative approach, bearing in mind the strengths and limitations of qualitative methodology.

Qualitative research methods allow the collection of relevant, rich and in-depth information, enabling researchers to explore the attitudes and perspectives of individuals in the context of their individual circumstances (359, 414, 418). Smith (414) considered qualitative studies the most appropriate for “why?” and “how?” questions to explore the patterns and processes in participants’ behaviour and thoughts. According to Patton (359), there are three types of qualitative data: interviews, observations and documents. Of these, data collected through the medium of interviews best suited the objectives and purpose of Stage 2, which employed a semi-structured interview guide to assist in the evaluation of breastfeeding women’s perspectives and to seek in-depth understanding of the major findings of Stage 1.

The value of qualitative research lies in its flexible approach and the ability to be receptive to participants’ viewpoints. According to Smith (414),

Qualitative researchers, however, must remain sensitive to the respondents' viewpoints and be prepared to consider new issues and ask questions throughout data collection and analysis. To gain insights into the respondents' interpretations and perceptions of events, experiences and surroundings, qualitative researchers must be attentive to the perspectives of the respondents, and endeavour to leave their own preconceptions behind (414).

In accordance with the essence of qualitative exploratory research there is justification for the need, at appropriate times, to deviate from an interview guide. For example, some participants from Stage 2 raised their thoughts on the health system and the potential role for expanded breastfeeding-related professional services within the community pharmacy setting. These topics were not specifically included in the interview guide. However, as the study was conducted through the form of interviews, the methodology allowed the interviewer to probe in order to elicit further information about the participants' perspectives. This also enabled the participants to elaborate on their thoughts which added to the richness and quality of the data collected.

As Stages 1 and 2 identified some common themes in that pharmacies were a common source of CMs supply and that breastfeeding women were likely to access pharmacies and seek advice from pharmacists, Stage 3 of the study was conducted to evaluate the perspectives of community pharmacists on the use of herbal medicines and other non-prescription medicines in breastfeeding, as well as their role in supporting breastfeeding women in the community and any associated facilitators and barriers emerging from the themes. Justification for gathering information in the broader context of non-prescription medicines has previously been provided in Section 4.5.6. To meet the research objectives of Stage 3 (provided in Section 5.2), interviews with pharmacists were considered the best form of data collection as it allowed the interviewer to explore pharmacists' viewpoints towards the major findings of Stages 1 and 2, and enabled participants to elaborate on their thoughts and the factors impacting their behaviour. For example, Questions C7 and C8 of the interview guide were designed to collect participants' views on the Stage 1 findings; whilst Questions E6 and G3 explored their views on Stage 2 findings. As this was the

first study in the Western Australian context to evaluate the perspectives of pharmacists towards providing advice on herbal and non-prescription medicines to breastfeeding women and supporting breastfeeding in the community, a series of closed and open-ended questions were incorporated to meet the study objectives. Semi-structured interviews with community pharmacists were used to obtain detailed descriptions and an understanding of their experiences and perspectives that allowed the development of perspectives and understanding of the current and potential future role of community pharmacists in supporting breastfeeding women.

The number of participants and types of data collected in each stage of the study also strengthened the research. Stage 1 was a survey with 304 respondents, which enabled quantitative data collection from a large number of women. Stages 2 and 3 focused on smaller numbers of participants (n = 20 for Stage 2 and n = 30 for Stage 3) to collect more in-depth qualitative data. Interviews with breastfeeding women and community pharmacists ceased when the interviewer (in this case the candidate) did not identify new emerging concepts coming forward. The initial analysis was also discussed in detail with the supervisors to ensure that data saturation had been reached.

6.2.2 Limitations

Any research design has its limitations and challenges, and the limitations should be taken into consideration when analysing and interpreting findings of the studies. Stage 1 collected quantitative data through self-administered structured survey questionnaires. The reliability of this research method depended on the willingness and ability of respondents to provide accurate information or responses to the questions in the questionnaire, which could have presented as a challenge specifically if participants could not accurately recollect the information needed (414). As the surveys were self-administered and anonymous, the research method employed in Stage 1 did not allow follow-up of responses or the opportunity for the candidate to clarify viewpoints of the respondents. Nevertheless, this was overcome through Stages 2 and 3, which provided opportunity for clarification and in-depth understanding of the major findings of Stage 1. As with all qualitative research, the

background and perspectives of the researchers may have had an impact on the analysis of the interview findings (359). As previously stated in Section 5.5.6, the candidate is a registered pharmacist in Australia carrying out research through a School of Pharmacy, which could have impacted the interviews and analysis. However, to counterbalance the potential bias, regular meetings were scheduled throughout the period of data collection and analysis with the supervisors, who have different disciplinary backgrounds and had no affiliations with any community pharmacies. Therefore, considering the strengths and limitations of the chosen research methodology, it was considered appropriate in fulfilling the overall aims and objectives of the research. The collection of both quantitative and qualitative data from breastfeeding women and pharmacists allowed the researchers to obtain in-depth insight into the topic of interest.

6.2.3 Prevalence of the Use of Herbal Medicines in Breastfeeding

Stage 1 showed that there was a high prevalence of breastfeeding women using herbal medicines amounting to approximately 60% of the study population. In addition, many of these were using two or three different herbal medicines. Approximately 25% of respondents took one or more herbal medicines specifically to increase breast milk supply. The major factor influencing the use of herbal medicines was that women born in Asian countries were 2.2 times more likely to use herbal medicines during breastfeeding than participants born in other countries.

There is no database from which a sample of breastfeeding women living in Western Australia can be accessed. Hence, recruitment strategies may have impacted on the above findings. To maximise the sources for recruitment, four strategies were employed with approximately equal recruitment resources distributed through each strategy. It is accepted that it is possible that women who were using herbal medicines may have been more inclined to respond. However, the selection criteria were all breastfeeding women or women who had breastfed in the past 12 months and who were over 18 years of age. When compared with a nationally representative sample from the 2010 Australian National Infant Feeding Survey (340), age and parity of the respondents of Stage 1 were reasonably well matched. The majority of

the respondents in both studies were women with university degrees and were born in Australia. This is a likely outcome for Stage 1 considering respondents had to initially volunteer to participate for the study. Nevertheless, a higher proportion of Stage 1 respondents were born overseas than those of the national survey.

A cross-sectional study of the general population in Victoria, Australia, in 2007 found nearly one-quarter of the sample had used at least one herbal medicine in the preceding 12 months (25). Other studies have shown between 20% and 30% of adult Australians use herbal medicines (7, 160). A 2004 South Australian study revealed that women between the ages of 25 and 34, with higher education and income levels showed greater use of CAM (in general) (160). The South Australian study also demonstrated that women's use of herbal medicines rose from 16.6% in 2000 to 24.9% in 2004 ($p < 0.01$) (160). Pregnant (36%) (26) and mid-life (41%) (419) Australian women have shown higher rates of herbal medicines usage. Although 60% (in Stage 1) is a high estimated prevalence of use which may have been influenced to an extent by respondent bias, there is clear evidence of a high utilization of herbal medicines by breastfeeding women. There are no comparable data available in Australia with regard to the prevalence of herbal medicine use amongst breastfeeding women, however overseas data indicated estimated prevalence between 15% and 88% (215, 219, 341). In a study conducted in Taiwan in 2006 (341), the authors reported a marked escalation of the prevalence of use of Chinese herbal medicines from 33.6% during pregnancy to 87.7% during the postpartum period. As Stage 1 involved a larger proportion of women born overseas compared to the 2010 Australian National Infant Feeding Survey, the above mentioned factor could explain the higher estimated prevalence found in Stage 1 and the other finding which indicated that women who were born in Asian countries were significantly more likely to use herbal medicines.

6.2.4 Breastfeeding Women's Perspectives

Despite the widespread use of herbal medicines and herbal galactagogues, very little is currently known about their effectiveness and safety in breastfeeding. This in itself is of concern considering the chemical complexities of herbal medicines and the

paucity of scientific evidence to support the clinical efficacy and safety of the majority of these medicines in breastfeeding. Additional risk arises for those using multiple herbal medicines. Nevertheless, the majority of the Stage 1 survey respondents (70.1%) reported that there was a lack of information resources. A review of the literature revealed that reliable data on the use, efficacy and safety of many herbal medicines in breastfeeding are lacking. It could also be argued that poor access to the available resources or the lack of credible resources could also contribute to women's perceptions of not having sufficient information. A need was therefore identified to address the information needs and that the available (or the lack of) information about the effectiveness and safety of these medicines needs to be disseminated to breastfeeding women in an effective manner. Health professionals who have regular contacts with breastfeeding women and their families are therefore well placed to provide support and to present as a reliable source of information. Despite the fact that the majority of the respondents believed there was a lack of information available to them, 43.4% of respondents perceived herbal medicines to be safer than conventional medicines. An overwhelming 71.6% of women who participated in the survey reported previous refusal or avoidance of conventional medicine treatments due to concerns regarding safety of their breastfed infants. As previously mentioned, there are no comparative data available in Australia in this context. However, a study conducted in Indiana which involved 461 Hispanic women found that the majority of the participants were aware of the potential risks associated with the use of herbal medicines in breastfeeding (219). Interestingly, the author revealed that 37% of the participants who breastfed reported ceasing the use of herbal medicines when they initiated breastfeeding (219). This finding identified a need to establish and implement a sustainable strategy to improve education to breastfeeding women in Australia in order to address the misconceptions about conventional and herbal medicines. It also justified the need for Stages 2 and 3 to explore breastfeeding women's perspectives and their unique needs during the postnatal period and how to address their information needs from the pharmacists' perspectives.

Fenugreek was the herbal galactagogue most commonly used by women with perceived insufficient milk supply. Community pharmacies were one of the most common sources of supply. The overall satisfaction and experience of women with

the use of fenugreek as a herbal galactagogue was positive. Most had perceived it as the herbal galactagogue of choice in promoting breastfeeding performance. As discussed in Chapter 2, domperidone is a conventional medicine commonly recommended by health professionals for use in breastfeeding as a galactagogue. However, domperidone is not registered in Australia for the indication of increasing breast milk supply (252). It is therefore prescribed off-label for this indication. Although the study did not specifically explore the use of domperidone, one participant from Stage 2 reported the use of this medicine in conjunction with fenugreek whilst breastfeeding. Information on the prevalence of use of domperidone as a galactagogue amongst breastfeeding women living in Western Australia is not available. Nevertheless, this study highlighted a mismatch between the perspectives of participants (breastfeeding women in Stage 2) and what is considered as mainstream management. According to a review conducted by Ilett and Kristensen (127), domperidone is considered the preferred choice of galactagogue in Australia based on the available evidence for efficacy and safety in breastfeeding. Other studies have also demonstrated the efficacy of domperidone in increasing breast milk production (234, 289). This in itself is of interest as despite the fact that higher level evidence is available to support the use of domperidone as a galactagogue, some women preferred to use herbal galactagogues and considered these options “safer” than conventional treatment. This finding further reinforces the need to provide better education and improved information dissemination to breastfeeding women. As community pharmacists were perceived by breastfeeding women as “easy to access” and “convenient” sources of information and supply of medicinal products, it appears that there may be a potential for these health professionals to expand their roles to fill the gaps in providing support and advice to breastfeeding women in relation to both herbal and non-herbal galactagogues.

In the absence of milk volume measurement, women described a range of subjective indicators to “measure” their breastfeeding performance. Complementing the findings of the Stage 1 study, women in Stage 2 described how their choice of therapy was influenced by their perseverance and determination to breastfeed, and their concerns over infants’ safety with the use of conventional treatments. An overarching theme that emerged was “confidence and self-empowerment”. A sense of autonomy and self-efficacy over their own health needs was recognised as influential

to their level of confidence, at the same time provided women with reassurance throughout the breastfeeding journey. This is an important finding considering that evidence is lacking to support the use, effectiveness and safety of the majority of herbal galactagogues in breastfeeding. As discussed in Section 2.3.1, psychological factors may influence the initiation and duration of breastfeeding (79). This study has highlighted the importance of considering the potential psychological benefits of using herbal galactagogues, and how this translates into breastfeeding performance. There appears to be an innate comfort in using herbal medicines with unknown toxicity profiles over a conventional medicine shown to have efficacy and low toxicity in breastfeeding women (420). In addition, herbal tinctures were used without concern of their contents or toxicity by women who expressed distrust arising from toxicity concerns for conventional medicines. Furthermore, the alcohol content of such a tincture is unknown. It further highlights the role that pharmacists could play in educating breastfeeding women to fully comprehend the available (or the lack of) information and the fact that other conventional medicines, such as domperidone, may have higher efficacy and known safety data to support their use in breastfeeding.

Stage 2 also explored the perspectives of breastfeeding women on community pharmacists' breastfeeding support role and whether there is potential for role expansion, as well as how community pharmacists can meet their healthcare-related needs in the community pharmacy setting. The overall perspectives of women with regards to the role of community pharmacists were positive. Pharmacists were perceived as trust-worthy, convenient and easily accessible sources of information and advice. Facilitating factors reported by women included pharmacists' knowledge and credibility, effective client-pharmacist relationships, and that no direct costs are involved when consulting a pharmacist. These findings were consistent with and supported the available literature which explored the potential for role expansion of pharmacists in Australia (382, 383). Nevertheless, this thesis contributes to our knowledge specifically in the context of their trust in pharmacists. This is a sound basis for support of breastfeeding women via the provision of advice on the use of herbal and other medicines, through understanding the perspectives of breastfeeding women and pharmacists.

A number of barriers or concerns were raised in the themes in Stage 2 which need to be addressed to provide better care and improve pharmacy practice. These included a lack of experience and breastfeeding-related knowledge or awareness, inappropriate pharmacy layout and privacy issues, and pharmacists' inconsistent approach. A previous Australian study has shown that pharmacy customers expected greater level of interaction and engagement with pharmacists and that there was an expectation for community pharmacists to have adequate knowledge on CMs (207). This research identified that Stage 2 participants, who were users of herbal galactagogues, also had similar expectations for community pharmacists. In addition, it was also the perception of some women that pharmacists may have pre-conceived negative perceptions towards herbal medicines or other alternative therapies.

Women also suggested several breastfeeding-related services perceived to be useful in the community pharmacy setting for example baby weigh-in services, lactation booths, in-store information sessions and distribution of pamphlets or educational materials in pharmacy. The pharmacists' views on the feasibility of these services were then explored in Stage 3. The question of whether pharmacists should expand their role into women and newborns' health in the community pharmacy setting should be explored in consultation with other groups working in this area, and, their specific roles and expertise should be clearly defined to avoid duplication of roles with other healthcare workers. The study also revealed opportunities for community pharmacists to expand their role to better support women and promote breastfeeding in the community, which informed the objectives of the Stage 3 study.

6.2.5 Pharmacists' Perspectives

There were some similarities between the findings of this study and previously published research (4, 5, 83, 87, 149). Pharmacists reported regular interactions with breastfeeding women and their infants in the community, and the common health issues presented by women for management in the pharmacy were mostly regarded as OTC treatable conditions. These included cough and cold, allergies, pain and inflammation, insufficient milk supply and other general primary care health issues. A range of reference resources was reported by pharmacists, similar to what was

described in a previous study (5). Nevertheless, the overwhelming concern raised by all participants was the lack of evidence-based clinical studies advising the efficacy and safety of CMs use in breastfeeding. It was notable that LactMed[®], a TOXNET database was one of the websites used by up to 25% of the community pharmacists in Australia who participated in the survey conducted by De Ponti et al. (5) in 2011. However, the use of this database by WA pharmacists did not arise in any of the Stage 3 interviews. This was despite that throughout the interviews, pharmacists described how the lack of information and resources influenced their confidence level and decision-making processes, contributing to the perception of “complexity”, “uncertainty” and “dilemma” when making clinical recommendations. Concern over infants’ safety was also regarded as one of the crucial factors affecting pharmacists’ decision-making, often leading to pharmacists adopting conservative approaches in the provision of advice to breastfeeding women in relation to CMs.

Pharmacists acknowledged that promoting the safe and effective use of non-prescription medicines in all clients, including breastfeeding women and their infants, were part of their professional responsibilities and duty of care. Health professionals have an ethical obligation to continuously improve their professional ability to ensure optimum health outcomes of patients. Pharmacists participating in the Stage 3 study expressed their desire for continuing professional development and on-going training to improve their knowledge in the area of medicines use in breastfeeding, in particular CMs, and various aspects of breastfeeding. This finding correlates with breastfeeding women’s desire for greater support from community pharmacists. By expanding their roles and services in the community, these health professionals may contribute to fulfilling breastfeeding women’s healthcare-related needs. Many aspects of the pharmacy profession’s ethical and legal obligation, as stated in the PSA’s Code of Ethics (33), were also recognised by all pharmacists who participated in the Stage 3 study. In addition, the findings broadened the body of knowledge about community pharmacists’ decision-making processes when making clinical recommendations to breastfeeding women. The positive attitudes of pharmacists identified in this study as well as relevant literature findings highlighted the opportunity for expansion of pharmacists’ professional roles (207, 382, 383), whilst the barriers and challenges should be addressed and taken into consideration when implementing related services in the community pharmacy setting.

6.2.6 Comparison between Perspectives of Breastfeeding Women and Pharmacists

The qualitative research methods employed in the Stages 2 and 3 studies facilitated interaction with participants and allowed in-depth investigation into the meanings of comments. Several areas of overlap emerged during comparison of the perspectives of breastfeeding women and community pharmacists.

Consistent with literature findings, breastfeeding women and pharmacists who participated in this research all agreed that community pharmacists were a convenient and accessible source of credible medicine and health-related information (4, 202, 386, 397). Both participant groups (from Stages 2 and 3) perceived the pharmacy profession as having drug knowledge or medicine expertise. The “no appointment” and “consultation at no cost” approach were appreciated by women and acknowledged by the pharmacists. Nevertheless, it was also emphasised by some pharmacists that despite their willingness to provide professional services and advice to the public, the lack of direct financial compensation or remuneration contributed to the challenge of maintaining the sustainability of the community pharmacy business model. This was also discussed in the context of “time constraints”, another common theme that emerged from the interviews of both participant groups. The issue with the current remuneration model was also identified as a barrier in an Australian study conducted by McMillan et al. (382) which aimed to explore new opportunities, roles and barriers for community pharmacists. However, the study focused on professional services targeting patients with chronic illnesses, whereas this thesis focused on how community pharmacists can better assist breastfeeding women with their needs, with an emphasis on herbal medicines.

The formation of a trusting relationship was recognised by breastfeeding women and community pharmacists as a vital aspect facilitating the expansion of the profession’s role. Previous experiences and the pharmacist’s perceived knowledge were also identified as influential to the building of an effective relationship between the breastfeeding woman and the pharmacist. This finding was in accordance with other

studies which identified that pharmacists' credibility and knowledge were one of the main facilitating factors enticing customers to pharmacies (4, 5). However, the reality of pharmacy practice is that workforce demands could make spending time with non-paying consumers challenging. Therefore, financial incentives need to be considered for pharmacists to provide professional services beyond medicine supply and counselling to maintain sustainability of the pharmacy business as previously discussed. Although some women expressed their desire for pharmacists to be more "open" to discussions and recommendations around the use of CMs in breastfeeding, many pharmacists showed disagreement to this statement. Pharmacists believed that it is their duty of care to provide evidence-based advice to facilitate quality use of medicines. However, the perceived lack of evidence and research regarding the use of CMs specifically in breastfeeding may have contributed to a misconception by breastfeeding women of the lack of support from pharmacists. Nevertheless, both participant groups agreed that advice and recommendations provided by the pharmacists should be patient-centred and that the well-being of the breastfeeding woman and her infant should be the main consideration.

Pharmacists in the study appeared to be aware of their legal and ethical obligations, as well as the expectations of their clients. With the increasing popularity of CMs and to meet the expectations of breastfeeding women, pharmacists acknowledged the need for further training and on-going CPD to improve their knowledge and confidence level when dealing with breastfeeding and medicine-related queries. Guidelines and policies should also be in place to ensure all pharmacists adopt a consistent approach in their daily practice.

There is a misalignment between the opinions of the users of herbal galactagogues (breastfeeding women) and pharmacists about the use of herbal medicines whilst breastfeeding and the available information to support their use when compared to conventional treatments. The assumption that herbal medicines are "natural" and "safer" than conventional medicines was apparent amongst the breastfeeding women group but not the pharmacists group, which was expected considering that pharmacists are trained to utilise evidence-based resources and are experts in medicines. The lack of evidence-based information on the efficacy and safety of many herbal medicines in breastfeeding, as well as the complexity of the chemical

constituents of herbal medicines contributed to pharmacists' cautious behaviour when it comes to recommending their use. Furthermore, the fact that the majority of these medicines are not registered in Australia on the ARTG (200) suggests to pharmacists that these products may not have efficacy data. The aforementioned factors could have led to women who are advocates of herbal medicines believing that pharmacists are "unwilling" or "not open" to discussion around the use of therapies other than conventional medicines. This in itself is of interest as it shows the difference in the level of awareness between the public and health professionals and identifies gaps in pharmacy practice where improvements are needed in the dissemination and communication with the public regarding the differences between conventional and non-conventional medicines, especially in this case with breastfeeding women.

There is also a gap between what breastfeeding women expect of pharmacists and what services pharmacists are offering. Although some pharmacies in Western Australia currently do provide breastfeeding-related services, such as infant weigh-in stations and employing child health nurses, it does not appear to meet the demand and expectations of breastfeeding women based on the findings of Stage 2. It is also interesting in that pharmacists have raised their concerns with regard to the current business and remuneration model, and yet breastfeeding women perceive the fact that community pharmacy services are provided at no charge to be a facilitator. The gap or issue raised involves the source of funding, the feasibility and to what extent, if such services were to be implemented in pharmacies. Interviews with other stakeholder groups, such as representatives and policy makers of government and non-government organisations (including academia, leaders of the pharmacy profession and relevant breastfeeding associations), will provide useful insight to address this issue. It is notable that women have access to child health nurses free of charge, but paid for by the state or local authorities. This may possibly create women's expectation of free services.

Perspectives of breastfeeding women and pharmacists towards the potential for pharmacists to expand their professional roles and the provision of breastfeeding and other related professional public health services in the community pharmacy setting were favourable, provided the barriers are addressed. If community pharmacies are to

better support breastfeeding women especially those with breastfeeding-related issues, appropriate training is crucial to ensure pharmacists are well equipped with both the knowledge and resources to execute their expanded role and to meet the expectations of the public. If such services are to be implemented, there also needs to be improved community awareness of the scope and what pharmacists can offer.

6.2.7 The Interpretation of Available Information

Throughout the interviews, both participant groups expressed a clear need for further research into the commonly used herbal medicines to establish their efficacy and safety in breastfeeding, and that up-to-date, accurate and reliable information on CMs should be made easily accessible. This finding was in accordance to the recommendations made by the Expert Committee on Complementary Medicines in the Health System (421). The committee was commissioned in 2003 to report on the status of CMs in Australia and aimed to identify concerns and make recommendations to facilitate safe and effective use of CMs. One of the concerns raised by the committee was the need for health professionals and consumers to be able to make informed decisions about the use of CMs based on the availability of independent, accurate and reliable information on CMs, at the same time to acquire necessary skills to “interpret information” and be able to “discriminate between reliable and unreliable information” (421).

In addition to the lack of information about the safety of medicines in breastfeeding, in particular herbal medicines, this research has also raised concerns over the dissemination of the available information and how this translates into professional practice and the public’s perception. In the Breastfeeding Policy adopted in September 2010, the Public Health Association of Australia (422) notes “Health professionals and consumers need accurate information about safe use of medicines for breastfeeding women” (422). With reference to Briggs (423) and Hale (424), the association further states that “there are very few medicines which are unsafe for breastfeeding women” (422) and “the amount of maternal medicine an infant would receive is less than 1% of an infant dose for the vast majority of medications” (422). As the target audience of such policy documents include government and non-

government stakeholder groups as well as the Australian public, this may have a potential impact on women's perspectives and interpretation of the information which may subsequently influence their decisions and choice of therapy. Whilst it is true that only very few medicines have been proven to be unsafe in breastfeeding, the safety profiles of the majority of medicines in breastfeeding, including herbal medicines, remain unknown. Nevertheless, amendments were made to the September 2013 Breastfeeding Policy, and the Public Health Association of Australia states "Most prescription drugs and medicines are compatible with breastfeeding, but each case should be specifically assessed by a health professional" (425). The amended statement has therefore shown that the association has taken greater cognizance of the potential safety concerns or toxicity issues with the use of medicines in breastfeeding.

As discussed in Section 2.5.3, the majority of CM products are classified as AUST L and are subjected to less stringent advertising control compared to medicines classified as AUST R (198, 204). Widespread promotion of these medicines, including herbal medicines, through mainstream media may potentially have an impact on breastfeeding women's perception of the safety margins of these products. Considering the popularity of herbal medicines amongst breastfeeding women and the chemical complexities of these medicines as discussed in Chapter 2, the safety of herbal medicines in breastfeeding should not be assumed based on the absence of information. The lack of information on the majority of herbal medicines may be misinterpreted as "safe" to use whilst breastfeeding. Therefore, it is of paramount importance that breastfeeding women and health professionals are mindful that the absence of safety reporting should not be interpreted as evidence of safety.

6.2.8 Contemporary Pharmacy Practice

In the recent Australian government's healthcare reform to achieve an improved healthcare system in Australia, there has been a call for primary healthcare to be provided by the community healthcare providers, thus relieving costs and pressure on GPs (426). It is stated in the *Primary Health Care Reform in Australia: Report to Support Australia's First National Primary Health Care Strategy* published in 2009

(426) that “primary healthcare is more than the provision of services by a GP through Medicare, and also includes specialists, nurses, pharmacists and other allied health workers, providing publicly and privately funded services”. The current and potential future roles of pharmacists as part of the primary healthcare team have also been highlighted (426). As Australian community pharmacies have been recognised as highly accessible (4, 427), there appear to be opportunities for pharmacists to expand their services and contribute towards healthcare amongst Australians (426). According to the Pharmacy Guild of Australia (381), “A key focus for Australia’s healthcare reform is to create a stronger primary healthcare system through the better integration and coordination of care for consumers. Community pharmacy can play a pivotal role in this model as one of the most frequently accessed primary healthcare services” (381). The needs and expectations of the Australian community drive and form the basis of change in how the profession practises pharmacy. There is evidence that the role of Australian community pharmacists is expanding from being a conventional medication dispenser to being a provider of holistic and patient-centred healthcare in the form of related professional services (382, 383, 427, 428). In keeping with the healthcare reform agenda, integration of a range of professional services such as disease-specific management programs and medication reviews is becoming a common practice of many pharmacists in Australia (429).

Through the continuously evolving practice of pharmacy in Australia, the scope of community pharmacy practice has expanded beyond the conventional medication dispenser and advisor role. There has been a shift towards holistic patient-centred care delivery which requires knowledge and necessary skills to conduct professional services that may not be directly related to medicines or drugs, for example, health checks, sleep apnoea programs, weight loss and healthy living programs. Whilst acknowledging the existing barriers, McMillan et al. (382) recognised a potential for Australian community pharmacy to be a “health hub destination of the future”. Interviews with breastfeeding women in Stage 2 identified a similar theme where pharmacies were imaged as a one-stop health destination. In fact, this was an important factor where advice and any medicines or other requirements could be obtained at the one location. Considering the objective and vision of the Australian National Breastfeeding Strategy 2010-2015 (1) and the call for a healthcare reform in Australia (430), this research provides first-hand insight and useful information on

the future potential role of pharmacists in supporting breastfeeding women in the Australian community, particularly in the provision of advice and supply of non-prescription medicines including CMs and being a service provider for breastfeeding-related services, which is an area that has not been well explored in the Australian context.

Nevertheless, contemporary pharmacy practice does not come without its challenge. Under the Fifth Community Pharmacy Agreement, the *Consumer Needs* project was funded by the Australian Government Department of Health and Ageing and managed by the Pharmacy Guild of Australia (381). One of the objectives of the project was to identify consumers' needs, experiences and expectations of community pharmacy services, and the first stage involved consultations with 30 stakeholders. In this project, the issue of privacy and pharmacy layout was raised by participants. It states "Without a sense of privacy consumers are often reluctant to engage with their pharmacist and ask questions about their health needs" (381). This finding is of relevance to this research as "new mothers" were specifically identified as consumers who "desire more privacy" (381). The issue of privacy and inappropriate pharmacy layout was also raised by breastfeeding women and pharmacists who participated in Stages 2 and 3 of this research. Unless the pharmacy has a private consultation area or room to overcome this barrier, pharmacists may not be in the optimal position to expand their services to meet the needs and expectations of breastfeeding women. This is a particular challenge to pharmacies which do not currently have this facility within their premises, considering the cost involved and the current pharmacy remuneration model. Without a viable remuneration model, the feasibility and sustainability for the provision of such services within the community pharmacy setting are of concern.

The findings arising from the perspectives of breastfeeding women and community pharmacists in Stages 2 and 3 support the argument that community pharmacists are well placed to provide advice and support to breastfeeding women using herbal medicines as galactagogues, at least amongst the participants of this research, with due consideration of the barriers and challenges raised by the participants. As this research had only focused on the perspectives of breastfeeding women and community pharmacists, future studies evaluating the perspective of other

stakeholders, for example child health nurses, lactation consultants and policy makers, will provide further insight into this topic in particular the feasibility and practicality of the pharmacists' role expansion.

6.3 Conclusions

This research has demonstrated a high utilization of herbal medicines amongst breastfeeding women in WA, while information supporting their safety and efficacy is limited. This usage includes particularly fenugreek being used as a galactagogue over prolonged periods of breastfeeding. An urgent need was identified for further research into the commonly used herbal medicines, evaluating their efficacy and safety in breastfeeding. Evidence-based information should be available to health professionals and breastfeeding women who wish to consider the use of all medicines, including herbal medicines, to avoid unnecessary cessation of breastfeeding, while allowing mothers to receive appropriate pharmacotherapy without compromising breastfeeding performance and the infant's health. This study provides insight into the perspectives and attitudes of breastfeeding women and pharmacists in Australia to explore breastfeeding and postnatal-related healthcare needs and expectations of the community pharmacy. As evident from this study, most women were willing to engage in discussions about breastfeeding and the use of herbal medicines during breastfeeding with pharmacists. In order to facilitate this, pharmacists themselves must have sufficient knowledge, an interest and be available to interact with women or their family members in the provision of advice. This will promote the quality use of medicines whilst breastfeeding and support successful breastfeeding practices in the community, especially with community pharmacies being viewed as a one-stop health destination. This research has also demonstrated a mismatch between the perceptions of breastfeeding women and pharmacists with regards to the issue of safety and toxicity of herbal medicines. This is an important finding which requires further investigation. This study has revealed that community pharmacists are perceived favourably by breastfeeding women in the Western Australian community. Opportunities have also been identified for community pharmacists to expand their professional role and to potentially collaborate with other healthcare workers such as lactation consultants and child health nurses to provide breastfeeding women with support and postnatal care at the community level. Government and professional pharmacy bodies should consider these findings when promoting an expansion of community pharmacy services.

6.4 Future Studies and Recommendations

The results from the research presented in this thesis suggest a number of future studies and recommendations about the use of CMs in breastfeeding women and the role of pharmacists. These are summarised in four categories, namely:

- i) Use, safety and efficacy of CMs in breastfeeding
- ii) Pharmacy profession and the role of pharmacists
- iii) Role of other healthcare workers and interdisciplinary collaboration
- iv) Resources and health promotion initiatives.

i) Use, safety and efficacy of CMs in breastfeeding

- As the backgrounds and experiences of women and the availability of herbal preparations may vary in different Australian states and specific ethnic groups, a nationally representative study among breastfeeding women should be conducted to compare with the findings of the Stage 1 study.
- A further study of breastfeeding women in Western Australia would be useful to explore their use of all medicines including prescription and non-prescription medicines during breastfeeding, their sources of recommendation, supply and information, and who they would be likely to consult for general breastfeeding advice. This study could be conducted using self-administered questionnaires with carefully planned questions. Recruiting potential participants from a maternity hospital is one recruitment option, where invitations to participate could be sent out to all women after giving birth during a defined period, and questionnaires to be posted at three and six-month intervals to those who have expressed interest in participating. As with other recruitment strategies, recruiting participants through the above mentioned strategy has its limitations. Hospitals in Australia cater for public patients (often from lower socioeconomic background) or private patients (higher socioeconomic background), hence some bias is likely unless many hospitals are used. In addition to the possibility of low response rate,

such a recruitment strategy could also contribute to a degree of bias in sample selection, in that breastfeeding women of a certain socio-economic background or who are living in a specific geographical area could be preferentially selected, which would not be representative of all breastfeeding women in Western Australia. Nevertheless, the findings of such a study could then be compared with findings of the Stage 3 study, at the same time provide an opportunity to explore breastfeeding women's views on the broader role of community pharmacists in the provision of breastfeeding support, using a quantitative approach.

- Further studies are warranted to confirm the safety of commonly used herbal medicines in breastfeeding, and their effects on infants' safety and breastfeeding performance. These include studies investigating the transfer of herbal ingredients, if any, into breast milk, and whether they have any effects in terms of reducing breast milk supply and quality, and affecting infant feeding behaviour.

- As perceived insufficient milk supply was identified in the Stage 2 study as a common reason for use of herbal galactagogues in breastfeeding, and that it has also been reported in literature as the most common reason for early weaning or supplementation with formula, approaches that help increase milk production during the early post-partum period may reassure mothers and help ensure exclusive breastfeeding for six months (2, 31, 75). Opportunities should also be given to women to discuss whether there really is a lack of milk production and to educate them on the signs to monitor. Double-blinded RCTs are needed to evaluate the clinical efficacy and safety of commonly used herbal galactagogues as reported in the Stage 1 study, particularly fenugreek, to increase breast milk production in the early post-partum period and their effects on breastfeeding exclusivity and success.

ii) Pharmacy profession and the role of pharmacists

- Interviews with the pharmacists identified a need for developing training and continuing professional education modules for pharmacists and pharmacy assistants in relation to use of medicines in breastfeeding and the various aspects of breastfeeding. Online CPD modules that assist pharmacists to improve their

awareness and knowledge could address this need. It will also be useful to develop a “topic-based” reference guideline or textbook, with clear and concise recommendations of medicines that could be used or avoided in the treatment of various common ailments or health issues while breastfeeding. The guidelines could then be used to assist health professionals in making informed clinical recommendations to breastfeeding women presenting for treatment.

- Further qualitative studies to explore the perspectives of pharmacy students and teaching staff could enhance our understanding of the topic and help justify the need for further integration of educational materials related to various aspects of breastfeeding and the use of CMs in general into the formal university curriculum.
- As pharmacy support staff may have regular contact with breastfeeding women in community pharmacies, further studies exploring their perspectives and experiences could enhance our understanding of the topic and help identify, if any, the need to provide training to pharmacy staff.
- As part of the initiative to expand the professional roles of pharmacists, it is worth considering postgraduate accreditation courses at universities to allow pharmacists to specialise in women and newborns’ health and to encourage the option to be qualified as an International Board Certified Lactation Consultant. With the medication knowledge and educational background, pharmacists who are also lactation consultants will be able to provide better support to women who are required to use medicines while breastfeeding.
- Pharmacist prescribing is an area of research that is increasingly important to pharmacy practice in Australia. Further studies should be undertaken to evaluate the potential role of pharmacists in prescribing domperidone for women diagnosed with insufficient milk supply.

iii) Role of other healthcare workers and interdisciplinary collaboration

- As lactation consultants and child health nurses have been consistently mentioned by women throughout the studies, further qualitative studies could be undertaken to explore the perspectives and attitudes of these healthcare workers towards the use of herbal medicines in breastfeeding and the factors affecting their decision-making. A greater understanding of their role and perspectives may help inform opportunities for interdisciplinary collaboration with community pharmacists.
- Based on the results of the Stages 2 and 3 studies, a pilot study should be conducted to facilitate and evaluate the practicality or impact of interdisciplinary collaboration in providing women with postnatal care and breastfeeding support at the community level. This could be achieved by firstly forming a joined network consisting of pharmacists, child health nurses and lactation consultants, working collaboratively to meet the needs of women in the postpartum period. Although current government initiatives include funding of one or two visits to women's homes by child health nurses, involving pharmacists with their convenient accessibility and pharmacists' medicine knowledge in the network, could provide women with improved continuity of care at the community level.

iv) Resources and health promotion initiatives

- In order to address the issue of the lack of information resources, the setting up of a local lactation resource centre in Western Australia for professionals and the public should be investigated to provide access to up-to-date information relating to breastfeeding. This could be done in collaboration with the Australian Breastfeeding Association. Nevertheless, further research into the perspectives of key stakeholders would be necessary to assess the need and feasibility of such centres.
- Lastly, health promotion campaigns could be a practical and effective intervention to increase public's awareness of the potential risks associated with

the use of all medicines in breastfeeding, and that women should always consult their health professionals before deciding to use any medicines, including CMs.

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APPENDICES



Appendix A: Publication BMC CAM 13_317

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RESEARCH ARTICLE

Open Access

The use of herbal medicines during breastfeeding: a population-based survey in Western Australia

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Abstract

Background: Main concerns for lactating women about medications include the safety of their breastfed infants and the potential effects of medication on quantity and quality of breast milk. While medicine treatments include conventional and complementary medicines, most studies to date have focused on evaluating the safety aspect of conventional medicines. Despite increasing popularity of herbal medicines, there are currently limited data available on the pattern of use and safety of these medicines during breastfeeding. This study aimed to identify the pattern of use of herbal medicines during breastfeeding in Perth, Western Australia, and to identify aspects which require further clinical research.

Methods: This study was conducted using a self-administered questionnaire validated through two pilot studies. Participants were 18 years or older, breastfeeding or had breastfed in the past 12 months. Participants were recruited from various community and health centres, and through advertising in newspapers. Simple descriptive statistics were used to summarise the demographic profile and attitudes of respondents, using the SPSS statistical software.

Results: A total of 304 questionnaires from eligible participants were returned (27.2% response rate) and analysed. Amongst the respondents, 59.9% took at least one herb for medicinal purposes during breastfeeding, whilst 24.3% reported the use of at least one herb to increase breast milk supply. Most commonly used herbs were fenugreek (18.4%), ginger (11.8%), dong qual (7.9%), chamomile (7.2%), garlic (6.6%) and blessed thistle (5.9%). The majority of participants (70.1%) believed that there was a lack of information resources, whilst 43.4% perceived herbal medicines to be safer than conventional medicines. Only 28.6% of users notified their doctor of their decision to use herbal medicine(s) during breastfeeding; 71.6% had previously refused or avoided conventional medicine treatments due to concerns regarding safety of their breastfed infants.

Conclusions: The use of herbal medicines is common amongst breastfeeding women, while information supporting their safety and efficacy is lacking. This study has demonstrated the need for further research into commonly used herbal medicines. Evidence-based information should be available to breastfeeding women who wish to consider use of all medicines, including complementary medicines, to avoid unnecessary cessation of breastfeeding or compromising of pharmacotherapy.

Keywords: Herbal medicines, Breastfeeding, Lactation, Breastfeeding women, Survey, Prevalence

Background

Breastfeeding provides numerous benefits for newborn infants and mothers. Breast milk provides tailored nourishment to the growing needs of infants [1], offering optimal nutrition, improved cognitive performance and neurological development [2] and enhanced immunity

[3,4]. It reduces the incidence of Sudden Infant Death Syndrome (SIDS), allergic/hypersensitivity diseases, and development of Type 1 (insulin dependent) and Type 2 (non-insulin dependent) diabetes mellitus [3,5-7] relative to the use of infant formula. Breastfeeding may also play a role in decreasing post-partum depression, bleeding, and improving weight control [8]. Furthermore, women who have a history of breastfeeding experience a reduced risk of osteoporosis and reduced incidence of breast and ovarian cancers [8-10]. Besides these health advantages,

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mothers and their babies are brought into closer contact through nursing itself [11]. Guideline 4 "Encourage, support and promote breastfeeding" of the Australian Dietary Guidelines 2013 published by the National Health and Medical Research Council [12] acknowledges the positive physical and mental health outcomes of breastfeeding for both infants and mothers. The Guideline recommends exclusive breastfeeding until the age of six months, when solid foods are introduced to the infant's diet. Breastfeeding should be continued until 12 months of age and beyond as complementary feeding if the infant and mother both wish [12]. Many national efforts, including the initial development of the *National Breastfeeding Strategy (1996–2001)* [13] followed by the *Australian National Breastfeeding Strategy 2010–2015* [14], have been initiated to support and promote successful breastfeeding in Australia. With our increasing awareness of the advantages of breastfeeding, health professionals from all disciplines should work together to promote breastfeeding. In Australia, the percentage of women who choose breastfeeding instead of formula-feeding immediately post-partum has increased from approximately 48% in the 1970's to over 90% in 2010 [15,16]. However, the continuation rate declined sharply with time post birth with percentages of any breastfeeding and exclusive breastfeeding at six months only at 56% and 14% respectively in 2004 [14,17].

A concern for lactating women who are taking medications is the transfer of medicines into breast milk [5,8]. Medicines circulating in the maternal bloodstream can potentially be transferred into human breast milk, exposing breastfed infants to medicines that may potentially be harmful [5,8]. Another concern is the effect of medication on the quantity and quality of breast milk produced, which may impact on the exclusivity, duration and success of breastfeeding [15,16]. Medicines that have been reported to compromise production of milk include cabergoline [18], bromocriptine [19], ergotamine [20], pseudoephedrine [21], and oestrogens [20,22]. Besides conventional medications, some natural substances have also been associated with reduction of breast milk supply. Peppermint, sage and parsley have been used traditionally for weaning, however there is a lack of research-based evidence to support their clinical use [15,23]. While medicine treatments include both conventional and alternative medicines, most available studies have focused on evaluating the transfer of conventional medicines into breast milk.

The use of complementary and alternative medicines (CAMs) is increasingly common worldwide. Research undertaken in the last couple of decades in many countries including the United States [24,25], Canada [26], the United Kingdom [27,28] and the United Arab Emirates [29] all demonstrated substantial increase in the use of

CAMs amongst the general population. Research conducted in Australia has shown results consistent with the above findings [30-36]. A prevalence study conducted in 2005 by Xue *et al.* [35] showed that 68.9% of the participants recorded use of one or more forms of CAMs in the previous twelve months of a survey. Zhang *et al.* in 2008 [33] further reported the prevalence and pattern of use of the top 24 most commonly used herbal medicines in Victoria, Australia amongst the general population. These included aloe vera, garlic, green tea, chamomile, echinacea, ginger, cranberry, peppermint, ginseng, ginkgo biloba, evening primrose, dandelion, valerian, licorice, St. John's wort, slippery elm, milk thistle, dong quai, black cohosh, bilberry, senna, hawthorn, saw palmetto and chasteberry, in decreasing order of popularity amongst the survey respondents [33].

Many women self-medicate with complementary medicines and supplements, most commonly on recommendation by friends or family, or as prescribed by their health care professionals [37-43]. Studies conducted by Nordeng *et al.* [37] in a group of 400 Norwegian women and by Forster *et al.* [38] among 588 Australian women both showed that 36% of women had taken one or more herbal medicines during pregnancy. We anticipated that some use of herbal medicines was likely to occur during breastfeeding as Stultz *et al.* [44] suggested that women generally use more medications post-partum compared to during pregnancy.

Despite the increasing popularity of herbal medicines, there is currently limited information available on the extent of use and safety of these medicines amongst breastfeeding women. This study aimed to provide current information on the prevalence and pattern of herbal medicines used by women whilst breastfeeding in Western Australia, and to identify commonly used herbal medicines. This information will inform and direct future clinical research. The study also explored the attitudes of breastfeeding women towards herbal medicines and their perceptions of the safety and efficacy of herbal medicines used during breastfeeding, as well as their information-seeking behaviour.

Methods

This study was conducted using a self-administered structured questionnaire validated through two pilot studies which followed the steps described by Portney and Watkins [45]. The pilot questionnaire was initially circulated among colleagues and lactation consultants, seeking feedback and suggestions. All comments were taken into consideration and the questionnaire was amended following discussion with the research team. The second pilot study was then conducted using the revised questionnaire. The study was approved by the Human Research Ethics Committee of Curtin University.

Study population and recruitment strategies

The target population was women who were 18 years or older, breastfeeding or who had breastfed in the 12 months prior to the time of the survey. To achieve the study objectives, there were no restrictions as to whether the participant was on any medications or had any medical conditions. Women from all cultural or ethnic backgrounds were eligible for the study. Balancing the need to minimise selection bias and maximise response rate, the decision was made to recruit participants through four main avenues to enable a wide range of participant characteristic types to be recruited:

- i) *Mothers and parenting groups.* With written approval from the Australian Breastfeeding Association (ABA), breastfeeding women were recruited from local mothers and parenting groups where the primary investigator (TFS) attended the group meetings.
- ii) *Community pharmacies.* A list of 557 WA community pharmacies was provided by the Pharmacy Registration Board of Western Australia. A stratified sampling technique was used to obtain sets of pharmacies within three defined geographical areas: North metropolitan, South metropolitan or regionally based according to postcodes. The lists of pharmacies were arranged in a random order by attaching a computer generated random number to each record and sorting each list by the number. Permission was sought from a total of 30 randomly selected pharmacies, 10 from each region, to place 10 sets of recruitment forms in each pharmacy. The pharmacists in-charge were requested to hand out the sets of forms to any women who visited their pharmacy whom they believed could have been eligible for the study. For example: women who came into the pharmacies with an infant or a young child to purchase any infant-related or breastfeeding-related products, or if they had declared that they were breastfeeding.
- iii) *Immunisation clinics and child health centres.* Written site authorisation was obtained from the Child and Adolescent Community Health Executive (CACH), Health Department of Western Australia, to display posters advertising the study at all immunisation clinics and child health centres registered with the CACH in the Perth metropolitan area.
- iv) *Advertisement in newspapers and local parenting papers.* This strategy was implemented to advertise the study to the general public.

Data collection

All participants who had expressed interest in participating in the study were provided, either face-to-face or via

postal mail, a set of forms consisting of the participant information sheet, the survey questionnaire and a reply paid envelope. The participant information sheet explained that responses would be treated in confidence in order to guarantee anonymity. Consent was assumed upon return of the completed questionnaire. Participant recruitment and data collection occurred concurrently between February and December 2012.

The questionnaire comprised four sections. See Additional file 1. Sections 1 and 2 collected participants' demographic profile and their family background characteristics including their origin and ethnicity. This information was collected to explore the association between these factors and the pattern of use of herbal medicines during breastfeeding. Section 3 requested information on the prevalence and pattern of use of herbal medicines during breastfeeding. This section explored the reasons for use, sources of recommendation, users' perceived efficacy and side effects experienced. Section 4 explored the participants' information-seeking behaviour as well as their attitudes and beliefs towards the use of herbal medicines during breastfeeding. The types of questions in the questionnaire determined the response options, which were a mix of open-ended and closed-ended questions using Likert-style scaled responses.

Data analysis and statistics

The survey responses were de-identified and analysed using the Statistical Package for Social Sciences (SPSS) version 20 software for Windows. Qualitative responses obtained from open-ended questions were identified and coded. Reasons for use were categorised and coded concurrently with data entry. Upon completion of data entry, all categories were reviewed and reclassified if necessary to ensure consistency in coding and that there was no duplication. These coded responses were then analysed in the same manner as the closed-ended (quantitative) responses. Quantitative data were summarised using standard descriptive statistics (frequencies and percentages for categorical variables; means and standard deviations for variables measured on a continuous scale). The prevalence of use of herbal medicines during breastfeeding was calculated, along with its 95% confidence interval. Univariate associations between demographic data and use of CAM were assessed using Chi-square statistics or t-tests, as appropriate. A multivariate logistic regression model was used to identify any factors independently associated with use of CAM. The optimum model was obtained using a 'backwards elimination' strategy, whereby all demographic variables were initially included in the model, and then dropped, one at a time, until all variables remaining in the model were significantly associated with the use of CAM. Respondents were classed as "users" or "non-users" for the purpose of analysis depending on whether or not they

had used any herbal medicines during breastfeeding. A p -value < 0.05 was taken to indicate a statistically significant association in all tests.

Results

Respondents

A total of 1118 survey forms were distributed and 304 questionnaires were returned, a response rate of 27.2%. The mean [SD] ages of respondents were 32.8 [4.2] years for users and 32.3 [5.0] years for non-users ($p = 0.30$). The majority of the respondents resided in the Perth metropolitan area, were born in Australia or New Zealand, had completed secondary school education, had a relatively high total annual household income (\geq AUD 80,000), had only one child and were not living with their parents. For those respondents not born in Australia, the years spent in Australia was not significantly different ($p = 0.39$) between users (14.1 [8.9]) and non-users (15.7 [10.8]). The characteristics of respondents and factors affecting the use of herbal medicines during breastfeeding are summarised in Table 1.

Prevalence and pattern of use

Participants were classified as 'users' if they had specified the use of any herbal medicines for the purpose or intention of treating or managing any medical condition or to improve their health. Amongst the 304 respondents, 182 (59.9%) indicated that they had used one or more herbal preparations for various medicinal purposes during breastfeeding (CI 54.4-65.4%). The number of herbal products used by respondents ranged from none to six, with an average of 1.25 products per participant. Of the 182 respondents who took at least one herbal medicine during breastfeeding, 70 (38.5%) reported use of only one herb, 51 (28.0%) used two herbs, 37 (20.3%) used three herbs, 16 (8.8%) used four herbs, 5 (2.7%) used five herbs, and 3 (1.6%) used six herbs.

Over half (60.4%) of users indicated that the reasons for use of these herbs were breastfeeding-related. Approximately one in four of the respondents (74/304; 24.3%; 95% CI: 19.5% - 29.1%) took one or more herbal medicines specifically to help increase milk production or supply during breastfeeding.

A logistic regression model was used to investigate if any respondent characteristics or demographic factors were associated with the decision to use herbal medicines during breastfeeding, with the results shown in Table 2. The multivariate model shows that respondents with an Asian birthplace were more likely to use herbal medicines, as well as those from middle income families (total annual household income of AUD 37,000 - AUD 80,000). These factors were the only two which remained after the backwards-elimination model-fitting strategy. Other variables which were initially included in the model

Table 1 Respondents' demographic profiles and factors affecting herbal medicines use

Variable	Proportion of users, n/N (%)	p -value
Total number of participants	182/304 (59.9)	
Residential area, determined by postcode (n = 303)		0.51
Perth metropolitan	171/284 (60.2)	
Other WA region	10/19 (52.6)	
Country of birth (n = 304)		0.0180
Australia/New Zealand	97/180 (53.9)	
Asia/Africa	58/80 (72.5)	
Europe/USA/Canada	27/44 (61.4)	
Ethnic background (n = 301)		0.0328
Caucasian	55/105 (52.4)	
Asian	57/80 (71.3)	
Others	68/116 (58.6)	
Level of education (n = 302)		0.56
Secondary education	12/24 (50.0)	
Secondary school certificate of education	13/24 (54.2)	
Diploma or advanced diploma	12/16 (75.0)	
Trade certificates I, II, III or IV	15/27 (55.6)	
Bachelor degree	88/137 (64.2)	
Graduate diploma or graduate certificate	19/33 (57.6)	
Master degree	19/31 (61.3)	
Doctoral degree	4/10 (40.0)	
Total annual household income last year (n = 302)		0.0219
Low (< AUD 37 K)	7/17 (41.2)	
Middle (AUD 37 K - AUD 80 K)	61/86 (70.9)	
High (AUD 80 K+)	113/199 (56.8)	
Parity (n = 304)		0.54
1 child	102/176 (58.0)	
2 children	58/94 (61.7)	
3 children	16/27 (59.3)	
4 children	6/7 (85.7)	
Living with parents (n = 304)		0.68
Yes	19/30 (63.3)	
No	163/274 (59.5)	

*P*values were obtained from the Chi-square test.

were dropped since they appeared to be not significantly associated with the outcome.

A total of 51 different herbal medicines or ingredients were revealed amongst the survey respondents in this study. The top ten most commonly used herbal medicines during breastfeeding in the descending order of popularity were fenugreek (18.4%), ginger (11.8%), dong quai (7.9%), chamomile (7.2%), garlic (6.6%), blessed thistle

Table 2 Logistic regression model: factors associated with the use of herbal medicines

Variable	Odds ratio	95% confidence interval	p-value
Country of birth			
Asia	2.20	1.25 to 3.88	0.0061
Other	1 (reference)		
Family income			
Low (<\$AUD37K)	0.29	0.10 to 0.84	0.0234
Mod (\$37 K to \$80 K)	1 (reference)		
High (>\$80 K)	0.53	0.31 to 0.91	0.0214

(5.9%), cranberry (4.9%), fennel (4.9%), aloe vera (3.3%) and peppermint (3.3%). Women were asked to indicate the reasons for use, who recommended the use, and their perceived efficacy of whether the herbal medicine was helpful to address their intended indication. The proportion of women who perceived the herbal medicine as helpful varied from 20.0% to 83.3%. These findings along with their prevalence are shown in Table 3.

There were 18 different herbal medicines or ingredients indicated by the respondents specifically as a galactagogue, that is to increase breast milk supply and breastfeeding performance. Table 4 reports on the top seven most commonly used herbal galactagogues along with their perceived efficacy, in descending order of priority.

Sources of recommendation, supply and information-seeking behaviour

Participants were asked to state who had recommended the use of each of the specified herbal medicines. Responses were tabulated separately, and grouped into seven main categories as presented in Table 5. Approximately two-thirds of the users (n = 112) had chosen to use herbal medicines during breastfeeding based on recommendations from their family members. Prescribers and specialists, including general practitioners, gynaecologists and obstetricians were least likely to recommend use of herbal medicines during breastfeeding, as results have shown that only 2.2% of users were recommended to use herbal medicines by this group of health professionals.

Table 3 Top ten most commonly used herbal medicines during breastfeeding (in descending order of popularity)

Common name of herbal medicine	Binomial/scientific name	n (%) reporting use of this herb	n (% of specific herb users) who believed the herb helped	Reasons for use (% of specific herb users)
Fenugreek	<i>Trigonella foenum-graecum</i>	56 (18.4)	44 (78.6)	Increase breast milk supply (98.2) Boost immune system during cold (1.8)
Ginger	<i>Zingiber officinale</i>	36 (11.8)	17 (47.2)	General health enhancement, tradition (65.7) Relief of "winds" and "air" (22.9), Others (11.4)
Dong quai	<i>Angelica sinensis</i>	24 (7.9)	10 (41.7)	General health enhancement (90.9) Others (9.1)
Chamomile	<i>Matricaria chamomilla</i>	22 (7.2)	13 (59.1)	Calming and relaxation, stress (86.4) Others (13.6)
Garlic	<i>Allium sativum</i>	20 (6.6)	7 (35.0)	Boost immune system during cold (38.9) General health enhancement, tradition (50.0) Antifungal (5.6) Improve blood circulation (5.6)
Blessed thistle	<i>Cnicus benedictus</i>	18 (5.9)	15 (83.3)	Increase breast milk supply (100.0)
Cranberry	<i>Vaccinium macrocarpon</i>	15 (4.9)	6 (40.0)	Urinary tract infections/bladder health (76.9) Others (23.1)
Fennel	<i>Foeniculum vulgare</i>	15 (4.9)	10 (66.7)	Increase breast milk supply (80.0) Relieve of colic (13.3) Energy, restore iron levels from blood loss (6.7)
Aloe vera	<i>Aloe vera</i>	10 (3.3)	2 (20.0)	Detox (n = 6) Aids digestion, intestinal health (n = 1) General health enhancement (n = 1) Sunburn, cooling effect (n = 1)
Peppermint	<i>Mentha piperita</i>	10 (3.3)	7 (70.0)	Calming and relaxation (n = 6) Relieve of bloating (n = 2), Others (n = 2)

Table 4 Top seven most commonly reported herbal galactagogues

Common name of herbal galactagogue	Binomial/scientific name	n (%) reporting use of this herb	n (% of specific herb users) who believed the herb helped
Fenugreek	<i>Trigonella foenum-graecum</i>	56 (18.4)	44 (78.6)
Blessed thistle	<i>Cnicus benedictus</i>	18 (5.9)	15 (83.3)
Fennel	<i>Foeniculum vulgare</i>	15 (4.9)	10 (66.7)
Goat's rue	<i>Galega officinalis</i>	7 (2.3)	7 (100.0)
Nettle/stinging nettle	<i>Urtica dioica</i>	5 (1.6)	4 (80.0)
Blackthorn berry	<i>Prunus spinosa</i>	5 (1.6)	4 (80.0)
Shatavari	<i>Asparagus racemosus</i>	4 (1.3)	4 (100.0)

Table 5 also summarises the sources of supply based on the users' responses. The majority of the users (n = 105) had obtained or purchased their herbal medicines or products from community pharmacies. Health food stores and supermarkets were two other common sources of supply,

followed by naturopathic clinics, family and friends and the internet.

All respondents to the survey (users and non-users) were asked to identify resources where they had in the past or would in the future seek information concerning

Table 5 Sources of recommendation, supply and information

Survey questions	n (% of users/respondents)*
Who has recommended the use of herbal medicines? (n = 182 number of users)	
Family members	112 (61.5)
Naturopaths, herbal or health food stores	86 (47.3)
Friends	57 (31.3)
Self (including self-reading of magazine, internet)	56 (30.8)
Health professionals (including clinic/child health nurses, midwives, lactation consultants)	26 (14.3)
Pharmacists and pharmacy staff	24 (13.2)
Prescribers and specialists (including doctors/general practitioners, gynaecologists, obstetricians)	4 (2.2)
Sources of supply: Where have they obtained or purchased their herbal medicines? (n = 182 number of users)	
Community pharmacies	105 (57.7)
Herbal or health food stores	88 (48.4)
Supermarkets	73 (40.1)
Naturopathic clinics	27 (14.8)
Family or friends	26 (14.3)
Internet	4 (2.2)
Sources of information: Where to seek information concerning use of herbal medicines during breastfeeding? (N = 303)	
Pharmacists	154 (50.8)
Doctors	146 (48.2)
Family or friends	139 (45.9)
Internet	133 (43.9)
Lactation consultants	89 (29.4)
Naturopaths or homeopathic practitioners	87 (28.7)
Child health nurses	83 (27.4)
Herbal or health food stores	71 (23.4)
Books, literature or journal articles	59 (19.5)
Others	11 (3.6)

*Does not total 100% as more than one response had been indicated by some participants.

the use of herbal medicines during breastfeeding. Results indicate that respondents were most likely to seek information and advice from pharmacists and doctors. Family and friends as well as internet resources were also common reported sources of information, followed by lactation consultants, naturopaths or homeopathic practitioners, child health nurses, health food stores, and books, literature or journal articles. Despite doctors being identified as one of the common sources of information, only 52 (28.6%) of the users in this study had made their doctors aware of their decision to use herbal medicines whilst breastfeeding.

Attitudes and beliefs towards the use of herbal medicines during breastfeeding

Over 70% of respondents strongly agreed or agreed that there was a lack of information resources available to them regarding the use of herbal medicines during breastfeeding, whilst 23.6% selected the option "no idea" and 6.3% strongly disagreed or disagreed.

Many of the respondents (43.4%) believed that herbal medicines are generally safer when compared to conventional medicines during breastfeeding. Most (71.6%) had indicated a previous refusal or avoidance of medicine treatments during breastfeeding due to concerns regarding safety of their breastfed infants. When given a choice, the majority of the women (75.9% of respondents) preferred more information to be available regarding the safety and efficacy of herbal medicines specifically when used during breastfeeding.

Discussion

Although many studies have been conducted to investigate the prevalence and pattern of use of CAMs in Australia in the general population, few have focused specifically on the use of herbal medicines by breastfeeding women. In this study, 59.9% of the women used at least one herbal medicine during breastfeeding for various medicinal purposes. This prevalence (59.9%) appeared to be higher than results from a similar study conducted in a group of Australian women during pregnancy (588 participants; median age 32; 57% born in Australia/New Zealand; 17% born in Asia; 26% born in other countries) published in 2006 [38], which found that herbal medicine use was higher during the postpartum than the prenatal periods [44]. Furthermore, many studies conducted worldwide have shown a steady increase in the use of herbal medicines, most likely due to the increased awareness and availability or accessibility of herbal products [24,29,35-38,43,46]. An association was identified between the respondents' birthplace or their ethnic background and the decision to use herbal medicines. Women with an Asian background in this study were more likely to use herbal medicines during breastfeeding. A study conducted in Taiwan explored the

use of Chinese herbal medicines by women during both pregnancy and postpartum period [46]. The authors not only reported a relatively high prevalence of herbal medicine use in the cohort, but also demonstrated a marked escalation of prevalence from 33.6% during pregnancy to 87.7% during the postpartum period. Our results suggest higher prevalence of herbal medicine use by women from the middle income families, supporting the argument that cost and affordability may be a factor to consider when selecting type of therapy [31,32,35]. The relationship between women from the middle income families and the higher prevalence of herbal medicine use should be further explored.

The most commonly used herbal medicines found in this study were consistent with previously published reports. Herbs which were not used specifically as galactagogues including ginger, dong quai, chamomile, garlic, cranberry, aloe vera and peppermint were all included in the 24 common medicinal herbs used by the general Australian population as reported by Zhang *et al.* [33]. Furthermore, the reported indications for use of these herbs were consistent with the traditional uses in many of the previous studies [33,35,37,38].

Over 24% of respondents took at least one herbal medicine for the purpose of increasing breast milk supply or promoting breastfeeding performance. Amongst the top ten herbs identified in this study, fenugreek, blessed thistle and fennel emerged as the top three herbal galactagogues. Other herbal galactagogues included goat's rue, nettle, blackthorn berry and shatavari. All these herbs have gained their reputation as galactagogues over the years, however mostly based on anecdotal evidence [43,47,48]. Limited clinical trials or large-scale studies are available to ascertain their efficacy as galactagogues. Nevertheless, this study identified the common herbal galactagogues used by women living in Australia and highlighted the need to conduct clinical research to confirm their efficacy and safety.

Sources of recommendation, supply and information-seeking behaviour

This study investigated the sources of recommendation and supply, and explored breastfeeding women's information-seeking behaviour. Family and friends were the most common source of recommendation, yet approximately half of these breastfeeding women (57.7% of reported users) obtained or purchased their herbal medicines from a community pharmacy. This finding indicates a potential role for community pharmacists and pharmacy staff in influencing breastfeeding women's decisions regarding the use of herbal medicines during breastfeeding.

When given a choice, breastfeeding women were most likely to seek information and advice regarding the use of herbal medicines from pharmacists and doctors. Internet resources, family and friends were also commonly reported

sources of information. Interestingly, only 52 (28.6%) out of the 182 users of herbal medicines in this study had made their doctor aware of their decision and choice of therapy. Other studies have also revealed a lack of communication between users of CAMs and their doctors in terms of their use of alternative therapies [42,49]. Nevertheless, all health care professionals, including doctors and pharmacists should take the initiative to ask and provide evidence-based advice regarding the appropriateness of using herbal medicines during breastfeeding. Considering the high prevalence of herbal medicines used during breastfeeding and the risk of potential interactions and adverse outcomes, all health care providers, including community pharmacists and pharmacy staff, should routinely ask female customers if they are breastfeeding and if they are using any medicines including CAMs. Although other studies have investigated the role of community pharmacists in providing advice regarding the use of CAMs in the general population [50-55] and the role of community pharmacists in counselling breastfeeding women [56,57], few studies exist to examine the role of this health care professional group in providing advice regarding the use of herbal medicines specifically to breastfeeding women and their families. Besides the community pharmacists, this study has also identified a greater need for both conventional healthcare providers and CAM practitioners to develop an interdisciplinary network, working collaboratively to ensure optimum health outcomes for their clients.

Attitudes and beliefs

Forster *et al.* [38] suggested the reason for the high prevalence of women not informing their doctors regarding their decision to use herbal medicines during pregnancy was the assumption that CAMs are 'natural' and hence safety would not be an issue. It is likely that this factor may also be contributing to the high prevalence of use identified in this study as the majority of the women who participated (43.4%) perceived herbal medicines as safer options compared to conventional medicines during breastfeeding. Although most herbal medicines are readily available over-the-counter without a prescription, it is important to take into consideration the potential risk of drug-disease interactions and interactions between herbal medicines of their choice and medicines prescribed by doctors.

Approximately seventy-percent (70.1%) of the respondents indicated that they either strongly agree or agree that there was a lack of resources available to them regarding the use of herbal medicines during breastfeeding. Nevertheless, some women continued to use their therapy of choice based on limited readily available evidence-based information. Over 70% of respondents indicated that they had previously refused or avoided medicine treatments

during breastfeeding due to concerns regarding safety of their breastfed infants. The study has demonstrated the urgent need for further research into this area as both untimely cessation of breastfeeding and mother denial of medicine treatments to meet their medical needs may lead to unwanted consequences.

Limitations

As the research involved a voluntary self-administered questionnaire, this study may overestimate the use of herbal medicines during breastfeeding as a result of voluntary response bias [45,52]. Women who had a personal interest or were taking herbal medicines may have been more likely to participate in the study. The 2011 Census indicated that 27% of the Australian population were born overseas, with the majority of migrants from European and Asian countries [58]. According to the Australian Bureau of Statistics (ABS), a total of 31,820 babies were born in Western Australia in 2011 [59]. Assuming approximately 90% of women initiated breastfeeding [16], the sample size of this study is small relative to this population. There was also a low response from women from lower income families and thus the views expressed by the study participants may not accurately reflect those of the complete breastfeeding population. Due to the self-reporting nature of this study, some respondents might not have correctly identified herbal ingredients or could have omitted herbs from the more complex products or formulas. Although the study suggested an association between the use of herbal medicines and users' country of birth and ethnic background, all questionnaires were administered in English. Further studies conducted in other languages would encourage women from a non-English speaking background to participate, which would also provide an improved representation of the broader population. Despite identifying the potential role of community pharmacists and pharmacy staff, this study did not explore the women's perspectives and reasons for their choice to utilise community pharmacies. In-depth qualitative studies would be valuable to assess if women's expectations and needs are met, at the same time identifying areas for improvement in the health care system. All surveys were treated anonymously and hence identification of the recruitment location or avenues of those surveys that were returned was not possible. As the survey included personal information, for the purpose of this study, the researchers felt that it was necessary to maintain anonymity of the participants to ensure privacy and confidentiality.

Conclusion

The use of herbal medicines is common amongst women during breastfeeding, while information supporting their safety and efficacy is lacking. The presumption of safety

for some of these medicines, especially when taken concurrently with other conventional medicines, may not be justified. This Western Australian study provides exploratory data on the use of herbal medicines during breastfeeding and identifies those most frequently used. The results support the need for further research and documentation about the safety of herbal medicines in breastfeeding, allowing breastfeeding women to make informed decisions. The herbal medicines most urgently in need of investigation appear to be fenugreek and ginger. Furthermore the efficacy of fenugreek as a galactagogue requires clinical scrutiny. Health professionals and health care providers should be aware of the latest information regarding safety and efficacy of the commonly used herbal medicines in lactation and provide appropriate advice to breastfeeding women.

Research-based information should be available to breastfeeding women who wish to consider use of all medicines, including herbal or alternative medicines. This could avoid interruption or cessation of breastfeeding due to unnecessary safety concerns, while allowing mothers to receive appropriate pharmacotherapy without compromising breastfeeding performance and the infant's health. Health professionals have an ethical obligation to continuously improve their professional ability to ensure optimum health outcomes of patients. Hence, the research questions now include whether there is sufficient and reliable information and resources available to health professionals, and if they are confident in advising on the use of herbal medicines during breastfeeding.

Additional file

Additional file 1: The study questionnaire.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

TFS designed, conducted and analysed the data of the project as part of her PhD degree. LT, JS and LH supervised the project and contributed to the design and analysis of the survey. RP provided statistical assistance and contributed to the analysis of data. All authors read and approved the final manuscript.

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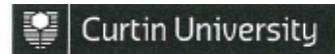
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Appendix B: Stage 1 Ethics Approval



Memorandum

To	Tin Fei Sim, School of Pharmacy
From	Alison Smith, R&D Coordinator, School of Pharmacy
Subject	Protocol Approval Form B PH-03-11
Date	6 March 2012
Copy	Dr Lisa Tee, School of Pharmacy

Faculty of Health Sciences

School of Pharmacy

TELEPHONE 9266 7418

FACSIMILE 9266 3793

EMAIL a.j.smith@curtin.edu.au

Thank you for your "Form C Application for Approval of Research with Low Risk (Ethical Requirements)" for the project titled "*The Use of Herbal Medicines in Lactation: Clinical Implication in Lactating Women and Breastfed Infants*". On behalf of the Human Research Ethics Committee I am authorised to inform you that the project is approved.

Approval of this project is for a period of twelve months **06/03/2012 to 06/03/2013**.

The approval number for your project is **PH-03-11**. Please quote this number in any future correspondence. If at any time during the twelve months changes/amendments occur, or if a serious or unexpected adverse event occurs, please advise me immediately.

Sincerely,

Alison Smith
Research & Development Support Coordinator
School of Pharmacy

Please Note: The following standard statement must be included in the information sheet to participants:
This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number «Approval_Number»). If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or hrec@curtin.edu.au

Appendix C: Stage 1 Participant Information Sheet

Participant Information Sheet for project entitled:

The Use of Herbal Medicines in Lactation: Clinical Implication in Lactating Women and Breastfed Infants

 **Curtin University**
Dr Lisa B.G. Tee
Senior Lecturer
Division of Health Sciences
School of Pharmacy
GPO Box U1987 Perth
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Breastfeeding is widely recommended as the best feeding choice for most infants and their mothers. One of the main concerns for breastfeeding mothers using medication is the entry of medication into breast milk. This could happen when the drug pass from the mothers' blood circulation into the breast milk, then being fed to the infants. Another concern is how these drugs will affect the quality and quantity of the breast milk, which may then impact on breastfeeding performance.

In Australia, the use of herbal medicines has increased over the years.¹⁻³ Many women are now taking these herbal medicines with or without recommendation from health care professionals. Currently very little is known about the use and safety of these medicines during breastfeeding. Although most of these herbal ingredients are deemed to be "weak" or "mild" in effects, it will be important to investigate the effects of these herbal medicines on the quality of the breast milk and to ensure the safety of the breastfed infants.

We have designed this survey in order to identify the most popular herbal medicines among breastfeeding women in Australia. This survey is aimed at finding out the percentage of women who is currently using or have previously used herbal medicines during breastfeeding, the types of herbal medicines, reasons for use, their believes and where they are exposed to such use. This survey will provide us with a better understanding on the use of herbal medicines during breastfeeding.

We are seeking for women who are 18 years or older, currently breastfeeding or have breastfed in the past 12 months to participate in this survey. This survey will take approximately twelve minutes to complete.

This survey is entirely voluntary and you may withdraw at any time. This survey will most likely not benefit you immediately, but the information gained from this study may help us to understand more on the effects and safety on the use of herbal medicines in breastfeeding mothers and to their infants. Only staff and students who are directly involved in this study will have access to the data collected. The results of this survey and the following studies may be published, however, any information which may potentially identify you will not be used in any publication. No personal contact details of participants will be recorded to ensure anonymity.

Further information on the study can be obtained from Miss Tin Fei Sim at the Curtin University (phone: 9266 1875 or mobile: 0401 649 800) or supervisor Dr Lisa Tee (phone: 9266 2526). This study has been approved by Curtin University Human Research Ethics Committee (Approval number: PH-03-11). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained either by writing to the Curtin University HREC, C/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth WA 6845, or phone 08-9266 2784 or email hrec@curtin.edu.au.

References: 1. MacLennan AH, Wilson DH, Taylor AW. Prevalence and cost of alternative medicine in Australia. *The Lancet*. 1996; 347(9001):569-573. 2. MacLennan AH, Wilson DH, Taylor AW. The Escalating Cost and Prevalence of Alternative Medicine. *Preventive Medicine*. 2002; 35(2):166-173. 3. Xue CCL, Zhang AL, Lin V, Da Costa C, Story DF. Complementary and Alternative Medicine Use in Australia: A National Population-Based Survey. *The Journal of Alternative and Complementary Medicine*. 2007; 13(6):643-650.

Appendix D: Stage 1 Cover Letter to Pharmacies



School of Pharmacy

GPO Box U1987
Perth Western Australia 6845

Web curtin.edu.au

7 September 2012

Dear Pharmacy Manager,

Breastfeeding and Medicines Research at Curtin University

Thank you for agreeing to assist with distribution of the survey forms to prospective participants for the study entitled "A Population-Based Survey on the Use of Herbal Medicines in Lactation among Breastfeeding Women in Australia". Please see enclosed 10 sets of forms (each with a Participant Information Sheet, Questionnaire Form, and a Reply Paid envelope).

As discussed earlier, we would be most grateful if the forms can be distributed to women who are 18 years or older, currently breastfeeding or have breastfed in the past 12 months, when they visit your pharmacy.

This study will help provide current information on the prevalence and pattern of herbal medicines used during breastfeeding, as well as to identify the commonly used herbal medicines which will help inform and direct further clinical research.

Please do not hesitate to contact me if you have any queries or if you need any further information. Thank you once again for your time.

Yours Sincerely

A handwritten signature in black ink, appearing to read "Tin Fei SIM".

Tin Fei SIM
B.Pharm (Hons), MPS
PhD Candidate
School of Pharmacy
Curtin University
Phone: 0401 849 800
Email: t.sim@curtin.edu.au

Appendix E: Stage 1 Cover Letter to CACH



School of Pharmacy
GPO Box U1967
Perth Western Australia 6845

Web curtin.edu.au

7 September 2012

Dear Manager,

Breastfeeding and Medicines Research – Poster Display at Child Health Centres and Immunisation Clinics

The School of Pharmacy at Curtin University is currently conducting a study entitled "*A Population-Based Survey on the Use of Herbal Medicines in Lactation among Breastfeeding Women in Australia*", to investigate the use of herbal medicines during breastfeeding and is currently in the recruitment stage seeking for more participants. This study has been approved by the Human Research Ethics Committee of Curtin University (PH-03-11).

We have recently been given approval by the Child and Adolescent Community Health Executive to display poster of our research at your facility.

Please see enclosed the poster to be displayed. We would be most grateful if the poster can be displayed in your waiting rooms.

Please do not hesitate to contact me if you have any queries or if you need any further information.
Thank you for your time.

Yours Sincerely

A handwritten signature in black ink, appearing to read 'Tin Fei SIM'.

Tin Fei SIM
B.Pharm (Hons), MPS
PhD Candidate
School of Pharmacy
Curtin University
Phone: 0401 649 800
Email: t.sim@curtin.edu.au

1 of 1

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CRICOS Provider Code 00301J (WA), 02557B (NSW)

Appendix F: Stage 1 Poster for Recruitment

The Use of Herbal Medicines in Lactation:
Clinical Implication in Lactating Women and Breastfed Infants



A Population-Based Survey on the Use of Herbal Medicines in Lactation among Breastfeeding Women in Australia

PARTICIPANTS NEEDED

**Are you currently breastfeeding or have breastfed in the
past 12 months?**

What is the purpose of this study?

The purpose of this study is to determine the prevalence and explore the patterns of herbal medicines administration amongst breastfeeding women living in Australia using a self-administered survey.

Who can participate?

To be eligible for this study, you need to be:

- 18 years or older
- Currently breastfeeding or have breastfed in the past 12 months

What does it involve?

This study involves filling in a self-administered questionnaire which will take approximately twelve minutes to complete.

Interested?

Please contact Ms Fei Sim (Phone: 0401 649 800 or Email: t.sim@curtin.edu.au) or supervisor A/Prof Lisa Tee (Phone: 08-9266 2526 or Email: l.tee@curtin.edu.au).

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number: PH-03-11).

Appendix G: Stage 1 Survey Questionnaire

The Use of Herbal Medicines in Lactation



If you are currently living in Australia, 18 years or older, currently breastfeeding or have breastfed in the past 12 months, we would greatly appreciate your participation in the following survey.

By returning this form, it is assumed that you have given consent to participate and for us to use the data in our research. Please be assured that this survey is completely voluntary and anonymous. No personal contact details will be recorded. Please refer to the Participant Information Sheet (Approval: PH-03-11).

Section 1: Participant Information

1.1 What is your home postcode? 1.2 What is your age?

1.3 What is your country of birth? 1.4 What is your ethnic background?

If not born in Australia, how many years have you been residing in Australia?

1.5 What is the highest level of education you have completed?

1.6 What is the total annual household income last year?

AUD 0 - 6, 000

AUD 6, 001 - 37, 000

AUD 37, 001 - 80, 000

AUD 80, 001 - 180, 000

AUD 180, 001 - and over

1.7 How many children do you have?

(If you are NOT CURRENTLY breastfeeding, please go to Section 2)

Regarding your child currently being breastfed:

1.8 What is his/her age? Gender: Male Female

1.9 Is this your first child? Yes No

Section 2: Participant and family background characteristics

2.1 What is your parents' place of origin?

2.2 What are their ethnic backgrounds?

2.3 Are you living with your parents or your partner's parents? Yes No

2.4 Who were you living with when you were breastfeeding your child?

2.5 Which of the following best describes your parents or your partner's parents' role in giving advices on decisions regarding your own health or nutrition during breastfeeding?

All the time

Quite frequently

Sometimes

Only very occasionally

Never

2.6 Which of the following best describes your parents or your partner's parents' role in giving advices on decisions regarding your child's health or nutrition?

All the time

Quite frequently

Sometimes

Only very occasionally

Never

Section 3: Use of herbal medicines during breastfeeding

The Therapeutic Goods Regulations 1990¹ defines herbal substances as “*all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin)*”¹.

3.1 Have you used any herbal supplements or preparations during breastfeeding? Yes No

If answered No, please go to Question 3.7.

3.2 Are the reason(s) for using any of them breastfeeding-related? Yes No

3.3 Please specify the name(s) of herbal preparations, reason(s) or purpose(s), who recommended and whether it was effective from your personal experience. *(If extra space required, please go to the last page)*

Name(s) of Herb	Why?	Recommended by?	Did it help?

3.4 Have you used any herbal supplements during breastfeeding to help increase milk production or supply during breastfeeding? Yes No

If answered Yes, please specify details in the table below. (If extra space required, please go to the last page)

Name(s) of Herb	Why?	Recommended by?	Did it help?

3.5 Did you experience any side effect(s) or unwanted effect(s) following the use of herbal supplements during breastfeeding? Yes No

If answered Yes, please specify the name(s) of the herb and side effects experienced in the box below.

3.6 Is your doctor aware that you are using these herbal supplements during breastfeeding? Yes No

3.7 Have you used any other products, special diets or methods to help increase milk production or supply during breastfeeding? Yes No

If answered Yes, please describe the products or methods used in the box below.

Section 4: Sources of herbal medicines and information resources

4.1 Where have you obtained or purchased your herbal products/preparations? Please tick where relevant.

- Herbal or health food store Naturopathic clinics Pharmacy
 Supermarket Family or friends Internet
 Others, please specify

4.2 Where have you or would you seek information concerning the use of herbal medicines during breastfeeding? Please tick where relevant.

- Herbal or health food store Pharmacist Doctor
 Naturopathic/ Homeopathic practitioner Family or friends Internet
 Books, literature or journal articles Lactation consultant Child health nurse
 Others, please specify

4.3 Do you agree that currently there is a lack of resources available to you regarding the use of herbal medicines during breastfeeding?

- Strongly agree Agree No idea Disagree Strongly disagree

4.4 Do you agree that using natural herbal medicines is safer than using conventional/prescribed drugs during breastfeeding?

- Strongly agree Agree No idea Disagree Strongly disagree

4.5 In the past, have you refused or avoided any drug treatments during breastfeeding due to concerns regarding safety of your breastfed infant(s)?

- Yes No

4.6 Would you like to know more about the safety and efficacy of herbal medicines use during breastfeeding?

- Yes No

THANK YOU FOR YOUR TIME

References:

1. Therapeutic Goods Regulations 1990 [statute on the Internet]. 1990 [updated 2010 July 1; cited 2010 September 7]. Available from: <http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/>.

Extra Space for Question 3.3

Name(s) of Herb	Why?	Recommended by?	Did it help?

Extra Space for Question 3.4

Name(s) of Herb	Why?	Recommended by?	Did it help?

Appendix H: Stage 1 Reply Paid Envelope



Dr Tin Fei Sim
School of Pharmacy
GPO Box U1987
Perth Western Australia 6845



Curtin University
Reply Paid 1987
PERTH WA 6845

Appendix I: Publication BMC CAM 14_216

Sim et al. *BMC Complementary and Alternative Medicine* 2014, **14**:216
<http://www.biomedcentral.com/1472-6882/14/216>



RESEARCH ARTICLE

Open Access

Perspectives and attitudes of breastfeeding women using herbal galactagogues during breastfeeding: a qualitative study

Tin Fei Sim¹, H Laetitia Hattingh¹, Jillian Sherriff² and Lisa B G Tee^{1*}

Abstract

Background: Some herbal galactagogues have gained reputation and recognition by the public and health professionals as alternative approaches to increase breast milk supply. This study explores the perspectives and attitudes of breastfeeding women towards the use of herbal galactagogues while breastfeeding, their experiences, and why and how they have chosen an alternative option over conventional treatments to enhance breastfeeding performance.

Methods: This exploratory research was conducted through in-depth semi-structured interviews with women living in Perth, Western Australia, who were using one or more herbal galactagogues during breastfeeding. Purposeful and subsequent snowball sampling methods were employed to recruit participants. All interviews, facilitated by an interview guide, were audio-recorded, then transcribed verbatim. Thematic analysis was used to analyse qualitative data to construct themes and subthemes.

Results: The perspectives and attitudes of the 20 participants are classified under three main headings: i) use of herbal medicines during breastfeeding, ii) available herbal medicines resources, and iii) level of breastfeeding support received. Throughout the interviews, participants described how their perseverance and determination to breastfeed, as well as concerns over breastfed infants' safety with conventional treatments, influenced their choice of therapy. A sense of self-efficacy and autonomy over their own health needs was seen as influential to their confidence level, supported self-empowerment and provided reassurance throughout the breastfeeding journey. There was also a desire for more evidence-based information and expectations of health professionals to provide credible and reliable information regarding the use of herbal medicines during breastfeeding.

Conclusions: This study has enhanced our understanding of the perspectives and attitudes of breastfeeding women towards the use of herbal medicines, in particular galactagogues, while breastfeeding. The positive attitudes of breastfeeding women identified in this study highlight the need for further research into evaluating the safety and efficacy of commonly used herbal galactagogues, whilst the negative views on breastfeeding education should be taken into consideration when implementing or improving breastfeeding-related health policies.

Keywords: Herbal galactagogues, Breastfeeding women, Lactation, Perspectives, Fenugreek

Background

The use of complementary and alternative medicines (CAM), including herbal medicines, amongst the general population is increasing worldwide [1-3]. Garlic, green tea, aloe vera, chamomile and echinacea are commonly

used herbs with potential medicinal properties [3,4]. Previous studies have highlighted the popularity of these herbs and herbal medicines amongst the general population as well as breastfeeding women [5-9]. Some herbal medicines including galactagogues have indeed gained some reputation and recognition by the public and some health care providers, for example naturopaths, as alternative approaches to enhance breastfeeding performance [9-11].

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A recent prevalence study in Western Australia which involved surveying women who were breastfeeding in the previous 12 months, revealed that 59.9% of the 304 survey respondents reported the use of at least one herbal medicine whilst breastfeeding, with the top ten most commonly used being fenugreek (*Trigonella foenum-graecum*), ginger (*Zingiber officinale*), dong quai (*Angelica sinensis*), chamomile (*Matricaria chamomilla*), garlic (*Allium sativum*), blessed thistle (*Cnicus benedictus*), cranberry (*Vaccinium macrocarpon*), fennel (*Foeniculum vulgare*), aloe vera and peppermint [5]. The same study reported that 24% of respondents were using herbal medicines for the purpose of increasing breast milk supply and to promote breastfeeding performance, regardless of whether participants had been diagnosed with insufficient milk supply or not [5]. Fenugreek was the most commonly used herbal galactagogue during breastfeeding amongst the survey respondents. Other commonly reported herbal galactagogues included blessed thistle (*Cnicusbenedictus*), fennel (*Foeniculumvulgare*), goat's rue (*Galegaofficinalis*), nettle (*Urticadioica*), blackthorn berry (*Prunus spinosa*), and shatavari (*Asparagus racemosus*) [5].

Despite the many efforts to facilitate breastfeeding, some women may still experience difficulty with breastfeeding due to numerous factors. For example: many societal and environmental factors such as cultural norms, hospital, home, work and community environments have been shown to impact on the rate of successful breastfeeding [12]. Another commonly reported reason for unsuccessful breastfeeding or early weaning is perceived low or insufficient breast milk supply [13]. Poor breastfeeding technique or latching leading to ineffectual milk removal, deficient mammary gland tissue and maternal hormonal imbalances can all contribute to insufficient supply of milk [14,15]. Once these issues have been addressed and other strategies have been followed, such as education about techniques by lactation consultants, and milk flow remains insufficient, galactagogues could be trialled [16].

Although certain herbs have a long history of being used as galactagogues, scientific evaluation is lacking to verify the clinical efficacy of most of these herbs [9]. However, many women continue to use herbal galactagogues based on anecdotal evidence [9,10]. Research into the potential impact on successful breastfeeding and perceived efficacy or psychological benefits of herbal galactagogues would provide insights into the use of these galactagogues as alternative options for breastfeeding women who wish to increase their breast milk supply. Gaining an understanding of breastfeeding women's perspectives, why and how they have chosen to use herbal galactagogues over conventional options to increase breast milk supply, their experiences and the

factors or indicators that influenced their breastfeeding performance, will provide insight into the potential value of herbal galactagogues and identify research gaps to guide direction of future studies.

This study aimed to obtain an understanding of the perspectives and attitudes of women towards the use of herbal galactagogues whilst breastfeeding. The study also aimed to explore why women have chosen alternative remedies to promote breastfeeding and what factors were influencing their decision-making. A better understanding of their unique needs and perspectives will enrich our knowledge in the area of CAM and in turn benefit women who need to use medicines during breastfeeding.

Methods

This study was approved by the Human Research Ethics Committee of Curtin University (approval number HR85/2012).

Study design

This study involved exploratory research conducted through in-depth semi-structured interviews with women who were using one or more herbal galactagogues during breastfeeding to increase breast milk supply and facilitate breastfeeding. An interview guide with a mix of ten closed and seven open-ended questions was used during the interviews to obtain information regarding the pattern of use of herbal galactagogues, and explore the perspectives and attitudes towards the use of these medicines during breastfeeding, as below:

- Questions one to eight focused on documenting the pattern of use and types of herbal galactagogues, dosage forms and administration, reasons for use and source of recommendation,
- Questions nine to 11 focused on exploring the perceived efficacy and safety based on participants' personal experience,
- Questions 12 to 17 (including sub-questions) focused on participants' general perspectives and attitudes towards the use of herbal medicines during breastfeeding, role of health professionals and the availability of information or resources.

Participants and recruitment

Breastfeeding women living in the Perth Metropolitan area were invited to participate. All participants had to: i) be 18 years or older, ii) be breastfeeding or have breastfed in the previous 12 months, and iii) previously have used or were using one or more herbal medicines as galactagogues during breastfeeding to increase breast milk supply or to improve breastfeeding performance. Participants were not required to have been diagnosed

with insufficient milk supply and could have been from any cultural or ethnic background.

Purposeful sampling and subsequent chain or snowball sampling methods were used to recruit participants, specifically targeting breastfeeding women who visited naturopaths or who had used herbal medicines. Purposeful method of sampling was considered most appropriate as it allows careful selection of cases which are information-rich to facilitate comprehensive qualitative data to be collected, which in turn improves credibility and reliability of the research findings [17].

Participants were initially recruited from naturopathic clinics with a focus on CAMs use and breastfeeding where posters with details of the study were displayed. The study was also advertised to the wider public through promotion in local health and parenting papers and the Curtin FM 100.1 Perth radio station. Interested women were encouraged to contact the researcher to express their interest. Subsequently, a snowball sampling method was adopted for further recruitment where participants were requested to share the study information with other breastfeeding women. Through the snowballing effect, two community pharmacies with a focus on breastfeeding and naturopathy were identified and approached for participant recruitment purposes. Study posters were subsequently displayed at the pharmacies.

Portney and Watkins [18] commented that sample size determination in qualitative research is based on experience, judgment and the research purpose. According to these authors [18], "samples that are too small will not support claims of having reached a point of data saturation. Samples that are too large will not permit the in-depth analysis that is the essence of qualitative inquiry". Based on a similar galactagogue study involving 23 participants in British Columbia [14], a decision was made to initially recruit up to 20 women and through the data analysis determine whether a point of saturation was reached, when no new themes emerged. Guest *et al.* [19] studied the variability and degree of data saturation in qualitative research and reported that data saturation took place within the first twelve in-depth interviews. Twenty participants were therefore considered sufficient to reach data saturation, as no new themes had merged, whilst also enabling in-depth analysis.

Data collection

Prior to conducting the interviews, an information sheet about the research and what the interview would cover was provided to participants. For the face-to-face interviews, participants were requested to sign a consent form prior to conducting the interviews. An electronic copy of the participant information sheet was emailed to participants who had provided their email contact and requested a telephone interview. In cases where email

contact was not available, the content of the participant information sheet was read to the participant over the telephone and verbal consent was obtained before the interview. Participants were given ample opportunity to ask questions and were reminded that the study was completely voluntary and that they could withdraw at any stage without prejudice.

Taking into consideration the variability between participants and at the same time ensuring that the topic of discussion could be thoroughly covered, the interviewer (TFS) followed a flexible and discrete approach throughout the process. Transgression from the interview guide was necessary in some instances for example when the interviewee mentioned an issue not necessarily addressing the questions in the guide, but still considered relevant to the topic. All interviews were audio-recorded and subsequently manually transcribed verbatim.

Data analysis

The transcripts were analysed using descriptive and qualitative approaches. Participants were de-identified and codes were used in the analysis (the first interviewee was BW1 for Breastfeeding Woman 1). This paper reports on the qualitative findings of this study, using thematic analysis as described by Boyatzis [20]. In order to achieve thorough understanding of the themes, contents of the transcripts were read repeatedly by the primary investigator (TFS). The emerged ideas or topics along with their supporting quotes were documented. These topics were then grouped and reclassified as sub-themes. The process continued until all subthemes were regrouped to form major overall themes. Throughout the process of analysis, project supervisors (LT, LH) provided input and reviewed the themes to ensure reliability.

Results

A total of 20 breastfeeding women living in the Perth metropolitan area who were using herbal galactagogues were interviewed between October 2012 and April 2013. All interviews were conducted on a one-to-one basis: ten face-to-face at a place convenient to the participant and ten via telephone. Of the 20 participants, one was of Middle-Eastern descent, two were of Asian descent, and the other 17 were of Caucasian descent. Interviews ranged between 18 to 78 minutes with a median duration of 34 minutes. All participants had used fenugreek during breastfeeding, with three of them having used a combination of fenugreek and blessed thistle, and seven having used naturopaths' own 'lactation tincture' containing a combination of herbal ingredients.

Table 1 provides a summary of the themes and sub-themes that emerged during data analysis with the major themes being: 1) reasons for the use of herbal medicines

Table 1 Perspectives and attitudes of women: major themes and sub-themes

Major themes	Sub-themes
1. Reasons for the use of herbal medicines	Perseverance and determination to breastfeed Confidence, self-empowerment and reassurance Concerns over breastfed infants' safety Role and expectation of health care workers Parental and peer influence
2. The need for herbal medicines resources	Information needs Credibility and reliability of information Expectations of health professionals
3. The level of breastfeeding support	Positive feedback Negative feedback

during breastfeeding, 2) the need for herbal medicines resources and 3) the level of breastfeeding support identified.

Use of herbal medicines during breastfeeding

Participants reported four main reasons for the use of herbal galactagogues, namely perceived insufficient milk supply, diagnosed insufficient milk supply, as a supplement and as part of the tradition. Besides those who had been diagnosed with insufficient milk supply by health professionals, all other participants embraced the "just-in-case" approach to use herbal galactagogues prophylactically in order to avoid breast milk supply issues. Five subthemes about the use of herbal medicines during breastfeeding were identified as discussed below with selected quotes to assist with explanation of the concepts.

Perseverance and determination to breastfeed

All participants seemed to have adopted the 'breast is best' philosophy. These women acknowledged and appreciated the health, physical and psychological benefits of breastfeeding to both mothers and infants.

"...how much it helped my bonding with my baby and even just a general satisfaction from it, not only satisfaction but also I would say the benefits were much higher". (BW 1).

Recognition of the importance and significance of breastfeeding was identified as the main facilitator to develop perseverance and a determined attitude to breastfeed:

"... basically I was just trying to get him back to the breasts and don't want to stop breastfeeding him, so

it's to try and increase the supply because there is a need there". (BW 11).

All participants were familiar with the recommendation of the Australian Dietary Guidelines 2013 to breastfeed exclusively for the first six months of an infant's life [21]. Taking into consideration the advantages of breastfeeding along with endorsement from their health professionals, perseverance and determination played a vital role in successful breastfeeding as the women were prepared to take all required actions to avoid the use of infant formula as much as possible.

"Breastfeeding is not easy, definitely not. You need to persevere and you need to be absolutely patient with everything that you do. You need to have very high patience level and you need to feel comfortable and confident doing it". (BW 20).

An underlying theme was observed when women described their strong mental will to breastfeed.

"I mean honestly, if drinking snake oil would make me have more breast milk I would have done it, anything that helps!" (BW 3).

"I certainly am not opposed to the idea of using herbs to support breastfeeding. Really, I don't care what it is, as long as I can tolerate it and it helps, I am willing to try anything". (BW 18).

Confidence, self-empowerment and reassurance

There seemed to be a relationship between the women's breastfeeding confidence level and duration of exclusive breastfeeding. Even in the absence of milk volume measurement, one participant described how the use of herbal galactagogues promoted her confidence and fostered self-empowerment to breastfeed.

"...because this [fenugreek] works so quickly and it just gave me that confidence straight away. It took away that anxiety and stress". (BW 6).

Many participants also mentioned the feeling of reassurance through the use of herbal supplements during breastfeeding, which was especially important for first-time mothers. Hence, the use of herbal galactagogue was described as a method of reassurance in the context of their own perceptions. The positive emotional impact contributed to the success of breastfeeding practices amongst the participants.

"I think it's [fenugreek] worth trying. And as for me, I certainly find that useful and reassuring that I have

found something effective to increase my milk supply. As a new mum, you just never know, you never know what is coming, what problems you will encounter and I certainly did not anticipate that milk supply will be an issue. I have always thought that breastfeeding is easy and will come naturally because everyone else does it, and I wasn't told about it being an issue". (BW 12).

Concerns over breastfed infants' safety

A number of participants voiced their concerns over breastfed infants' safety and the use of medicine by the mother. These participants were cautious and apprehensive over their decision on what to take or what to avoid whilst breastfeeding, expressing their fear of it affecting their infants' health.

"I really didn't want to take anything harsh that could affect my baby's health, so I was more cautious over what I take. I would say that because I was breastfeeding, I was more cautious over what I take and what I eat, and I think that using natural herbs would be safer than using chemicals". (BW 18).

Some participants associated the use of conventional or "Western" medicines as dangerous or harmful to take during breastfeeding. Limited awareness of potential side effects and medicine knowledge had for some women led to the refusal of conventional recommendations for treatment of insufficient breast milk supply, for instance with the prescription medicine domperidone (Motilium®).

"To me, it [herbal galactagogue] seems a lot safer, because when I was on Motilium®, the way how that works changes dopamine levels in the brain which then increases milk supply and prolactin. That to me has always felt like 'Frankenstein' sort of thing. It [fenureek] just seems more natural. I am not concerned about any transfer to my milk, because it's natural and it has been used for hundreds or thousands of years, really, I think over time it would have been tested and proven". (BW 7).

Participants described their concerns over the use of conventional medicine whilst breastfeeding. The general perception of 'herbal is natural, and natural is safe' was identified. Many participants displayed a tendency to use herbal alternatives during breastfeeding with the general assumption that herbal galactagogues were safer alternatives compared to other options.

"I think if you can avoid taking chemical pharmaceutical drugs, then I would exhaust every single herbal option before I go near any pharmaceutical... because the herbal options are

usually much safer, they usually don't cause any issues in the baby. For me, in any situation I would exhaust any homeopathic or herbal remedy before I went to pharmaceuticals". (BW 11).

Nevertheless, some women realised that natural remedies may not always be safe and that they would still be mindful and vigilant when choosing their therapy of choice. As one participant commented:

"Given that it comes from nature, even though you can't quantify how much the active ingredient is in there, I believe that it may be enough to cause any problems. So in my opinion, if a herb or substance is used whilst breastfeeding, as long as there is no or significant adverse effect, or it can be incorporated to part of your diet, then it should be okay..." (BW 1).

The decision and likelihood to use herbal options to promote breastfeeding performance was at times linked to women's personal preference. Some of the participants appeared to have previously used herbal medicines in managing other health issues separate to pregnancy and lactation. In conjunction with the perception of herbal galactagogues being "safer", women preferred to use the herbal alternatives during breastfeeding.

"Even before I was breastfeeding, I tend to choose herbal, during pregnancy I tend to use herbal and that carried through till I was breastfeeding, so that was definitely my first choice". (BW 8).

Role and expectations of health care providers

Breastfeeding women's expectations of health care providers emerged as a prevailing topic of discussion in these interviews. In the context of this discussion, health care providers included doctors and specialists, midwives, child health nurses, lactation consultants, naturopaths, as well as community pharmacists. Besides health information, expectations of participants centred on drug or product knowledge, including options of alternative therapies, at the same time respecting women's decision or choice. Participants expected all health care providers to have an adequate level of awareness and knowledge on the availability of all different treatment options. Some of the participants indicated a need for health care providers to be more open-minded, supportive and prepared to provide alternative options should women wish to be able to choose. Participants preferred to receive suggestions or options with information about the available evidence in order to make an informed decision.

"I think it's the attitude of people. So you know you go and see the lactation consultant, and they don't tend

to, in my experience they don't tend to believe that herbs do very much. Even other health professionals like doctors and pharmacists should be aware or should know about the alternative options, so we can make our own decision, that would have been very helpful". (BW 5).

One participant who showed preference to the use of herbal remedies described her experience with health care providers and discontentment after being diagnosed with insufficient milk supply:

"It [using herbal galactagogue] is not talked about. Not to boost subject, but no one takes these sorts of things seriously I supposed. I think hospitals need to be more open-minded and willing to talk about other things other than just manufactured drugs". (BW 2).

It was also noticeable from the interviews that involving breastfeeding women in decision-making regarding their own health care creates a sense of autonomy which increases the likelihood of adherence to therapy regardless of whether it is conventional or alternative therapies. Many participants believed that information regarding herbal medicines to support breastfeeding should be provided in the information pack supplied at pre-natal clinics.

There was also a perception that many health care providers were not supportive of the use of herbal medicines during breastfeeding, and were not knowledgeable of the range of herbal products available and their evidence in terms of safety and efficacy. Regular users of herbal medicines believed that alternative options should be made available to all breastfeeding women by their health care providers. Some participants further commented on the potential value of awareness in reducing distress and anxiety during early days postpartum.

"I think people need to know that it does actually work, not just some crazy hippy thing. Because actually that was what I thought, I initially thought that the herbs were for people who didn't want to use conventional medicines because they have issues with big "pharma" or whatever, but honestly for me, it has worked wonders, like far better than anything that any doctors have ever recommended it to use. So I just wish that more women actually are aware of it". (BW 7).

Despite the criticism about the lack of information about herbal remedies from most health care providers, some of the participants did report receiving information and recommendations relating to the use of herbal medicines from these providers. A need for reassurance from

health care providers emerged as an underlying theme as some participants elucidated their experiences and relationships with their trusted health care providers. Participants appeared to be comfortable with recommendations from health care providers.

"I am certainly not opposed to the idea of using herbs during breastfeeding, as long as I know and have checked with my child health nurses and doctors or even ringing up a pharmacist". (BW 12).

"I never even thought twice about taking it, I never had any hesitation in it, because of the people who have recommended it to me, like the lactation consultants and the naturopaths. I know a naturopath who is very cautious over what she prescribes when you are breastfeeding, so I never thought twice. I don't know much of it or how much benefit it had, but I have no problems taking it, I suppose it is a natural herb". (BW 10).

The need for research and evidence-based information on the use of herbal medicines during breastfeeding was identified by several participants. They expected health care providers to be up-to-date with the latest research data and be able to translate the information into their daily practice.

"I guess the supplements out there just need more studies. There's lots of research that goes into glucosamine and fish oil and all these that we think is going to help us, but not for breastfeeding, it will be nice to have that knowledge to know that it works and it is safe". (BW 3).

Parental and peer influence

The impact of peer and parental influence on breastfeeding women's decision and choice of therapy was discussed from the perspectives of sources of recommendation and supply. It was evident that some participants were more likely to believe and follow certain recommendations if these were made by parents or peers whom they could relate their experience to or women who had breastfeeding experience.

" [The best thing is] talking to people on the mothers group page and the breastfeeding support groups, they have all walked through the journey, they understand, and tried different things and suggested different options". (BW 4).

Some participants described feeling stressed from parents and peer pressures to breastfeed as the drive to exploring all available methods to ensure successful

breastfeeding. In these instances, potential psychological or emotional benefits of using herbal galactagogues had further benefits in terms of confidence and reassurance.

Available herbal medicine resources

Three sub-themes were apparent in the interviews as participants described their views on the resources available to them as breastfeeding women regarding the efficacy and safety of herbal medicines.

Information needs

Despite their decision to use herbal galactagogues during breastfeeding, the majority of the participants (17 of 20) commented that there was a lack of resources available regarding the use of herbal medicines during breastfeeding. Although these herbal medicines were widely available over-the-counter in Australia, information regarding their efficacy and safety during breastfeeding was perceived as not being well established, or at least not made readily available to them.

"I don't think there is much out there, at least they weren't easily available. If it wasn't for my friend at mothers' group, I wouldn't have known to take fenugreek". (BW 12).

"...I think we can do with a lot more information and make it more widely available so that people who are in need of it can use them". (BW 8).

The majority of participants expressed a need for accessible evidence-based information and more research to be conducted to facilitate safe and effective use of medicines during breastfeeding to promote successful breastfeeding and avoid unnecessary early cessation of breastfeeding.

"If it was proven medically and endorsed, more people would be able to use that [herbal galactagogue], instead of just giving up breastfeeding when they feel the supply is low or grabbing the first bottle of formula". (BW 18).

In addition to the general need for further research, a need for research specifically conducted locally was also identified to facilitate the application of findings to the Australian health care context. As herbal preparations exist in various brands and dosage formulations throughout the world, some participants found it impractical to relate to information or studies conducted overseas.

"I think it's better if we have our own, because obviously in all countries the culture is different, obviously you can't do research in every single country,

but I think I will be more inclined to believe it if it was from Australia rather than from overseas. Also different countries have different brands, which to me in my case, different brands gave me a different effect. So like for example if you see a brand from an American website, but then you may not get it in Australia. I think it is really important to have an Australia sort of research around it". (BW 7).

Credibility and reliability of information

Many participants relied on the internet or their friends and family for information, advice and recommendations. Unknown credibility and reliability of information accessed from the internet was highlighted during the interviews. Although many participants questioned the trustworthiness of information obtained from non-accredited sources, they were left with no other option but to use the internet.

"Most of the stuff you get from the internet, I am just always worried about reliability, and the more you read, you tend to trust it more, which may not necessarily be a good thing sometimes". (BW 5).

Participants further cited the need for reliable information to be endorsed by organisations such as the Australian Breastfeeding Association (ABA).

"I had to rely on [internet] forum discussions and word of mouth to make up my mind whether a herbal product is suitable for me or not. So if it was endorsed by a medical [group] or I know the Australian Breastfeeding Association is not a medical, but if it was endorsed more medically in some way or another, it might be more helpful, people might be able to use it more". (BW 17).

Along with the general perception of the lack of easily accessible reliable information, one participant who was both a health professional and a mother of an eight-month old at the time of the interview, described her views on the information resources. Inconclusive information was seen as confusing and further posed a dilemma:

"If there is something available, I find that it is usually inconclusive. There is just not enough data and they [the resources] leave the ball to the mothers' court to decide whether they want to take it. I feel like there is no conclusive information as such regarding herbal medicines during breastfeeding". (BW 1).

From the perspectives of some participants, reliance on parents or close family members and friends for breastfeeding-related information was considered sufficient

"I only went to where my mum told me, so I personally never looked into safety and efficacy of herbal medicines during breastfeeding". (BW 1).

Expectations of health professionals

In general, health professionals were viewed as reliable sources of information. Besides voicing their need for additional research studies, participants also demonstrated a desire for written and verbal information from their health care professionals with regards to the use, safety and efficacy of herbal medicines during breastfeeding. It appeared that some participants perceived that there was a lack of health professionals' awareness about the availability of evidence-based information regarding use of herbal medicines during breastfeeding. Participants expected information related to the use of herbal medicines to be provided in a leaflet or pamphlet format by their health professionals.

"The info packs that you get from the hospitals and pamphlets from nurses don't have much information about herbal remedies for use during breastfeeding. Like I mentioned earlier, if I had known the presence of fenugreek for example, I would have tried that with my first child and may have a better or easier time with breastfeeding". (BW 6).

Acknowledging that there is a lack of available information, participants believed that health professionals should endeavour to provide guidance. Information on herbal options during breastfeeding should be made readily available to all breastfeeding women as suggested by some participants.

"At least on what's available, I mean there might not be a lot of information available, but at least to guide us on where to look out for information". (BW 5).

Despite expecting health professionals to have adequate levels of knowledge, participants had varying expectations of different health professionals:

"I find people who are working in natural health are more comfortable than people who are working in main stream health, they are more hesitant to recommend stuff, they have a more complex... I mean they couldn't really say whether something was safe or not". (BW 8).

In the context of reliable information resources, community pharmacy was perceived as an easily accessible health destination and pharmacists were recognised by participants as overall medicine experts.

"...the few times when I had questions about medications during breastfeeding, I called up the pharmacies and they were fantastic". (BW 9).

Level of breastfeeding support

A multidisciplinary team consisting of a diverse group of health care providers including doctors, pharmacists, child health nurses, midwives and lactation consultants was seen by participants as contributors to the current health care system. Many of the health care providers were mentioned throughout the interviews when participants described their experiences and understandings with "health care" and "breastfeeding support". Despite her perception of insufficient information available regarding the use of herbal medicines during breastfeeding, one participant acknowledged the level of assistance and support provided:

"I would say there is certainly a lot of help out there, I mean a lot of breastfeeding help. You have the child health nurses, midwives, lactation consultants, chemists, doctors and all to help and ask questions if you need to, but I don't think there is enough information out there about use of herbal medicines". (BW 15).

Despite some positive experiences, participants highlighted several areas for improvement. Immediate postpartum and early parenthood were viewed as challenging and may be associated with anxiety, stress and confusion in some women, which may impact on their ability to take in any information. According to some participants, in-depth practical information regarding breastfeeding were not provided until immediate postpartum. Although some pre-natal classes may have touched on the subject, the level of breastfeeding-related information was viewed as insufficient to enable a full understanding and anticipation of the potential breastfeeding-related issues which women may encounter. Hence, participants suggested that breastfeeding and related information be part of the focus during pre-natal classes or information sessions to avoid confusion during the lactation stage.

"Before birth, because that's when you want to learn as much as possible about what's going to happen when the baby comes because you have no idea. But after baby arrives, you are so consumed and you don't pay attention to what's happening around you. Especially, I didn't really remember anything during the first week. So doctors and nurses could have told me things but I wouldn't remember, but information should be available before birth". (BW 2).

Many of the participants were not aware of insufficient breast milk supply being a potential issue before the baby was born. Besides the provision of breastfeeding-related information during pre-natal classes, participants further suggested that potential issues with insufficient breast milk supply and information on options available to boost supply, including herbal galactagogues and non-pharmacological therapies should be made available prior to delivery. Pre-natal classes and visits to health care providers were proposed as the most appropriate avenues. This valuable information was perceived as potentially useful and expedient when discussed before the birth of their infants, especially for first-time new parents.

"I only found out that [fenugreek] after it [low milk supply] became an issue. We are told the importance of breastfeeding and all that, but not really about being aware that supply could be an issue. So, if this was discussed earlier on before delivery, we can prepare and start taking some supplements, rather than addressing it way down the track when you realized that you have a supply issue". (BW 9).

"Most mothers will be going to prenatal classes before the baby is born. They do explain breastfeeding but they don't go through the different things that you can do to help the situation. They sort of tell you this is how you should breastfeed to get the attachment right and things like that, but not really like the issues that could come with it. They can prepare themselves if it didn't happen the way it was meant to". (BW 15).

"Sometimes it is so, you are so sleep deprived, when the baby arrived, you are thinking, I am just trying to keep my head above water, so it's great to have information out there before the baby arrives, or particularly with your first baby. I think maybe they should have given you a little bit more information on breastfeeding and other options out there if you have problems with supply, as well". (BW 16).

To avoid confusion, it is also crucial that all health care providers across the multidisciplinary team are up-to-date with recommended guidelines to ensure consistent and dependable information be delivered.

"I don't think that there's, this is my opinion, there isn't a massive amount of support or in hospital for my first baby. I was told different things in regards to breastfeeding, different ways, it was just confusing, so I had to work out how it would work for me, and that's very common in first time mum. They are told different things and ended up feeling very confused". (BW 16).

Discussion

Although many previous studies have examined the perspectives of women towards the use of medications during breastfeeding, most had focused on the use of conventional medications [22]. To address the research gap, this study focused on the perspectives and attitudes of this population towards the use of herbal galactagogues.

All of the participants of this study appreciated and valued the benefits of breastfeeding and supported the 'breast is best' philosophy. Participants showed a positive attitude towards breastfeeding and were willing to make efforts necessary to ensure the success of breastfeeding, including the use of herbal medicines to promote breastfeeding performance. For most participants, the strong desire to continue to breastfeed accompanied by recommendations from family and friends had led to the use of herbal galactagogues during breastfeeding.

The potential psychological or emotional impact of using herbal galactagogues during breastfeeding should not be underestimated. As evident in this study, confidence and self-empowerment emerged as an over-arching theme throughout the interviews, especially when participants described their positive experiences. This finding was also observed in a similar study conducted by Westfall, who highlighted the positive feedback provided by her participants despite the lack of scientific evidence for most herbal galactagogues' efficacy [14].

It is not surprising that women who had used herbal galactagogues during breastfeeding had accepted and adopted an integrative and holistic approach for their own healthcare. Many studies have demonstrated the acceptance and practice of integrative healthcare amongst the general Australian population [23-26]. Some women who had used herbal galactagogues during breastfeeding used herbal medicines prior to pregnancy and lactation. Consistent with previous research on perspectives of alternative health care users, this finding demonstrated that some women chose alternative therapies to gain autonomy and a sense of control over their own health, and that the decisions are accustomed to their values and beliefs [27-31]. The sense of empowerment when a breastfeeding woman actively seeks out and adheres to an alternative regimen plays a positive role in her breastfeeding journey. As perceived insufficient milk supply is one of the major causes of premature cessation of breastfeeding, the use of herbal galactagogues provides a sense of empowerment and self-efficacy which may aid in overcoming the issue [32].

Some of the participants were concerned about adverse effects and the risk of harming their infants with the use of conventional medicines. Despite this concern, considering the popularity and acceptance of integrative or holistic healthcare in the general population, some women may be likely to opt for alternative options,

for example herbal remedies, to promote breastfeeding performance. Previous dissatisfied experience with conventional treatments may also encourage the use of alternative therapies whilst breastfeeding [27]. Due to the potential of misperception by some women that herbal remedies are always safe, the public should be encouraged to consult health professionals prior to using any medicine whilst breastfeeding.

Consistent with the literature and previous findings, breastfeeding women identified the need for more in-depth information, including scientific evaluation of the efficacy and safety of herbal galactagogues and other herbal medicines during breastfeeding [22,28,33]. Women expect health professionals to have adequate knowledge and to be willing to offer advice and discussion over alternative therapies to promote breastfeeding performance. By acquiring up-to-date knowledge and involving women in decision-making, health professionals may help to promote compliance and success of breastfeeding-related therapies. Further research into the safety and efficacy of herbal galactagogues and ongoing education about CAMs will enable health professionals to be equipped with the knowledge to meet the expectations of the public.

Although none of the questions in the interview guide was designed to address this topic, breastfeeding women's perspectives on the current health care system and the lack of breastfeeding support provided emerged as a common focus of discussion by some participants as they described their experiences before, during and after delivery. A mix of positive and negative feedback were noted from the narrative conversation during the interviews.

Limitations

As the nature and process of recruitment involved recruiting participants from naturopathic clinics initially, and all participants self-volunteering to be interviewed, there is a possibility for some degree of bias in the sample selection. Recruiting participants from naturopathic clinics increases the likelihood of recruiting women with similar positive perspectives and attitudes towards the use of herbal galactagogues. Participants of this study were self-selected and hence are not likely to be a true representative sample of all breastfeeding women in Australia, nor a representation of all breastfeeding users of herbal galactagogues. As with all qualitative studies, a known limitation is the challenge in attempting to generalise findings to the wider population, as at times, the findings may be unique only to the specific participants [34]. Nevertheless, this study has enhanced our understanding of women's perspectives and factors which may influence their choice of therapy whilst breastfeeding.

Conclusions

This qualitative study provides insight into the perspectives and attitudes of breastfeeding women towards the use

of herbal galactagogues. The positive attitudes of herbal galactagogue users should prompt health professionals and researchers to further explore this topic whilst the negative views regarding timing of education on breastfeeding and inconsistency of information should be taken into consideration to improve services for breastfeeding women. Further research into the safety and efficacy of herbal galactagogues, including clinical trials and case reports, are urgently required to provide research-based evidence to inform health professionals and breastfeeding women.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

TFS conducted and analysed the data as part of her PhD degree. TFS, JS and LT were responsible for the design of the study and developed the interview guide. TFS and LH were responsible for data analysis. TFS, LH, JS and LT all contributed to writing of the manuscript. All authors read and approved the final manuscript.

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Appendix J: Publication Submitted

Exploring the role of community pharmacists in promoting safe and effective use of herbal medicines during breastfeeding: breastfeeding women's perspectives

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TFS designed, conducted and analysed the data of the project as part of her PhD degree. LT, JS and LH supervised the project and contributed to the design and analysis of the interview transcripts. All authors read and approved the final manuscript.

This study was approved by Curtin University Human Research Ethics Committee (HR85/2012).

Abstract Objectives

Community pharmacies remain one of the main sources of herbal medicines in the Australian community. Information from pharmacists may affect breastfeeding women's decision and choice of herbal therapy. This study aimed to explore experiences and perspectives of breastfeeding women on community pharmacists' role and whether there is potential for role expansion as well as the facilitators and barriers in meeting their health care related needs in the community pharmacy setting.

Methods

Semi-structured interviews were conducted with breastfeeding women who were using one or more herbal galactagogues while breastfeeding. Interviews were audio-recorded and transcribed verbatim. Transcripts were analysed using qualitative approaches. Extracts and quotes were compared then combined to form themes and subthemes.

Key findings

Twenty breastfeeding women from Western Australia were interviewed between October 2012–April 2013. Views of participants were classified into three major themes: i) facilitators and ii) barriers to an increased role of community pharmacists related to breastfeeding, and iii) implementation of breastfeeding related-services in community pharmacy settings. Overall perspectives of participants were positive about the potential for role expansion of community pharmacists to meet their breastfeeding-related needs. Whilst most participants perceived community pharmacies as convenient sources of trusted information, some recognised barriers to an increased role of pharmacists. Several breastfeeding support services perceived to be useful in community pharmacy settings were identified.

Conclusions

Issues raised by breastfeeding women highlighted areas of pharmacy practice which required improvement and revealed opportunities for expansion of community pharmacists' role to better support women and promote breastfeeding in the community.

Keywords

Community pharmacy; pharmacists; herbal medicines; breastfeeding; women's perspectives

Introduction

Breastfeeding has been shown to contribute to the improvement of nutrition and well-being of infants and mothers, leading to positive health outcomes.[1] Besides offering tailored nourishment to the infants, breastfeeding also plays a role in reducing the risk and incidence of many diseases including otitis media, diabetes mellitus, hypersensitivity reactions and Sudden Infant Death Syndrome.[1-3] In addition to the physiological health advantages, breastfeeding may also contribute to some psychological benefits through promoting the relationships between mothers and their breastfed infants.[4] Based on many published studies over the years, breastfeeding is now widely recommended as the best feeding choice for most mother-infant dyads.[5-9]

The use of complementary and alternative medicines (CAMs) by women during pregnancy and breastfeeding is growing, as is the case with CAMs use amongst the general population.[10-13] A recent Western Australian study reported that 59.9% of 304 survey respondents had used one or more herbal medicine during breastfeeding, which further highlighted the prevalence of CAMs use amongst this specific population group.[13] Taking into consideration the potential safety aspects and impact on breastfeeding performance, caution should be exercised and the use of all medicines or xenobiotics, including CAMs, during breastfeeding should be considered on a case-by-case basis.

Community pharmacies represent one of the major providers of CAMs in Australia.[14] Therefore, community pharmacists are in a unique position to influence the public's use of CAMs as evidenced by the positive consumer satisfaction and expectations from previous Australian as well as international studies.[15-17] Being one of the major providers of CAMs provides opportunity for pharmacists and pharmacy staff to intervene and provide advice about their safe and effective use during breastfeeding.

A 2011 systematic review of consumers' views regarding the provision of health care in pharmacies revealed that community pharmacists were assumed to meet the expectations of the public as having adequate levels of knowledge.[18] A recent Australian study demonstrated the high expectations of the general public towards community pharmacists' knowledge and ability to provide information related to CAMs products.[17] Similarly, information from pharmacists may affect women's experience, decision and choice of therapy whilst breastfeeding. Understanding the perspectives of breastfeeding women, their views and expectations of community pharmacists and whether they believe there could be a bigger role for community pharmacists in CAMs use may lead to an expansion of the current

role of pharmacists, whilst contributing towards positive breastfeeding and infant outcomes. Identifying the facilitators and barriers of breastfeeding women in utilising the expertise of community pharmacists in providing breastfeeding-related health advice and care in a community pharmacy setting will identify areas of pharmacy practice which could be improved or expanded.

Several studies reported the perspectives and attitudes of health professionals as well as breastfeeding women towards the use of medications during breastfeeding.[19-21] Nevertheless, there has been limited research to explore the perspectives of women towards the role of community pharmacists on this topic. This study aimed to explore experiences and perspectives of breastfeeding women on community pharmacists' role and whether there is potential for role expansion as well as the facilitators and barriers in meeting breastfeeding women's related health care needs in the community pharmacy setting.

Methods

This exploratory research was conducted through in-depth semi-structured interviews with breastfeeding women who were using one or more herbal medicines to increase breastfeeding performance. This study was approved by the Curtin University Human Research Ethics Committee in September 2012 (approval number HR85/2012).

Recruitment

Purposeful sampling was used to recruit participants, targeting breastfeeding women who had experience in using herbal medicines to enhance milk supply. The inclusion criteria included women aged 18 years or older who had been breastfeeding in the previous 12 months at the time of interview, and had used one or more herbal medicines during breastfeeding. According to Patton,[22] purposeful sampling method is powerful as it involves selection of information-rich cases which allows in-depth inquiry into the topic. Hence, careful selection of participants with experience using herbal medicines to enhance milk supply was considered appropriate to enable relevant and quality data to be collected, improving reliability and credibility of the findings.

Four different approaches were employed to recruit participants. Firstly, recruitment was done through promoting the study at naturopathic clinics with a focus on breastfeeding and CAMs use. Posters with details of the study were displayed at a health centre that agreed to collaborate in the recruitment process. This health centre was located in a metropolitan area in Western Australia and the clinic staff supported the regulation of Western herbal medicine

through the Therapeutic Goods Administration (TGA) to ensure that products comply with specific quality and safety criteria.

Secondly, the study was promoted to the wider public through a media release prepared by a public relations consultant from Curtin University Corporate Relations and Development Department. The media release was used to promote the study in local health and parenting papers and was also announced via the Curtin FM 100.1 Perth radio station. Contact details of the primary investigator were provided to enable women who wanted to participate in the study to contact the research team.

Thirdly, a snowball sampling technique was adopted and interested participants were provided with additional study information and requested to share this with other breastfeeding women.[22] Unlike other studies where a specific participant type may be identified or recruited from an organisation or setting, the use or purchase of herbal medicines in Australia are not required to be reported nor recorded and can be sold from many retail outlets, hence there was not a specific setting or location to recruit this specific target population. Therefore, the purposeful chain sampling technique fitted the scope of this study.[22, 23]

Fourthly, through the snowballing effect, participants suggested community pharmacies where more participants were likely to be recruited and two community pharmacies were subsequently identified for further recruitment. Both of these community pharmacies had a focus on naturopathy and CAMs and provided a range of breastfeeding-related services. Participants were then recruited from these pharmacies through expression of interest in response to study posters and participant information sheets. The recruitment of participants ceased when the point of saturation was considered achieved.[23, 24]

Design and conduct of interviews

The interviews were conducted on a one-to-one basis, either face-to-face at a place convenient to each participant or via telephone if preferred by the participant. An interview guide was developed with a mix of closed (10) and open-ended (7) questions to gather information about the use of herbal medicines during breastfeeding, and explore the perspectives of breastfeeding women towards the role of pharmacists in meeting their breastfeeding-related health care needs in the community pharmacy setting. The interview guide was piloted through two breastfeeding women. Taking into consideration the variability between participants and at the same time ensuring that the topic of discussion

could be thoroughly covered, the interviewer (TFS) adhered to a sensitive and flexible approach throughout the interview process. As participants were mothers with a young child, all of them were reassured that priority would be given to their infant or child if they needed to be attended to, and interviews were stopped and resumed when convenient for the participant. Qualitative narrative data were collected through recordings of the dialogues between the researcher and the individual participant.

Data analysis

All interviews were audio-recorded and manually transcribed verbatim. Participants were de-identified and codes used in the analysis. For example: the first interviewee was given a code “BW1”. The seven open-ended questions in the interview guide which explored the experiences and perspectives of participants were analysed using thematic analysis.[25] Firstly, contents of the transcriptions were read repeatedly by the primary investigator to attain a thorough understanding of topics that emerged from the interviews. Emerged “ideas” or themes were recorded and supporting quotes documented under each theme category. Different “units of ideas” were then reclassified as subthemes under a specific “collective idea” or theme. These themes were then regrouped under distinctive headings addressing the research questions. To ensure reliability of the process of analysis, project supervisors (LH, LT) reviewed the themes and provided input throughout the data analysis process.

Results

A total of 20 in-depth semi-structured interviews were undertaken with breastfeeding women living in the Perth metropolitan area between October 2012 and April 2013. Saturation of data was reached after 15 interviews but a decision was made to continue until all 20 participants were interviewed, after which the research team was confident that no new themes were emerging. Ten interviews were conducted face-to-face and ten via telephone. Out of the 20 participants, 17 were of Caucasian descent, two of Asian descent and one of Middle-Eastern descent. Interviews took an average of 33.9 minutes (range: 18 - 78 minutes).

Three major themes emerged as the participants described their perspectives. Although their views varied widely, participants perceived community pharmacy in general as a convenient source of information which can be trusted. When asked whether they believed that there was a role for community pharmacists to play in the area of herbal medicines and breastfeeding, common facilitating factors and barriers were identified. Throughout the

interviews, participants identified several breastfeeding support services perceived to be useful and beneficial in the community pharmacy setting. These are summarised in Table 1.

Facilitators to an increased role of pharmacists

Participants identified several facilitating factors which supported the increased role of community pharmacists, including convenience and accessibility, client-pharmacist relationship, staff knowledge and credibility, and cost factors. These facilitators are summarised in Table 2 and explored below. Participant quotes are included to illustrate the concepts.

Convenience and accessibility

Participants highlighted the convenience and accessibility of community pharmacy as a facilitator to expand the role of community pharmacists in supporting breastfeeding, whilst at the same time promoting safe and effective use of medicines, mainly non-prescription medicines including CAMs, during breastfeeding. Participants perceived community pharmacy as an easily accessible source of information and supply of a wide range of products.

In the context of convenience and accessibility, locality emerged as an underlying theme. Community pharmacies are spread out in the Perth metropolitan area and were perceived as “everywhere” and “local” by participants.

“My local chemist is very near my house, it is literally just behind us, I can walk there. I think that is the case for most people as there are so many pharmacies around. You don’t have to make [an] appointment, and you can ask to speak to a pharmacist.” (BW 18)

Participants felt at ease and comfortable to discuss issues relating to breastfeeding with their local trusted community pharmacists.

“... it is just another avenue that new mothers can use. As a new mum, we are so confused and so bombarded with information that we do look for recommendations and if I knew of one that was close to me that is easy for me to get to, I think I would use them the same as how I would use my child health nurses to answer my questions... The fact that they are near and local, they are definitely very easy to access.” (BW 13)

In addition to locality, availability was recognised as a facilitator by some participants. The opening hours and the “no appointments required” common practice of community pharmacies were valued, especially for those who labelled themselves as “busy mums”.

“I know I can go anytime, they are open quite late, and you can get the support and advice when needed because often when you are breastfeeding with the young child it is very difficult to get a doctor’s appointment or another appointment. So it’s not easy having that accessibility.” (BW 9)

Participants labelled community pharmacy as a one-stop destination involved in many aspects of their health, from a source of information, to a source of supply and to monitoring of medical conditions in the community or an “alternative to doctors”. Some had utilised community pharmacies as the source of breastfeeding-related information, source of herbal galactagogue supply and source of advice regarding breastfeeding performance and infants’ health.

“...it is convenient because you can just buy the products or whatever they recommend at the products. It’s just easier to go to one place, especially when you know you can get most of the things from one place when you are so busy with baby and other stuff.” (BW 14)

Participants experienced community pharmacy as a provider of a vast range of health-related products and facilities. Pharmacists were expected to play the role of health and medicine-related information provider and product supplier. There was an expectation that community pharmacists should set aside their personal opinions, follow ethical obligations and have an adequate knowledge of all products available at the pharmacy.

“I would ask more questions at the place where I get my products. For example, if I go to the chemist and get my fenugreek, I would ask the pharmacist or the staff questions about the product, because I would assume they would know best because they have it in their store. I would trust the information because they are trained in that area and from my past experience, they have always been quite helpful.” (BW 12)

Client-pharmacist relationship

Participants who managed to build a trusting relationship with their local community pharmacists were more likely to perceive community pharmacy as a valuable resource.

“I just notice that my local chemist is very good with all the over-the-counter medicines, asking about what I am taking and you know, any contraindications with other medicines and things...” (BW 10)

Staff knowledge and credibility

Information attained from pharmacists was seen as trust-worthy and credible. As some participants were concerned about the reliability of information obtained from non-reputable sources such as the internet, participants appreciated the value of information given by the pharmacists.

“I think getting information or recommendation from a pharmacist would be more reputable than your own internet search, because you don’t know how reliable that website is, it may be leading you down the wrong path, so I think a pharmacist might have the advantage of that part, plus they know what they are talking about, because they are trained in that field.”
(BW 13)

Cost factors

Cost factors were quoted as a reason for the role of community pharmacists to be expanded. Visits to a doctor or other health professional(s) were seen as costly to some participants, while many believed that similar information could be obtained from a pharmacist without a charge.

“...it would be less expensive this way, knowing that starting a family would cost some money, pharmacists are there all the time, you can just ask and get some answers you trust.”
(BW 16)

Barriers to an increased role of community pharmacists

A number of potential barriers were identified, which included the lack of advertisement, publicity and promotions, inconsistent approach, breastfeeding-related inexperience and low awareness, pharmacists’ pre-conceived perception towards herbal medicines, overlap of role with other health professionals, and privacy issues, as summarised in Table 3 with selected participant quotes.

Although many community pharmacies may be involved in expanding their services to the public, the lack of advertisement, publicity and promotions were identified by participants as a barrier. Participants commented that many women were unaware of the services currently available in community pharmacies. As the conventional scope of a community pharmacy was predominantly dispensing of prescription medicines and the supply of medicinal products, in the absence of adequate publicity, breastfeeding women were not aware of and utilising these other services. The lack of a consistent approach along with some enquiries handled by pharmacy assistants was seen as a hindrance to building a trusting relationship with the pharmacist. A lack of some pharmacists' personal breastfeeding-related experience, knowledge and awareness was also identified as prohibitive in breastfeeding women seeking and accepting advice.

Some participants appeared to believe that pharmacists may have pre-conceived negative perceptions towards herbal medicines and alternative therapies. Participants who believed that there was a limited role for pharmacists to be involved in natural or herbal remedies perceived pharmacists as "over-cautious" and fearful to recommend herbal medicines with little or no scientific evidence to support their efficacy and safety during breastfeeding, which was seen by regular users of herbal remedies as a lack of willingness to supply and inadequate knowledge in the area of CAMs.

Some further expressed their concerns with regards to privacy when discussing breastfeeding-related issues in the pharmacy. The layout of some pharmacies was seen as not facilitating privacy. Despite the availability of a vast range of products and brands across pharmacies, some participants expressed their frustrations in terms of the availability of herbal galactagogues specifically. Despite the lack of confidence in some, many participants still believed that it would be promising and favourable if community pharmacists were better educated in the area of herbal medicines and breastfeeding.

Discussion

This study highlighted the role of community pharmacists through provision of information and advice on the efficacy and safety aspects of CAMs use and other alternative therapies during breastfeeding. Besides information on conventional medicines and CAMs, breastfeeding women also expect pharmacists to have a basic knowledge of breastfeeding and the various issues related to breastfeeding.

The interviews provided an understanding of women who are regular users of herbal medicines and their perspectives of community pharmacists as suppliers of CAMs in Australia. Convenience and accessibility, client-pharmacist relationship, knowledge and credibility of pharmacists, as well as cost factors all represent important factors when women decide the source of breastfeeding advice. Several barriers to expanding community pharmacists' role were identified by participants that, once addressed, could expand pharmacy practice into breastfeeding services.

This study has limitations. The method and process of recruitment may have resulted in selection bias. Participants were self-selected throughout expression of interest and hence may not represent all breastfeeding women who were regular users of herbal medicines. Furthermore, all participants of this study were users of herbal galactagogues, and may not represent users of other herbal products. However, this method was deemed most appropriate to identify or contact potential participants. The interviewer (TFS) is a pharmacist which may have influenced the interviews and affected the analysis. In an attempt to counterbalance the potential bias, TFS had regular meetings throughout the interview period with the third and last authors, both of whom have different disciplinary backgrounds and have no affiliations with any community pharmacies. Data were also analysed and cross-checked with the other authors to improve validity of the findings.[26, 27]

Breastfeeding women regarded pharmacists as a trusted health professional, an expert in medicines, and the first port of call for questions relating to medicines use during breastfeeding. Although pharmacists were not reported to be actively recommending the use of herbal galactagogues during breastfeeding, being one of the major suppliers of CAMs, women expect pharmacists to play a substantial role in providing advice and recommendations regarding CAMs use. This finding was in accordance with previous studies which explored consumers' views on CAMs and their expectations of pharmacists.[17, 18]

The characteristics and values of both the community pharmacies and the staff (pharmacists and assistants) are factors which influence breastfeeding women to utilise their services. Women in the study appreciated the convenience and accessibility of community pharmacies as facilitators to obtain advice in a timely manner. This aspect, in contrast to the appointment-based services provided by most other health professionals, enhanced the role of community pharmacies in providing health care services to breastfeeding women. Women perceived pharmacies as a convenient one-stop health destination, to obtain health and medicine-related advice, purchase products, and receive monitoring services as well as an

alternative to their local general practitioners. This finding demonstrated a switch from the traditional 'shopkeeper' image of pharmacists to the 'health care provider' image.[28] Besides contributing to the expansion of pharmacists' role in the community, this reduces the burden on the health care system and potentially frees up general practitioners for other consultations or reduces appointment waiting times.

As community pharmacies are local this facilitates the development of trusting relationships between pharmacists and breastfeeding women and their family members. As observed from this study, client- pharmacists' relationships play an important role in allowing breastfeeding women to discuss breastfeeding issues freely and comfortably. Building rapport between client and pharmacist is indeed fundamental in many aspects of health care promotion in the community pharmacy setting. This is particularly the case with breastfeeding which could be seen as a very personal issue.

In many previous studies, pharmacists' knowledge and credibility were identified as one of the facilitating factors driving consumers or clients to community pharmacies.[18, 19, 28-30] In this study, the knowledge and credibility of both pharmacists and pharmacy staff were cited as facilitators. However, the context of discussion was often more focused on pharmacists' knowledge on general health conditions and the use of conventional medicines and less on the use of CAMs including herbal galactagogues.

Some participants expressed their desire for pharmacists to be more 'open' to discuss various issues related to breastfeeding and to offer more information on CAMs and alternative therapies during breastfeeding. Consistent with the literature, the women expected pharmacists to be knowledgeable of CAMs.[17] They also expressed a need to have a greater level of engagement and interaction with pharmacists.[17] Taking into consideration the scope of practice and skills of pharmacists, it is therefore vital that pharmacists are clear about their role and be able to identify the need to refer breastfeeding women to other health professionals, for example child health nurses or lactation consultants for further breastfeeding-related advice when necessary. This would also help foster inter-professional collaboration and relationships.

The perceived lack of a consistent approach at pharmacies in the provision of CAMs was considered a hindrance to building a trusting relationship between the breastfeeding woman and the pharmacist. Time constraints were identified as barrier to appropriate pharmacists' advice. In a study conducted by Jones and Brown,[31] only 11% of the 820 surveyed breastfeeding women who had purchased over-the-counter medications from pharmacies

were asked their breastfeeding status or whether they were breastfeeding by the pharmacists or pharmacy staff. Hussainy and Dermele[19] further commented that this issue should be addressed to enable accurate information and advice be provided to breastfeeding women. All pharmacists and pharmacy staff have an ethical obligation to provide relevant as well as accurate advice to clients, including breastfeeding women. This may be facilitated by staff enquiring, as part of the standard process, of all women of childbearing age whether they are pregnant or breastfeeding.

Taking into consideration the potential sensitivity issues related to breastfeeding, the lack of pharmacists' personal breastfeeding-related experience was identified as a barrier. Nevertheless, the gender of pharmacists was not one of the issues raised by the participants. Need for improved privacy was also identified as a barrier which could be overcome by staff having a basic knowledge about breastfeeding in order to communicate sensitively with breastfeeding women. As a primary care provider, effective communication is indeed essential to enable holistic care and appreciate and recognise breastfeeding women's needs.[32]

Some women believed that pharmacists may have a pre-conceived negative perception towards herbal medicines and alternative therapies, and expressed a need for pharmacists to consider their use during breastfeeding. On the other hand, some saw the supply of herbal medicines and breastfeeding advice as outside the scope of pharmacy practice, causing a barrier to obtain pharmacists' advice. However, a study conducted by Bushett et al[33] in 2010 which investigated rural Australian community pharmacists' perspectives towards CAMs found that despite the varied views on CAMs, most pharmacists acknowledged the popularity of these alternative medicines amongst consumers and the important role of pharmacists in promoting the safe and effective use of these medicines.

One of the challenges to providing advice to consumers regarding the use of CAMs is the lack of awareness or access to high quality resources and information.[33, 34] To address this issue, further studies are warranted to explore pharmacists' knowledge of and perspectives regarding the resources and information available to them. Further studies to explore community pharmacists' opinions will enhance understanding and identify initiatives or strategies required to address this gap, for example continuous professional development targeted towards breastfeeding and CAMs.

From the perspectives of breastfeeding women, the findings of this study have enhanced our understanding of the current and potential roles of pharmacists and pharmacy staff. While

many studies have investigated the role of other health professionals in promoting breastfeeding, few studies and initiatives have examined the role of community pharmacists.[19, 35-37] Taking into account the facilitators and the views of breastfeeding women, this study has identified opportunities to enhance community pharmacists' involvement.

Conclusion

The current study highlighted an opportunity for community pharmacists to expand their role through the provision of breastfeeding specific advice and services. Unlike some conventional medicines, herbal galactagogues and other CAMs are readily available over-the-counter. Pharmacists and staff should therefore enquire women if they are breastfeeding prior to providing advice or supply products to ensure appropriate recommendations can be provided. More research into CAMs use and breastfeeding will allow health professionals like pharmacists to provide evidence-based advice to their clients.

The results from this study have identified a need for community pharmacy staff to provide breastfeeding related services and advice and provides an opportunity for community pharmacy to expand the scope of practice.

Declarations

Conflict of interest

The authors declare that they have no conflicts of interest to disclose.

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Table 1 Major themes and subthemes

Main theme	Subthemes
1. Facilitators	Convenience and accessibility Client-pharmacist relationship Staff knowledge and credibility Cost factors
2. Barriers	Lack of publicity and public awareness Inconsistent approach Breastfeeding -related inexperience and low awareness Pharmacists' pre-conceived perception towards herbal medicines Overlap of role with other health professionals Privacy issues and pharmacy layout
3. Breastfeeding-related services	Baby weigh-in service or station Lactation booth Distribution of pamphlets/ educational materials Information sessions in-store One-on-one counselling service in consultation room

Table 2 Facilitators to an increased role of community pharmacists

Subthemes	Supporting Quotes
Convenience and accessibility	<p data-bbox="676 342 1382 499"><i>“I didn’t really remember anything during the first week. So doctors and nurses could have told me things but I wouldn’t remember... and this is when pharmacy can help because you don’t need to go to a doctor to ask a question when you have settled down at home.” (BW 2)</i></p> <p data-bbox="676 533 1382 689"><i>“It would be fantastic if you could go to one place for all the information rather than having to go here and there, you know, one place for the medical information, and another place for the herbal information. It will be like a one-stop for busy mums to get all the information they needed.” (BW 5)</i></p>
Client-pharmacist relationship	<p data-bbox="676 723 1382 880"><i>“... because you get to know your little pharmacy, like I mostly go to one pharmacy down in XXXXX and they know me now. When I go in, they ask how is the baby going... so if they have the information, that would be much easier to just talk to them.” (BW 5)</i></p> <p data-bbox="676 913 1382 981"><i>“...they [breastfeeding women] are used to the place [community pharmacy].” (BW 8)</i></p>
Staff knowledge and credibility	<p data-bbox="676 1014 1382 1081"><i>“We or the public would generally trust community pharmacists as good source of information.” (BW 1)</i></p> <p data-bbox="676 1115 1382 1328"><i>“I suppose pharmacists are very trusted in the community to a lot of people. So if someone can go to a pharmacy, and they say we do recommend you can use these herbs to increase supply, people will be more incline to believe and try it. Whereas if it is just from word of mouth, or if you see something on TV or hear about it, there’s not actually any credibility behind the claim perhaps.” (BW 7)</i></p> <p data-bbox="676 1361 1382 1451"><i>“It would be so much easier for new mums to just walk in [to a community pharmacy] and get some reliable answers to their queries.” (BW 12)</i></p>
Cost factors	<p data-bbox="676 1485 1382 1608"><i>“It’ll be great to have someone with medical knowledge, not having to go to the doctor and spend eighty-dollars just for a question and not having to rely on the internet for basic questions to make sure I get the right information.” (BW 2)</i></p>

Table 3 Barriers to an increased role of community pharmacists

Subthemes	Supporting Quotes
Lack of publicity and public awareness	<i>"It needs to be more advertised, or maybe mothers are told while at the hospital stay. A lot of women actually don't know about the services available." (BW 2)</i>
Inconsistent approach	<i>"Depends if I am shopping with the kids... if I am, they will ask [if I am breastfeeding], if not, they won't. Most never ask me if I don't have kids with me. Just the assumption that someone is not with a child, doesn't mean they are not breastfeeding. You look okay, not messy, just doing shopping in nice clothes, they obviously made the assumption that you are not breastfeeding. Without kids, very rarely they ask." (BW 3)</i>
Breastfeeding -related inexperience and low awareness	<p data-bbox="673 685 1383 743"><i>"I am not sure how much they know or whether they have experience with breastfeeding and all..." (BW 18)</i></p> <p data-bbox="673 775 1383 913"><i>"I think community pharmacists are accessible, except during busy times, if community pharmacists are better educated and have better awareness in this area or focus a lot more about safety and efficacy of medicines including herbal options during breastfeeding, that will be helpful." (BW 3)</i></p>
Pharmacists' pre-conceived perception towards herbal medicines	<p data-bbox="673 945 1383 1025"><i>"I know that there are a few people out there who just don't believe in natural medicines. I know my original GP I went to said that it was a load of crap, don't bother trying it." (BW 15)</i></p> <p data-bbox="673 1057 1383 1236"><i>"I think if all health professionals, not just community pharmacists, if they can be more aware of and be more open to discussion about the use of alternative therapies during breastfeeding, this would definitely help breastfeeding women. I am saying this not because I am being an advocate, it's about giving women the choice and option that they are comfortable with..." (BW 18)</i></p>
Overlap of role with other health professionals	<i>"[If] it was about herbal stuff, maybe the naturopaths and friends who are naturopaths... but if it was to do with Motilium® or medical or drugs, I will be talking to a lactation consultant, a GP or district nurse or pharmacists." (BW 4)</i>
Privacy issues and pharmacy layout	<i>"When I went to the pharmacy, there was only one bottle of fenugreek, they were nearly out of it, it should be stocked, and there should be a breastfeeding section..." (BW 6)</i>

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Appendix K: Stage 2 Ethics Approval



Memorandum

To	Associate Professor Lisa BG Tee, School of Pharmacy
From	Professor Stephan Millett, Chair, Human Research Ethics Committee
Subject	Protocol Approval HR 85/2012
Date	6 September 2012
Copy	Miss Tin Fei SIM, School of Pharmacy

Office of Research and Development
Human Research Ethics Committee

TELEPHONE 9266 2784

FACSIMILE 9266 3793

EMAIL hrec@curtin.edu.au

Thank you for your application (4297) submitted to the Human Research Ethics Committee (HREC) for the project titled "*The use of herbal medicines in lactation: interview-based qualitative study to document use, safety and efficacy of herbal galactagogues during breastfeeding*". Your application has been reviewed by the HREC and is **approved**.

- You have ethics clearance to undertake the research as stated in your proposal.
- The approval number for your project is **HR 85/2012**. Please quote this number in any future correspondence.
- Approval of this project is for a period of twelve months **04-09-2012 to 04-09-2013**. To renew this approval a completed Form B (attached) must be submitted before the expiry date **04-09-2013**.
- Your project has the following special conditions: NIL

Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **FORM B** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development:

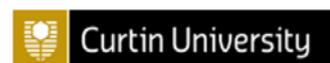
When the project has finished, or

- If at any time during the twelve months changes/amendments occur, or
- If a serious or unexpected adverse event occurs, or
- 14 days prior to the expiry date if renewal is required.
- An application for renewal may be made with a Form B three years running, after which a new application form (Form A), providing comprehensive details, must be submitted.

Yours sincerely,

Professor Stephan Millett
Chair Human Research Ethics Committee

Appendix L: Stage 2 Participant Information Sheet



School of Pharmacy, Curtin University

Participant Information Sheet for project entitled:

The Use of Herbal Medicines in Lactation: Interview-based Qualitative Study to Document Use, Safety and Efficacy of Herbal Galactagogues during Breastfeeding

Breastfeeding is widely recommended as the best feeding choice for most infants and their mothers. Despite all efforts to promote breastfeeding, some women may still experience difficulty breastfeeding with perceived low or insufficient milk supply being the most commonly reported reason for unsuccessful breastfeeding and early weaning. Many herbal medicines and galactagogues have gained their reputation and recognition by the public and health professionals as alternative approaches to enhance breastfeeding performance. Taking into consideration that herbal galactagogues are available in Australia in various different dosage forms for administration and the fact that choice of dosage forms may directly affect their safety and efficacy, efforts should be made to investigate and document the dosage forms and directions that breastfeeding women in Australia have followed. Despite the increasing popularity, currently very little is known about the use, safety and efficacy of these medicines during breastfeeding.

Purpose of Research

We aim to investigate and document the use, safety and efficacy of herbal galactagogues during breastfeeding based on participants' personal experience and observations including their perceptions and opinions, observed efficacy, adverse effects experienced and dosages administered.

We are seeking for women who are 18 years or older, currently breastfeeding or have breastfed in the past 12 months, have used one or more herbal galactagogues during breastfeeding to participate in a semi-structured interview to share their experiences. This interview will take approximately 20 minutes.

Consent to Participate and Confidentiality

This survey is entirely voluntary and you may withdraw at any time. This survey will most likely not benefit you immediately, but the information gained from this study may help us to understand more on the efficacy and safety on the use of herbal medicines in breastfeeding mothers and to their infants.

Only staff and students who are directly involved in this study will have access to the data collected. If you sign the consent form I will assume that you agree to participate and have agreed to use the data in this research. Data collected from this study may be published; however, any information which may potentially identify you will not be used in any publication.

Further Information

Further information on the study can be obtained from Miss Tin Fei Sim at the Curtin University (phone: 9266 1875 or mobile: 0401 649 800) or supervisor A/Prof Lisa Tee (phone: 9266 2526). This study has been approved by Curtin University Human Research Ethics Committee (Approval number: HR85/2012). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained either by writing to the Curtin University HREC, C/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth WA 6845, or phone 08-9266 2784 or email hrec@curtin.edu.au.

Thank you sincerely for your involvement in this research.

Your participation is greatly appreciated.

Appendix M: Stage 2 Consent Form



CONSENT FORM

School of Pharmacy, Curtin University

Project Title:

The Use of Herbal Medicines in Lactation: Interview-based Qualitative Study to Document Use, Safety and Efficacy of Herbal Galactagogues during Breastfeeding

I have been given a Participant Information Sheet.

I have read and understood the information given to me. I understand the purpose and procedures of the study.

I have been given opportunity to ask questions and any questions I have asked have been answered to my satisfaction.

I understand that my participation is voluntary. I understand that I may withdraw at any stage of the study without prejudice and withdrawal will not interfere with routine care.

I understand that all data and information will be securely stored for 5 years before being destroyed.

I agree that research data gathered from the results of this study may be published; however any information which may potentially identify me will not be used in any published materials.

I agree to participate in the study outlined to me.

Name of participant:

Dated day of20.....

SignatureContact (Tel/email):.....

I,have explained the above to the

(Investigator's full name)

signatory who stated that she understood the same.

Signature:

Appendix N: Stage 2 Poster for Recruitment

The Use of Herbal Medicines in Lactation:
Clinical Implication in Lactating Women and Breastfed Infants



Interview-based Qualitative Study to Document Use, Efficacy and Safety of Herbal Galactagogues during Breastfeeding

PARTICIPANTS NEEDED

**Have you used a herbal galactagogue to increase milk supply during breastfeeding?
If yes, we would like to hear from you!**

What is the purpose of this study?

To investigate and document the use, efficacy and safety of herbal galactagogues during breastfeeding based on participants' personal experience and observations including their perceptions and opinions, observed efficacy, adverse effects experienced and dosages administered.

Who can participate?

To be eligible for this study, you need to be:

- 18 years or older
- Currently breastfeeding or have breastfed in the past 12 months
- Have used one or more herbal galactagogues during breastfeeding

What does it involve?

This study involves an interview which will take approximately 20 minutes.

Interested?

Please contact Ms Fei Sim (Phone: 0401 649 800 or Email: t.sim@curtin.edu.au)

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number: HR85/2012).

Appendix O: Stage 2 Interview Guide



(Part 2)

The Use of Herbal Medicines in Lactation: Interview-based Qualitative Study to Document Use, Safety and Efficacy of Herbal Galactagogues during Breastfeeding

Instrument 1 – Questions to Guide the Interview

Aims and Objectives:

Document use, safety and efficacy of herbal galactagogues during breastfeeding based on participants' personal experience and observations

Investigate the types of herbal galactagogues used, the dosage forms and administration (ie tabs/caps, tea, seed etc), dosages or amount/frequency of consumption, period and duration of administration since immediate post-partum

Explore reasons for use and who recommended the use

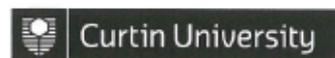
Determine their perception or opinions regarding safety and efficacy of herbal galactagogues, whether it worked or if they have experienced any side effects themselves or noticed any adverse events or changes in behaviour in their breastfed infants, based on their personal experience with the herbal galactagogue(s)

Provide direction to guide future clinical research to confirm safety and efficacy of commonly used herbal galactagogues.

1. Which herbal galactagogue(s) have you used during breastfeeding?
2. Can you tell me why you have used/are using a herbal galactagogue?
 - a. Can you share your experiences in this area and tell me more about that? (for investigator's note: This question is to further explore reasons for use - for example whether it is due to perceived or diagnosed insufficient milk supply, tradition etc etc)
3. Can you tell me who has recommended the use?
4. How did you or have you been administering this herbal galactagogue (for example taking commercially available products in capsules or tablets formulation, in tea, or raw material)?
5. At what dosages and directions have you taken them? (or if taking tea/seed/raw materials etc – how much do you take?)
6. How often do you take them?
7. When have you started taking the herbal galactagogues (how many days/weeks since post- partum)?
8. How long did you or have you been taking them?
9. Have you found this herbal galactagogue effective in increasing breastmilk production or enhancing breastfeeding performance?
 - a. If yes, how long after the first administration of this herb did you find that it started working?
 - b. Can you give me an idea of how much more it has increased your milk supply (e.g. number of feeds per day, duration of each feeding session, or volume of milk if expressed and measured, infant's perceived satisfaction and behaviour?)
 - c. Have you continued or discontinued using this herb after it started working?
10. Have you experienced any side effects both in yourself or noticed in your breastfed infant? If yes, can you tell me more about that?
11. Can you tell me more about your experience and opinion on this herbal galactagogue?
12. What do you think or what is your perception on the use of herbal medicines in general during breastfeeding?
13. Can you comment on the available resources available to you in Australia as a breastfeeding woman in terms of the safety and efficacy of using herbal medicines during breastfeeding?
 - a. Where have you obtained your herbal medicines or products?
 - b. Where have you or would you seek information concerning the use of herbal medicines during breastfeeding? Do you think that there is a role for community pharmacists to play to this area?
 - c. Do you agree that currently there is a lack of resources available to you regarding the use of herbal medicines during breastfeeding?
 - d. Do you think that using herbal medicines is safer than using conventional/prescribed drugs during breastfeeding?
 - e. In the past, have you refused or avoided any drug treatments during breastfeeding due to concerns regarding safety of your breastfed infant(s) and/or breastfeeding performance?

Do you have any other comments on the use of herbal medicines during breastfeeding? What would help? What kind of information do you think would help you in decision-making?

Appendix P: Stage 3 Ethics Approval



Memorandum

To	Tin Fei Sim, School of Pharmacy
From	Alison Smith, R&D Coordinator, School of Pharmacy
Subject	Protocol Approval Form B PH-24-12
Date	18 January 2013
Copy	Dr Lisa Tee & Laetitia Hattingh

Faculty of Health Sciences

School of Pharmacy

TELEPHONE 9266 7418
FACSIMILE 9266 3793
EMAIL a.j.smith@curtin.edu.au

Thank you for your "Form B Progress Report of Research with Low Risk (Ethical Requirements)" for the project titled "How confident are community pharmacists in advising patients on the use of medications during breastfeeding using currently available resources? A survey of health professionals' perspectives in Western Australia". On behalf of the Human Research Ethics Committee I am authorised to inform you that the project is approved.

No changes are required to your application however the reviewer queries the relevance of Question 2 to the interview, stating "The research topic relates to non-prescription medicines in breastfeeding, whereas Q2 covers pharmacists' general confidence advising on breastfeeding issues. It may be required to set the scene, but it is not directly related to the research objectives."

If at any time during the project any changes occur, or if a serious or unexpected adverse event occurs, please advise me immediately.

Sincerely,

Alison Smith
Research & Development Support Coordinator
School of Pharmacy

Please Note: The following standard statement must be included in the information sheet to participants: *This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number PH-24-12). If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or hrec@curtin.edu.au*

CRICOS Provider Code 00301J

Appendix Q: Stage 3 Interview Guide



Interview Guide: The role of community pharmacists in supporting safe and effective use of non-prescription medicines during breastfeeding and promoting breastfeeding in the community: The pharmacist's perspective

Section A: Details and experience of pharmacist

1. What is your gender and age?
2. Were you trained to practise as a pharmacist in Australia?
3. Do you have any post-graduate qualifications? If yes, what qualifications?
4. On average, how many hours do you work per week in the community setting?
5. How many years have you been practising as a pharmacist in the community?
6. In which year did you first obtain your registration to practise as a pharmacist?
7. How would you consider your current role in the pharmacy?
Prompt: Dispensary pharmacist, patient care-focused, managerial role etc...
8. Do you have personal experience with breastfeeding (yourself or your partner or close family and friends)? If yes (yourself or partner), how many children?

Section B: Principal place of practice

1. What is the postcode/suburb of area of practice?
2. Is this pharmacy an independent or a banner pharmacy? (*Note: banner pharmacy may be independently owned but operate under same marketing banner*)
3. How would you classify this pharmacy? *Prompt: Discount type, volume and sales-focused, professional services-driven, a mix of both etc...*
4. Do you consider your work place as located in an area serving high proportion of young families?
5. Does your pharmacy provide breastfeeding-support services? If yes, what kind? Can you describe what is involved and how popular are these services at your pharmacy?
6. Does your pharmacy employ/ have a clinic child health nurse? If yes, how often?
7. Does your pharmacy employ/ have a lactation consultant? If yes, how often?
8. Does your pharmacy have a quiet area suitable for providing private counselling to breastfeeding women?

Section C: Identifying needs

1. How often do you get enquiries (including face-to-face and telephone calls) asking for your advice on the use of a medicines (including complementary and herbal medicines) during breastfeeding?
 - a) On a daily basis – frequency?
 - b) On a weekly basis – frequency?
 - c) On a monthly basis – frequency?
2. What proportion of your enquiries relate to:
 - a) Prescribed medications (S4, S8)
 - b) OTC medications (S2, S3 and other non-scheduled conventional medicines)
 - c) Complementary and alternative medicines including herbal medicines and supplements
3. How often are these enquiries answered/ handled by the pharmacy assistants? Please give a percentage to indicate the frequency.
4. What medicines or products have been most commonly requested by breastfeeding women from your personal work experience?
5. What kind of information has been most commonly asked by breastfeeding women or their family members? Can you give me an example?
6. Can you describe a case where you had to provide advice to a breastfeeding woman? What was the enquiry? What was the approach and process you followed in order to provide the advice? What was the recommendation and outcome?
7. From one of our previous studies which involved surveying breastfeeding women in Western Australia, we found that approximately 60% of the breastfeeding women had used one or more herbal preparations during breastfeeding. Although the majority of users were recommended to use herbal medicines by their family and friends, about half of these women had purchased their herbal products from a pharmacy. What is your view on this research finding?
8. Results have also indicated that breastfeeding women are most likely to seek information and advice regarding use of herbal medicines during breastfeeding from their pharmacists and doctors, via internet, family and friends, with 48.6% indicating that pharmacists are the main source of information. What is your view on this research finding?

2. Do you think that there is a role community pharmacists can play in promoting breastfeeding and supporting the safe and effective use of medicines during breastfeeding? Can you explain further? What kind of role?
3. How do you feel about pharmacists providing advice and support for women regarding issues and information about breast pumps and other breastfeeding-related products or equipment, how often should an infant be fed, issues with difficulty latching or insufficient milk supply etc?
4. What do you think are the barriers/challenges of community pharmacists in promoting breastfeeding and providing professional advice to breastfeeding women regarding the use of non-prescription and OTC medicines in a community pharmacy health-care setting?
(*Prompt: Lack of evidence-based information/resources, safety concerns, time constraints, lack of confidence, lack of knowledge in this area, privacy issues – inappropriate pharmacy layout, no direct financial compensation, lack of needs due to demographics*)
5. What do you think are the facilitators?
(*Prompt: Convenience - pharmacy is local, easily accessible by breastfeeding women and their family, trust – pharmacist-client relationship, expanding role of the profession, promoting better health in the community by encouraging breastfeeding, facilitate complementary selling – increasing sales and business for the pharmacy, promoting image of pharmacy in the community*)
6. Some breastfeeding women who have used one or more herbs to support breastfeeding have commented that they would prefer if their community pharmacists be more “open” to discuss issues relating to breastfeeding and use of herbal or complementary products during breastfeeding. What is your view on this research finding?

Section F: Knowledge

1. The following questions relate to self-awareness of knowledge level. Please choose your responses from “*Strongly Agree – Agree – Neither agree nor disagree – Disagree – Strongly Disagree*”:
 - a) I am confident in discussing the safety and efficacy of non-prescription medicines use with breastfeeding women;
 - b) I am confident in recommending non-prescription medicines to breastfeeding women;
 - c) I feel comfortable in discussing any aspects and issues related to breastfeeding;
 - d) I understand how medications and nutrients are transferred into the breast milk;
 - e) I am aware of the factors determining infants’ exposure to medicines in the breast milk;
 - f) I know how to advise women who require to use medicines during breastfeeding on how to minimise the transfer of medicines to their infants;

2. Are you aware of the Australian National Breastfeeding Strategy 2010-2015?
3. In the above strategy, pharmacists are listed as one of the breastfeeding support staff, in addition to doctors, midwives, nurses, lactation consultants, voluntary counsellors and Aboriginal Health Workers and support workers. What is your view on this? What do you think is the community pharmacists' role in promoting and supporting breastfeeding in the community?

Section G: Implementation of Strategies

1. What do you think could be done to enhance community pharmacists' involvement in these national health strategies in order to benefit breastfeeding women and their breastfed-infants?
2. What do you think can be done to improve/promote practice of safe and effective use of non-prescription medicines during breastfeeding?
3. From our previous study, women suggested several strategies or services to be implemented in community pharmacies. These included baby weigh-in service/ station and lactation booth in pharmacy, breastfeeding information sessions in-store with lactation consultants/ nurses, pharmacy to liaise with the Australian Breastfeeding Association (ABA) to provide and distribute pamphlets/educational materials in the pharmacy, one-on-one counselling service in a specified consultation room/corner of the pharmacy. What is your view on these?

Section H: Continuing Professional Education (CPE)

1. Do you think that there should be Continuing Education (CE) modules for pharmacist on various aspects of breastfeeding and the use of medicines during breastfeeding?
2. What kind of CE information or topics do you think will help you to increase your confidence level when dealing with breastfeeding women regarding various aspects of breastfeeding and the use of medicines? Please give examples. (*Prompt: how to look for evidence-based information, how medications are transferred into breast milk and how to minimise the transfer, what are the factors involved in determining the exposure of infants to medicines in the breast milk, signs of a healthy breastfed infant, signs of mastitis or insufficient breast milk supply, conventional and alternative methods to increase milk supply etc.*)
3. What do you think of the idea of a registered pharmacist specialising in women and newborn's health?
4. What do you think of the idea of a registered pharmacist obtaining postgraduate qualifications to be an International Board Certified Lactation Consultant?

Appendix R: Stage 3 Participant Information Sheet



School of Pharmacy, Curtin University

Participant Information Sheet for project entitled:

The role of community pharmacists in promoting safe and effective use of non-prescription medicines during breastfeeding: The pharmacists' perspective

Although there are several textbooks and numerous studies on the safety of medications in breastfeeding, many of these references have inconclusive data on a number of medications. This often places the advising health care professional and the patient in a challenging situation as they base their decision to use or not use the medication on the information available to them at the time. Results from a previous study have shown that breastfeeding women are most likely to seek information and advice regarding use of herbal medicines (classified as non-prescription medicines) during breastfeeding from their pharmacists and doctors. Health professionals have an ethical obligation to continuously improve their professional knowledge and skills to ensure optimum health outcomes of patients. Hence, this research examines whether there is sufficient evidence and reliable information resources available to pharmacists, how confident are community pharmacists in giving advice on the use of non-prescription medicines during breastfeeding, and their experiences, views and perceptions on their role in promoting safe and effective use of non-prescription medicines during breastfeeding.

Purpose of Research

We aim to examine the role of community pharmacists in supplying, recommending and giving advice to breastfeeding women regarding the use of non-prescription medicines during breastfeeding, investigate the factors facilitating or inhibiting the provision of high-quality professional advice to breastfeeding women in a community pharmacy health-care setting and explore the perspectives of community pharmacists.

We are seeking community pharmacists to participate in a semi-structured interview to share their views and experiences. This interview will take approximately 20 minutes.

Consent to Participate and Confidentiality

This study is entirely voluntary and you may withdraw at any time. This study will most likely not benefit you immediately, but the information gained from this study may help us to further explore the potential role of community pharmacists and how the profession can play a role in promoting the health of breastfeeding women and their infants. Only staff and students who are directly involved in this study will have access to the data collected. If you sign the consent form I will assume that you agree to participate and have agreed to use the data in this research. Data collected from this study may be published; however, any information which may potentially identify you will not be used in any publication.

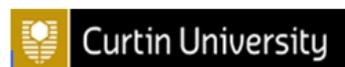
Further Information

Further information on the study can be obtained from Miss Tin Fei Sim at the Curtin University (mobile: 0401 649 800) or supervisor Dr Laetitia Hattingh (phone: 9266 7376). This study has been approved by Curtin University Human Research Ethics Committee (Approval number: PH-24-12). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained either by writing to the Curtin University HREC, C/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth WA 6845, or phone 08-9266 2784 or email hrec@curtin.edu.au.

Thank you sincerely for your involvement in this research.

Your participation is greatly appreciated.

Appendix S: Stage 3 Consent Form



CONSENT FORM

School of Pharmacy, Curtin University

Project Title:

The role of community pharmacists in promoting safe and effective use of non-prescription medicines during breastfeeding: The pharmacists' perspective

I have been given a Participant Information Sheet.

I have read and understood the information given to me. I understand the purpose and procedures of the study.

I have been given opportunity to ask questions and any questions I have asked have been answered to my satisfaction.

I understand that my participation is voluntary. I understand that I may withdraw at any stage of the study without prejudice and withdrawal will not interfere with routine care.

I agree for this interview to be audio-recorded.

I understand that all data and information will be securely stored for 5 years before being destroyed.

I agree that research data gathered from the results of this study may be published; however any information which may potentially identify me will not be used in any published materials.

I agree to participate in the study outlined to me.

Name of participant:

Dated day of20.....

Signature Contact (Tel/email):

I, have explained the above to the

(Investigator's full name)

signatory who stated that she understood the same.

Signature: