Curtin Medical School

Evaluation of an Obstetric Medicines Information Service: Analysis of Medicines Enquiries and User Satisfaction

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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 acknowledgment has been made.

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

The research presented and reported in this thesis was conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007) – updated March 2014.

The proposed research study received human research ethics approval from the Curtin University Human Research Ethics Committee (EC00262), Approval Number HR84/2016.

Abstract

Background: Medicines use in pregnancy and breastfeeding is common, with 90% of Australian women taking at least one medicine whilst pregnant or breastfeeding. Medicines information centres specialising in obstetric care aim to provide evidence-based, up-to-date information to health professionals and the public regarding the safe use of medicines in pregnancy and breastfeeding. The King Edward Memorial Hospital Obstetric Medicines Information Service (KEMH OMIS), in Perth, Western Australia, was established in 1988, with electronic documentation of information requests since 2001. Despite comprising 20 years of call records, this database had not been analysed to determine whether the service indeed meets callers' requirements and compares to similar services in Australia.

Aim: To identify patterns of use of the KEMH OMIS over 20 years and evaluate user satisfaction, to inform recommendations for further development of the OMIS.

Methods: This research comprised two stages. Firstly, records of KEMH OMIS enquiries from 2001 to 2020 were analysed to identify demographic data and trends over 20 years. Descriptive, bivariate and multivariate analyses were guided by research questions identified from the literature. Secondly, a prospective telephone survey of 181 randomly selected KEMH OMIS users was conducted over three months to provide recommendations for the service. Results were reported descriptively, with verbal feedback analysed thematically.

Results: Following data cleaning, 48,458 enquiries were analysed, with 48.2% (n=23,334) pertaining to breastfeeding and 42.1% (n=20,425) pertaining to pregnancy. Health consumers were the predominant users of the service but declined from 60% of callers in 2001 to 38% in 2020. Enquiries relating to medicines use in breastfeeding (48%, n=23,334) outnumbered those relating to pregnancy (42%, n=20,425). Most commonly, calls related to use of antimicrobials. The user survey identified high levels of satisfaction with the service, with all users indicating they would continue to use the KEMH OMIS. Feedback suggested a need for online capability, educational material and increased awareness of the service.

Conclusion: Increase in health professionals' use of the KEMH OMIS over 20 years reflects changes in the complexity of medication and prescribing considerations and

supports the ongoing need for this specialised service. Increasing awareness and accessibility of the service to health consumers should reduce risks with self-management of medication, particularly given the increasing volume of open-access and often unverified information.

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Dedication

I would like to dedicate this thesis in honour of my parents,

Mehndi Hassan Kerbelker and **Najemunnisa Kerbelker**

who sacrificed a great deal to migrate from Zimbabwe to Australia to enable my and my siblings' further education.

They have always supported and guided me in everything I have done and placed a high importance on education; I will forever be grateful to them.

Abbreviations

ABS	Australian Bureau of Statistics
ACE- Inhibitors	Angiotensin Converting Enzyme Inhibitors
ADEC	Australian Drug Evaluation Committee
Ahpra[a]	Australian Health Practitioner Regulation Agency
AIHW	Australian Institute of Health and Welfare
AMH	Australian Medicines Handbook
ATC	Anatomical Theoretical Chemicals
KEMH	King Edward Memorial Hospital
MFAU	Maternal Fetal Assessment Unit
NHMRC	National Health and Medical Research Council (Australia)
NHS	National Health Service (UK)
NPS	National Prescribing Service
NSAID	Non-Steroidal Anti-inflammatory
NSW	New South Wales
OMIS	Obstetric Medicines Information Service
OTIS	Organization of Teratology Information Service (United States of America)
PBMI	The Pregnancy and Breastfeeding Information Hub (KEMH)
PBS	Pharmaceutical Benefits Scheme
PMHS	Patient Medicines Helpline Services (UK)
SHPA	Society of Hospital Pharmacists Australia
TAIS	NPS Therapeutic Advice and Information Service
TGA	Therapeutic Good Administration (Australia)
UK	United Kingdom
UKTIS	United Kingdom Teratology Service
USA	United States of America
WA	Western Australia
WHO	World Health Organization
WNHS	Women and Newborn Health Service

[a] The Australian Health Practitioner Regulation Agency lists their abbreviation (Ahpra) as lowercase.

Glossary

Advice	Guidance or recommendation provided
Calls	Information requests solicited through a telephone service
Counselling	Provision of guidance and professional information to rectify a problem
Enquiries	Information requests or calls solicited through a telephone service
Fetus	In 2013, the NHMRC removed the 'o' from the spelling of fetus; for this reason, the research presents the spelling of the word as 'fetus', despite the Australian Oxford Dictionary listing 'foetus' as the primary spelling
Health Consumer	Members of the public who utilise health services, also users
Information	Facts provided based on available evidence or learned experience
Woman/Women/ Mother	For the purposes of this research, a person who is pregnant or breastfeeding is identified by the terms 'woman', 'women' and 'mother'. The researcher acknowledges that not all health consumers identify with this denomination.

Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction

With the ever-increasing complexity of medicines and availability of therapeutic options, health professionals and the public require readily available, balanced and comprehensive drug information facilities for health professionals and the public to ensure optimal understanding of medicines and their use in therapy. This access to information, while vital to the general population, is particularly important in relation to pregnancy and breastfeeding. This research examines access of medicines information for, and by, pregnant and/or breastfeeding women, and how that information has been utilised, to enhance clinical care for this sector of the population.

Within Australia, approximately 90% of women take one or more medicine during pregnancy or while breastfeeding.[1-4] These medicines include over-the counter medicines, prescribed medicines, complementary or alternative therapies, and/or illicit substances.[1, 5, 6]

Use of medicines by women during pregnancy and breastfeeding may be associated with potential adverse outcomes in the fetus or breastfed infant, who inadvertently becomes the recipient of these medicines via the placenta or the breast milk. These potential adverse outcomes increase the risk profile of medicines when used in this population and understanding and clinical assessment of the risk is required to adequately evaluate the potential outcomes. Current information is required to establish a safety assessment in women who are pregnant or breastfeeding to enable informed decisions regarding continuation or cessation of medicines use, given that these medicines may have been initiated for chronic or acute conditions present during this period or associated with the consumer's pregnancy or breastfeeding status.
There is limited information regarding the safe use of medicines in pregnancy and breastfeeding, and the available information varies widely depending on its type and source.[3, 7] When utilising multiple sources of information, there is a risk that information, and the interpretation of that information, will vary or even conflict, even when considering peer-reviewed literature and specialist books and publications.[8, 9]

Medicines use in breastfeeding, while a recognised risk, does not pose the same challenges as medicines use during pregnancy, due to the ability to observe the infant

to monitor signs of adverse events. During pregnancy, information about the exposure of the fetus to the medicine is required for decision making.[4] This exposure is difficult to estimate. In addition, pregnant and breastfeeding women are generally excluded from clinical studies potentially further limiting development of knowledge and research in this area.[2, 10] This lack of information or inadequate access to relevant information, poses a significant challenge in the medical management of these patients, and contributes to an increased level of anxiety in women for whom information is variable or in some instances, unavailable.[3, 11, 12]

The risks associated with medicine exposure in either pregnancy or breastfeeding are determined by a multitude of factors that include, but are not limited to, understanding the pharmacokinetics and the pharmacodynamics of the medicine and the implications on the fetus and breastfed infant.[5, 13-15]

Risks associated with medicines exposure exist throughout pregnancy, including exposure during the pre-conception phase, which may affect a woman's health and well-being for conception. The first trimester is characterised by a period of rapid cell division and growth, with fetal limb and organ development. The second and third trimester predominantly involve growth and development of the fetus, including cerebral development.[1, 6] At any of these stages, medicines could interfere with adequate development of the fetus or the course of the pregnancy. This exposure to the medicine may result in some or no harm, and that harm may be reversible or irreversible.[6] Varying degrees of this potential harm is the determinant for understanding the risks associated with medicine use in pregnancy.[7, 16]

To contextualise this, in Australia, it is estimated that 2-3% of pregnancies are affected by congenital malformations.[19] Approximately 60% of these malformations remain of uncertain aetiology, with a further 25% linked to an array of genetic disorders and only 1-2% likely to be associated with environmental factors which includes medicines.[19] Similar findings have been reported in other countries, including the United Kingdom (UK) and France.[17, 18]

Medicines taken by breastfeeding women may enter the breast milk via passive diffusion. Transfer is generally low but there may be some associated risks to the

infant.[19] These risks will be affected by the amount of transfer into the breast milk and the amount of medicine inadvertently ingested by the breastfed infant.[19]

In both pregnancy and breastfeeding, the above factors need to be considered when women are presented with information regarding the safe use of medicines. This information can be self-sourced or provided by health professionals. Consumers have an unprecedented access to an array of information with the availability of 'Google Searches" posing an ongoing problem in the provision of current, evidence-based information.[20] It is this access to current and relevant information that poses concern and requires review into how information is accessed and its clinical relevance for each scenario. Appropriate clinical care is determined by the availability of, and access to, information, and the ability of the individual to interpret the information. This research aimed to identify patterns of access to medicines information, including the most common information required by health professionals and pregnant and breastfeeding women. This enabled reporting on utilisation of current resources available and to inform the future of pharmacist-staffed medicines information services.

Research into the information sought by health professionals and the public is required to ensure optimal understanding of medicines when used in pregnancy and breastfeeding. Ultimately, this will facilitate access to resources and information to support decision making and medicine therapy within this cohort.

Chapter 2: Literature Review

This chapter establishes the body of research into medicines information for pregnancy and breastfeeding, how this information is utilised within a clinical context, the use of medicines in pregnancy and breastfeeding to identify trends and common medicines within this setting, as well as health professionals' and the public's view on medicine use and access to medicines information relating to pregnancy and breastfeeding. Establishing this information will identify gaps in the literature and the significance of this research topic.

Due to the sequential nature of pregnancy and breastfeeding, the literature review and subsequent discussions amalgamates pregnancy and breastfeeding information. Where separated information was available in the literature, this has been segregated.

2. Literature Search Strategies

2.1 Published Literature

The literature review presented in this research resulted from searches in: PubMed®, MEDLINE®, Elsevier Science Direct®, the Cochrane Database® and the Wiley Online Library®. Databases were accessed via the Curtin University Library and the KEMH Library. Searches were limited to peer-reviewed articles in English, and there were no limitations on the year of publication. While contemporary literature underpinned this review, historical information was sometimes required to review the evolution of medicines information services. Older articles pertaining to medicines information centres (1970s) and articles in the specialty of obstetrics not available online were obtained through the Document Delivery Service provided by the KEMH Library.

Table 1 identifies the keyword searches conducted, including MeSH terms for MEDLINE® and PubMed®. Searches were structured to elicit studies in Australia and across the world, focussing on developed nations to allow for comparison with the Australian context. Search results were refined by review of the title and abstract. Search results that rendered an abstract covering the topics in Table 1 were managed by utilising an Endnote® Library. As this research was conducted on a part-time basis

over a number of years, updates searches were repeated periodically to ensure currency. In addition, the researcher subscribed to the KEMH Library's "Articles of Interest" service which allowed for periodic updates regarding related research and recently published articles. Furthermore, the author engaged with the KEMH librarians, who would notify the author of any new articles of interest as they became available for access to the KEMH Library. Additional literature was identified from the reference lists of relevant articles.

2.1.1 'Grey' Literature

Searches of 'grey' literature included health organisation websites, and electronic and hard-copy textbook references and government reports and statements. Websites searched included the Australian Institute of Health and Welfare (AIHW)[21] for current pregnancy rates and risks of malformations in pregnancy; the World Health Organization (WHO);[22] the Society of Hospital Pharmacists in Australia (SHPA);[23] the Royal Women's Hospital in Melbourne;[24] The UK Teratology Information Service and the Organization of Teratology Information Specialists (OTIS).[25]

Hard-copy resources included the Society of Hospital Pharmacists Medicines Information Training Log[26] and Teratology Information Handbooks[27] available at KEMH through the Obstetric Department case study reviews.

The literature search results identified key areas relating to medicines information services, their establishment and use within the context of medicines use in pregnancy and breastfeeding. Providers' and users' experience with medicines information for pregnancy and breastfeeding and current trends and patterns were reviewed across similar services in Australia and internationally. This literature review aimed to highlight these areas and provide an overview of the information available, the shortcomings of the extent of research and the gaps in the body of knowledge to inform current research.

Table 1: Literature Search Strategies

Search 1 (Section 2.2) – searches conducted between 12 May 2015 to 30 January 2022 Medicine* OR Medication* OR Drug* OR Teratogen* AND Information Centre* OR Call Centre* OR Information OR Knowledge OR Service* OR Provision OR Teratology AND Pharmacist* OR Health Professional* OR General Practitioner* **MeSH terms used**: *pharmacists, drug information services, health knowledge, attitudes, practice, consumer health information, prenatal care, infant, newborn, abnormalities, drug-induced, drug prescriptions, pregnancy, teratogens, maternal exposure*
Search 2 (Section 2.3, 2.4 and 2.5) Medicine* OR Medication* OR Drug* OR Teratogen* AND Pregnancy OR Pregnant OR Breastfeeding OR Lactation AND Use OR Consumption OR Prescribing OR Usage AND Australia OR International OR Dr Google **MeSH terms used:** *humans, pregnancy, infant, newborn, abnormalities, drug-induced, pregnancy complications, infectious, prenatal exposure delayed effects, milk-human, breast feeding, lactation, infectious disease transmission, search engine, information storage and retrieval, information seeking behaviour, patient education, search engine, internet, consumer health information*
Search 3 (Section 2.6 and 2.7) User OR Consumer OR Patient AND Satisfaction OR Experience OR Access OR Evaluation AND Pregnancy OR Pregnant OR Breastfeeding OR Lactation AND Information Centre* OR Call Centre* OR Information OR Knowledge OR Services OR Provision OR Teratology **MeSH terms used:** *drug information services, pharmacists, primary health care, attitude of health personnel, decision making, humans, internet, surveys and questionnaires, decision support, user-computer interface.*

2.2 Medicines Information Centres

The complexity of medicines and medicine therapy warrants provision of readily available, balanced and comprehensive medicine information for health professionals and the public, to contribute to the safe and effective use of medicines in pregnancy and breastfeeding.

In 2002, the World Health Organization (WHO) defined 12 core recommendations to promote the safe and appropriate use of medicines and ensure rationale therapy for all patients.[28] These recommendations were established based on the WHO Essential Drug Monitor which identified that 50% of medicines were used inappropriately in patients around the world.[29] Examples of "irrational medicine use" included polypharmacy, inappropriate antimicrobial use, over-use of injectable medicines and deviation from available clinical guidelines.[28] Causes of irrational medicine use were identified as lack of knowledge, skill or independent information as well as unrestricted availability of medicines or inappropriate promotion of medicines.[28] Four of the 12 core recommendations are relevant to clinical services: drug use evaluation, drugs and therapeutics committees , clinical guidelines and access to independent medicines information; these are also recommended by the SHPA as part of ongoing promotion of appropriate use of medicines.[23, 28]

Of particular relevance to the current research is the recommendation for accessible independent medicines information. This recommendation arose from the increase in medicines information from pharmaceutical companies that may be biased or non-committal from a legal point of view and which may influence clinical decision making.[28, 30] The WHO highlighted that Drug Bulletins and Drug Information Centres are two methods recommended to distribute information. These could be operated by government or non-government entities, provided they were serviced with suitably trained health professionals. In addition evidence-based medicines information must be used, with assurance of transparency in advice given or recommendations made.[28]

Medicines information centres provide a centralised point of contact for medicines information as health literature increases over time. An observational study by Bornmann *et al.* in 2015 showcased an analysis of the number of publications and cited

references held across the Web of Science, a citation index, and how the volume of published information has increased from the 1900s and into the 2000s.[31] The cited reference rate tripled between 1900s and 2010 from 3% to 9% per annum "increasing the number of publications held as a source within the Web of Science and the number of cited references in the publications held at the source".[31] With the increase in literature published, staying abreast of information within a specific field is becoming more challenging for clinicians[12] who may turn to information from professional bodies or drug information centres for efficiency.[32, 33] As such, information systems and services need to provide accessible information to healthcare providers and the public. Reliance on individuals to source and interpret information has been described as a barrier between current evidence and best practice, and is apparent in pharmacotherapy across clinical areas.[32] For health professionals, the multitude of information platforms, along with inter-professional collaboration, has slowly bridged the gap of medicine knowledge for health professionals[33]. While the gap of knowledge has slowly decreased overtime, the surplus of information fails to overcome the ability to adequately access and interpret information in a timely and effective manner. This can be due to time constraints and competing demands on clinicians as well as the overwhelming plethora of information that is available or can be accessed.[12, 32, 33]

Access to medicines information is a different landscape for members of the public when compared to health professionals. Methods for navigation medicines information varies from speaking directly to health professionals, to accessing published research and medicines information from the internet, and the emergence of the 'Dr Google' trend.[20] The public present as active in their information seeking behaviour on the internet to self-educate and be informed of their medical condition or to elaborate on information presented by a health professional.[34] Whilst there is evidence that the information on the internet may be useful for some patients, the literature suggests that this is mainly the case with patients with chronic conditions.[20, 35] For a number of the public, the internet has an array of information that may be of low quality or conflicting information with the ability to make information available that is not subject to peer-review or clinical review to verify the accuracy of the information.[20] This may contribute to incorrect information obtained or an increase in confusion or anxiety in the public where health professionals may be able to alleviate any concerns.[20, 36] In the area of pregnancy and breastfeeding , misinformation sought from a variety of sources

such as peer advice, ‘old wives tales’, traditional and cultural information as well as that sourced on the internet via online forums and can increase concern to an expectant or lactating mother’s concerns regarding potential harm to their child.[36]

One of the first documented Medicines Information Centres was established in the United States of America (USA) in 1962.[37] This medicines information centre was established by the University of Kentucky and was designed to “support, assist, and promote a rational drug therapy program” providing a medium to deliver knowledge and information pertaining to drug therapies amongst colleagues and health care staff to endorse the safe use of medicines within a healthcare setting.[38] The medicines information centre in Kentucky was credited for initiating role transition for pharmacists from provision of medicines towards becoming a medicines expert and an important part of the patient care model. Over the years, this model of delivering medicines information was adopted and expanded across the USA and into developed countries.[38]

Medicines information centres transitioned from University Pharmacology Departments into hospital settings to deliver information directly to clinicians based on clinician need and patient requirements. Centres evolved to incorporate pharmacists and specialists within specific areas creating shared expertise and an expanse of knowledge and advanced training to assess and distribute medicines information more efficiently.[38-40]

Medicines Information Centres initially provided in-hospital services to health professionals in secondary and tertiary hospitals where individualised patient-care information was required to inform decision making in a timely manner. This service has, for the most part, been provided by pharmacists.[27] Both in the community and hospital setting, the primary care role of the pharmacist, alongside their medicine expertise, makes pharmacists well suited for the provision of medicines information.[41]

A 2018 survey of medicines information centres in the USA, identified 118 entities that were contacted to categorise the nature of their service. Staff from 93 centres responded (79%), revealing 45% of centres (n=37) were based in pharmacy/pharmacology departments at universities and 44% (n=36) based in a

hospital setting. The majority, 84%, (n=68) were operated by pharmacists and provided training and preceptorship for pharmacy students and interns. Fifty-seven of the centres (70%) had been in operation for more than 20 years.[41]

While some medicines information centres remain generalist, those proving specialist services span toxicology, poisons information, emergency medicine, obstetrics and gynaecology care, neonatology and academia services.[38, 40, 42]

'Academia services' was described as the provision of information to academic researchers affiliated with the medicine's information centre.[41]

Predominantly, medicines information centres answer enquiries via telephone and/or email. A Norwegian medicines information service established in 2011, initially began as a web-based service only and added a telephone-service in 2016. Comparison of the two models revealed a steady rise in the number of web-based enquiries over telephone enquiries, suggesting a web-based service for the public may be the preferred method of communication.[43]

The Australian Medicines Handbook (*AMH*) lists current medicines information centres in Australia.[44] A total of 23 centres were identified as offering a medicines information across Australia (Appendix 1), 22 are hospital based, with the exception of Mothersafe in New South Wales (NSW) which provides a stand-alone service.[44] Five centres provide a medicines information service incorporated within a women's hospital, and are listed as obstetric medicines information services by the Therapeutics Goods Administration of Australia.[45] Most centres are predominantly serviced by trained pharmacists; however Mothersafe is staffed by pharmacists, medical practitioners, obstetricians and enquirers can be referred to an on-site geneticist for further consultation.[46]

The Poisons Information Centre at Westmead Hospital in New South Wales is the only centre that provides a national service 24 hours per day for information relating to poisons or toxicology. The centre liaises with other state based Poisons Information Centre to cover the hotline across Australia.[47, 48]

All 23 centres within Australia provide a free telephone-based service; and provide email addresses and/or 'Contact Us' portals for written communication.[44]

2.2.1 Provision of a Medicines Information Service

The availability of medicines information centres allows for access to timely, evidence-based and patient-centred information when those seeking information are unable to access relevant resources, or do not have the skill set or time to locate the information themselves.[40] In addition, the amount of available medicine information may be difficult to interpret in specialty medical fields. Further to this, multiple sources can offer conflicting information, and the reliance of experts becomes paramount in understanding the information.[40, 49]

The information or advice given in response to a medicine's information request is provided to the user to assist them in making an informed decision. Medicine information services aim to provide advice only and recommendations are to be made in conjunction with the enquirers health professional.[27] Medicines Information, as a service, as defined by the SHPA's Standards of Practice, is "*the provision of written and/or verbal information or advice about medicines and medicine therapy in response to a request from other health care providers, organisations, committees, patients or members of the public*".[26]

Medicines information services, which typically offer a free service, are predominantly telephone-based centres, with some services offering internet-based and/or 'Contact Us' pages and email addresses. These services are operated by health professionals who utilise their knowledge and skills to research references and publications in order to provide sound, evidence-based responses for medicine-related enquiries.[26, 50] As established above, provision of medicines information is integral to patient- or disease-specific care. In this manner, medicines information centres are able to provide unbiased, individualised information and advice to patients and health professionals, which can assist in informed decisions pertaining to appropriate evidence-based patient care.[27] The evaluation of the medicine profile by medicines information pharmacists provides health professionals an increased ability to interpret and tailor

the specific clinical question and provide optimum medicines use and patient care outcomes.[26, 27]

SHPA's *Standards of Practice* position pharmacists as appropriately qualified for the role of medicine information providers and defines a medicines information pharmacist as "*a pharmacist who has extensive knowledge and skills in medicines information, a sound knowledge of evidence-based medicine and therapeutics, completed training in medicines information and specialises in providing medicines information*".[27]

As established in the Introduction, medicine use in pregnancy and breastfeeding is common and the ability for women to seek information regarding their medicines use is important to alleviate concerns that medicines may cause harm to their child.[51, 52]

Women who seek information regarding medicine safety in pregnancy and breastfeeding highly regard the information provided by their healthcare professionals, who are seen as a trusted source of information and whose expertise in the area of pregnancy and breastfeeding can reduce concerns to the expectant or breastfeeding mother.[1, 53] Given the trust and reliance on health professionals, it is apparent that health professionals require high-quality information in order to provide informed decisions for their patients. These informed decisions promote the safety of medicines for women in the at-risk stages of pregnancy and breastfeeding to be able to continue a trusted relationship with their patients and colleagues. Medicines information centres are able to address this need for quality, by providing accurate, evidence-based, up-to-date information about the risks and benefits of medicine use, and interpreting this information for each patient.[27]

An Australian study by Lee *et al.*, surveyed the public regarding their accessing of health information from the internet, more commonly known as 'Dr Google', versus health information accessed in the traditional manner from a health professional.[54] A high proportion of respondents reported difficulty in accessing information from the internet, and would prefer assistance in accessing information from their health professional.[20, 54] The need for quality information is paramount in pregnancy and breastfeeding. To this end, specialist telephone-based services are available in six states and territories across Australia (Appendix 1) providing obstetric medicines

information to women and health professionals to ensure the safe use of medicine during this period.[45, 55]

In 1982, a general medicines information centre in Victoria, Australia identified an increase in enquiries related to pregnancy and breastfeeding and the centre proposed a trial of a specialised information service. This service would specialise in medicines that affected the pregnant mother and/or her fetus.[56] Over an 18-month period, the service received 863 enquiries related to pregnancy and/or breastfeeding, 60% of the overall calls received by the centre. Following its introduction, the service has seen a steady increase of calls related to pregnancy and breastfeeding and received positive feedback from their users.[56]

Mothersafe, established in New South Wales in 2000, is a stand-alone teratology centre, serviced by health professionals, including pharmacists and obstetricians, who provide information and counselling regarding potential exposure of medicines in pregnancy and breastfeeding. Retrospective analysis of enquiry data, identified that enquiries increased by 772% in the first 7 years (n=2,025 to 17,668) with ongoing demand for the service.[4] This suggests that understanding the use of medicines in pregnancy and breastfeeding is important to identify the current expectation from the public and health professionals for medicines information services.

2.3 Medicines Use in Pregnancy

Medicine use in pregnancy is common. It requires an understanding of treating the mother, the *intended* subject, as well as the *unintended* subject, the unborn fetus.

Throughout both developed and developing nations, studies have shown that approximately 90% to 96% of women take one or more medicine during their pregnancy. This includes a range of medicines: over-the counter medicines, prescribed medicines, complementary or alternative therapies, and/or illicit substances.[1, 5, 6] The notion that medicines can be avoided in pregnancy cannot be achieved, as pregnant women still require treatment of their existing conditions, emerging or pregnancy-related conditions, and other acute and chronic illnesses.[46, 57]

There is general acceptance within society that when medicines are used in pregnancy, any exposure could harm the fetus.[4] This perception of risk can lead to chronic or acute conditions being left untreated or the consideration of pregnancy termination by the women.[4, 53, 58] Further to this, due to the ongoing perceived risks, and/or the predetermination to remain risk averse, and for ethical reasons, pregnant women are generally excluded from clinical trials, and data surrounding the use of medicines in pregnancy are limited.[59] For most medicines, this information is limited to animal studies or based on routine use of the medicine in clinical studies. Studies are also observational and lack of clarity around safety in pregnancy is not appropriated highlighted.[2, 46]

A cross-sectional study by Lupattelli *et al*. in six regions, including Australia, between 2011 and 2012, aimed to showcase the common use of medicines in pregnancy whether for acute or chronic illnesses. The study was conducted using an online questionnaire where pregnant women and mothers of newborns less than one year of age were asked to participate.[6] The study population comprised 9,459 women, 81.2% of whom self- reported use of at least one medicine during their current pregnancy or the preceding pregnancy within the previous 12 months. The category of medicines were noted as either those prescribed by a health professional or those purchased over-the-counter.[b] Recreational substances were not elicited. Two-thirds (66.9%) of pregnant women reported having used an over-the counter medicine with or without the advice of a health professional. Similarly, 68.4% of women reported the use of at least one medicine for acute illnesses, compared to 17.0% of women reporting the use of at least one medicine for chronic illnesses. Medicines used for chronic illnesses were started prior to pregnancy and required management throughout the antenatal period.[6] The study identified similar self-reported patterns of use across Asia, America and Australia.[6]

In 1999, the Medicines in Adelaide during Pregnancy (MAP) Study (Australia), interviewed 140 pregnant women who presented to their outpatient antenatal clinic appointment at the Women's and Children's Hospital in Adelaide. Women were asked to recall their consumption of prescription, non-prescription and non-therapeutic

[b] An over-the-counter medicine is a medicine that does not require a prescription for purchase.

medicine usage during their current pregnancy and the three months prior. The study identified that 96-97% of women had taken some form of medicines during their pregnancy and in the three-month period before. Data were available for all 140 women in their first trimester and/or the three-month period prior to pregnancy, for 108 women in their second trimester and for 47 in their third trimester. However, the prevalence of medicine usage across all trimesters was consistently 96-97%.[1] Trimester data are of note due to the stages of fetal development that could be affected by exposure to medicines. The usage prevalence described in this study is noted to be higher than the later international study by Lupatteli *et al*., reporting a prevalence of 81.2%. This study also noted that the participants in the MAP study were all of Australian, of Caucasian background, married and with a high level of education and a high rate of employment. This demographic profile was proposed to be associated with the high usage pattern.[1, 6]

The MAP study has not been replicated in Adelaide or elsewhere in Australia, although these prevalence data remain commonly cited.[4, 52]

2.4 Medicine Use in Breastfeeding

While medicines use in pregnancy is challenging, use in breastfeeding also presents concerns due to the intention to avoid disruption or cessation of nursing, treat the mother as the *intended* subject, and minimise potential exposure to the infant, as the *unintended* subject.[51]

The WHO and the National Health and Medical Research Council of Australia (NHMRC) recommend that infants should be fully breastfed for at least the first six months of their life.[22, 60] The health benefits for a breastfed infant are well documented, and information to support breastfeeding women regarding the safety of medicines is recommended to minimise any disruption to breastfeeding.[60]

Understanding the passage of medicines into breastmilk is important to gauge the amount of medicines transferred into the breastmilk. This passage can be compounded by the nature and type of medicine, the degree of oral absorption by both the mother and infant, the dosage and duration of therapy, and the age of the infant.[13]

Understanding this complexity is important to establish an informed decision in a patient's care.

The rate at which medicines are used in breastfeeding is not clearly documented in the literature internationally or locally. While the previous section established the prevalence of medicine use in pregnancy as at least 96%[1] and, the literature identifies that postpartum medicine use is "*common*", a prevalence estimate has not been published.[3, 51] However, some literature describes the types of medicines used during breastfeeding (Section 2.5).

The literature also discourages the unnecessary discontinuation of breastfeeding prior to six months but recognises that this has resulted where medicines have been required to treat either an acute or chronic illness.[51, 61]

In Europe, the breastfeeding rate decreased from a range of 98% to 56% immediately after delivery to a range of 39% to 3% when the infant was six months old.[62] This rate is comparable to that in Australia with a breastfeeding rate of 95.9% immediately after delivery with a decrease to 50% of infants being breastfed at six months.[60] One of the reasons noted for early weaning or cessation of breastfeeding is concerns pertaining to the safety of medicines in breastfeeding.[51, 61]

2.5 Current Trends and Patterns of Medicine Use in Pregnancy and Breastfeeding

Obstetric Medicines Information Services and Centres in Australia and around the world have published retrospective data on the nature of the enquiries they have fielded. Of the six Obstetric Information Services listed by the Therapeutic Goods Administration[45] (TGA) and the *AMH*[44] (Appendix 1) , only two have published reports regarding their services: Mothersafe in New South Wales and the National Prescribing Service (NPS MedicineWise) from the Mater Hospital in Queensland. The TGA notes that it "does not provide advice on the use of medicines in pregnancy for specific cases" and provides a list of obstetric drug information services that can be

used by health professionals and/or the public.[45] Mothersafe and MedicineWise are reviewed below in the international context.

MothertoBaby, a teratology service based in Utah, USA, published a retrospective analysis of their data relating to medicines information for pregnancy and breastfeeding between 2009 and 2012. A total of 27,299 calls were received over the four-year period, of which, 82% were made by pregnant or breastfeeding women, 13% by health professionals and 5% by a family member or friend of the pregnant or breastfeeding woman. Health professionals were not described by type in this study. More calls related to medicines use in pregnancy (67%) compared to breastfeeding at 34%. Of these, 44% (n = 6,527) related to use in the first trimester, 33% (n = 4,814) related to use in the second trimester, and 23% (n = 3,465) related to the third trimester.[9] MothertoBaby lists enquiries based on the "exposure type" which broadly corresponds to a medicine class or type. The most common exposure type was cold and flu medicines representing 2% of calls, followed closely by immunisations, then herbal products, analgesics, psychotropics, anti-infectives and gastrointestinal medicines. The database did not capture the specific details of herbal products.[9]

Between January 2005 and December 2007, Mothersafe in New South Wales conducted a retrospective, descriptive study of the services activity over a three-year period. Of 47,138 calls logged by Mothersafe during this period, 81% were from the pregnant or breastfeeding woman, 10% from a medical practitioner, 6% from an allied health professional, 3% from a relation or friend of the pregnant or breastfeeding woman and 1% from pharmacists. Over half of the calls (54%) were related to pregnancy enquiries and 39% related to breastfeeding. The remaining 7% of calls were related to pregnancy planning and general or retrospective enquiry.[4]

For the pregnancy related calls, 35% were regarding the first trimester, 38% the second trimester and 27% in the third trimester. The most common medicine types or classes of exposure were enquiries regarding over-the-counter medicines (11%), generally cold and flu products, followed by herbal products (8%), antidepressants and other psychotropics (9%), antibiotics, gastrointestinal medicine and topical products all at 7%.[4]

Medicines enquiries managed by the National Prescribing Service (NPS) MedicineWise service span all medicines and conditions. Pregnancy and breastfeeding are a subset of the calls received by the NPSMedicineWise. Between 2002 and 2010, data were published separately for pregnancy and breastfeeding. Of 123,217 calls received by the centre over nine years, 4,573 related to pregnancy, accounting for 4% of all calls.[52] The majority of enquiries were from women enquiring for themselves (83%), with 6% off calls made by the woman's partner. Calls by health professionals were not identified, as the NPS MedicineWise service is consumer-focused; however, a category of "other callers" was listed for 5% of pregnancy enquiries. The narrative of the calls was available for 42% of all calls and the trimester data were only available for 25% of calls (n=1,116). The first trimester (including preconception) was the subject of 40% of calls, while 26% and 18% were noted for the second and third trimesters respectively. The most common medicine classes subject to enquiry were antidepressants (11%), followed by analgesics (9%), antihistamines and cold and flu preparations (10%), anti-inflammatories (4%), penicillin antimicrobials (3%) and antivirals (3%). The NPS MedicineWise data captured the reason a call was made; and the primary motivation was *"inadequate information"* with callers seeking further clarification (53%), followed by a request for a second opinion (30%).[52]

Breastfeeding enquiries from Queensland were captured by Stephens *et al.* between 2000 and 2010 from the NPS MedicineWise database. This analysis spanned enquiries from consumers, along with health professional enquiries from the NPS Therapeutic Advice and Information Service (TAIS). The TAIS was a service funded by the NPS to provide a medicines information service to health professionals within primary care. This service ceased its existence in 2010 with activity data published during its operation. TAIS data included information across five Australian states provided by six hospital-based centres. Between the two datasets a total of 183,791 calls were received, with 5,662 consumer calls and 2,219 health professional calls coded as 'breastfeeding'. Of the consumer data, 96% of calls were from the women themselves. Of the health professional data, 45% of calls were from medical practitioners, 36% from community pharmacists and 12% from nurses.[51]

The most common medicine classes consumers enquired about were regarding anti-inflammatories (9%), followed by antihistamines (7%) and cough and cold

preparations (6%). Amongst the health professionals, antidepressants were the most common medicine class identified from the enquiries (17%) followed by antihistamines (6%) gastrointestinal medicines (4%), and then penicillin antimicrobials (4%). The age of the infant was not reported.[51]

All three studies above provided descriptive analysis of their databases capturing caller demographics and the nature of the calls taken. While varying in the number of calls taken and the period of time, general themes emerged across the studies. The data recognised that women were seeking information regarding their medicines use in pregnancy and/or breastfeeding, with all services reporting that at least 80% of consumer calls were from the woman herself. Making an informed decision regarding the use of medicines whilst pregnant or breastfeeding is an important choice for women, to empower them with the correct knowledge and alleviate concerns regarding medicine safety.[63] During pregnancy, these studies consistently identified the first trimester as the period most frequently associated with enquiries (34% to 44% of calls). This is in line with the first trimester being the critical time for initial growth and development of the fetus.[1] The studies reported varying rates around health professionals accessing the service for pregnancy-related enquiries; all also varied in their identification of the type of health professionals or limited the classification to general practitioner, nurse or pharmacist. The trimester of concern in health professional calls was not identified in any of the studies.

Each of the studies identified their top five to 10 medicine classes associated with enquiries. Although the rankings differed, there was commonality amongst the medicine classes. The medicine classes that appeared in the top 5 for each of the studies, at various percentages, were [1] cold and flu medicines, [2] antidepressants, including antipsychotics, [3] analgesics and anti-inflammatories, [4] antimicrobials and [5] gastrointestinal medicines.[4, 9, 51, 52] MothertoBaby in the USA and Mothersafe in New South Wales both highlighted herbal preparations in their top five medicine classes, with MothertoBaby recognising the limitation in their coding for herbal and complementary medicines.[9]

An outlier within the MothertoBaby data was the class of medicines identified as “immunisations”, of which 69% directly related to the influenza vaccine.[9] In the

Australian data, immunisations did not appear within the top 10 medicine classes for any of the studies. In 2015, the outbreak of the Zika virus in the Americas sparked global concern for pregnant women and the risk of exposure to the fetus and the subsequent possibility of malformations. Medicines information centres that provide information in pregnancy and breastfeeding would be well placed to educate the public on this disease and its effect on the fetus. [64]

As noted above, herbal medicines were amongst the top 10 medicines classes behind enquiries. There has been an increased trend in use of complementary medicines worldwide.[65] In 2010, it was estimated that complementary medicines would attribute towards an estimated AU$33 billion sales market.[65] The use of complementary medicines in pregnancy is prevalent, due to perceptions around these medicines being 'safer and natural' therapy.[65, 66] An Australian study conducted between 2005 and 2007 investigated the health and wellbeing of women during their pregnancy.[67] It involved a questionnaire administered to 321 pregnant women, which requested them to list information regarding their complementary medicine usage during pregnancy. Nearly three-quarters (73%) of women self-reported use of at least one complementary medicine prior to and during pregnancy to treat common conditions such as the common cold or leg cramps.[67]

2.6 Users' Experiences with accessing Medicines Information in Pregnancy and Breastfeeding

Medicines information centres are available to provide accurate, current information to callers, saving them time whilst providing them with an informed answer. Health professionals need to maintain continuous professional development to ensure their skills, knowledge and competence within their area of expertise remains current. With the increasing availability and access to information, filtering through the volume of regularly changing, and in some instances conflicting information about medicines can pose a challenge to health professionals to provide patient-centred, informed advice.[68] Within the area of pregnancy and breastfeeding, the determination of risk versus benefit for the woman and her fetus or child can present as a challenge for health professionals. Available information can be limited to animal studies, minimal or

conflicting human data, pharmacokinetic data or based on varying classification systems around the world.[13, 59]

For the public, seeking information regarding their medicine use in pregnancy and/or breastfeeding is a mechanism to become an active participant in their medical care and reduce anxiety that may be associated with taking a medicine during this period of time.[52] The level of risk medicines may pose in pregnancy and/or breastfeeding will impact a women's decision about whether to take a medicine or not.[69] Variability in information can impact this decision further. While the internet has brought a wealth of information that is generally easier to access, navigating and interpreting the information to determine the most relevant and appropriate advice can be difficult for the public. In some instances, the information can be conflicting, which has the potential to cause anxiety or confusion for the public.[20]

Conflicting information has been recognised as a barrier for women. A study by the University of Oslo, surveyed 1,821 women regarding their perception of risk of medicine during their pregnancy or while they were breastfeeding and how information affected their decisions. Over three-quarters of women (77%, n=1,373) stated they needed access to safety information regarding their medicines, and the three most common sources were their doctor, the product information leaflet and the pharmacist. One quarter (25%, n=1,219) of women identified that when more than one source of information was used, this resulted in conflicting information. Of concern, 17% of women who identified that the information was conflicting, chose to discontinue their medicine with 9.1% reporting they became anxious.[69]

The use of common resources, such as the product information, can identify a disparity in information in both pregnancy and breastfeeding.[3, 69] Information may be different from a variety of perspectives which could include clinical trials or animal studies. However, one of the main reasons that can lead to conflicting information is the currency of resources to which health professionals have access, and the maintenance of these resources. Within medicines information centres, dedicated pharmacists or collaboration with librarians have the ability and resources to maintain the currency of information and references available.[69, 70]

In breastfeeding, Hegedus *et al.* identified that consumer, product and online information sources continue to provide inconsistent and misleading information that may result in unwarranted cessation of breastfeeding.[3] Product information, which is predominantly manufacturer information, typically advises a cautious approach to medicines use in pregnancy and breastfeeding and can result in a recommendation not to use the medicine. This is reportedly to ensure cover of the manufacturer in terms of liability from adverse outcomes.[59, 70] Breastfeeding advice in product or manufacturer information does not include pharmacokinetic data of the medicine; this information can be useful in understanding the medicine properties for consideration in breastfeeding. These medicine properties include the medicine concentration in the breastmilk, protein binding , molecular weight, half-life, absorption by the infant's gut and oral bioavailability, all of which can be used to determine the possibility, if any, of the medicine entering the breastmilk and subsequently the breastfed infant.[3, 51, 55]

In pregnancy, access to safety information also presents with inherent complications or paucity of information and health professionals can face difficulties in accessing and interpreting information.[4, 52, 59] Safety information around medicines in pregnancy can be limited as a result of pregnant women being excluded from clinical trials for ethical reasons, and information instead being based on clinical expertise, retrospective use and therefore older medicines.[1, 52]

In Australia, the categorisation system for the safety of medicines in pregnancy is based on the Australian Drug Evaluation Committee (ADEC) categories.[71] This committee and the categories, alongside a multitude of regulatory bodies across the world monitoring the use of medicines in pregnancy were a direct result of the thalidomide disaster of the 1950s[71]. Thalidomide was marketed for morning sickness, however, was soon found to be the causal agent of an epidemic of birth defects and deformities in the children of women who had taken thalidomide. Marketed as relatively non-toxic, the medicine was taken by pregnant women; however, there were no robust studies to understand the toxicity or teratogenicity of the medicine. Thalidomide was withdrawn from the market due to the suspected association with fetal abnormalities. Following animal studies conducted by German regulatory bodies, toxicity in the fetus was demonstrated. Had robust and extensive animal studies been performed prior to human use, the thalidomide disaster could have been avoided.[72]

The ADEC system was designed to assess medicines on their risk profile in pregnancy and to classify that risk based on available information.[71] The rating system applies a category to each medicine: Category A medicines have been taken by large number of patients with no adverse pregnancy outcomes; Category B is divided into B1, B2, and B3 based on insufficient human and animal data to indicate safety without risk both to the mother and the fetus; Category C indicates that some reversible risk to the fetus has been documented, and caution is generally advised; Category D medicines have demonstrated some increase in the incidence of fetal malformations or irreversible damage, making medicines in this category not recommended for use in pregnancy. The final category, Category X, indicates a high incidence of irreversible malformations, and these medicines should be avoided in pregnancy (Appendix 2).[71]

While these categories were born out of necessity and well intentioned to provide safety advice of medicine use in pregnancy, they are also known to be ambiguous and non-committal in their analysis of information, utilising available and/or historic evidence-based practice based on a safety assessment on human data and animal studies and the outcomes in the assessed pregnancies.[66] The manufacturer's product information is also considered, despite its reported conservation bias and potential for misinterpretation.[73] The TGA suggests that the ADEC categories do not imply a hierarchical system in terms of safety in pregnancy, i.e., that a Category B medicine is safer than a Category C medicine. The alphabetical nature of the ADEC system, implies, incorrectly so, a hierarchy system where a gradient of risk is associated with A being the lowest and X being the greatest. This assumption negates the original rationale behind the categories being a non-hierarchical classification system.[55, 71]

Additional caveats regarding the ADEC categories are the assumptions that all medicines in the same category hold the same level of risk regardless of the information available. With ADEC categories not often reviewed and based on initial clinical studies emphasised at the time the medicine is released the level of assumed risk may remain the same. Another caveat is ADEC categories do not identify the risk in relation to the timing of exposure throughout the 40 weeks of pregnancy.[66] Medications such as oral corticosteroids can increase the risk of cleft palate in the fetus. By week 16 of the pregnancy, the cleft palate has formed and the risk becomes lower, but this information is not relayed in a simple letter classification system.[44] The

dose and route of the medicine taken during pregnancy is also not taken into account with the ADEC categories, and fails to provide a valuable understanding of pharmacokinetic data and the risk profile associated with different routes of administration. These inconsistencies and the paucity of information can increase the difficulty for health professionals in assessing the safety of a medicine in pregnancy. This promotes the need to utilise medicines information services to gain a clear understanding of the potential risk factors for their pregnant patient in the context of her medicine journey and risk profile.[74]

In 2016, the *AMH* removed reference to the ADEC categories from its medicine profiles for a number of reasons, which included the aforementioned confusion around the alpha-denominated system, the lack of specificity in relation to the timing of exposure during pregnancy, the historical nature of the categories that are based on initial product information released at the time the medicine was marketed, and the inability to identify an individual risk-benefit ratio for a patient.[55] The *AMH* replaced the ADEC categories with a statement of risk that evaluated the available information and assessed the safety profile of each medicine, providing a summary of these findings to the user.[55, 66]

These inconsistencies, while more complex in nature, are not unique to pregnancy. The evaluation of medicines use in breastfeeding also raises concern in the paucity of information and the available safety information to health care professionals. Safety information for breastfeeding is usually based on product information, that from a legal perspective, errs on the side of caution, and due to the medicine not being trialled in breastfeeding women, there may be no available information.[75] This can lead to a decision to not use the medication or cease breastfeeding to allow for the medicine to be taken. This method of attaining information in a health care setting is not ideal, and furthermore, does not take into consideration the risk profile of the breastfed infant, their age and the amount of breastmilk ingested. Health care professionals may err on the side of caution and provide variable information that may lead to the medicine not being used.[55] Interpretation of the pharmacokinetics of a medicine and integration of available information about the medicines, the user and her child, can be attained more efficiently and accurately from medicines information centres with a specialty in obstetric care.[19]

2.7 Evaluation of Medicines Information Services

Research reporting users' experience with medicines information services is minimal, with the literature predominantly analysing the nature of enquiries and the information requested. Medicines information services should be evaluated to ensure a robust, evidence-based approach is taken to deliver quality information to the callers and demonstrate value and impact of the service[76, 77] and should be assessed on the quality of the information given and the value of the service to provide evidence based information.[77]

No published retrospective user surveys or user engagement studies were found in the literature for Australian medicines information centres that field enquiries about pregnancy and breastfeeding. Extension of this review internationally did not identify any published articles, even when specifically searching for specific services such as Mothersafe, MothertoBaby and the United Kingdom Teratology Service (UKTIS). Some international user surveys were located, as described below; however, these are based on general medicines information centres with no specific specialty.

A German medicines information centre, operated by pharmacists reported a steady rise in calls to their centre, having responded to more than 14,000 calls over a 10-year period.[76] The centre identified that user satisfaction with the service was an area they were required to assess. A questionnaire was formulated, tested and optimised, and was in place for one year between 2003 and 2004. The questionnaire consisted of seven key themes which included professionalism, clarity, timeliness, helpfulness, if a positive outcome occurred and any suggestions for the service. Over the year, the service answered 1,693 requests with 95% of information requests from pharmacists. In the same period 1,107 questionnaires were sent to health care professionals to gauge user satisfaction. A response rate of 45% was achieved with 455 questionnaires answered and returned. No negative outcomes were noted across the responses, with 42% (n=190) identifying a positive outcome and the remaining 58% no response or 'unknown'. Using a five-point rating scale to assess the helpfulness, timeliness, clarity and professionalism of the interaction with the service, the mean grade assigned to each category was 4.6 or greater, indicating a high level of satisfaction with the service. The authors noted that at the time there were no similar studies available to compare

results, and recommended routine evaluation of the outcomes and efficacy of medicine information centres, based on a recommendation from the American Society of Health-System Pharmacists, that follow-up assessment should be conducted to assess if the information provided was useful and provided an appropriate outcome for the patient and their medication management plan.[76, 78] This patient outcome quality assurance model was also noted in studies establishing medicine information centres to build in prospective user satisfaction and outcome monitoring.[78, 79]

A user satisfaction survey conducted in the state of Khartoum in Sudan aimed to evaluate the Ministry of Health Drug Information Centre by interviewing the users of their service, who were contacted and consented to participate in the survey. The users were identified through call records taken at the time of the interaction. Two-thirds (66%, n=277) of the 423 participants were health professionals, 22% were from the public, with the remaining 12% identified as 'other'. The users were queried on the frequency of using the service, with 20% reporting having consulted the service more than five times, 50% two to five times and 34% at least once. More than 90% of users rated the service as either 'good' or 'excellent' with 95% identifying that they would use the service again in the future. The study concluded that users were satisfied by the quality of service, and by retaining users, this indicated a good level of satisfaction with the service.[80]

The National Health Service (NHS) in the UK assessed user experiences of their Patient Medicines Helpline Services (PMHS) by way of a satisfaction survey to assess the benefits of the service and to identify areas for service improvement.[81] Users were interviewed by telephone utilising a peer-reviewed, user-tested questionnaire that aimed to understand the users' need to contact the service, how they usually managed their medicines, what they would do if the service was unavailable, how the information the pharmacist provided was perceived, and how the service could be improved. Participants answered 17 open-ended questions in approximately 25 minutes. Forty questionnaires were completed. Due to the largely open-ended nature of the survey, two key themes were identified from the responses. These were identified as *timeliness* and if *PMHS was best placed to help.* The data were presented as written extracts from the open-ended questions with no statistical analysis available. The results explained the nature of the concerns of the users and their interaction with

the service. As presented, the findings identified that the service met user requests in a timely and easily accessible manner, with requests being resolved quickly. However, lack of an after-hours service affected the timeliness of the service, and the availability of an answering machine indicated that some calls may have been missed if the recorded message was not reviewed in a timely manner. The PMHS was perceived by users as a valuable service, approachable and providing succinct information in a timely manner. Some respondents identified that the existence of the service was not well known, and that more advertising and campaigns were recommended to increase awareness of the service.[81]

The studies illustrate the evaluation of medicines information centres by their users, identifying the timely access to information and the value of the service in being able to provide access to medicines information to users in a professional manner that is beneficial to them and aims to provide a positive outcome to users. The user surveys and evaluations were based on general medicine centres with no specific specialty such as obstetric care. Review of the literature did not result in any user evaluations after having used a pregnancy or breastfeeding information centre and even within the broad scope of general medicine. The Sudanese medicines information centre identified that there was no comparator for their results due to the scarcity of user evaluations published.

The methods of these user-experience studies ranged from hand-written responses to a telephone-based survey, with the telephone-based survey capturing a higher response rate. A mixture of both closed and open-ended questions appeared suitable to capture and quantify information. The NHS survey was predominantly open-ended free-text questions that was unable to be quantified; however, these data were rich, and thematic analysis provides useful data reduction.

Timeliness and appropriateness of the services was identified as key in all three studies.[76, 80, 81] Inclusion of an overall satisfaction rating is a useful parameter to monitor over time, along with the likelihood of utilising the service again. The studies did not provide detailed insight into the nature of their callers, whether the advice was indeed followed, or the impact of the advice. There was some opportunity to provide

suggestions for the information centres as a method of recognising areas for improvement and development.

This literature review has summarised the issues around accessible, complete and credible information for health care professionals and consumers to make informed decisions relating to medicine use in pregnancy and breastfeeding. There is a particular evidence gap in terms of the value of medicines information services within this speciality area. No local data were available for the state of West Australia although available resources address needs within two larger states. This thesis and the aims for this research intend to address this gap and provide relevant information to assist the provision of safety information for the use of medicines in pregnancy and breastfeeding.

Chapter 3: Methods

3.1 Aims and Objectives

This research aimed to identify patterns in enquiries received over a 20-year period by a specialist Obstetric Medicines Information Service (OMIS) provided by the clinical pharmacists at King Edward Memorial Hospital (KEMH) and offer recommendations for service enhancement. These aims were achieved by the following objectives:

Objective 1: To evaluate the database of medicine information enquiries received by the KEMH OMIS over a 20-year period (2001-2020).
Objective 2: To conduct a user survey to address knowledge and use of the service for continuous quality improvement.

3.2 Study Setting

The setting for this research was the KEMH OMIS. KEMH is a specialist tertiary Women's and Newborn Health Service that provides obstetric, gynaecological and neonatal care to the women of Western Australia (WA) and their families. The KEMH OMIS is a service providing safety information for the use of medicines in pregnancy and breastfeeding since 1988 and is the only service available of this nature in Western Australia. At the onset of the service in 1988, the KEMH pharmacists utilised their clinical expertise to assist onsite healthcare professionals in clinical decision making regarding the safe use of medicines during pregnancy and breastfeeding. Historically, as reported by pharmacists who had worked through this period, this was an internal service only provided to KEMH clinical personnel. As time progressed, and specialists moved across Western Australia, the clinical pharmacists were contacted to provide ongoing medicines information in pregnancy and breastfeeding and the inherent nature of the KEMH OMIS emerged.

One of the advantages of being onsite at KEMH at the time was access to relevant information resources predominantly as hard-copy references, from which the pharmacists were able to provide evidence-based medicines information to clinicians.

Technological advancements improved the availability of online resources to the pharmacists staffing the KEMH OMIS. Access to information has greatly improved in recent years; however, the specialist nature of pregnancy and breastfeeding resources is such that most detailed and reliable resources are subscription based. The KEMH Library has an expanse of pregnancy and breastfeeding resources to which the hospital subscribes and are recommended and used by the KEMH clinical pharmacists.

The KEMH OMIS was designed to undertake, whenever appropriate, the provision of unbiased, relevant, up-to-date, evidence-based and accurate information on all matters concerning medicines and medicine therapy in pregnancy and lactation. It was initially designed to accept enquiries regarding medicines in pregnancy and lactation; however, this scope has increased to also include neonatal medicine dosing, enquiries relating to chemical and recreational substances, interactions of medicines and general antenatal, postnatal and neonatal health matters. Over a number of years, the KEMH Pharmacy Department has expanded in its operational requirements with an increase in the number of pharmacists available to participate in the KEMH OMIS and contribute to medicine enquiries.

Enquiries to the KEMH OMIS are predominantly via telephone; however, email, written and facsimile communication are also accommodated.

The KEMH OMIS is serviced by pharmacists and intern pharmacists (under supervision) of the hospital's Pharmacy Department and receives on average 2,500-3,000 enquiries per year. The telephone line is answered by available pharmacists Monday to Friday from 8.30am to 5.00pm, including public holidays. Pharmacists at KEMH have acquired expertise regarding the safety of medicines in pregnancy and breastfeeding due to providing clinical services within the health service, and their participation in review of clinical guidelines and provision of medicines information to external governing bodies relating to pregnancy and breastfeeding, including publishers of the *AMH* and the Therapeutic Guidelines (TG). This expertise has been developed over a number of years utilising training logs and establishing a systematic approach to enquiries to ensure consistency in responses from the KEMH OMIS pharmacists. The SHPA provides Australian hospitals with a *Procedural Manual*

Guide to assist with the establishment, operation and maintenance of a Medicines Information Service.[27]

Training of each pharmacist involves, but is not limited to, evidence-based lectures highlighting the importance of the stages of development of pregnancy and where medicines can possibly interfere with fetal development and positive pregnancy outcomes. Pharmacists are trained to further utilise their pharmacokinetic medicines knowledge to make informed decisions based on available resources and clinical case studies in pregnancy and breastfeeding. Upon completion of a theoretical component of Medicines Information Training, pharmacists then undergo a range of practice case enquiries and shadow a trained KEMH OMIS pharmacist for a period of two weeks to establish the method and skills to answer enquiries. There is a suite of sample enquiries that each trainee must complete in written form and these cases are reviewed and responses confirmed as part of the training process. The suite of sample cases ranges from common enquiries in pregnancy and breastfeeding to more complicated enquiries where information is often unavailable or difficult to ascertain. Trainee pharmacists answer enquiries alongside a trained pharmacist, and clarification of responses is sought prior to initiating a response during this training period. Intern pharmacists who respond to enquiries are required to ensure all their responses are confirmed with a trained pharmacist prior to providing any information to the enquirer.

While enquiries are usually answered at the time of the call, pharmacists are encouraged to return the enquiry at a later stage to allow adequate time for research and collaboration with the other pharmacists. Complex cases are promoted within the service to establish further investigation and discussion within the team. This internal collaboration has shown to be valuable for learning as well as ensuring the caller receives adequate, reliable information. Where an enquiry raises significant concern for potential harm to a fetus or breastfed infant, the KEMH OMIS pharmacist have referral pathways within the hospital to refer the query to specialists' obstetricians with the Maternal Fetal Assessment Unit at KEMH. This unit is managed by consultant and senior obstetricians who assist with information based on their areas of expertise. Callers are routinely asked for their contact details as part of the record-keeping process and as a method to facilitate clinical follow-up if required, as well as feedback. Enquirers are asked the following statement by pharmacists "For quality improvement

and record-keeping purposes, could you please provide us with your name and a contact number". This caller information is then saved into the Microsoft Access® database for record-keeping.

The KEMH Library, alongside the KEMH OMIS Team, have created a Pregnancy and Breastfeeding Information Hub to establish a peer-reviewed list of commonly used resources to assist the KEMH OMIS in access to medicines information. The nature of an obstetric hospital indicates that access to resources and the ability to purchase relevant resources increases accessibility to information.

At the establishment of the KEMH OMIS in 1988, enquiries were recorded manually in a diary for each year. These records were handwritten, and in some cases, written in shorthand to capture the information. The pharmacist recorded basic information pertaining to the call that they received, including date, time, requested information and a brief description of the response. At the time, the KEMH Pharmacy comprised of 4.0 FTE (Full-Time Equivalent) pharmacist positions. Over the course of the years the pharmacist FTE within the KEMH Pharmacy increased, currently comprising of 19 pharmacists (15.4 FTE). With the expansion of the KEMH Pharmacy and available free technology resources, in early 2000, a Microsoft Access® database was created to electronically capture the enquiries. The database was designed to capture both built-in selections and free-format text to record the KEMH OMIS enquiries. The database was created based on access to free software that could be manipulated in particular fields to capture this data. The database was designed by the KEMH Pharmacy secretary, and the nature of the database was limited to the availability of the resource itself and the skill set of the staff member. The database, notwithstanding its limitations, proved to be a substantial improvement in information capture when compared to the handwritten data in earlier years. Continuous use of the database has allowed for enquiries to be recorded electronically and exported to a Microsoft Excel® for archiving and record keeping.

Both external and internal enquiries are recorded by the KEMH OMIS pharmacists. Enquiries were predominantly received via the telephone with a fraction received via email or electronically, as such, the enquiries will be referred to as calls from this point forward. External calls are defined as calls received from personnel outside health

professionals and staff within KEMH hospital. Internal calls captured any enquiries from health professionals and staff within KEMH hospital. Only external calls are recorded electronically, while internal calls are recorded manually in data sheets. The rationale for only recording external calls electronically was due to the time commitment required for data entry as well as internal calls being captured within a different Key Performance Indicator (KPI) log for departmental and hospital requirements.

Since 2000, the Microsoft Excel® record has been utilised for reporting operational data regarding the number of calls taken per month, the designation of the caller, whether they were a health professional or member of the public, and the patient's status relating to pregnancy, and/or breastfeeding. Calls pertaining to enquiries that were not pregnancy and/breastfeeding related were captured in a neonatal or other category where appropriate.

The KEMH OMIS is a non-funded service provided by the current pharmacists at KEMH. No dedicated pharmacist FTE is available for this service, and the provision of medicines information is provided by every trained pharmacist on the KEMH Pharmacy Department Roster. Where the department is fully staffed, a pharmacist is allocated a minimum of 45 minutes of rostered time to cover the direct OMIS telephone line; however, should operational requirements result in a reduction of available pharmacists, the KEMH OMIS telephone line becomes an additional duty for the dispensary pharmacists available at the time.

3.3 Ethics Approval

Approval for this study required a range of Ethical and Governance procedures to meet the standards of both the Women and Newborn Health Service Ethics Committee, overseeing research and governance for KEMH and Curtin University.

Initial approval to access the information from the Microsoft Access® database and release of the records from the KEMH Pharmacy Department was obtained from the WA Department of Health Governance, Evidence, Knowledge and Outcomes (GEKO)

system which manages Quality Activities in Clinical Services. The GEKO Approval Number is GEKO9210.

Ethics approval was sought from the Women and Newborn Health Service Ethics Committee and subsequently approved via the Research and Governance System, (approval number RGS0000003085).

Reciprocal approval was also obtained from the Curtin University Human Research Ethics Committee once approved from KEMH, to ensure all ethics requirements were fulfilled (approval number HR84/2016).

3.3.1 Ethical Considerations

As the researcher for this thesis is an employee of the KEMH Pharmacy Department, with a supervising role that overseers the KEMH OMIS, the author had a number of real and perceived conflicts of interest.

A significant conflict was access to identifiable data within the current database and the extraction of the database for analysis. The KEMH OMIS records had not been analysed in a method other than monthly statistics on the total number of calls, and no large data extraction had occurred prior to this research. To minimise the access to identifiable data, the Chief Pharmacist was asked to extract the data and de-identify the data for the research. Whilst the data extract was to be saved on the KEMH Pharmacy Services 'W' Drive network, access to this file path could be traced by the Health Department's Health Support Services as required, and the Chief Pharmacist felt that this level of security for the data would be appropriate. Within the author's pharmacist role, the author had authority to access the identifiable data for the purposes of patient care. The author was also rostered to cover the KEMH OMIS telephone line on a daily basis. Although this conflict of interest was not perceived by the author to affect her clinical conduct, the enquiries recorded between 2012 and 2020 inclusive, would contain enquiries that the author had answered. The potential for bias during analysis of her own records was managed by de-identification of the attending pharmacist as discussed in Section 4.5.

Objective 2 was addressed via a prospective user survey. To this end the callers may have been serviced by the author when rostered on to the KEMH OMIS. Management of this second bias is addressed in Section 5.2.

A further ethical consideration was management of situations where misinformation or harmful information was uncovered in the analysis. The ethical duty of the researcher was to inform the Chief Pharmacist to escalate an appropriate action. Given the expanse of information over 20 years, it is unlikely that the information would have an acute effect on a current pregnancy or breastfeeding outcome however due to this risk, it is important to note that there could be an adverse effect on the then fetus, or a current child. The Chief Pharmacist was to be alerted to the date and time of the call, and nature of the concern, for investigation outside the scope of the current research.

Restriction of access to the database and security of the data was paramount to ensure caller details remained confidential. With the research taking place part-time within allocated research time based at KEMH, the crossover of data over multiple platforms increased the risk for a data breach. The database was maintained in the KEMH Pharmacy Services 'W' Drive Network; this network pathway has limited access to KEMH pharmacists and access to specific files and references can be traced by the Health Department's Health Support Services as required. The database was password protected to ensure a further level of security. In addition, a Data Management Plan was prepared with secure storage space requested on the Curtin University 'R' drive.

Chapter 4: Database Analysis

This chapter addresses Objective 1: evaluation of the database of medicine information enquiries received by the KEMH OMIS over a 20-year period (2001-2020).

4.1 Introduction

Pharmacists routinely capture the details of the KEMH OMIS enquiries. The database is analysed by the clinical supervisor pharmacist to provide high-level descriptive statistics on a month-by-month basis. However, comparative annual evaluation of the database has not been conducted, and neither has multivariate analysis of the enquiries to address relevant operational and topical questions.

Descriptive analyses of similar services across Australia – Mothersafe and NPSMedicineWise – have been published.[4, 51] These analyses, which reported patterns of enquiries in either pregnancy or breastfeeding, spanned data from three years to 19 years.[3, 4] The current research aimed to advance this literature via more comprehensive analysis of both pregnancy and breastfeeding enquiries over a 20-year period in Western Australia. In addition, the current research utilised bivariate and multivariate statistics to identify patterns over the 20-year period. Data were categorised and summarised using frequency distributions. Comparisons of data were made using Chi-square tests, with p-values <0.05 were considered statistically significant.

Access to reliable and relevant information can inform health professionals' clinical decision making regarding the safety of medicines in pregnancy and breastfeeding. This can alleviate anxiety and concern regarding the safety of medicines in pregnancy and breastfeeding.[51, 52] In two recent NPSMedicineWise studies which captured information from health professionals and health consumers regarding the reason for their enquiry, more than half of the 2,219 respondents indicated the need for more information (53%), followed by the need for a second opinion (30%) and to clarify conflicting information (9%).[46, 51] Medicines information centres providing advice in pregnancy and breastfeeding within Australia reported steady increases in their rates of enquiries from health professionals and health consumers from the conception of the service, with Mothersafe reporting a 772% increase in the first seven years of the service.[4]

The aim of this research stage was to describe the KEMH OMIS calls data and identify common themes and trends that could inform the future of the service. This chapter discusses the processes and challenges involved in data preparation, the analytical approach, and the findings that inform and guide discussions around the future of the service.

4.2 Database Conversion and Storage

The KEMH OMIS originated in 1988, with enquiries documented in handwritten journals. In 2001, the electronic Microsoft Access® database was created to assist pharmacists in capturing enquiry information in an electronic format. The Microsoft Access® database was able to be extracted into Microsoft Excel®, producing spreadsheets of the enquiries. This research captured all electronic data recorded between 2001 and 2020. The end date for the analysis was determined as 2020 to provide two decades of data and up to 50,000 enquiries.

Data extracted from the Microsoft Access® database (2001 to 2020, inclusive) were converted to Microsoft Excel® for cleaning and analysis. The original Microsoft Excel® worksheet was 23.5GB in size and comprised 49,811 records of enquiries. All enquiries were external. Internal enquiries were documented manually by the attending pharmacist and were excluded from the current research.

The worksheet for analysis was saved on the KEMH Pharmacy Services 'W' Drive network with restricted access, as well as the Curtin University 'R' drive accessible only by the research team. The worksheet was further protected using a password held by the researcher and the KEMH Chief Pharmacist.

4.3 Ethical Considerations

The researcher's conflict of interest as a pharmacist servicing the KEMH OMIS required steps to ensure separation of these roles:

1. The caller's name and contact details were removed by the KEMH Chief Pharmacist to ensure deidentification of the database prior to access by the

researcher. The original data set was maintained by the Chief Pharmacist to allow for reidentification if required, as described in Section 4.5.

2. At the time of recording an enquiry in the Microsoft Access® database, a unique identifying number was automatically generated to the record. This number was available within the Microsoft Excel® extraction. While the current study was not an audit of the accuracy of the advice, the unique identifying number would become a point of reference should any enquiries be noted with incorrect, inappropriate or harmful information. In this event, the unique identifying number would be used to alert the Chief Pharmacist that an investigation was required. This theoretical event was unlikely to have an acute effect on a current pregnancy or breastfeeding outcome, although there could be an adverse effect on the then fetus, or a current child.

An identifying field that was retained was the name of the pharmacist who recorded the response in the Microsoft Access® database. This pharmacist was assumed to also be the pharmacist who provided the response (see Section 6.2). The reason this information was retained was to capture the clinical experience of the pharmacist providing the response, which could shape the recommendations for the KEMH OMIS from this research. Ethical considerations that arose from the pharmacist's identification were two-fold: the researcher herself had access to enquiries by all KEMH OMIS pharmacists, including those conducted by herself between 2012 (commencement of employment) and 2020, inclusive. In the initial data transformation, the pharmacist field was coded by the researcher. The code categorised each pharmacist into the number of years of experience they had at the time of the call prior to analysis. The number of years' experience was based on years since registration with the Australian Health Practitioner Regulation Agency (Ahpra),[82] and not the number of years the pharmacist had participated in the KEMH OMIS, as it was not possible to access employment records.

4.4 Research Questions

Objective 1 aimed to evaluate the database of medicine information enquiries received by the KEMH OMIS over a 20-year period (2001-2020). With this significant date range and predicted volume of data, a focussed approach was required for analysis. Table 2 explores the research questions that were prioritised for data analysis.

Table 2: Research Question(s) for Evaluation of the Medicines Information Enquires over a 20-year Period

Aim	Research Question(s)
Descriptive Analysis of Enquiries	1 What was the total number of enquiries documented over the 20-year period? 2 What was the type of caller and reason for calls, including usage, over the 20-year period? 3 Can the most common gestational age of pregnancy enquiries be determined to understand trimester of most concern? 4 What was the most common breastfed infant age, and age associated with greatest frequency of calls? 5 What were the common medicine classes in pregnancy and breastfeeding? 6 Which medicine references were most commonly used to provide recommendations to callers?
Patterns of Enquiries	7 Were there changes to the number of enquiries over the 20-year period with respect to specific medicines? 8 What were the reasons for enquiries over the 20-year period and the changes over time? 9 Were there patterns of use for the most common medicine class enquiries? 10 How many enquiries pertained to medicines contraindicated in pregnancy, and what were the changes over time? 11 How many enquiries pertained to medicines contraindicated in breastfeeding, and what were the changes over time?
Review of Enquiries over Time	12 Did experience of the pharmacist change the number of resources used? 13 Could the complexity of the enquiry be identified based on the references used and pharmacist experience? 14 Werethere any specific medicines where a change of regulation or advice has occurred or expected usage increase and does this impact enquiries about the medicine? 14.1 Sodium Valproate 14.2 Codeine 14.3 Ranitidine and Proton Pump Inhibitors 14.4 Recreational Substances 14.5 COVID-19

To be able to address Research Question 14, a review of changes pertaining to the specific medicines was conducted to inform the data analysis.

As previously mentioned, ADEC Category X medicines, which are contraindicated in pregnancy, are associated with an increased risk of fetal malformations when taken

prior to or during pregnancy.[71] A study by Raichand *et al.* reviewed the utilisation of teratogenic medicines in New South Wales women before and during pregnancy, by examining a list of medicines categorised by the TGA as teratogenic (Category X).[83] A similar process was adopted in the current study to identify the number of calls received by the KEMH OMIS regarding similar Category X medicines. Table identifies examples of medicines listed as ADEC Category X by the TGA and utilised within the Raichand *et al.* analysis.[71] KEMH OMIS data were reviewed to identify enquiries related to the medicines listed in Table 3.

Table 3: Medicines Contraindicated in Pregnancy (Therapeutic Goods Administration Category X) (n=14)

Acitretin	Ambrisentan	Arsenic
Azacitidine	Bosentan	Etretinate
Isotretinoin (Oral and Topical)		Lenalidomide
Misoprostol	Raloxifene	Ribavarin
Thalidomide	Tretinoin	Warfarin

As with pregnancy, some medications are contraindicated or strongly recommended not to be used whilst a woman is breastfeeding. Thomas Hale of HalesMeds®, formerly *Medicines and Mother's Milk*, recognised that medicines taken by a breastfeeding woman would transfer into the breastmilk to some degree, although for the most part this proportion would be low.[19] Table lists examples of medicines identified in both HalesMes® and by Hotham *et al*. as contraindicated for use during breastfeeding with the most data available to inform decision making.

Table 4: Examples of Medicines Contraindicated in Breastfeeding and Recommendations[15, 19]

Medicine	**Breastfeeding Recommendation**
Amiodarone	Avoid due to risk to infant thyroid function
Iodine	Avoid due to increased risk of infant hypothyroidism
Isotretinoin	Contraindicated due to potential for serious side effects
Lithium	Avoid if rigorous monitoring cannot be conducted

In 2008, a study by Whitehall and Smith highlighted the effect of sodium valproate on the fetus and the potential for known fetal malformations.[84] Shortly after, in 2009, the TGA released a "serious reaction" reminder in their *Australian Adverse Drug reaction Bulletin*, warning of the fetal malformation risk with sodium valproate.[85] In 2014, the United States of America Food and Drug Administration (FDA) announced changes in their pregnancy category for sodium valproate. Sodium valproate was listed as Category X (see Section 2.6) and contraindicated for the use of migraine treatment in pregnancy, due to the risk of fetal malformations.[86] The KEMH OMIS data were used to capture changes over time in the number of sodium valproate enquiries.

In 2018, the TGA reassessed the available safety information of the use of fluconazole in pregnancy. The TGA information advised against the use of fluconazole in pregnancy and all fluconazole packaging were amended to include the warning "*Do not use if pregnant or [trying/likely] to become pregnant"*.[87] Due to this change in safety information, the KEMH OMIS data was reviewed to identify any changes in enquiries pertaining to fluconazole use in pregnancy.

The KEMH OMIS data were used to identify changes in codeine enquiries in breastfeeding. Historically, advice surrounding the use of codeine in breastfeeding indicated that short-term use was safe in women who were breastfeeding.[15] In 2015, following a review by both the FDA and NHS in the UK, the TGA recommended that codeine should no longer be used in breastfeeding women, to minimise the risk of transfer to the breastfed infant. This recommendation was based on the adverse outcomes, including death, of children exposed to codeine and who were ultra-rapid metabolisers of the medicine.

In 2019, the TGA released information regarding a worldwide medicine recall of all ranitidine products due to the existence of a contaminant within the product; this contaminant was known to be *N*-nitrosodimethylamine (NMDA) and resulted in the global shortage of all forms of ranitidine.[88] Following further investigation, by 2020 the TGA had suspended all registration of any form of ranitidine, and it was effectively removed from the market.[88] Ranitidine was considered safe to use in pregnancy and breastfeeding, and was the second choice for relief of gastro-oesophageal reflux after the use of antacids. Due to the unavailability of ranitidine, there was an increased recommendation and use of proton-pump inhibitors (PPIs), including pantoprazole,

omeprazole and esomeprazole. The change in the KEMH OMIS enquiries relating to ranitidine and PPIs (in general) was compared between 2019 and 2020 using a Chi-square test.

The KEMH OMIS database captured a medicine class named 'recreational substances', which included medicines or drugs prohibited from manufacture, sale or possession by Australian law. Examples were cannabis, cocaine, heroin and amphetamine-type stimulants.[89] Enquiries relating to 'recreational substances' were analysed descriptively in terms of the reason for the enquiry, and trends over the 20 years.

With the emergence of the COVID-19 pandemic through 2020, enquiries pertaining to medicines use in COVID-19-positive consumers were captured during the final year of data collection.

For all the above-mentioned changes in specific medicines over time, temporal trends were noted over the 20-year period with Chi-square tests conducted to compare number of queries throughout different periods, before and after the change or update in information.

4.5 Data Preparation

Due to characteristics of the Microsoft Access® database and a number of free-text fields, a significant number of manipulations were required to prepare the data for analysis and create a manageable dataset retaining key data spanning the 20 years.

4.5.1 Variables included for Data Extraction

The KEMH OMIS Microsoft Access® database had data-entry fields for 16 variables. Table 5 lists the variables that were extracted to the Microsoft Excel® worksheet for subsequent cleaning, transformation and analysis, and how these compared with both the previously mentioned Mothersafe and MedicineWise studies.[4, 52] The current research did not aim to analyse the quality of the responses provided; therefore, the 'information requested' and 'advice provided' fields were not included. The 'caller's

contact details' field was also not extracted to maintain anonymity within the deidentified data.

Table 5: Comparison of Variables Captured During Recording of a Medicines Information Query (Mothersafe vs NPS MedicineWise vs KEMH OMIS)

Variables from each Study	Mothersafe [4]	NPS MedicineWise [46, 51]	KEMH OMIS
Unique Identifier (ID)	N/A	N/A	✓
External call	N/A	N/A	✓ #
Date of Enquiry	✓	✓	✓
Caller Category – health professional or consumer	✓	✓	✓
Reason for Call – pregnancy, breastfeeding, other	✓	✓	✓
Exposure/Medicine of Concern	✓	✓	✓
Information Requested	N/A	N/A	✓ *
Patient's Age	✓	✓	N/A
Caller's Relationship to Patient	N/A	✓	N/A
Caller's Gender	N/A	✓	N/A
Caller's Post Code	✓	✓	N/A
Caller's Contact Details	✓	✓	✓ *
Pregnancy Status and Gestational Age	✓	✓	✓
Breastfeeding Status and Age of Infant	✓	✓	✓
Date of Exposure	✓	N/A	N/A
Dose of Medicine	✓	N/A	N/A
Non-English-Speaking Background Status	✓	N/A	N/A
Method of Referral	✓	N/A	✓ #
Advice Provided	N/A	N/A	✓ *
Motivation for Calling	N/A	✓	N/A
Medicine Class	N/A	✓	N/A
Condition/Treatment Required	N/A	N/A	✓ #
Responding Pharmacist Details	N/A	N/A	✓
References Used to provide Advice	✓	N/A	✓
Time Taken for Enquiry	N/A	N/A	✓ #
✓ *** Available variable that was not extracted from KEMH OMIS database** ✓ **# Variable excluded from analysis (Section 4.5.3)** **N/A Not Applicable**			

4.5.2 Data Included for Analysis

Call records that were complete, i.e., had all variables populated with information, were retained for data transformation and analysis. All variables that were able to be populated by a 'drop-down' list selection were included for analysis, as these variables had been programmed for 'forced completion' within the Microsoft Access® database. Free-text variables were also included, recognising that these would require significant coding for analysis (Section 4.5.4).

4.5.3 Data Excluded from Analysis

4.5.3.1 Excluded Variables

Four variables were removed from the extracted dataset due to a significant proportion of missing information. One of these variables was 'time taken for enquiry'. Within the Microsoft Access® database, this variable allowed selection of either '0 to 15 minutes' or 'longer than 15 minutes'. More than 75% of the records had data missing from this field, subsequently, this variable was removed from potential analysis.

The 'method of referral' was poorly populated within the data. Data were available for less than 1% of the extracted records, with the additional barrier of free-text entry. This variable was removed from the database extraction.

The 'external call' variable was also removed, as all calls were external to the KEMH, and this variable was redundant. Internal calls to KEMH, as described in Section 3.2, were excluded from the study.

The fourth variable removed was the 'condition/treatment required'. This free-text entry variable had an inconsistent standard of documentation. The decision to remove this variable was coupled with the decision to add a variable 'medicine class' (Section 4.5.4).

4.5.3.2 Excluded Call Records

A record was deemed as incomplete, and therefore qualified for exclusion, if the free-text field of 'exposure/medicine of concern' and/or the 'references used to provide advice' were both missing. These variables were required for comparison analyses; hence entries with this information missing were removed. Any duplicated 'unique ID' records were also removed. A total of 3% of records were removed based on the above criteria.

4.5.4 Transformation of Data for Analysis

The nine retained variables (Table 5) were then transformed for analysis, as described below. The data transformation resulted in the creation of new variables that added to or replaced the original nine variables.

The 'unique ID' and the 'date of enquiry' were the only variables that did not require transformation or coding prior to analysis. These two variables were present for all records retained for analysis, as they were pre-populated by the Microsoft Access® database.

Three variables were populated by a 'drop-down' list selection. These were the 'responding pharmacist details', the 'caller category' and the 'reason for call'. The 'drop-down' list selection included an 'other' option for all three of these variables, and free-text entry was permitted. All remaining variables were solely populated by free-text entry. Given the KEMH OMIS is staffed by a minimum of eight pharmacists rostered for a minimum of 45 minutes at a time, and the database spanned 20 years, there was a high degree of variability with the free-text entries.

The 'responding pharmacist details' were used to create a variable named 'experience'. This variable represented the experience of the responding pharmacist in terms of the length of time since registration as a pharmacist with Ahpra.[82] 'Experience' was classified as: 'pre-registration' pharmacist; 'early-career' pharmacist with 1 to 5 years' experience; pharmacists with '5 to 10 years' experience'; and pharmacists with 'more

than 10 years' experience'. Some pharmacists' experience code changed multiple times over the 20-year period, and this code had to be allocated manually per year.

The variable 'caller category' enabled selection of 'medical practitioner', 'public', 'pharmacist' or 'other'. The 'other' category required coding due to free-text entries. Each row was analysed to adequately interpret and clarify the free-text entry. This clarification generated five codes: 'medical practitioner'; 'nurse/midwife'; 'pharmacist'; 'other health professional'; and 'public'.

The variable 'reason for call' enabled selection of 'pregnant', 'breastfeeding' or 'other'. Following review of the case, the resulting codes were: 'pregnant'; 'breastfeeding'; 'preconception'; 'neonatal'; 'medicine interactions'; and 'general medicines information'.

The number of weeks of gestation for 'pregnant' enquiries and the age of the infant for breastfeeding enquiries were both free-text entries. Each enquiry that was identified as pertaining to pregnancy was sorted alongside the gestation age, and a code was allocated. Codes were based on the stage of pregnancy: 'early conception'; 'first trimester'; 'second trimester'; 'third trimester'; 'all trimesters' (for general pregnancy enquiries); and 'no information available'. The same clarification was applied to breastfeeding enquiries, with a code allocated to capture the age of the infant: 'all ages'; 'no information'; '0 to 4 weeks'; '1 month to 3 months'; '3 to 6 months'; '6 to 12 months'; and 'older than 12 months'.

Due to the free-text nature of the 'references used to provide advice' variable, the data required significant interpretation of abbreviations and recoding. In some records, up to four references were used, and an allocation for multiple entries was introduced.

The medicine associated with each enquiry had been entered as free-text. The quality of data in this field was highly variable, with misspelt medicine names, the use of proprietary names over generic names, multiple entries per enquiry and combination products. Spelling and presentation of medicine names were brought to a consistent standard as per the *AMH*. Where multiple medicines had been recorded into the free-text field, the medicine names were separated into a column each. A new variable, 'medicine class', was added during data preparation, with reference to *AMH* nomenclature.[44] The nomenclature was based on the chapters and subheadings of the

AMH.[44] The *AMH* was chosen due to this reference text being the primacy reference for pharmacists listed by the Pharmacy Board of Australia[90].

The final variables for analysis are identified in Table 6.

The original timeline to clean the data was planned for three months part-time, however, due to the volume of the data requiring cleaning, familiarisation and manual coding, this took over eight months to complete.

Table 6: Final Variables for Data Analysis

Variable	Transformation	Data Type
Unique Identifier	Unchanged	Ordinal
Date of Enquiry	Unchanged	Ordinal
Caller Category	Coded • Medical Practitioner • Nurse/Midwife • Pharmacist • Other Health Professional • Public	Nominal
Reason for Call	Coded • Pregnancy • Breastfeeding • Preconception • Neonatal • Medicines Interactions • General Medicines Information	Discrete
Exposure/Medicine of Concern	Standardised with *AMH* nomenclature[44]	Nominal
Medicine Class	New – *AMH* nomenclature[44]	Nominal
Gestational Age	Coded • Early Conception • First Trimester • Second Trimester • Third Trimester • All Trimesters • No Information Available	Discrete
Age of Infant	Coded • All Ages • 0 to 4 weeks • 1 to 3 months • 3 to 6 months • 6 to 12 months • Older than 12 months • No Information Available	Discrete
Responding Pharmacist Details	Removed	
Experience Code	Created from 'Responding Pharmacist' • Pre-registration pharmacist • Early career (1-5 years) • 5-10 years' experience • More than 10 years' experience	Continuous
References Used to Provide Advice	Code Allocated for each reference (34 in total)	Ordinal

4.6 Data Management and Analysis

Once the data cleaning and transformation were completed as described above, the final variables of Table 6 were utilised for analysis. Quantitative analysis occurred in both Microsoft Excel® and SPSS® Version 25 (IBM SPSS, Armonk, New York, USA). Over the duration of the research, two statisticians guided SPSS® use and multivariate analysis in the form of linear regression.

Univariate and bivariate analysis were used to report cumulative and percentage frequencies of each variable and inter-relationships. Categorical data was summarised using frequency distributions. Microsoft Excel® pivot tables were utilised for bivariate analysis. Data from pregnancy-related calls were compared with breastfeeding-related calls, using chi-square tests where the variable for comparison was nominal or ordinal. Changes over time, between 2001 and 2020 were identified, a p-value for linear trend was reported when changes over time (years) were analysed. Pregnancy and breastfeeding calls were also compared by the type of caller and the top 10 medicine classes enquired to the KEMH OMIS in order to explore the medicines information needs for callers in relation to pregnancy and breastfeeding status. The relationship between the experience of the pharmacists and the number of resources used was also compared using a one-way ANOVA for non-parametric data. All hypothesis tests were two-side and p-values <0.05 were considered statistically significant.

4.7 Results

A total of 49,811 calls were extracted from the database for the 2001 to 2020 period. Of these, 1,353 records were discarded due to data-entry errors, which included duplicate entries and incomplete data entries as described in Section 4.5.3, leaving 48,458 calls for analysis. The research questions in Section 4.4 were addressed using these data.

4.7.1 Call Characteristics: Non-Temporal

Analysis in this section addresses Research Questions 1 and 2. Of the 48,458 calls, nearly half (48.2%, n=23,334) of all calls related to medicines use in breastfeeding, with 42.1% (n=20,425) relating to use in pregnancy. General medicines information accounted for 4.1% of calls (n=1,997), and the remaining 5.5% related to preconception, neonatal medicines and medicine interactions (Figure 1).

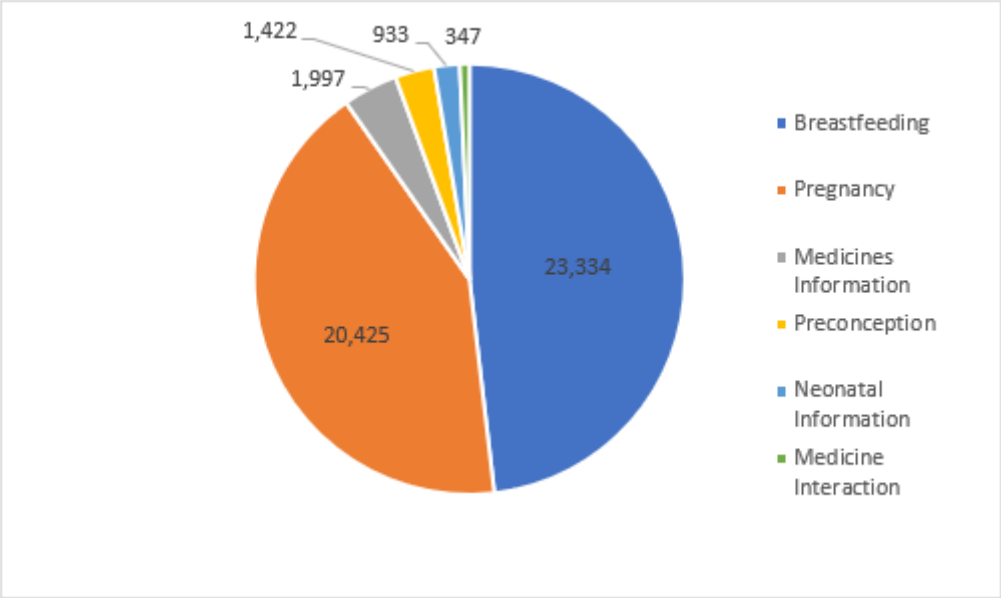

Figure 1: Categories of Enquiries to the KEMH OMIS (n=48,458)

4.7.1.1 Characteristics of Callers

Health professionals accounted for more than half of all the enquiries recorded (51.9%, n=25,173), with the public accounting for 48.1% (n=23,285) of all calls.

The health professionals were classified into their respective professions (Table). Medical practitioners accounted for 36.2% of all recorded pregnancy enquiries and 19.6% of breastfeeding enquiries. Other health professionals, accounting for 0.9% (n=415) of enquiries comprised of physiotherapists, psychiatrists, obstetricians and dentists.

The public enquiries represented 56.0% (n=13,063) of breastfeeding calls. There were no demographic data available to distinguish whether a public caller was the pregnant or breastfeeding woman for whom the medicine was intended.

Table 7: Type of Callers and Medicines Information Calls in Pregnancy or Breastfeeding

Type of caller	**Medicines Information in Pregnancy (n= 20,425)**		**Medicines Information in Breastfeeding (n= 23,334)**		**Chi-Square Test**
	n=	**%**	**n=**	**%**	*p*
Medical Practitioner	7,402	36.2	4,570	19.6	*p<0.001*
Nurse/Midwife	1,153	5.6	3,091	13.2	*p<0.001*
Pharmacist	3,129	15.3	2415	10.3	*p<0.001*
Other Health Professionals	163	0.8	195	0.8	*p=0.09*
Public	8,578	42.0	13,063	56.0	*p<0.001*

4.7.1.2 Time Period of Concern: Gestation or Age of Infant

Analysis in this section addresses Research Questions 3 and 4. Of the 20,425 calls pertaining to medicines use in pregnancy, 17,114 calls (83.8%) related to a gestational period and the most common period of concern was the first trimester (n=6,201, 36.2%). Comparatively, amongst health professionals, 3,620 calls (21.2%) identified the first trimester as the gestation of concern. The public calls identified the second trimester as the gestational period most commonly of concern, with 2,637 calls (15.4%), followed closely by the first trimester, with 2,581 calls (15.1%) (Figure 2). Nurses and midwives identified the second and third trimesters as the most common period of concern.

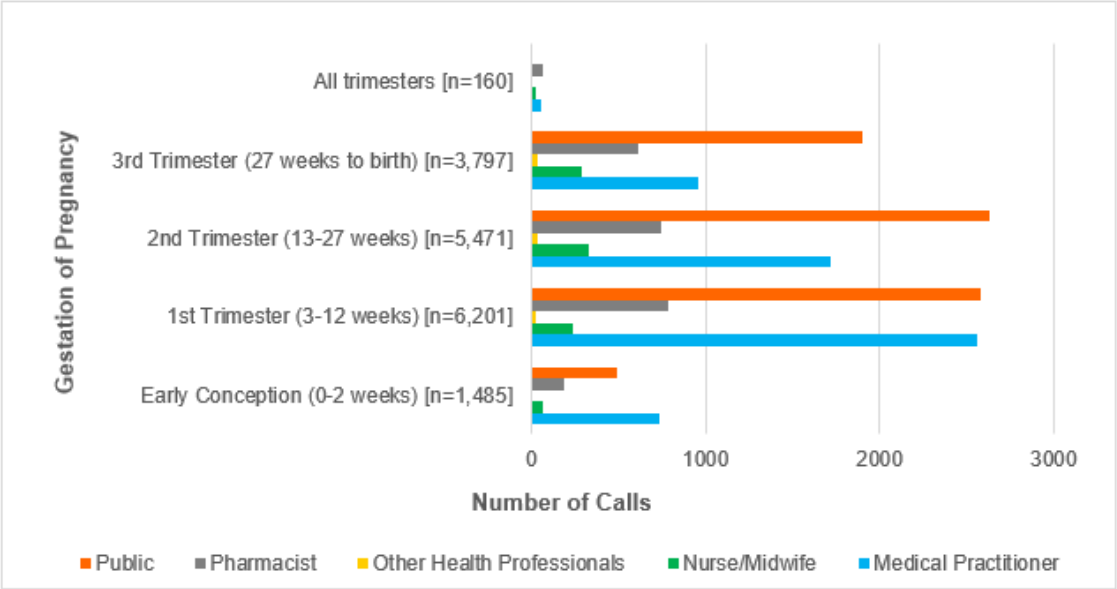

Figure 2: Most Common Period of Concern during Pregnancy by Type of Caller (n=17,114)

Of the 23,334 calls that related to breastfeeding, 16,905 (72.4%) recorded the age of the infant, with the majority (24.3%) within the first four weeks of an infant's life. This age of the infant was the most common age of concern amongst all variations of caller types (Figure 3).

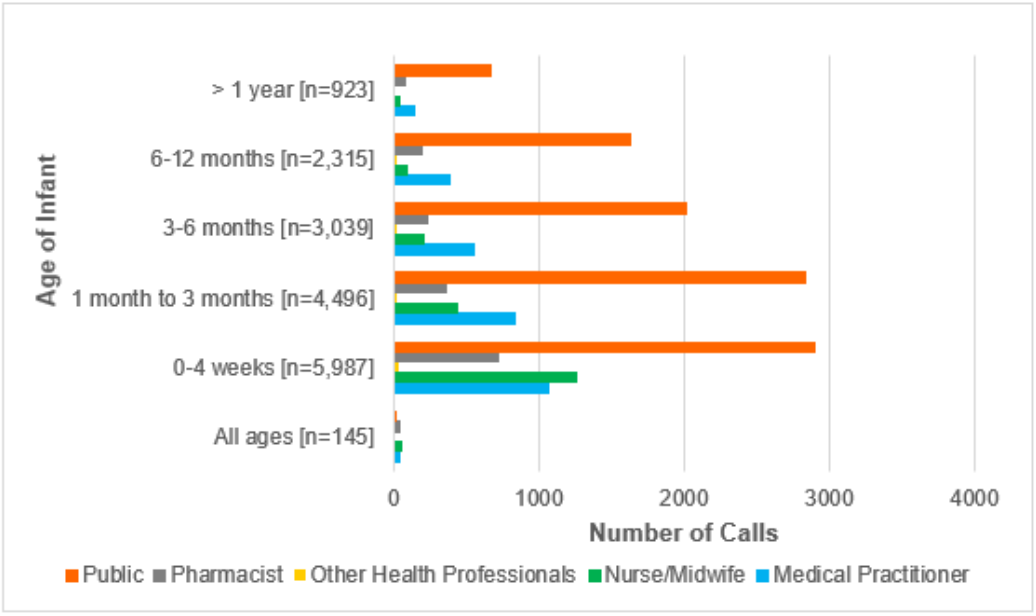

Figure 3: Most Common Age of Infant during Breastfeeding by Type of Caller (n=16,905)

4.7.1.3 Reference Material Used for Enquiries

Analysis in this section addresses Research Question 6. Analysis of the clinical literature and resources used to answer the enquiry revealed 58,139 documented data, while 6.2% of the 48,458 records did not have a documented reference that was used to answer the query. Table identifies *The Royal Women's Hospital: Pregnancy and Breastfeeding Medicines Guide* as the predominant reference (22.8% of all documented references). This is a quick reference guide for healthcare professionals that provides practical and unbiased specialised information on medicine use in pregnancy and breastfeeding. The second most commonly cited reference was *Medicines and Mothers Milk*: Thomas Hale (20.7%), a reference solely providing medicine safety information in breastfeeding. Appendix 3 lists in full the reference materials that were reportedly accessed by the KEMH OMIS pharmacists.

Table 8: The Ten Most Commonly Used References by KEMH OMIS Pharmacists (n=58,139)

Reference Material	**Number of Times Referenced (n= 58,139)**	**%**
*The Royal Women's Hospital: Pregnancy and Breastfeeding Medicines Guide**	13,243	22.8
Medicines and Mothers Milk: Thomas Hale	12,029	20.7
KEMH Clinical Guidelines	9,881	17.0
Drugs in Pregnancy and & Lactation: Gerald Briggs	5,229	9.0
Australian Medicines Handbook (AMH)	4,521	7.8
MIMS- Australian Drug Reference System	3,066	5.3
Micromedex®	1,721	3.0
Historical KEMH OMIS Enquiries	1,608	2.8
LactMed®: Drug and Lactation Database	1,414	2.4
Herbs and Natural Supplements: Lesley Braun	773	1.3
Other References	4,654	8.0

4.7.1.4 Enquiry Medicine Details

Analysis of this section addresses Research Question 5. Of the 48,458 calls analysed, 85.5% (n=41,468) related to 20 medicine classes (Table 9) . Antimicrobials dominated the enquiries, representing 19.5% of calls (n=9,454), followed by antidepressants, analgesics and complementary medicines. Data regarding anaesthetics did not capture the route of administration and whether these were administered as local or general anaesthetics. Chemicals were a broad category with variation in the data presented. Chemicals were noted to include paint, insecticides and pesticides.

Table 9: The 20 Most Common Medicine Classes Documented within OMIS from 2001 to 2020

	Medicine Class	**n=**	**% Calls**
1	Antimicrobial	9,454	19.5
2	Antidepressant	5,181	10.7
3	Analgesic	4,978	10.3
4	Complementary Medicine	3,840	7.9
5	Antihistamine	2,556	5.3
6	Antiemetic	1,841	3.8
7	Cold and Flu	1,668	3.4
8	Corticosteroid	1,628	3.4
9	Hormonal	1,561	3.2
10	Anti-reflux	1,388	2.9
11	Gastrointestinal Drug	1,077	2.2
12	Antihypertensive	1,061	2.1
13	Benzodiazepine	883	1.8
14	Vaccine	855	1.8
15	Antiepileptic	831	1.7
16	Antipsychotic	814	1.7
17	Anaesthetic	613	1.3
18	Chemicals	427	0.9
19	Blood and Electrolyte	407	0.8
20	Iron Replacement	405	0.8
	Others	6,990	14.5
	Total	**48,458**	**100.0**

A variety of over-the-counter and prescription medicines were noted, as well as complementary medicines. As depicted in Table , the 20 most common medicines accounted for one-third of enquiries over the 20-year period (30.6%, n=14,835).

Table 10: 20 Most Common Medicines Documented within OMIS from 2001 to 2020

	Medicine	n=	% Calls
1	Paracetamol	1,226	2.5
2	Sertraline	1,125	2.3
3	Local anaesthetic	1,027	2.1
4	Codeine	998	2.1
5	Escitalopram	997	2.0
6	Loratadine	932	1.9
7	Domperidone	859	1.8
8	Ibuprofen	820	1.7
9	Amoxicillin	770	1.6
10	Cold and Flu preparations	765	1.6
11	Fluconazole	724	1.5
12	Metronidazole	627	1.3
13	Citalopram	564	1.2
14	Pyrantel	549	1.1
15	Aciclovir	529	1.1
16	Cefalexin	512	1.1
17	Venlafaxine	473	1.0
18	Tramadol	464	1.0
19	Dexchlorpheniramine	447	0.9
20	Omeprazole	437	0.9
	Others	33,623	69.4
	Total	**48,458**	**100.0**

4.7.2 Call Characteristics: Changes over the 20-Year Period

4.7.2.1 Number of Calls: Annual Data

Analysis of this section addresses 7 and 8. From the total of 48,458 calls between 2001 and 2020, an average of 2,422 of calls were taken each year, with a sharp increase by 46.6% ($p<0.001$) between 2001 and 2011, which was maintained until 2014 (Figure 4). At this point, a slow decline was noted from 2015, with calls lower than the annual average calls. Calls from 2014 to 2020 significantly declined by 51.8% over this period ($p<0.001$).

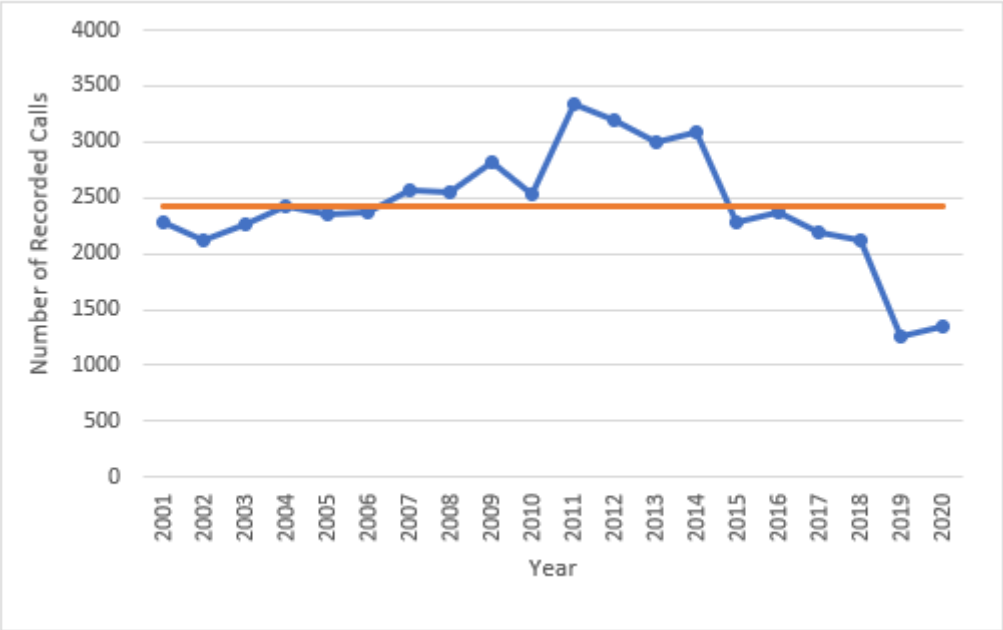

Figure 4: Number of Documented OMIS Calls per Year

4.7.2.2 Characteristics of Callers (Yearly Analysis)

Analysis of this section addresses Research Question 8. Health professionals generated 51.9% of all calls (n=25,173), with medical practitioners the predominant type of caller.

The public accounted for 48.1% of calls (n=23,285). The percentage of calls from all health professionals significantly increased from 39.9% in 2001 to 61.8% in 2021 (Figure 5). The converse trend was evident in calls from members of the public, which comprised 60.1% of annual calls in 2001, reducing to 38.2% (*p=0.021*) in 2021 (Figure 5).

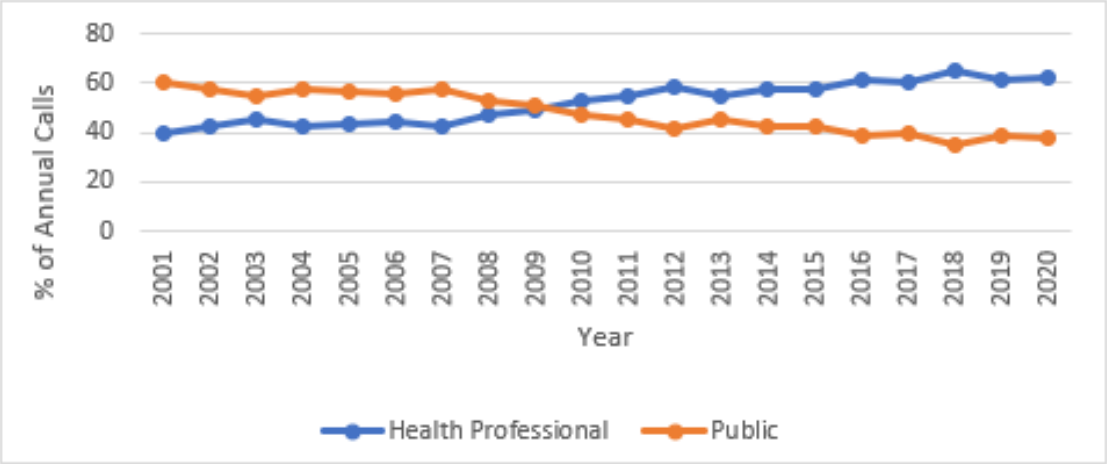

Figure 5: Percentage of Health Professional and Public Calls to the OMIS per Year

This trend was further explored by type of health professional. Between 2001 and 2020, calls from medical practitioners increased from 14.9% of annual calls in 2001 to 40.1% in 2021 (*p<0.001*). Calls from all other health professionals, i.e., pharmacists, nurses, midwives and other health professionals, remained relatively consistent over the 20-year period (Figure 6).

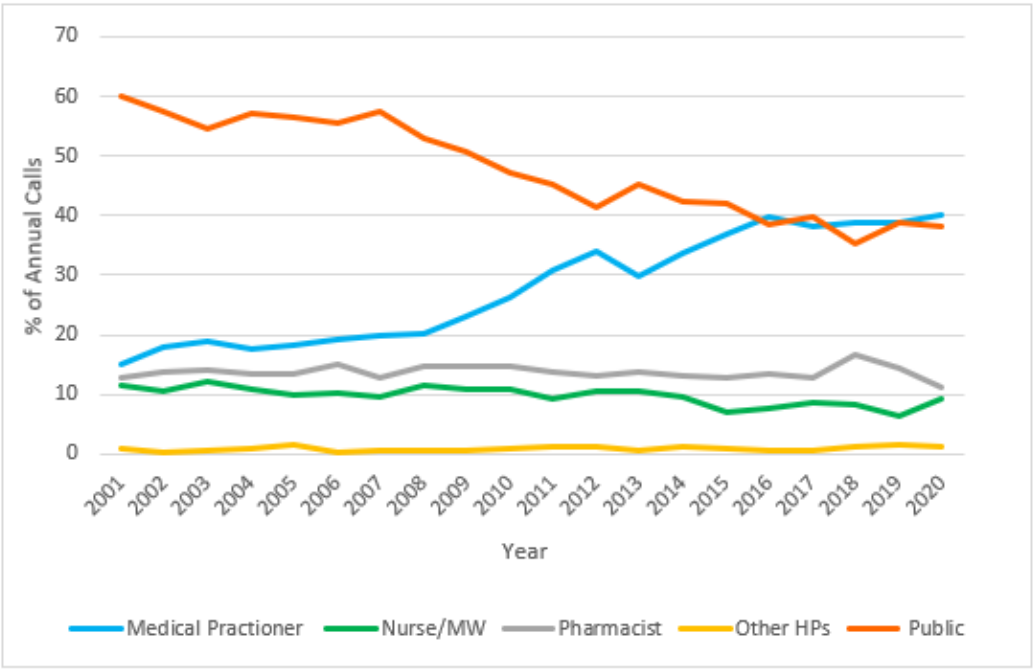

Figure 6: Percentage of Annual calls per Caller Type (n=48,458)

As established in Figure 1, nearly half (48.2%, n=23,334) of all calls related to medicines use in breastfeeding, with 42.1% (n=20,425) relating to use in pregnancy. Enquiries by medical practitioners were predominantly regarding medicines in pregnancy, accounting for 36.2% of all calls. This trend was significant when compared with the 19.6% of enquiries regarding medicines in breastfeeding by medical practitioners (*p<0.001*) (Table 7).

The type of caller was reviewed in both pregnancy and breastfeeding, and it was evident that the increase over time in calls by medical practitioners was associated with both pregnancy-related enquiries (Figure 7) and breastfeeding-related enquiries (Figure 8). The percentage of pregnancy-related calls by medical practitioners significantly increased from 20.4% in 2001 to 48.3% in 2020 (*p<0.001*).

The decrease over time in calls by health consumers was noted in both pregnancy- and breastfeeding-related enquiries. The declining trend over time of calls by health consumers saw the percentage of pregnancy-related enquiries from the public decrease from 62.2% in 2001 to 33.1% by 2020 (*p<0.001*). In breastfeeding, the same downward trend was seen, from 60.8% in 2001 to 48.8% in 2020; however, this was not statistically significant (*p=0.74*).

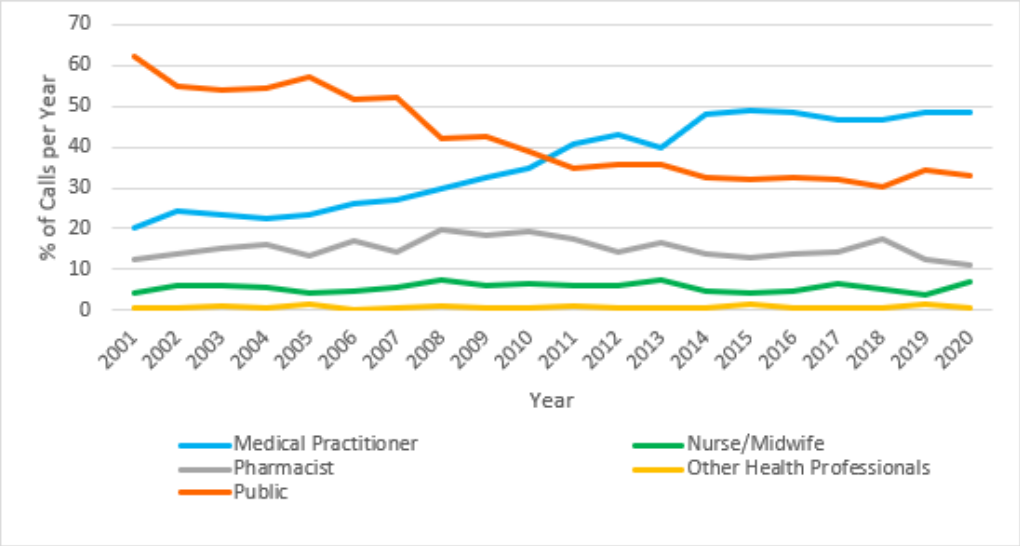

Figure 7: Type of Caller and Percentage of Pregnancy Related Medicines Information Enquiries

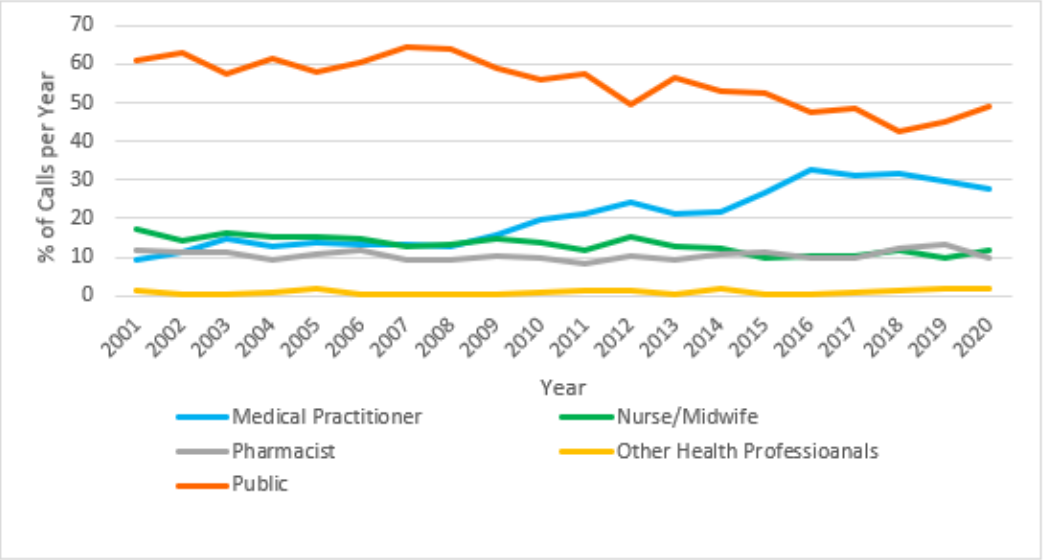

Figure 8: Type of Caller and Percentage of Breastfeeding Related Medicines Information Enquiries

These trends of medical practitioner and health consumer trends matched the same pattern as the number of calls received by the KEMH OMIS per year (Figure 5). For all other health professionals, the trend appeared consistent with similar numbers of enquiries in both pregnancy and breastfeeding over the years.

4.7.2.3 Patterns of Medicine Use: Annual Data

Analysis of this section addresses Research Questions 9. Table 9 identified the 20 most common medicine classes as the subject of enquiries. Of these, enquiries relating to the 10 most common medicine classes were analysed to identify temporal trends (Figure 9). The 10 medicine classes appeared to have relatively consistent proportions when compared to the years previous and after. The trends in the number of enquiries is further explored within this section.

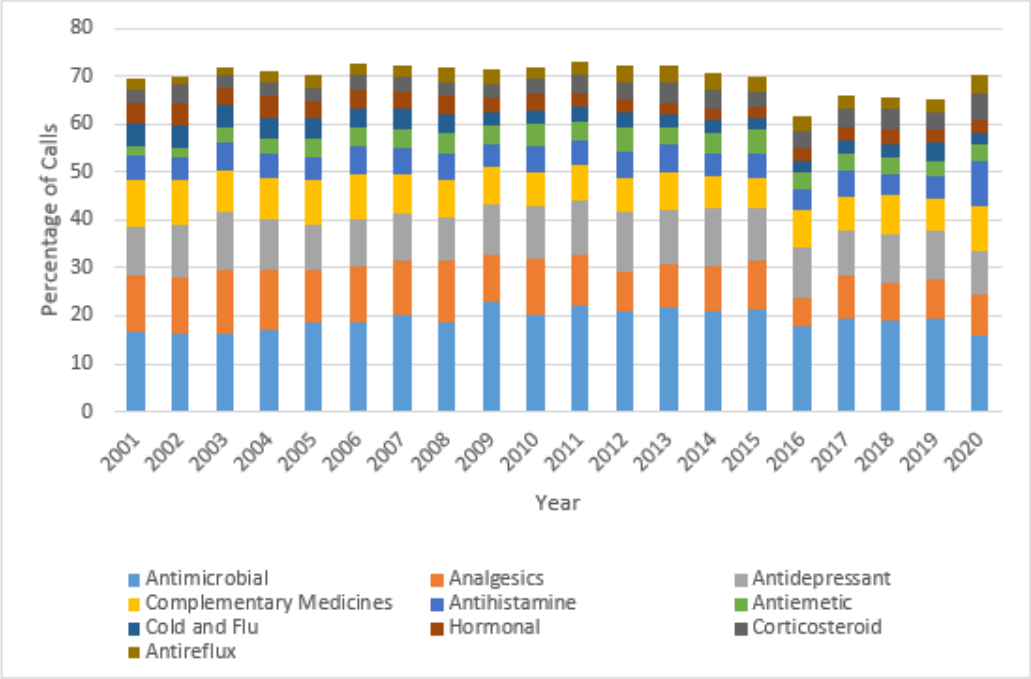

Figure 9: Pattern of Use of 10 Most Common Medicine Classes between 2001 and 2020 (n=34,095)

For further specificity, the five most common medicine classes were reviewed at the level of the medicine to identify patterns of enquiries over the 20 years. Figure 9 identifies the proportion of calls per year as a percentage of all enquiries received by the KEMH OMIS. The five most common medicines classes reviewed below demonstrate the number of enquires, by number.

Antimicrobial Enquiries

Antimicrobials were the most common medicine class amongst all 48,458 calls, accounting for 19.5% (n= 9,454). Figure 10 demonstrates the patterns of enquiries over the years, which is similar to the overall calls, with a decline from 2015. The antimicrobials that comprised the enquiries included penicillin, cephalosporin and macrolide antibiotics, antifungals, anthelmintics and antivirals. The most commonly queried antimicrobial was amoxicillin, at 8.1% of calls (n=762), followed by fluconazole at 7.6% (n=717), metronidazole, pyrantel and aciclovir at 6.6% (n=627), 5.8% (n=545) and 5.5% (n=523), respectively. Antimicrobials showed an increasing

linear trend between 2001 and 2015 ($p<0.001$), with a declining trend seen from 2015 to 2020, however this was not statistically significant ($p=0.82$).

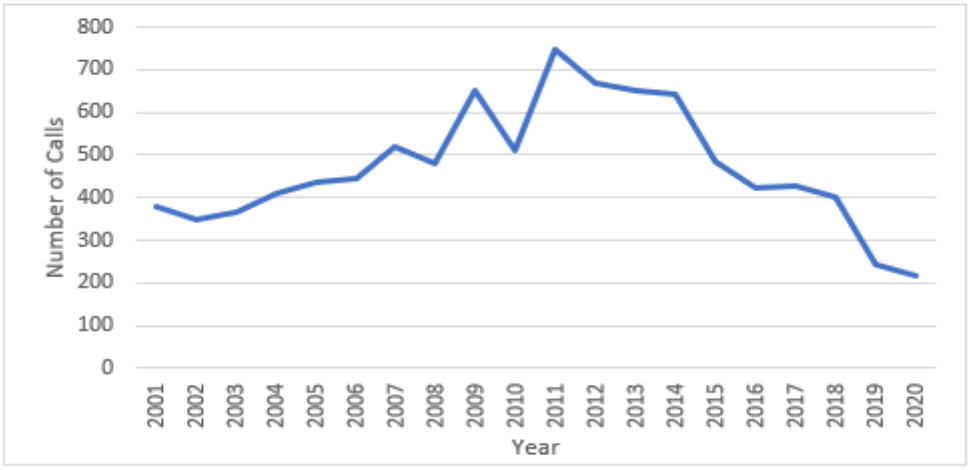

Figure 10: Number of Antimicrobial Enquiries Per Year (n=9,454)

Antidepressant Enquiries

Antidepressants were the second most common medicine class identified from all calls over the 20-year period, accounting for 5,181 of all calls (10.7%). Enquiries about antidepressants peaked around 2011 to 2014 (Figure 11). The pattern of enquiries relating to antidepressants between 2001 and 2020 indicates escitalopram, sertraline and citalopram, all selective serotonin reuptake inhibitors (SNRIs), were the most commonly queried antidepressants, accounting for almost half of all antidepressant calls (45.6%, n=2,362). These were followed by both selective norepinephrine reuptake inhibitors (SNRIs), venlafaxine and desvenlafaxine (n=849, 16.4%). No significant trend over time in enquiries relating to antidepressants was noted ($p=0.69$).

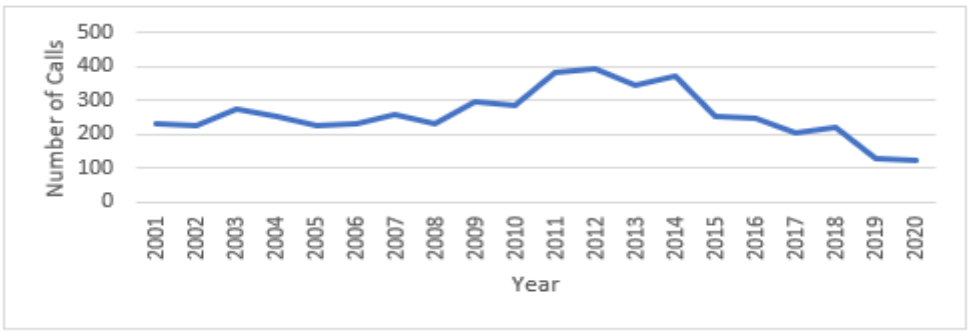

Figure 11: Number of Antidepressant Enquiries per Year (n=5,181)

Analgesic Enquiries

Analgesics included opioid and non-opioid formulations, which encompassed both over-the-counter and prescription medicines. The route of administration was not noted for any of the analgesics within the original dataset. Figure 12 illustrates a declining trend in enquiries about analgesics ($p<0.001$), particularly in the past five years.

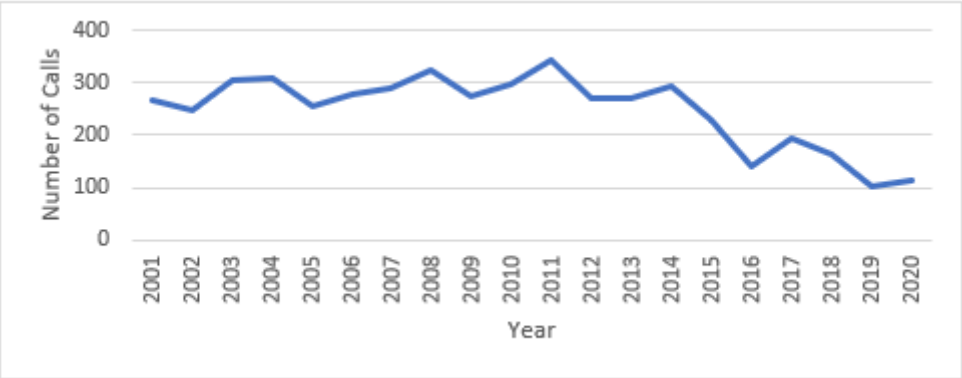

Figure 12: Number of Analgesic Enquiries per Year (n=4,978)

Paracetamol was the most common analgesic amongst the enquiries, accounting for 24.5% of calls (n=1,220). Codeine related enquiries accounted for 19.8% of calls (n=988). Non-steroidal anti-inflammatories (NSAIDs) included ibuprofen (14.4%, n=715) and diclofenac (7.2%, n=359). Tramadol accounted for 9.3% of enquiries (n=462).

Complementary Medicine Enquiries

Complementary medicines were the fourth most common medicine class amongst all enquires, at 7.9% (n=3,840), albeit with some variability in number of enquiries over the 20 years (Figure 13). A decreasing linear trend was noted in the number of complementary medicine enquiries over the 20-year period ($p<0.001$).

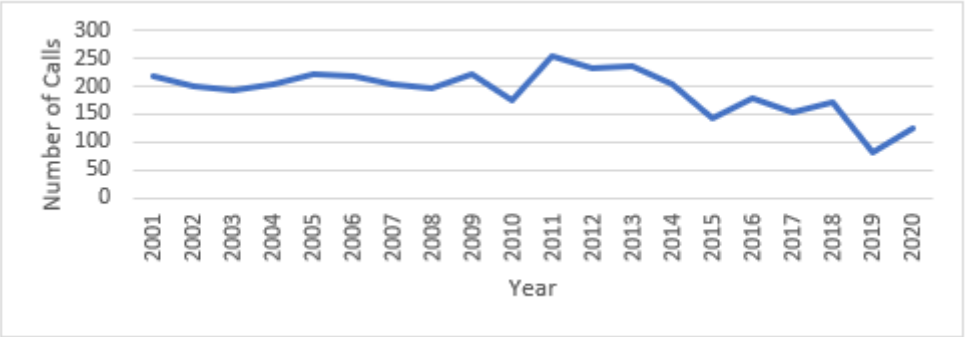

Figure 13: Number of Complementary Medicine Enquiries per Year (n=3,840)

Vitamin D (colecalciferol) was the most commonly queried complementary medicine (n= 201, 5.2%). Pregnancy multivitamins accounted for 4.6% (n= 178) and magnesium supplements at 4.3% (n=166) of complementary medicine enquiries. Lysine and St John's Wort were also amongst the five most commonly queried complementary medicines at 3.6% (n=140) and 3.3% (n=126) respectively.

Antihistamine Enquiries

Queries related to antihistamine use in pregnancy and/or breastfeeding accounted for 5.3% (n=2,556) of all enquiries. The pattern of antihistamine enquiries over the 20 years was highly variable (Figure 14).

Loratadine was the most common antihistamine subject to enquiry, at 27.6% of antihistamine-related calls (n=926). This was followed by dexchlorpheniramine (n=443, 17.3%), doxylamine (n=328, 12.8%) and promethazine (n=302, 11.8%). These were all centrally acting antihistamines that could be used in the management of nausea and vomiting.

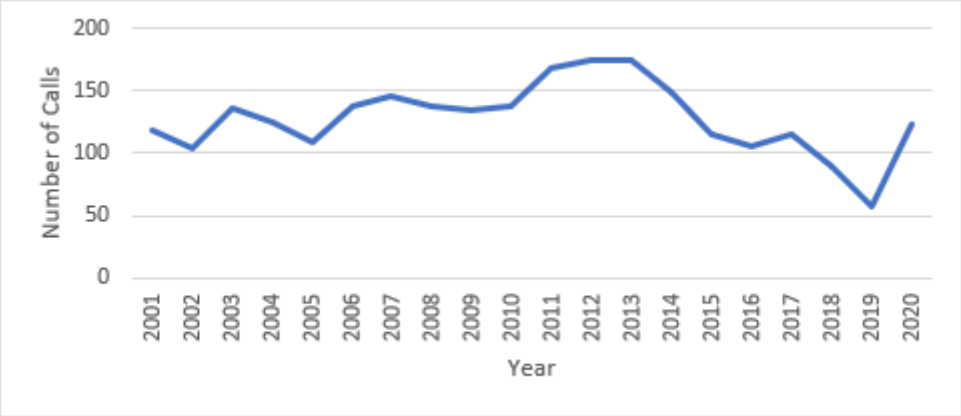

Figure 14: Number of Antihistamine Enquiries per Year (n=2,556)

Figure 15 shows the trends over time of each of the five most common medicines classes. The patterns of use identify variation over each year for the medication class, although the overall proportions of calls relating to each medicine class is remarkably consistent. The volume of enquiries appears confounded by the enquiries relating to antimicrobials and antidepressants, with the combination of these medicine classes accounting for a third of the total enquiries received (30.2%).

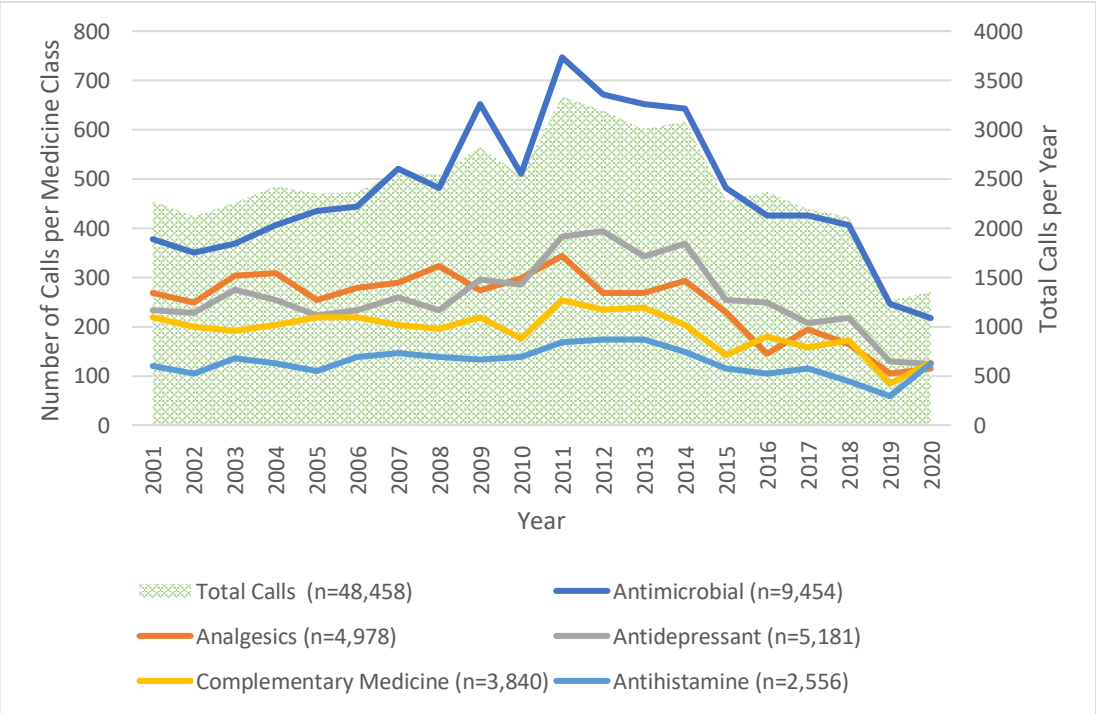

Figure 15:Five Most Common Medicine Class Enquiries per Year in Comparison with Total Calls (n=48,458)

4.7.3 Management of Enquiries

Analysis of this section addresses Research Questions 12 and 13. The KEMH OMIS training indicates that *"two or more references are recommended to be used to answer enquiries."* Comparison of the pharmacist's experience, in years, and the number of references (Figure 16) revealed that the majority of enquiries (76.3%, n=36,984) were addressed using a single reference. In a minority of cases, four references were cited. Proportionately, pre-registration/intern pharmacists were the highest documenters of using two references. Seventy-six records had no references documented or experience code allocated; given the low number these are likely to be an omission of data, as opposed to a breach of protocol in addressing the enquiry.

In comparing the number of references used based on years of experience of a KEMH OMIS pharmacist, more references (three or four) were used by pre-registrant pharmacists compared to early career pharmacists, a difference of 8.1% being notes ($p<0.001$). A further difference (1.8%) was observed between pharmacists with five to ten years' experience compared to those with more than ten years' experience ($p<0.001$).

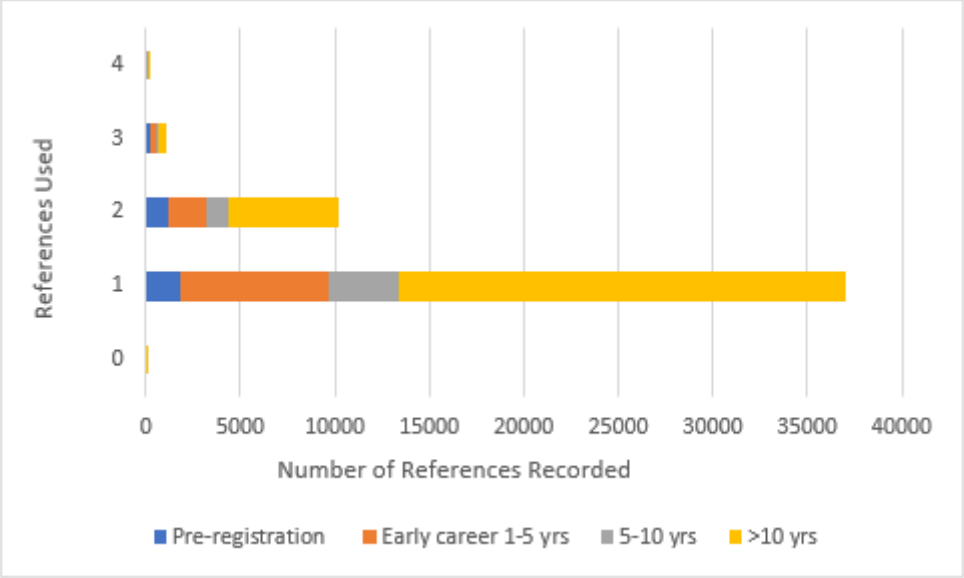

Figure 16: Pharmacist's Years of Experience and Number of References Used (n=48,448)

An OMIS colleague was listed as a reference for 274 enquiries (0.6%). These 274 records were explored in terms of the level of experience of the attending pharmacist. Pharmacists in their pre-registration year documented the use of an OMIS colleague for over half of the enquiries(n=145) (Table 11). When compared to pharmacists within their first 5 years of experience, pre-registration pharmacists used an OMIS colleague as a reference, 4.5% more times when compared to an early career pharmacist.

Table 11: Utilisation of an OMIS Colleague as a Reference Source

	OMIS Colleague Involved (n=48,458)	
	Yes (n=274)	**No (n=48,184)**
Experience	**n**	**n**
Pre-registration Year [n=3,215]	145	3,070
Early Career (1-5 years) [n=10,290]	55	10,235
5-10 years [n=5,014]	15	4,999
>10 years [n=29,929]	59	29,870
Missing [n=0]	0	0

The 107 medicine enquiries that resulted in documentation of four different references were explored (Table 12). Early-career pharmacists were most likely to consult four references (n=41, 38.3%), followed by the pharmacists who had more than 10 years' experience. The most common medicines for which four different references were consulted were centrally acting, including antidepressants, opioid analgesics, antipsychotics and anticonvulsants.

Table 12: Medicine Enquiries for which Four References were Consulted to Provide a Response (n=107)

		Experience			
	Medicine (n=107)	**Pre-registration**	**Early Career (1-5 years)**	**5-10 years**	**>10 years**
1	Sertraline		4		
2	Codeine				3
3	Dexamphetamine		3		
4	Aripiprazole	1	2		
5	Escitalopram		2		
6	Pseudoephedrine				2
7	Ondansetron		2		
8	Duloxetine	1	1		
9	Buprenorphine	1	1		
10	Pregabalin	1			
	Other Medicines	17	26	11	29
	Total (n=107)	**21 (19.6%)**	**41 (38.3%)**	**11 (10.3%)**	**34 (31.8%)**

4.7.4 Medicines Information Changes over Time: Impact on Enquiries

Analysis of this section addresses Research Questions 10,11 and 14. The availability of safety information in pregnancy and/or breastfeeding changes with the introduction of new research and information. At times, this information can enhance the safe use of medicines in pregnancy and breastfeeding, or it can create confusion or doubt in how medicines are use in this cohort of patients, depending on how the information is interpreted or portrayed. This section aimed to highlight changes in medicines information in pregnancy and breastfeeding and how this may have impacted the number of calls taken by the KEMH OMIS. Chi-square tests were used for categorical variables with additional data analysis methods also described in Section 4.6.

4.7.4.1 Medicines Contraindicated in Pregnancy

Table 3 (Section 4.4) identified 14 ADEC Category X medicines contraindicated in pregnancy. Six of these medicines listed in Table were identified in the KEMH OMIS enquiries and comprised a total of 60 enquiries regarding their use in pregnancy to the KEMH OMIS between 2001 and 2020. The remaining eight medicines had no enquiries recorded in the KEMH OMIS between 2001 and 2020. Calls pertaining to use of isotretinoin in pregnancy accounted for 61.7% (n=37) of these 60 calls, specifically in the first (27.0%, n=10) and second trimester (48.6%, n=18), or categorised as a general pregnancy query (16.2%, n=6). Misoprostol enquiries comprised 18.3% (n=11) of the ADEC Category X calls, with most calls not listing a gestational period (n=7). The distribution of ADEC Category X enquiries and relation to gestational period (Figure 17) illustrates the predominance of enquiries relating to isotretinoin in the second trimester.

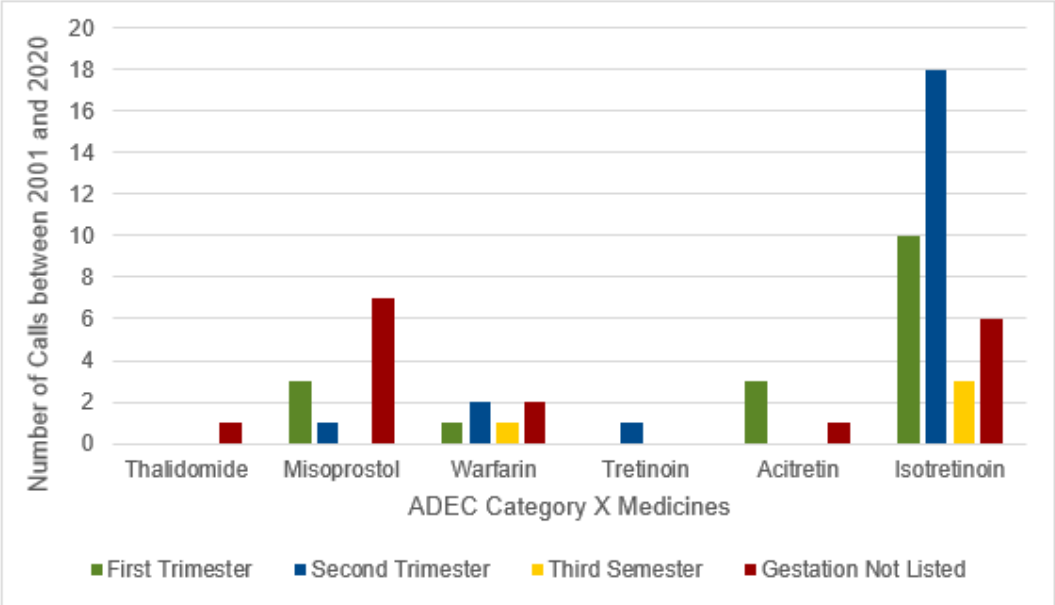

Figure 17: ADEC Category X Medicine Enquiries to KEMH OMIS (n=60)

4.7.4.2 Medicines Contraindicated in Breastfeeding

Referring to the medicines listed in Table 4, 111 enquiries were taken by the KEMH OMIS between 2001 and 2020 regarding the safety of one of these medicines in breastfeeding. More than half of the 111 calls related to products containing iodine

(65.8%, n=73), predominantly within the first six months of the infant's life (46.6%, n=34), although 31 calls did not list the age of the infant. Furthermore, 25 enquiries related to use of lithium in breastfeeding (22.5%), again with the first six months of the infant's life the most common period of concern (40.0%, n=10) (Figure 18).

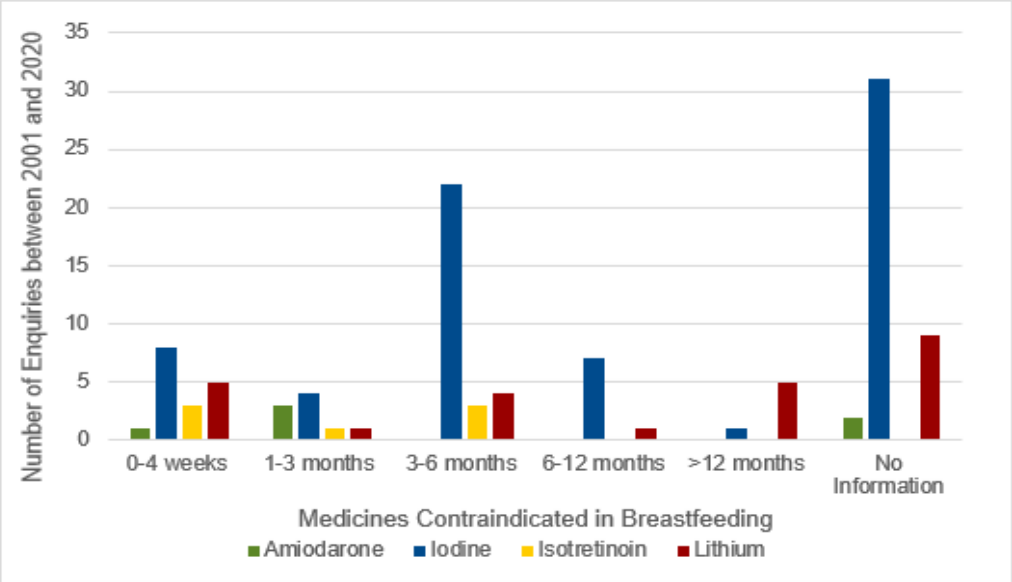

Figure 18: Enquiries to the KEMH OMIS Related to Medicines Contraindicated in Breastfeeding (n=111)

4.7.4.3 Sodium Valproate Use in Pregnancy

An increase in enquiries relating to use of sodium valproate in pregnancy was noted in 2014 (Figure 19). No obvious trends were noted in 2008 and 2009, the years in which the warnings were published. Of note is the significant decline in enquiries when number of enquires in 2014 were compared to those received in 2020 ($p<0.001$).

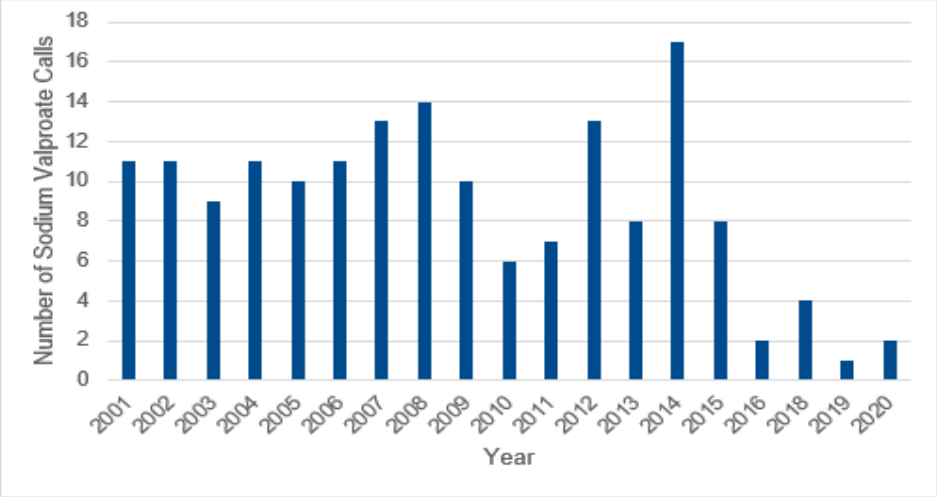

Figure 19: Number of Sodium Valproate Calls in Pregnancy to the KEMH OMIS (n=168)

4.7.4.4 Fluconazole Use in Pregnancy

Fluconazole-related calls to the KEMH OMIS (Figure 20) were variable over the years; however, the second highest peak of fluconazole calls in pregnancy occurred in 2018, coinciding with the TGA warning, a significant increase when compared to the number of enquiries since 2001 (*p=0.03*).

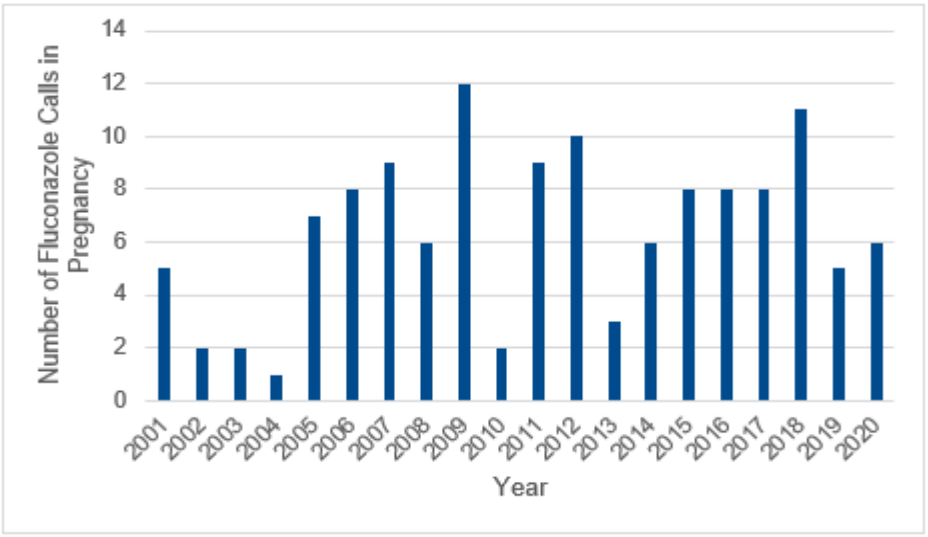

Figure 20: Number of Fluconazole Related Calls in Pregnancy to the KEMH OMIS (n=128)

4.7.4.5 Codeine Use in Breastfeeding

Figure 21 illustrates a reduction in codeine-related enquiries in breastfeeding since 2016. From 2001 to the TGA advice release (2015), the codeine related enquiries identified a significant declining trend over the 20-year period ($p<0.001$). Since the release of the updated information in 2015, a steady decline is noted in enquiries from 35 enquiries in 2015, to 12 enquiries in 2020.

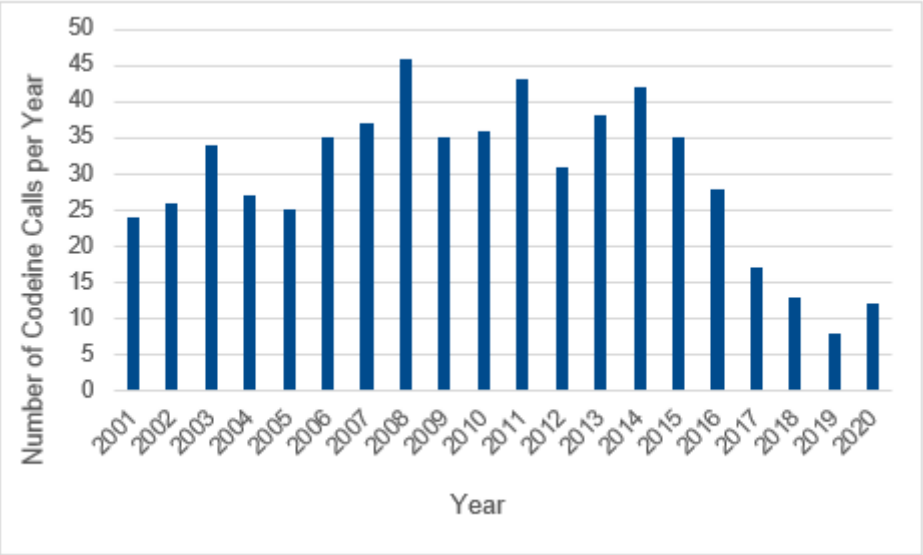

Figure 21: Number of Codeine Related Calls in Breastfeeding to the KEMH OMIS (n=592)

4.7.4.6 Ranitidine Availability

The non-availability of ranitidine in 2020, and subsequent recommendation of PPIs, were reflected in significant changes to enquiries relating to these medicines (Table 13).

Table 13: Ranitidine and Proton Pump Inhibitor Enquiries to KEMH in 2019 and 2020

Medicine (Class)	**2019 Enquiries**	**2020 Enquiries**	***p*-value**
Ranitidine	12	3	0.002
Proton Pump Inhibitors	19	41	0.004

4.7.4.7 Recreational Substances

During the 2001 and 2020 period of data collection, 373 enquiries (0.8%) related to use of recreational substances in pregnancy or breastfeeding. More than half of the calls pertaining to recreational substances were breastfeeding enquires (Figure 22).

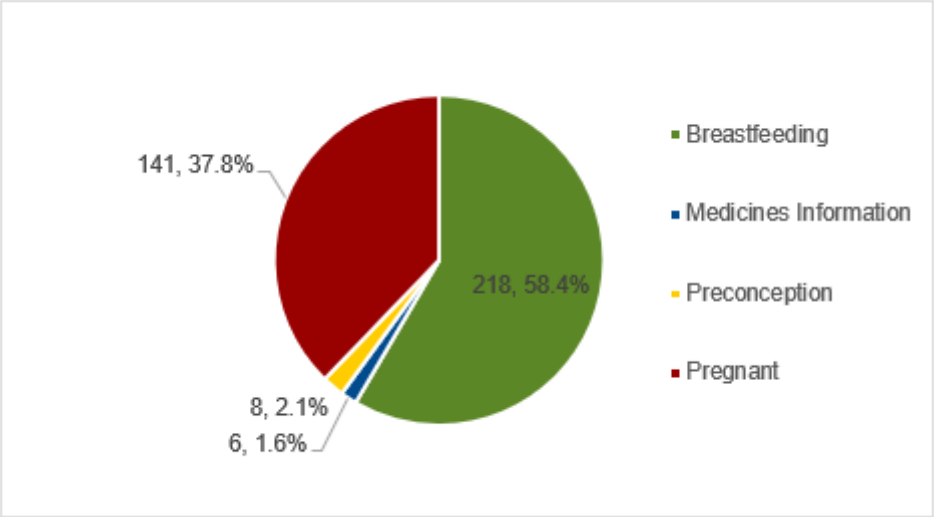

Figure 22:Types of Recreational Substance Enquiries to the KEMH OMIS (n=373)

The number of recreational substance enquiries showed a declining linear trend from 2001 until 2020 ($p<0.001$), from 50 calls in 2001 to five in 2020 (Figure 23).

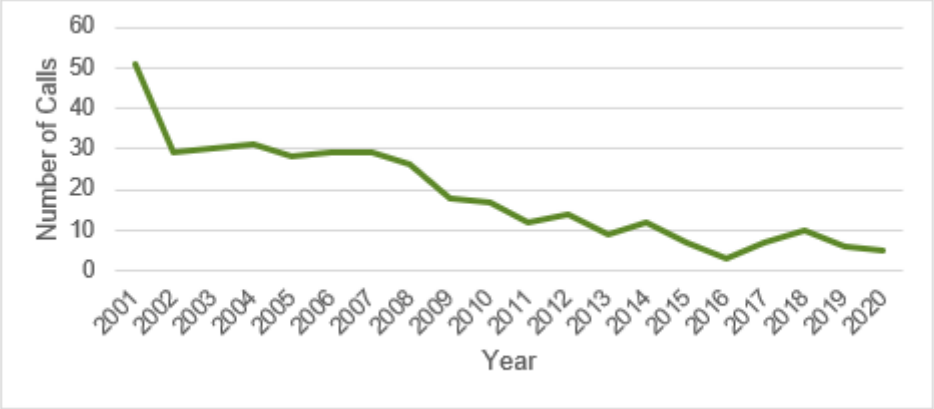

Figure 23: Number of Recreational Substances Enquiries per Year (n=373)

Amphetamines and cannabis accounted for 41.6% and 39.1%, respectively, of enquiries relating to recreational substances (Figure 24).

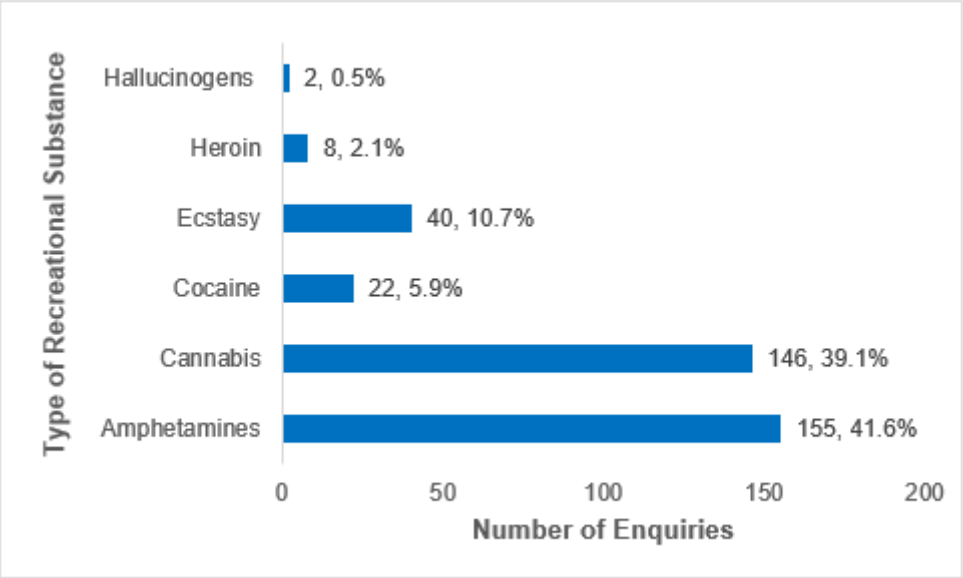

Figure 24: Types of Recreational Substance Enquiries to the KEMH OMIS (n=373)

4.7.4.8 COVID-19

There were only five COVID-19-related enquiries recorded in the database. Two enquiries related to breastfeeding and one related to the third trimester of pregnancy. The remaining two were categorised as medicine interactions with methotrexate, possibly indicating an enquiry related to an immunocompromised individual and their risk of contracting COVID-19. There were no references documented within the enquiry record.

4.8 Discussion

This research aimed to evaluate the database of medicine information enquiries received by the KEMH OMIS over a 20-year period.

4.8.1 Enquiry Details

Enquiries fielded by the KEMH OMIS pharmacists were associated with breastfeeding and pregnancy at 48.2% and 42.1%, respectively. Data from Mothersafe in NSW identified a slightly higher incidence of pregnancy-related calls (53.8%), compared to breastfeeding calls (38.8%). While medicines use in breastfeeding poses a risk, this situation can be less challenging to manage than medicines use in pregnancy, due to potential harm to the fetus, which may not be evident for some time. In 2006, a study by Hauck *et al.* identified that 93% of Western Australian women initiated breastfeeding postpartum and continued on discharge from hospital.[91] This was higher than 2019 data from NSW that reported a breastfeeding rate of 77.1% on discharge from hospital.[92] The Australian Breastfeeding Association indicated that in 2017, 64.9% of Western Australian women were still exclusively breastfeeding one-month postpartum.[93] The higher breastfeeding rate in WA could contribute to the increased incidence of enquiries regarding medicines in breastfeeding.

Health professionals were the dominant users of the KEMH OMIS. Conversely, the majority of calls taken by Mothersafe were by health consumers (48.1% of all calls to the OMIS, compared to 82.8% of calls to Mothersafe). In the current analysis, the most common health professionals were medical practitioners, consistent with data from Mothersafe and NPS MedicineWise. An understanding of the marketing and advertising approach of other obstetric medicines information services may shed light on the recognition of the KEMH OMIS within the public domain. The current WA advertising of the KEMH OMIS is limited to print media associated with KEMH and word of mouth (see Section 6.3).

The data showcased that the most common period of concern for callers in relation to pregnancy was the first trimester. The concern during this period of time is warranted

due to rapid cell division and growth occurring during this time, and the potential for medicines to interfere with fetal limb and organ development.[1] Proportionately, the number of calls relating to the first trimester indicated a predominance of enquiries by medical practitioners over nurses or midwives. This association was expected, due to the medical practitioner being the health professional most likely to confirm and manage the first stages of pregnancy, prior to referral to a midwife for ongoing pregnancy management. In the same token, it was noted that the public callers were most concerned with the second trimester of pregnancy, which may be associated with the woman's expanding knowledge or increased awareness of her pregnancy and how medicines may affect her fetus.

In breastfeeding, the KEMH OMIS data highlighted that the first four weeks of the breastfed infants' life was the period resulting in the majority of medicines enquiries. This period may be when the breastfeeding woman requires medicines post-partum to manage pain, possible infections, breastfeeding complications or ongoing pregnancy-related diseases such as hypertension or diabetes.[3] This period of concern was consistent across all users of the KEMH OMIS. Similar studies reported by Mothersafe and NPSMedicinewise, did not identify the age of the infant in breastfeeding queries. However they did acknowledge that postpartum medicines use is common, with most women having to take at least one medicine, either for an acute or chronic conditions.[3, 4, 51] Pharmacokinetic data within the early weeks of breastfeeding also indicate that the transfer of medicines, while low overall, may be slightly increased due to large gaps within in the milk duct's alveolar cells that take a few days to close and further slow the entry of medicines into the breastmilk.[19] Considering these factors and the high incidence of postpartum Western Australian women discharged whilst breastfeeding (93%), the period of initial concern within these first four weeks is warranted as breastfeeding during this stage is expected to be common.[91]

Medicines use contributes to the quality of life of Australians in both preventative and curative health.[94] In 2017 to 2018, Australians spent approximately AU$22.3 billion on medicines. Pregnant and breastfeeding women formed part of these statistics, using both prescribed and over-the-counter medicines.[94] The KEMH OMIS data identified that more than 80% of enquiries over the 20-year period belonged to 20 medicine classes (Table 9). Antimicrobials, antidepressants, analgesics and complementary

medicines were the most common medicine classes in the WA data, with antihistamines, anti-emetics and cold and flu products also common. These findings were consistent with international and Australian pregnancy and breastfeeding service data, highlighting similar trends within the medicine classes used by women seeking medicine safety information.[4]

The AIHW *Medicines in the Health System* report, released in 2020, identified the top 10 prescriptions within Australia between 2017 and 2018; these broadly included medicines for hypercholesterolaemia, gastro-oesophageal reflux disease, hypertension, antimicrobials and antidepressants.[94] As medicines for hypercholesterolaemia and hypertension, mainly angiotensin-converting enzyme inhibitors (ACE-Inhibitors), are not recommended to be used in pregnancy and breastfeeding, these two medicines classes were not captured within the 20 most common medicines identified in the KEMH OMIS results. However, the KEMH OMIS data identified alignment through a high proportion of enquiries relating to antidepressants, antimicrobials and anti-reflux medications. During pregnancy, the incidence of gastro-oesophageal reflux symptoms may increase,[1] and would account for the increased request regarding the safety of this information in pregnancy. Additionally, the risk of postpartum infection after delivery can be increased, especially after complicated Caesarean sections requiring the mother to be on antimicrobials to decrease her infection risk.[19] Depression, during and after birth, occurs in 10-15% of women, a rate comparable across western countries, and can increase the requirements for medicines to assist with symptoms of depression and anxiety.[95] Appreciating the sensitivity of this period of change in a woman, health professionals need to be able to confidently prescribe antidepressants safely to ensure the woman's symptoms can be relieved and inadvertent exposure to the infant is minimised. In the AIHW report, escitalopram was listed in the top 10 medicines prescribed.[94] Both sertraline and escitalopram occurred in the 10 most frequent enquiries relating to antidepressants, and based on current evidence, these medicines are the most preferred for the management and treatment of depression in pregnant and breastfeeding women.[74]

The 20 most common medicines enquired to the KEMH OMIS, appeared to have relatively consistent proportions when compared to the years previous and after. These

data were not able to be used to draw conclusions about the *prevalence* of use of medicines in pregnancy and breastfeeding. More accurately, these data represent the prevalence of *concerns* about use of these medicines, which could be influenced by new medicines entering the market and media publicity about risks. Furthermore, the data are local to Western Australia, where particular local influences on medicines usage (e.g., prescribing preferences) and concerns about medicines (in local media) may apply.

Calls to the KEMH OMIS varied over the 20-year period, with a notably significant decline in the number of calls per year. A total of 48,458 enquiries were recorded over the 20 years, with an average of 2,422 calls per year. Mothersafe recorded an average of 15,700 calls per year,[4] while NPSMedicineWise data recorded 4,573 pregnancy-related calls over an eight-year period, an average of 571 pregnancy calls per year, although this was a subset of data from more than 120,000 medicines information calls received to the service in the same eight-year period.[46] This variability in service utilisation could be influenced by population statistics, number of births per year, the location of the service and accessibility of the service. The KEMH OMIS is situated in the principal hospital for high-risk obstetric care within WA, with smaller hospitals across the state managing non-high-risk pregnancies. In the latest published Australian Birth Rates by the Australian Bureau of Statistics (ABS), WA recorded 32,420 births in 2020, compared with 93,579 births in New South Wales. Those data also demonstrated a decline in the number of births across Australia from 2019 to 2020, by 11,463 births (3.7% nationally). WA saw a comparable 3.3% decline in births from the same period.[96]

Between 2011 and 2015, there was a notable increase (46.6%) of enquiries recorded by the KEMH OMIS. This increase in the number of calls could not be attributed to any direct changes within the KEMH OMIS service, with staff recruitment and retention remaining consistent over this time frame. Due to the nature of the Microsoft Access® database, it was assumed unlikely that duplication of records could occur. This was confirmed during review of the raw data for analysis which was provided in consecutive order and no duplications were noted. These data also did not correlate with a significant increase in birth rates listed by the ABS,[96] hence, for Western Australia this incline is speculated to be due to the mining boom, and the increase in

financial stimulus and migrant population arriving within the state. This migrant population may have contributed to the increased use of the service. The likely reason(s) for the notable increase in enquiries between 2011 and 2015 remains unknown and inconclusive, with the above factors evaluated and eliminated during the process. Whether the environmental factors potentially impacted the service records and/or enquiries over this period also remains unclear.

Aside from population statistics and birth rates that can invariably affect enquiry rates to a service offering medicines information in pregnancy and breastfeeding, there are numerous observations and experiences amongst the KEMH OMIS pharmacists, including from the researcher herself, that may account for the decline in recorded queries. The KEMH OMIS is an unfunded service, with no dedicated staff to support the service. Multiple KEMH pharmacists cover the OMIS telephone line throughout the day, in a shared office. When a pharmacist is unavailable, a message is taken for the caller to be contacted at a later stage. Once an enquiry has been completed, it should be recorded into the OMIS database; however, there are a number of reasons this may not occur. Firstly, the OMIS database only allows access to one user at a time and should that be 'in-use' and therefore locked, the pharmacist may forget to input the enquiry at a later stage. Secondly, KEMH pharmacists may answer queries while performing a different task, such as dispensing; the details of the enquiry are handwritten and may be misplaced before recording. Thirdly, in 2015, KEMH became a Pharmaceutical Benefits Scheme (PBS) Hospital, with additional pharmacists appointed to assist with the medicine management changes on clinical wards. At this time, request for a dedicated OMIS pharmacist was declined due to the functional brief prioritising implementation of PBS services. As such, as clinical pharmacists' workload reportedly increased and their ability to service the OMIS was a competing priority, the recording rate of KEMH OMIS enquiries declined. Collectively, the single-user availability of the database, lack of a dedicated staffing and generally increasing workload of the pharmacists may account for the diminishing documentation of enquiries since 2015.

4.8.2 KEMH OMIS Access

When comparing the KEMH OMIS to similar services, it should be noted that the platform on which the KEMH OMIS can be contacted is via a standard telephone number or the hospital switchboard. No online platform is available. A review of a Norwegian online medicines information service noted a steady rise in the number of web-based enquiries compared to telephone enquiries, and concluded that a web-based service for the public may be the preferred method of communication.[40] Mothersafe is not restricted to having a standard telephone number, offering a convenient 1800 number to New South Wales residents.[44] The KEMH OMIS is recognised by the TGA[45] and the *AMH*[44] as a state-wide service for WA; however, it is not recognised within the organisational structure of the Women and Newborn Health Service (WNHS).

The KEMH data identified that health professionals were the predominant users of the service, with medical practitioners the most common health professional enquiring about medicines in both pregnancy and breastfeeding. As established in Section 2.3 and 2.4, the interpretation of medicines safety information in pregnancy and breastfeeding can be misleading or confusing due to conflicting information or inability to access current, evidence-based information. In addition, health professionals are, for the most part, time poor, and the ability to adequately research and assess information to make an informed decision during a patient consultation can compromise the work flow and optimal patient care.[40, 49] Therefore, the ability for health professionals to be able to contact a service such as the KEMH OMIS can be assumed to assist in their practice and patient outcomes. The KEMH OMIS data demonstrated a significant increase in health professionals' use of the service over the 20 years, with a linear trend from 2007. The process of contacting the service could become habitual by health professionals, particularly after a positive initial experience with the service. Furthermore, in 2015, five factors increased the disease burden within Australia: tobacco use, overweight and obesity, dietary risks, high blood pressure, and high blood glucose levels (including diabetes). These factors accounted for 38% of the total disease burden in Australia, most of which are preventable.[97] The increase in health professionals' usage of the KEMH OMIS over the years may also be due to increased disease burden within society, along with increase in chronic medical

conditions that require treatment, with this becoming additionally complex when a woman becomes pregnant or is breastfeeding.

Health consumers' usage of the service generally decreased over time. A trend for patients to become informed about their medical conditions and treatments is recognised in the literature, typified by the use of freely available internet search engines, also colloquially known as 'Dr Google'.[20] Conversely to health professionals who may routinely manage pregnant and breastfeeding women, for the consumer, the period of pregnancy and breastfeeding is relatively short-lived, and time bound. Repeat and ongoing use of the service may not be warranted or expected amongst health consumers. There are insufficient insights from the current data to draw conclusions about word-of-mouth awareness of the service in the community and long-term consumer commitment to using the service. As the KEMH OMIS does not have the ability to capture call data through automated recording, the attending pharmacist would need to identify if a caller was a regular user of the service.

The decline in use of the service by consumers may also coincide with the introduction to smartphones and increased availability of online information on these devices. Without an online pharmacist or a 'Chat Now' function, this could further decrease consumer access to the KEMH OMIS as commented by the Norwegian study, that online formats of contact appeared to be a favourable medium for participants.[43]

Both Mothersafe and MothertoBaby reported a higher number of pregnancy-related calls than for breastfeeding.[4, 9] This prevalence was expected due to the higher risk posed by medicines in pregnancy[69]. The gestational period of pregnancy is nine months, although a woman may not be aware of her pregnancy for the first two months. An assumed seven months of known pregnancy is longer than the recommendation by the NHMRC for infants to be exclusively breastfed for at least six months of their life.[60] In the latest *Australia's Children* report by the AIHW, the average length of time an infant is breastfed from birth in Australia is at least four months.[98] This rate has been consistent in Australia since 2015.[98] This relative duration of 'known pregnancy' to 'typical duration of breastfeeding' reflects the current distribution of calls relating to medicines use in pregnancy versus breastfeeding. The decrease in pregnancy enquiries over the 20 years reflected in the KEMH OMIS data, may be due to the fact

that prior to or during pregnancy, women are more likely to cease medicines rather than incorporate them into their healthcare due to the perception of a greater risk of continuing the medicine, than ceasing it during pregnancy.[99, 100]

Medical practitioners predominantly contacted the KEMH OMIS for enquiries regarding pregnancy when compared to nurse and midwives, whose enquiries largely surrounded medicines in breastfeeding. This correlation between the two groups of health professionals can be expected given that more pregnancies that are low risk are moved from a medical practitioner care model to a midwife-led care model. [101] During delivery and at the time of birth, this chain of custody changes to the midwife, nurse or child-health nurse, whose concerns include breastfeeding and the infant's growth and development.[101]

4.8.3 Understanding the Patterns of Medicines Use

As previously stated, the five most commonly queried medicine classes identified within the data were consistent with those from studies in Australia and America. These included antimicrobials, antidepressants, analgesics, complementary medicines and antihistamines.

Of the antimicrobials, amoxicillin was the most common subject of enquiries, which would be expected given amoxicillin's broad antimicrobial spectrum and established availability.[44] The same rationale can be applied to both sertraline and escitalopram, the older of the SSRIs, which appeared in a higher proportion within the calls, this was anticipated due to the longer history of safe use resulting in more common use amongst pregnant and breastfeeding women, thus increasing the probability of an enquiry to the service. The volume of enquiries appears confounded by the enquiries relating to antimicrobials and antidepressants. The volume of these medicine classes or monitoring of medicine classes can be used to anticipate if or when certain medicines begin to appear as 'hot topics' and therefore be utilised for training and education purposes. However, to be able to utilise this information, this would require real-time monitoring of trends to identify and potential increasing demand relating to particular medicine classes.

Paracetamol was the most common medicine amongst the analgesic enquiries. Its wide availability and prevalence of use aligns with the proportion of enquiries relating to this medicine. Of note, in 2021, data disputing paracetamol's safety in pregnancy led to multiple news entities and online platforms reporting conflicting information regarding the continued safety of paracetamol in pregnancy.[102] Commentators identified a number of disparities in the information provided, and Bauer *et al.* and the Royal Australian College of Obstetrics and Gynaecology,[103] among other groups, queried the validity of the article for causing unnecessary concern about use of paracetamol in pregnancy. These studies recognised that paracetamol should be used short term, and that pregnant women should discuss their medicine-related needs with their health professional.[103] Ongoing analysis is recommended to observe any impact of this public debate.

Complementary medicines are increasingly used across the world, with international sales of herbal medicines an estimated AU$33 billion market.[65] Pregnant and breastfeeding women are no exception to this trend, with the perceptions that the 'natural' constituents of complementary medicines render them safe during pregnancy and breastfeeding, and that these medicines provide the patient with autonomy in her medical decisions and a holistic approach to her care. Medicines information services such as Mothersafe and MothertoBaby have identified complementary medicines within their most common medicine enquiries, representing 8.2% and 9.7% of enquiries, respectively.[4, 9, 46] There is a general lack of information or basic knowledge on the safety of complementary medicines in pregnancy and breastfeeding, and these products may not have a distinct indication that is known to the woman or her health professional.[9] Complementary medicines accounted for 7.9% of all KEMH OMIS enquiries over the 20-year period, similar to comparator studies.[4, 9] The most common complementary medicines included pregnancy multivitamins, and colecalciferol and magnesium, all of which could be appropriately and safely used in pregnancy and breastfeeding. Lysine featured commonly, and this is in line with the safety advice around lysine to minimise the incidence of cold sores.[104] St John's Wort also featured commonly. St John's Wort is indicated for anxiety disorders; however, safety information is limited.[104] The 'it is natural, therefore it is safe' mantra continues, despite conflicting information.[65]

The ease of availability of complementary medicines can increase their uptake by pregnant and breastfeeding women. For the most part, complementary medicines are unscheduled, and therefore available in health food shops and supermarkets, increasing their presence and perceived safety. In Australia, most complementary medicines are 'AUST-L' products, indicating they are listed by the TGA, i.e., "usually considered to be relatively benign".[105] They are assessed by the TGA for safety and quality, but not for efficacy. As such, the majority of listed medicines are self-selected by consumers and used for self-treatment.[105] Guidance in the use of complementary medicines in pregnancy and breastfeeding ensures women and health professionals understand the potential risks and benefits of these medicines so consumers are able to make relevant and safe clinical decisions.

Within the KEMH OMIS data, a number of medicines were listed as 'complementary medicines' without identifying specific ingredients. To allow for more accurate classification and identification, it would be worthwhile to ensure documentation of their brand name and label details.

The review of changes in medicines safety information and how this information affected calls did see some significant changes. For medicines that were considered contraindicated in breastfeeding it was noted the predominance of enquiries relating to these high-risk medicines did not have the age of the infant documented. Given this, it suggests that these enquiries may have been hypothetical in nature, i.e., by or for mothers who were considering breastfeeding or during the prescribing process. The data from these enquiries could be used to promote educational activities or guide the information available on the KEMH Pregnancy and Breastfeeding Information Hub. The other change noted was the decline in codeine related enquiries in breastfeeding. While part of this decline could be attributed to the decreased usage of codeine in breastfeeding, another confounding factor is likely due to the up-scheduling of codeine from an over-the-counter product to a prescription only product in 2018.[106] This up-scheduling would have resulted in decreased usage due to the access barrier of no longer being able to purchase codeine-containing products over-the-counter.

4.8.4 Pregnancy and Breastfeeding Medicines Information

The KEMH OMIS data included the reference material reportedly utilised by the pharmacists. This field was an optional free-text field within the Microsoft Access® database, and as such was subject to missing data, while the documented data required coding for analysis. The most commonly utilised reference was *The Royal Women's Hospital: Pregnancy and Breastfeeding Medicines Guide*. The rationale for this was two-fold. Between 2001 and 2016, this was a hard-copy reference and the KEMH OMIS procured multiple copies of the book for OMIS pharmacists. In 2016, the reference became available online via subscription, and the KEMH pharmacy maintained a three-user licence. In addition, *The Royal Women's Hospital: Pregnancy and Breastfeeding Medicines Guide* was developed to provide evidence-based, up-to-date medicines information in pregnancy and breastfeeding in a succinct and consumer-friendly manner.

The Pharmacy Board of Australia recommends a selection of resources as part of a Pharmacy Department's resource library.[90] Pregnancy and breastfeeding references are not listed in these guidelines. Appendix 3 highlights the extensive, although not exhaustive, reference list utilised and maintained by the KEMH OMIS to ensure access to the most current, evidence-based information to support the service. The KEMH OMIS, in conjunction with the KEMH Library, have created a platform within the WNHS Library Page, the *Pregnancy and Breastfeeding Information Hub (PBMI Hub)*. This online resource was designed to improve accessibility to pregnancy and breastfeeding information and provide resources that are peer-reviewed and relevant. Access to the PBMI Hub or other reputable pregnancy and breastfeeding medicines information resources should be ensured for health professionals within any setting in which they may provide care for pregnant and/or breastfeeding patients.

The KEMH OMIS Pharmacist Training Log indicates that when providing safety information, it is valuable to consult more than one reference to confirm or deny the safety of a medicine in pregnancy and/or breastfeeding. This process also assists in ensuring available information is non-conflicting, and should two references differ, subsequent references should be consulted. Interestingly, more than three-quarters (76.3%) of the KEMH OMIS calls only documented use of one reference. This

unexpected finding may be due to lack of adequate recording space within the non-mandatory free-text field in database. Without a 'selection list', documenting the references may be cumbersome and time consuming, and this may account for the 76 call records missing this information.

A single reference may indeed have been succinct and adequate to answer the enquiry, given that *The Royal Women's Hospital: Pregnancy and Breastfeeding Guide* and *Thomas Hales: Medication and Mother's Milk* were the references recorded for almost half of all calls. The level of experience of the pharmacist is another consideration, with pre-registration and early-career pharmacists more likely than senior pharmacists to document use of more than one reference.

If pharmacists understand the purpose of documenting the reference(s) they cited, this could improve the quality of their data entry and provide educational opportunities around use of references. Complex enquiries could be subjected to a tiered approach, with escalation to experienced pharmacists and obstetricians who are more familiar with a range of references and can provide tailored, current and evidence-based advice. This ability to escalate or collaborate regarding a complex enquiry promotes team work, quality and safety. An OMIS colleague was listed as a reference on 59 occurrences, and this is suspected to under-represent current practice. Forced menu selections in the database would provide more accurate data.

While information on medicines use in pregnancy and breastfeeding is available, it can be scant, controversial or conflicting. Assessing and monitoring changes to information can be challenging. Furthermore, marketing of new medicines may increase queries regarding these medicines, amid scant information for OMIS pharmacists. Primary healthcare providers are well positioned to provide information to consumers, easily accessible and trusted in the community.[46] However, the references available to these practitioners, including *MIMS*[107] product information, *AusDI*[108] and the *AMH*,[44] can provide conflicting information and encourage a more cautious approach to medicines use in pregnancy and breastfeeding. This may result in under-management of the consumer's condition or inappropriate discontinuation of breastfeeding.

The expertise and resources available within the KEMH OMIS can offer tailored, up-to-date education seminars to assist health professionals. In addition to professional collaboration, contribution by the KEMH OMIS to international collaborative databases can help promote further research and development within this area. These concepts are discussed in Section 6.3 (Recommendations). At the time of writing, the OTIS, ENTIS (European Network of teratology Information Services) and Mothersafe are in collaboration with the aim to publish information across continents to enhance the availability of current, evidence-based information in pregnancy and breastfeeding.[4] Local collaboration with entities, such as the Pharmaceutical Society of Australia (WA Branch), The Pharmacy Guild of Australia (WA Branch), the WA Primary Health Alliance, Curtin University and the University of Western Australia, would help promote Continuing Professional Development in this field.

For consumers, information access during pregnancy and breastfeeding may be more challenging than for health professionals.[11] With pregnant and breastfeeding women usually excluded from clinical trials, product information usually recommends avoiding use of the medicine whilst pregnant or breastfeeding.[73] Accessing information from the internet can reveal conflicting information, increase anxiety about the medicines and the risk of woman ceasing the medicine entirely.[20] The 48.1% of enquiries from the public, who may have been the pregnant or breastfeeding women herself, suggests a desire for empowerment in self-medication and decision making while their child is vulnerable to the adverse effects of medicines. Further development of the KEMH OMIS to enhance usability for the public should draw upon existing users of the service and the KEMH Consumer Advisory Committee to identify avenues that will promote and empower women to access relevant, evidence-based information that informs their healthcare.

A large proportion of this research involved data cleaning and coding in a predominantly free-text database. NPSMedicineWise and Mothersafe both make reference to the use of Anatomical Theoretical Chemicals (ATC) of WHO, [3, 22] where medicines are grouped by their function and pharmacological action.[51] Utilising these coding platforms may be useful in the future to facilitate data coding, collation and analysis and promote knowledge sharing across the specialty. The Microsoft Access® database and its subsequent Microsoft Excel® extract presented a number of challenges

in preparing the data for analysis, and accounts for the lack of descriptive and temporal analysis since its inception. Creation of a database or recording platform with more standardised data entry, and which facilitates data extraction and analysis, will enable ongoing analysis of the enquiries data and continuous quality improvement of the service.

The KEMH OMIS data expanded the variable of the age of the infant. This expansion of the age of the infant could be utilised to further explore the age of the infant and the concerns of the breastfeeding woman or her health professional. This information can be added to the pregnancy and breastfeeding information available and the data available pertaining to the type of information requested by the callers or information that could be of value to the health professionals providing the response.

Chapter 5: User Engagement

This chapter addresses Objective 2: determination of user engagement with the OMIS service by way of a user survey to address knowledge and use of the service for future development.

5.1 Introduction

The involvement of end users within health is integral to ensure services are designed and implemented that are appropriate, accessible and tailored to the consumers of the health service. User engagement can inform patient and provider education and policies, as well as enhance service delivery and governance and has become an important role in delivering quality care.[109] End users can provide a 'lived-experience' of the service, that can complement the expertise of health professionals, and together this can inform the design and delivery of health services.[110, 111]

The NHMRC recognised consumers' right to be involved in health and medical research as equal partners in the development of research goals, strategies, methodologies and dissemination of research that were "open to informed public scrutiny and debate" and ensured "the integrity of research and accountability to the community for the quality of the research".[112] Consumers' or end-users' participation in service evaluation and research is highly regarded and advocated for, to assist in shaping health systems and services, and develop ability of systems to become more inclusive, accountable and responsive to the needs of the users while improving health outcomes and access.[113]

The NHMRC recognised this potential in quoting the 1978 declaration by the WHO, which advised that "people have the right and duty to participate individually and collectively in the planning and implementation of their health care". This paved the way for consumer representation and participation in health care, health services and health and medical research in the UK, Western European countries, North America and Australia.[114]

Accessing the experience and opinions of the consumer or end user as a method of feedback within health services allows the researcher to gain an understanding of their audience and how to develop and implement changes that could positively benefit their clientele. By doing so, this can improve the reputation of their service or service delivery model.[115]

Numerous methods may be utilised to survey or engage with users to gain an understanding and insight to end-user feedback,[116] including face-face interviews and focus groups, hard-copy mailed surveys, telephone surveys, web-based survey and mixed-mode surveys. Face-to-face surveys usually comprise an interview by the researchers, either individually or in the form of focus groups. Mailed surveys consist of a hard-copy format of the survey mailed to respondents for self-completion independent of the researchers' involvement and then a completed survey returns for data collection. Telephone surveys comprise of an interview by the researcher over the telephone and the interviewer can collect data through a structured conversation. Table 14 identifies the advantages and disadvantages of each survey method, and how the choice of the method will impact the responses attained.[111, 116]

Table 14: Methods of Survey Delivery- Advantages and Disadvantages, Adapted from Cowles *et al.*[116]

Survey Method	Advantages	Disadvantages
Face-to-face	Researcher has control over data entry and can rephrase or adapt survey questions Establishment of rapport and personal contact with respondent Provides maximum contact between interviewer and respondent Interviewer can use respondents body language and voice inflections as cues to assist Consent may be more easily attained when face-to-face Ability to probe respondent for more information	Interviewer-administered Assumes all respondents understand each question in the same way Expensive model Suitable location required Time-consuming

Table 14 cont'd

Mailed Delivery	Self-administered by respondent Cover letter can provide good explanation of the survey and motivation to complete Clear instructions can be provided on how to complete the survey Visuals and graphics can be used to capture the respondent's attention in the survey Privacy for the respondents, which may allow for more truthful answers	Researcher has no control over data entry If question is ambiguous or misinterpreted, no explanation can be provided No personal contact with researcher Assumes respondents read and speak language in which the survey was written Associated printing and mailing costs Increased risk of non-response
Telephone Surveys	Researcher has control over data entry and can rephrase or adapt survey questions Establishment of rapport and personal contact with user Conversational-style questioning Opportunity to discuss the question if ambiguous and flexibility for interview to use vocal cues Ability to leave a voice message when respondent cannot be reached Data entry can be conducted in real-time Verbal consent can be easier to achieve Audio-recordings can be obtained with consent Less expensive than mailed surveys Larger cohort of respondents can be contacted over a short period of time	Time-Consuming which can become an expensive model Decreased capacity if utilising landlines, due to decreased availability No ability to use visuals or graphics within survey questions Questions need to be succinct to avoid loss of translation or interest when reading them to the respondent, Relies on the respondent answering the telephone Non-response requires follow-up
Web (Online) Delivery	Self-administered by respondent Easily accessible – where internet access is available Cost-effective Visuals and graphics can be added, including links for further information Survey design can allow sections to be skipped and not viewed by respondents	Researcher has no control over data entry No personal contact with respondent If question is ambiguous to the respondent, no explanation can be provided Assumes respondents read and speak language in which the survey was written Increased risk of non-response

For the KEMH OMIS user engagement survey, a telephone-survey was chosen for the following reasons:

1. The KEMH OMIS service is predominantly a telephone service, and users were assumed to be familiar with this method of communication
2. The telephone survey allowed for a cost-effective and time-efficient method to reach the target of 180 completed surveys
3. The researcher could establish a rapport with the caller based on their previous call history
4. The survey could be conducted efficiently, as opposed to waiting for completed questionnaires to be returned or submitted
5. Contact details provided at the time of the initial call by users were predominantly mobile telephone numbers.

The clinical supervisor pharmacist at KEMH extracts OMIS data to conduct brief periodic OMIS telephone surveys for informal quality assurance purposes; however, no data have been published from these surveys. The surveys have been utilised for training purposes or information sharing within the pharmacy department and reported bi-annually to the Director of Clinical Services, the direct reporting line for the KEMH Pharmacy within the WNHS organisational structure. While there is no historical record of why telephone surveys have been utilised, the advantages outlined in Table 14 suggest this mode of communication enabled timely reach to those utilising the OMIS service, while offering (although not assuring) privacy. It also mirrored the mode of communication through which the enquiries had been received. As indicated in Section 3.2, callers are routinely asked for their contact details as part of the record-keeping process and as a method to facilitate clinical follow-up if required, as well as feedback. The components of these telephone surveys are discussed in Section 5.3 with reference to design of the present survey.

5.2 Ethical Considerations

As reflected in the Section 3.3, the researcher was also a staff member of the OMIS. As such, steps were taken to ensure that the researcher's access to the enquiry data was limited to the purposes of this research. For integrity, database requests were made

through and provided by the Chief Pharmacist of KEMH, with identifying information unrelated to the research removed. The records of KEMH OMIS enquiries include callers' contact details, a request made by the pharmacists at the end of each query. These contact details were used for random selection of enquirers to participate in the telephone survey.

It was possible that the researcher could contact a caller whose medicines enquiry had been answered by the researcher. To reduce bias in the selection, the pharmacists' details were removed by the Chief Pharmacist prior to the survey. This ensured that all eligible enquiries, including those answered by the researcher (in her pharmacist capacity) were retained for equity with those of other pharmacists, and for completeness of the register. In the event that the researcher recognised a case, the researcher would identify this to the respondent and request consent to continue with the survey. Should consent be declined, the researcher would remove that enquiry from the data and allocate a newly randomised enquiry.

Appendix 4 contains the Patient Information Statement provided at the start of each survey. Enquirers were not obliged to participate in the survey and could withdraw at any time during the survey.

5.3 Survey Design

As previously mentioned, the KEMH OMIS had conducted telephone surveys periodically since its establishment. The survey comprised eight questions mainly using a five-point Likert-type scale to indicate agreement (Table 15).

Table 15: 2014 King Edward Memorial Hospital OMIS User Survey Tool

Question	Potential Responses
1. How did you find out about the service?	○ Your Doctor ○ The Purple Book[c] ○ Your Child Health Nurse ○ Other – please specify
2. Was your call handled in a timely manner?	○ Strongly Agree ○ Agree ○ Neutral ○ Disagree ○ Strongly Disagree
3. Was the pharmacist who handled your call polite and professional?	
4. The information I received from the pharmacist was relevant and useful	
5. Overall, how would you rate the service?	○ Highly ○ Very Good ○ Good ○ Below Average ○ Poor
6. Did you follow the advice you received from the service?	○ Yes ○ No – please specify
7. If the service was unavailable, what would you have done?	○ Free Text
8. Do you have any suggestions for the service?	○ Free Text

Ethics approval for the 2014 survey was provided by the WA Department of Health Governance, Evidence, Knowledge and Outcomes (GEKO) system, which manages Quality Activities in Clinical Services. The GEKO Approval Number was 006411. Callers were contacted to provide consent to a telephone survey or web-based survey comprising the same questions. All callers responded via the telephone-based survey.

Available documentation revealed the most recent KEMH OMIS survey (2014) produced a total of 16 responses from enquiries made to the service and feedback sought during one week in March 2014. Of the 3 responses, two callers had found out about the service from their doctor, the 'Purple Book[c]' or their child health nurse, while 10 cited the KEMH Breastfeeding Centre, graduate or university programs and the Australian Medicines Information Centre. All 16 respondents strongly agreed that their

[c] The 'Purple Book' is a free, parent-held child health record provided by WA Health to every child at birth.

call was handled in a timely manner, the pharmacist was polite and professional, and the information was relevant and useful. They all rated the service highly and reported following the advice they were provided.

Regarding avenues if the service was unavailable, respondents said they would call their doctor or obstetrician, or contact another pharmacist. Minimal improvements were suggested by respondents; two requested a 24-hour service. The final report, which was submitted for internal reference, did not make any recommendations for the service.

The 2014 KEMH OMIS survey formed the base for the user engagement survey in the current research. The current research aimed to survey both health professionals and consumers (i.e., the public). It was important to maintain brevity of the survey to ensure callers could understand the question over the telephone and maximise responses with a short timeframe; however, improvements were introduced, as described below. The final instrument is included in Appendix 5.

1. The 2014 survey had not documented whether the caller was a health professional or a health consumer. Studies from other services identified that approximately 80% of their callers were from the public and 10-35% were health professionals.[4, 9, 51, 52] A question was added to the survey to be able to capture the identity of the caller as either a health professional or health consumer. Health professionals were then further categorised into each profession, including medical practitioner, nurse or midwife.

2. The question identifying how the caller had found out about the OMIS was important to retain to understand how users locate resources and inform marketing of the service. As such, additional prompts were included: such as if they had 'Googled' the service, had been told about the service by their health professional or located the service on one of its advertised publishing, such as the *AMH* or the TGA website.

3. The future of the service is dependent on utilisation data, so a question elucidating prior use of the service was added. For those who recalled prior use, their frequency of use was categorised as ‘rarely’, ‘fairly often’ or ‘often’.

4. As the KEMH OMIS does not have its own staffing allocation, understanding how easily the user was transferred to a pharmacist was important. If the call transfer and/or response time was commonly difficult or lengthy, the user was asked about the possible reason. Health professionals identify as time poor, and utilising medicine information centres alleviates their time pressures in accessing information.[26] Understanding if users received a response in a timely manner would assist in assessing resource allocation to the service. The response options were ‘fairly quickly’, ‘a few minutes’ or they ‘received a call-back’.

5. The 2014 survey assessed the perceived relevance and usefulness of the response attained. Understanding if the information was useful to the user could be utilised to educate pharmacists on how to relay information. The survey retained this question in an effort to ascertain usefulness, however instead of using a scale of agreement statements, a five-point Liker-type statement scale of the degree of usefulness was used, with options of ‘not useful’; ‘slightly useful’; ‘neutral’; ‘very useful’ and ‘extremely useful’.

6. A question about the acceptability of verbal responses was introduced. This reflected developments in the Norwegian Medicines Information Centre, which began as a web-based service only, with a telephone service introduced in 2016.[40] A review of their services noted a steady rise in the number of web-based enquiries compared to telephone enquiries, and concluded that a web-based service for the public may be the preferred method of communication.[43] Addition of this variable to the current survey aimed to capture if the telephone-based service is sufficient or if introduction of a web-based service as an adjunct may be beneficial.

7. As previously mentioned, seeking information regarding medicine use in pregnancy and/or breastfeeding is a mechanism to inform consumers about appropriate medical care and to reduce perceived anxiety associated with taking a medicine during this period of time.[52] A question was included to assess if the

response alleviated the user's concerns. This was measured using a five-point Likert-type ranging from 'extremely well' to 'not well at all'.

8. Given the limited scope of the service for medicines information during pregnancy and breastfeeding, the survey asked if users would utilise the service again; this would also be influenced by the level of satisfaction with the service. This was a new question added to the 2014 survey as an overall indicator of satisfaction.

9. An addition to the 2014 survey was giving the users an opportunity to engage with the interviewer, as an OMIS pharmacist to discuss their previous call, and if they would like further information. As the researcher is a trained pharmacist in the provision of medicines information in pregnancy and breastfeeding, this allowed an opportunity to explore any concerns of the user or confirm the information previously provided and was considered the researcher's duty of care during this opportunistic follow-up contact. This opportunity would also identify to the interviewer if some instances required follow up or clarification.

Three questions retained from the 2014 survey were the following:

1. As in the 2014 survey, users were asked what they would have done if the service was not available to them or if it became unavailable in the future. The rationale for this query was to understand the alternate sources of information known to users that they may access. The responses would also inform the requirement for further stakeholder engagement.

2. The 2014 survey also invited enquirers to provide suggestions for the service. As this was a broad open-ended question, the survey included an interviewer prompt: "Can you suggest any changes you might like to see with the service, such as advertising, access or awareness as examples?"

3. To assess the overall rating of the service, the 2014 rating question was retained. This utilised a Likert-type five-point scale where the number one was regarded as lowest rating and the number five was regarded as the highest rating. The rating of the service aimed to estimate the value of the service to the user.

The user survey was constructed using Curtin University's Qualtrics® account for real-time data entry. This removed the risk of transcription errors from a hard-copy document and was time efficient. The use of electronic software allowed for real-time data entry, to minimise the time taken for recording responses. The software also assisted in collation of the data for extraction and analysis.[115, 116] The platform also enabled embedding of 'go to' links within the questionnaire for efficiency within the interview.

Initial peer review of the survey was undertaken by four OMIS-trained pharmacists at KEMH, to optimise face and content validity. The pharmacists assessed the survey for its readability, the flow of the survey and assessment and critique of the questions, if they were easily understood, as well as assessing the length of the survey. The aim was to complete each survey in less than 15 minutes, to minimise the time burden for users and attain adequate information for analysis.

Three changes were made to the survey following the peer review:

1. The time scale provided when asking users if they were repeat or first-time users required revision. The original query offered options of 'rarely', 'fairly often' and 'often'. The peer review identified that these were subjective, and options were subsequently changed to '1-2 times a year', 'every 3 months (quarterly)' and 'at least once a month'.

2. The same ambiguity was recognised within the question around timeliness of answering the caller's enquiry. The assessment scales were changed from 'fairly quickly', 'a few minutes' or they 'received a call-back' to 'within 5 minutes', 'between 5 and 15 minutes' or they 'received a call-back'. This quantification was also considered useful for determination of Key Performance Indicators for the service.

3. The final change was to include the 2014 question about whether the user reported heeding the advice received during the enquiry. This question was initially removed from the survey due to the nature of the advice given by the pharmacists

to be in consultation with a health professional; however, the reviewing pharmacists suggested that this question could be posed to both health professionals and the public to understand if the advice was used or heeded, noting that in the 2014 survey, the response rate was 'yes' for 100% (all 16) of the surveys.

After the final review and amendments, the user survey was trialled with a sample of 10 callers to assess the timeliness and flow of the survey. No further changes were indicated by this pilot sample, and hence the responses from these 10 callers were included in the final sample for analysis.

5.4 Data Collection and Analysis

To ensure consistency and minimise the risk of bias, the researcher conducted all surveys. This minimised the risk of variability in interpretation and documentation of callers' responses. The survey was conducted prospectively from September to November 2020, with a target of 180 respondents to facilitate descriptive analysis, univariate and bivariate analysis was conducted. The target figure of 180 respondents was based on an estimated 30% response rate from the approximately 200 users who contacted the KEMH OMIS per month. This figure was also calculated based on 16 responses in one week from the 2014 survey, over a proposed three-month period, which would total approximately 180 responses. No seasonal effects were anticipated, so an intensive survey period was considered appropriate, rather than year-round sampling. As this feedback survey was intended as a census, the duration of the study was dictated by the required number of responses; however, a three-month period was allocated as the timeframe to allow the researcher to conduct the surveys within her research timeline.

A list of enquiries reported in the preceding 24 to 48 hours was provided by the Chief Pharmacist to the researcher. As previously stated, the identity of the pharmacist answering the medicines query was deleted. Where the enquiry occurred on a Friday, the user survey was conducted on the following Monday. The short time frame was chosen to ensure users could recall their experience with the KEMH OMIS; however, this also increased the likelihood of the researcher contacting a user to whom she had provided advice (Section 4.3). Each enquiry had a unique identifying number

generated from the Microsoft Access® database. An online number generator was utilised to randomly select a unique identifying number. This number was then used to select the enquiry for the telephone survey as a quota sample, where the researcher continued to select random enquiries until three surveys could be completed per day and 15 per week.

5.4.1 Inclusion Criteria

All enquirers, health professionals and health consumers, who consented to having their details recorded at the time of their initial enquiry were eligible to be contacted for the telephone survey.

5.4.2 Exclusion Criteria

Non-conversational-English speakers were excluded from the study due to limitations with respect to the survey format; however, incidences of this were expected to be low due to the KEMH OMIS being a telephone-based service, with the original enquiry conducted in conversational English. The researcher would assess the level of conversational English and determine if the survey could be conducted effectively with the caller.

5.4.3 Recruitment Process and Consent

It is standard practice for KEMH OMIS pharmacists to ask callers, both health professionals and the public, for their contact details for pharmacy records and quality improvement activities. Therefore, the attending pharmacist was able to alert the caller regarding the current research and the likelihood of a call from the researcher. This process was continued for the duration of the research to ensure callers did not receive a ‘cold-call’ and could consider their consent to participate in the survey.

Once an enquiry was randomly selected, the researcher called the user during their designated time allocated by the Chief Pharmacist. A designated time was allocated, as part of the departmental roster, to minimise any disruptions to usual clinical care.

The Patient Information Statement (Appendix 3) was utilised to consent callers to the survey and ensure they were aware that they understand the requirements of the survey, the ethical approvals and the participant's ability to cease the survey at any time.

5.4.4 Data Collection

The researcher undertook the telephone interviews during an assigned 60-minute period per day, with authorisation from the Chief Pharmacist. The researcher contacted callers utilising their contact details from the database that were stored with their consent at the time of the enquiry. Consent at the time of enquiry was only provided to list the callers' contact details. As mentioned above, callers were consented to the study during the second call, prior to commencement of the survey.
If the caller did not answer the first contact by the researcher, the researcher noted the non-response and endeavoured to contact the caller once more within a 48-hour period, without leaving a voicemail message (to ensure privacy). A replacement caller was randomly selected following the initial non-response, in line with the quota sampling strategy of three calls per day. Using this approach, all feedback interviews were intended to be conducted between one and three days following the initial enquiry. The minimum was intended to allow time for implementation of the advice, while the maximum was intended to minimise recall bias about the consultation.
A summary of the enquiry was accessed from the database prior to the telephone survey. The summary provided the researcher with background details of the information provided, in the event that concerns were raised during the interview.

5.4.5 Data Management

The surveys were collected within Qualtrics® in real-time during the course of the telephone interview. Access to the Qualtrics® survey was passport protected linked to the researcher's Curtin University access.

Upon completion of all surveys, data was exported from Qualtrics® into a Microsoft Excel® spreadsheet, saved on the KEMH secure 'W' Drive and the Curtin University

'R' Drive. The data also remained on the Qualtrics® platform as an additional backup system.

Data cleaning was minimal due to the use of a solo interviewer, who maintained a consistent data entry approach and system. Free-text entry within the survey utilised an approach to document the same phrase for similar responses, to allow for easier data analysis. Free-text responses on account of selecting 'other' as their answer generated new variables to be analysed.

Microsoft Excel® was used for descriptive, bivariate and multivariate analysis, and generation of pivot tables.

5.5 Results

A total of 181 user surveys were conducted over the three-month period. Three to five surveys were completed during each daily session, with each interview taking a mean of eight to 12 minutes to complete. A total of 234 contact attempts were made to complete the 181 surveys, with 25 callers from the supplied database not answering the second contact attempt and replaced by another enquiry. Twenty-eight callers declined to participate in the survey, of whom 19 were health professionals (13 medical practitioners, two nurses, one midwife and three pharmacists). Of the 13 medical practitioners who declined, nine were declined by administrative staff due to medical practitioners being in a consultation with a patient at the time. Nine members of the public declined to participate in the survey. The predominant reason for non-participation across all users was lack of time when the call was made, with one health professional indicating they would be more likely to respond if an online survey was circulated. No participants withdrew from the survey once it was initiated.

Two-thirds (66%, n=119) of participants were health professionals, and 34% (n=62) were health consumers. Figure 25 identifies the type of health professionals who participated in the telephone survey; overall, 49% (n=58) of respondents were medical or general practitioners. The type of the public caller was not documented.

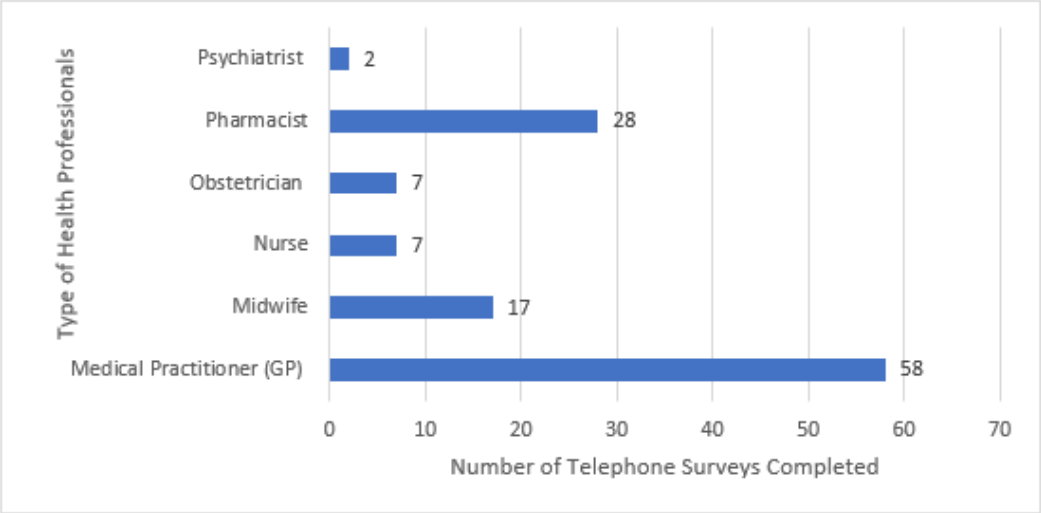

Figure 25: Type of Health Professionals who Participated in the User Survey (n=119)

In terms of how respondents knew about the OMIS, and how they obtained the service's contact details, 69 of all respondents (38%) indicated that they had always known about the service; these were all health professionals (Figure 26). This question also revealed that 24 of all respondents (13%) gained access to the details of the KEMH OMIS from the Breastfeeding Centre of Western Australia[d].

Furthermore, 20 of all respondents (11%), all health consumers, gained awareness of the service following a referral to the service by their health professional, including four who reported receiving this from their obstetrician. The KEMH OMIS is listed as a Medicines Information Centre in the *AMH*,[44] 13 health professionals (7%) identified the *AMH* as their source of the OMIS contact details. The KEMH OMIS information details feature in take-home packs for new mothers discharged from the hospital. Of all the respondents, 11 (6%) were aware of the service from their previous inpatient admission to KEMH. Some respondents discovered the KEMH OMIS details via Facebook (n=10, 6%), and a Google® search (n=3, 2%). Nineteen respondents were provided the KEMH OMIS details by a different service or information centre,

[d] The Breastfeeding Centre is affiliated with KEMH and provides breastfeeding information and support for the families of Western Australia.

including Ngala[e] (6%), the Poisons Information Centre[f] (3%) and the 'Purple Book'[c] (2%) issued to a child at the time of birth. A small percentage of all respondents were aware of the KEMH OMIS through being a KEMH employee themselves, from Curtin University lectures presented to Pharmacy students, and from a friend or colleague.

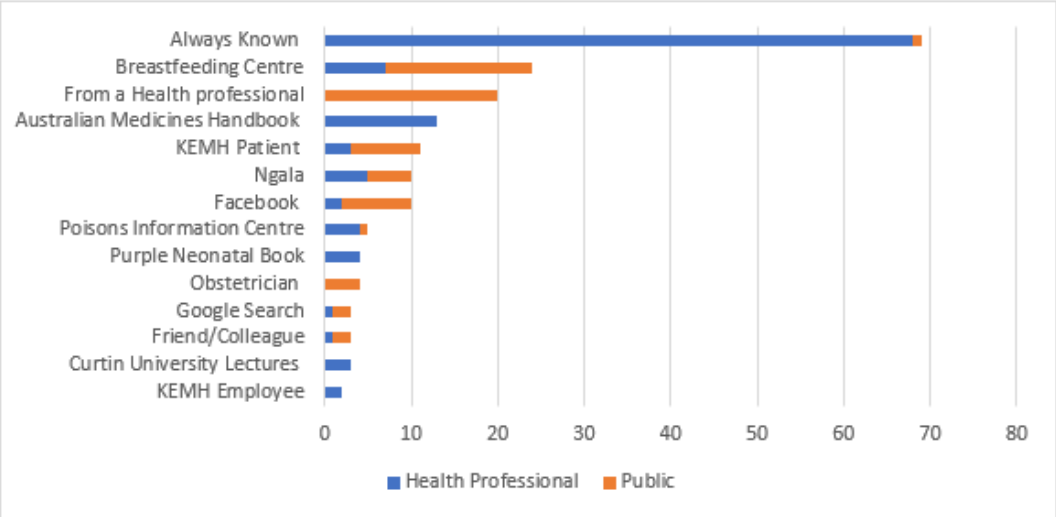

Figure 26: Source of KEMH OMIS Contact Details (n=181)

The above question revealed that 20 health consumers were referred to the KEMH OMIS by a health professional. Of these 20 health consumers, seven (35%) were referred by their child health nurse and six participants (30%) were referred to the KEMH OMIS by their local community pharmacist. Midwives referred one-quarter of the respondents to the service, while one participant was referred by their obstetrician, and one by their lactation consultant.

Regarding prior use, 118 respondents (65%) indicated they had used the service before (Table 16).

[e] Ngala assists parents, families, carers, children and young people in Western Australia
[f] The Poisons Information Centre provides the latest poisons information to the public, and toxicology advice to health professionals on the management of poisoned and envenomed patients

Table 16: Type of Caller and Previous Use of the KEMH OMIS

Type of Caller	Yes (n=118)		No (n=63)		Total
	n=	%	n=	%	%
Medical Practitioner (GP)	47	26%	11	6%	32%
Midwife	17	9%			9%
Nurse	7	4%			4%
Obstetrician	7	4%			4%
Pharmacist	18	10%	10	6%	16%
Psychiatrist	2	1%			1%
Public	20	11%	42	23%	34%
					100%

The 118 respondents who identified that they had used the OMIS service before were asked how often they would utilise the service within a year. Responses were categorised accordingly, from monthly to once or twice per year, and depended on whether the participant was a health professional or a health consumer. The majority of health professionals reported contacting the service at least monthly (n=55, 47%), and health consumers and a smaller proportion of health professionals claimed they accessed the service once or twice per year (n=54, 46%). Other responses categories included only using the service when pregnant or breastfeeding, while some health professionals indicating contacting the service for difficult questions that they were unable to answer using their current knowledge and resources. Sixty-four of the 118 respondents who had used the OMIS service before were identified as frequent users, having used the service at least every one to two months.

Figure 27 identifies the range of caller types and how often they had engaged with the OMIS service if they had used the service more than once. Of note, seven health consumers identified that they used the service approximately monthly; these participants were either pregnant or breastfeeding at the time of their most recent enquiry, with multiple ailments requiring medicines. One respondent identified calling the service at least once a month during her pregnancy to gain information regarding medicine use to alleviate concerns or anxieties she had with taking the medicine; she identified her trust in the service to provide her with information that informed her decision making.

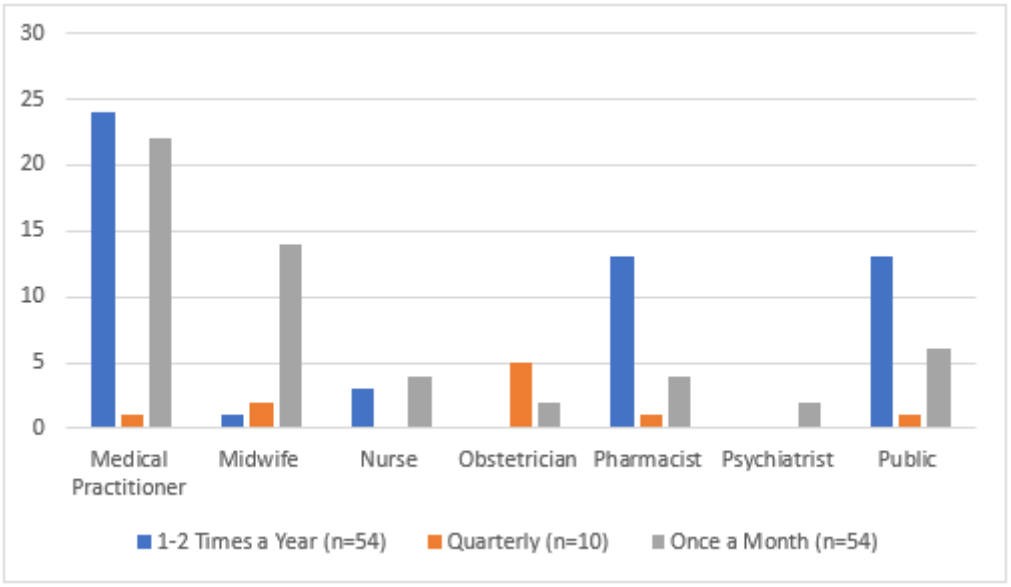

Figure 27: Frequency of OMIS Use by Repeat Users (n=118)

If respondents identified that they had used the service previously, clarification of the response revealed that the service was contacted by health professionals, due to complexity of their pregnant and breastfeeding patients being outside their usual scope of practice. Two pharmacists commented that their proximity to an obstetrician's rooms triggered their need to provide more information in pregnancy than a comparative pharmacy in a different location, and a rural midwife utilised the service alongside KEMH practice guidelines as a sole practitioner within the WA Country Health Service. One respondent was from New South Wales and utilised the service for after-hours access when local services had closed for the day.

Respondents were asked how easily, in terms of time waited, they were transferred to a pharmacist to answer their query. Most (83%, n=150) reported being transferred to a pharmacist within five minutes; of these, 96 were health professionals. Twenty-seven respondents (15%) recalled being transferred to a pharmacist within 15 minutes; of these, 20 were health professionals. Four participants responded that the call took longer than expected to be answered. Elaborating on these experiences, one call was placed on the weekend where there were limited resources available, two users left a message with a pharmacy technician when there was no available pharmacist, and one user claimed that the telephone rang for more than 15 minutes before it was answered.

In relation to the time taken to speak to a pharmacist, 135 respondents (75%) identified that their query was answered within five minutes, while 38 respondents (21%) identified that their query was answered between five and 15 minutes, and eight respondents (4%; five health professionals and three health consumers) had a pharmacist call them back. The reasons for the call-back were the pharmacist's need to research a medicine (n=3), multiple queries requiring a longer response (n=2), and enquiries concerning complementary medicines with multiple ingredients (n=3).

All respondents reported that they did follow the advice, and all found the information either 'very useful' or 'useful'. Of 172 (95%) users who responded that the advice provided was very useful, two-thirds (n=115) were health professionals (Table 17).

Table 17: Caller Identity and Usefulness Rating of Advice Received from KEMH OMIS

Type of Caller	**Very Useful (n=172)**		**Useful (n=9)**		**Total**
	n=	**%**	**n=**	**%**	**%**
Medical Practitioner (GP)	56	30%	2	1%	31%
Midwife	17	9%			9%
Nurse	7	4%			4%
Obstetrician	7	4%			4%
Pharmacist	26	15%	2	1%	16%
Psychiatrist	2	1%			1%
Public	57	32%	5	3%	35% **(100%)**

From the nine participants who found the information 'useful', as opposed to 'very useful', the consistent theme identified was the limited information available for the OMIS pharmacists to provide a definitive response. Six (67%) of these callers identified that their query related to a complementary medicine(s) for which there was limited information to safely recommend its use during pregnancy or breastfeeding. One user had queried a list of cosmetic agents and was unable to obtain definitive guidance about their use. One health professional identified that an intern pharmacist provided information to them; however, the intern placed the caller on hold in order to

clarify with a pharmacist for a final recommendation. The remaining explanation was from a member of the public for whom the pharmacist was unable to provide a yes-or-no answer based on the information available.

To the question regarding the type of response received, being verbal or written, of the 181 responses, 96% (n=173) of users received a verbal response from the pharmacist. The eight cases involving written advice were all health professionals; these callers comprised four medical practitioners, two pharmacists and both of the psychiatrists. All but one participant considered the information sufficiently detailed. The remaining participant was the above-mentioned member of the public for whom the pharmacist was unable to provide a definitive answer. Over half of the participants (54%) identified that their concerns were 'very well' alleviated by the advice provided by the OMIS pharmacist, with 43% identifying that their concerns were 'well' alleviated. Six participants selected their response to this query as neutral, three health professionals and three members of the public (Figure 28).

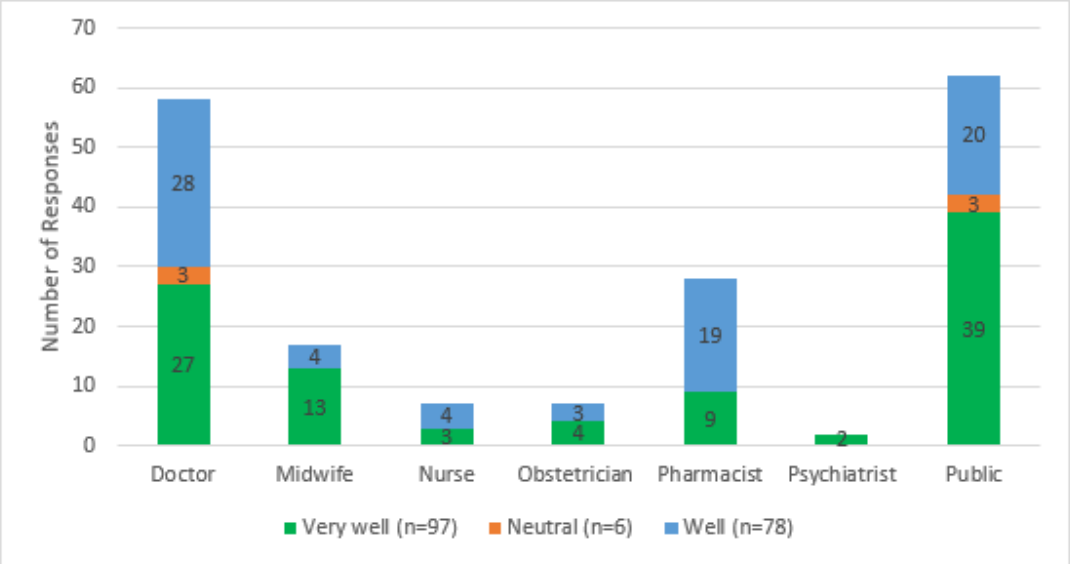

Figure 28: How Well User Concerns Were Alleviated by Advice Provided by KEMH OMIS (n=181)

All users rated the service positively, from three to five (Figure 29) with 56% (n=101) users indicating a score of four. No trend was obvious in health consumers versus health professionals' experiences with the service. The single rating of three was from a pharmacist who had found the information 'useful'; this was the pharmacist's first

encounter with the KEMH OMIS. All 181 users responded that they would use the service again.

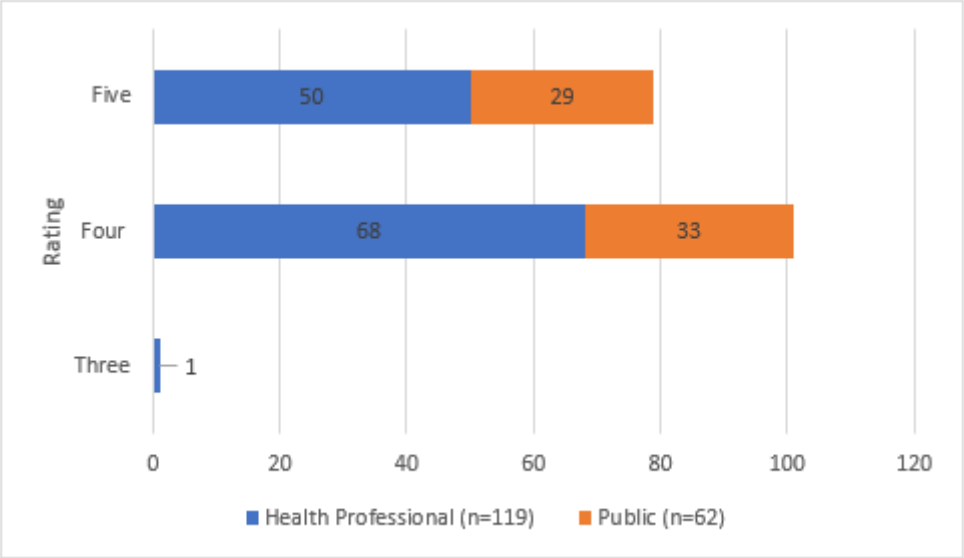

Figure 29: KEMH OMIS User Rating (On a Scale of One to Five[g])

When asked what users would do if the service was not available, the 181 respondents named up to four options that they would utilise, resulting in 388 responses. Four themes were identified from these responses:

1. Access to existing Medicines Information and Obstetric Services
2. Engagement with health professionals
3. Independent research of available information
4. Use of pharmaceutical literature and resources.

These four themes are presented in Table 18, which also identifies the type of resource that would be used in the absence of the KEMH OMIS. Of the 388 responses, 150 were provided by the public. Most users reported the use of health professionals (47%) and existing services in accessing medicines information (17%). A Google® search for information was captured in 3% (n=5) of responses.

The 119 health professionals who were surveyed provided 238 responses about resources they would access for information if the KEMH OMIS was not available.

[g] Lowest Rating = 1, Highest Rating = 5

The majority of health professionals' responses (171 of 238) cited the use of current pharmaceutical resources as an alternative source of information (Table 19).

Table 18: Resources Considered by Participants in the Absence of the KEMH OMIS (n=388 responses from 181 respondents)

Resource Theme	Resource Type	n=
Medicines Information and Obstetric Services	KEMH Breastfeeding Centre[d]	13
	Ngala[e]	2
	Poisons Information Centre[f]	57
	Royal Women's Hospital Information Service[h]	29
Health Professionals	Medical Practitioner	45
	Midwife	51
	Local Community Pharmacist	62
	Obstetrician	8
	Child Health Nurse	3
	Health Professional Colleague	1
Pharmaceutical Resources	*Australian Medicines Handbook*	42
	MIMS Australian Drug Reference System	61
	AusDI Information System	1
	Other Pharmaceutical Resources	1
Independent Searches	Literature Review	7
	Google® Search	5

[h] The Royal Women's Hospital Information Service is based in Melbourne, Australia and provides medicines information to health professionals and the public regarding medicines use in women's health, pregnancy and breastfeeding and neonates.

Table 19: Health Professional Responses Identifying Resources that would be used in the Absence of the KEMH OMIS (n=238 responses)

Participating Health Professionals	Nurses	Obstetrician	Pharmacist	Psychiatrist	Midwife	Medical Practitioner	Total% (n=238)
Resources Identified	n=						
AMH	1	1	25	1		14	18%
AusDI						1	0.4%
MIMS	3	4	15	2	7	30	26%
Pharmaceutical References			1				0.4%
Medical Practitioner	2		1		5		3%
Midwife	2						1%
Community Pharmacist	1	2			4	25	14%
Obstetrician	1			2		5	3%
Colleague					1		0.4%
Ngala[e]	1		2			5	3%
KEMH Breastfeeding Centre[d]					6		3%
Poisons Information Centre[f]	2	4	7		6	19	17%
The Royal Women's Hospital[h]	4		17		6	2	13%
Literature Review		3	2			2	3%

Of the 181 respondents, 65% (n=118) provided feedback about improving the service. Feedback was received from 52 members of the public and 66 health professionals. The responses were thematically analysed, with eight emergent themes (Figure 30):

1. Access to online resources: 32 participants suggested online access to resources and being able to contact the KEMH OMIS via an online option.

2. Increased advertising of KEMH OMIS: first-time and regular users of the service identified that knowledge of the service is potentially not widespread, and 29 respondents suggested more advertising of the service should be conducted.

3. Training and education: training and education for health professionals in accessing and assessing medicines information in pregnancy and breastfeeding was requested on 26 occasions.

4. Social media presence: 13 users requested a social media presence of the service, which could also relate to the increased advertising and awareness of the service.

5. After-hours access to KEMH OMIS: the KEMH OMIS operates during business hours only for non-KEMH users. After-hours access was requested by 10 respondents, particularly for medical clinics and pharmacies that remained open.

6. Improved auditory clarity: three users identified that they found it difficult to hear the pharmacist due to background noise.

7. Mobile telephone application: three users requested the use of a mobile application to submit enquiries and have access to useful information.

8. Record keeping: two users identified that their contact details had to be recorded; however, for previous users, the request for this information to be pre-populated was mentioned.

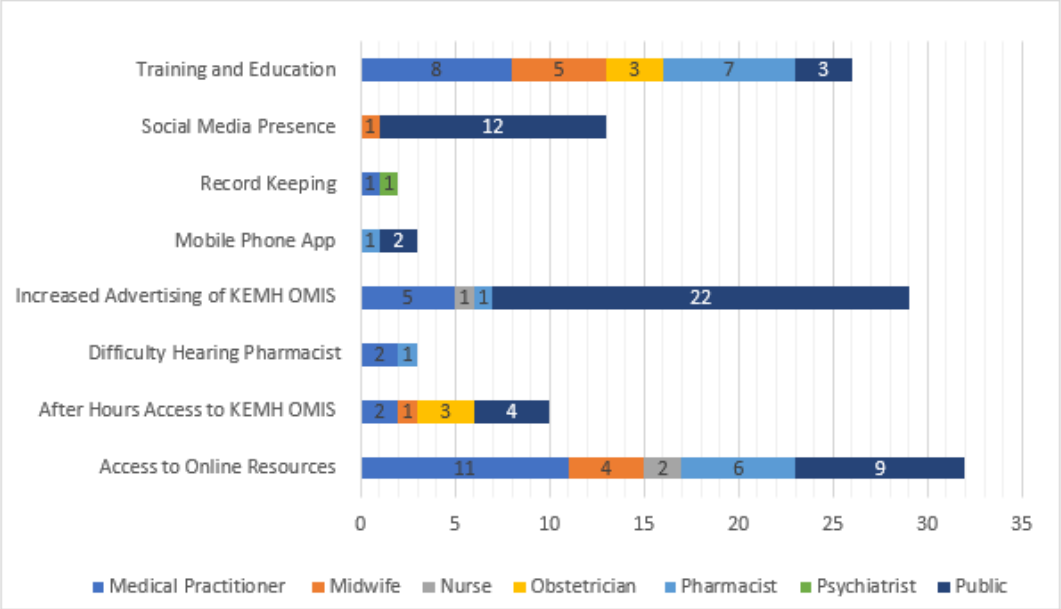

Figure 30: User Feedback and Recommendations for the KEMH OMIS (n=118 suggestions)

From the feedback and recommendations provided by the 118 respondents, 64 were from frequent users who identified as using the service every, one to two months. The 64 comprised 58 health professionals and six health consumers. The feedback provided by these frequent users formed part of the above-mentioned eight themes; however, there were three dominant themes from this cohort. The first theme was access to online resources, with the group requesting the ability to access information online, as well as access to the same or similar resources used by the KEMH OMIS. The second theme was training and education for health professionals to improve their knowledge in this niche area and to assist them in assessing the available information to make an informed decision. The third theme was after-hours access; these frequent users indicated an increased requirement to be able to contact the KEMH OMIS at their convenience. The 10 respondents who provided this feedback were all health professionals who were frequent users of the KEMH OMIS.

5.6 Discussion

This research aimed to determine the feedback of a sample of KEMH OMIS users, by using a telephone survey, and propose how the results could be used for service enhancement and development. The value of user feedback and their experience is integral in understanding how the service is perceived by its users, both health professionals and health consumers. The health professionals and health consumers who utilised the KEMH OMIS service confirmed that the service alleviated their concerns regarding the use of medicines in pregnancy and breastfeeding, although more flexibility in accessing the service would be preferable.

Almost two-thirds of participants in this survey were health professionals. Health professionals seek current, evidence-based information regarding the safe use of medicines in pregnancy and breastfeeding, and the ability to access the KEMH OMIS reportedly assisted in health professionals making informed decisions to positively impact patient care. This requirement to access a service like the KEMH OMIS stems from the disparity in information in pregnancy and breastfeeding resources, and possible conflicting information, when using more than one information source.[3, 69] Similar advice is sought by health consumers, who may find it difficult to navigate the plethora of information across the internet or advice attained from members of the public that can be further conflicting or confusing to the consumer.[20]

With this service being operational since 1988, it was expected that a high proportion of users already knew of its existence. This was indeed the case in the majority of the health professionals surveyed.

Being able to seek information regarding the use of medicines in pregnancy and breastfeeding allows the health consumer to become an active participant in their medical treatment, and the same information can be utilised by health professionals to assist in decision making in clinical care.[52] Service providers benefit from understanding how users gain awareness and knowledge of the service. This enables service providers to target relevant channels for increased awareness, promotional exercises and training and education. Affiliate organisations within WA Health, such as the Breastfeeding Centre[d], Ngala[e] and the Poisons Information Service[f], were noted

to be avenues that refer consumers to the KEMH OMIS. Identifying these stakeholders through the user survey provided an insight into the avenues through which the service could further improve awareness. Referral of health consumers to the KEMH OMIS by their health professionals demonstrates trust within the service by health colleagues, to provide reassuring advice and alleviate consumer concerns. Recognising this avenue is valuable for dissemination of information, training and education.

Awareness via word-of-mouth and social media channels was notable amongst health consumers. One recommendation from this research, to maximise public uptake of the service, is investment into active campaigning and advertising on social media platforms, including indexing the KEMH OMIS into search engines such as Google®. This is further explored in Section 6.3.

Frequent users can provide valuable insights to shape the development of the service. Regular use of the KEMH OMIS reportedly assisted users, particularly health professionals who had complex pregnant or breastfeeding patients, in responding to enquiries. Repeated use of the service demonstrates satisfaction with, and an ongoing need for, the service and safety advice regarding the use of medicines in pregnancy and breastfeeding. Within Australia, both Mothersafe and the NPSMedicineWise services operate within working hours, Monday to Friday from 9am to 5pm (Australian Eastern Standard Time) excluding public holidays.[117, 118] While the interstate providers are available, the time zones in the Eastern States are not favourable for health professionals and consumers within Western Australia for timely access to information. In addition, one user from New South Wales indicated the West Australian time zone allowed for them to contact the KEMH OMIS after-hours. Daylight savings in the Eastern States also presents as an additional barrier to WA health professionals and consumers due to the variability in contact times across the year. A local, Perth-based service is able alleviate time zone barriers that could be associated with the use of an interstate service. The KEMH OMIS is under the governance of the Women and Newborn Health Service[i] (WNHS), the placement of this service within the specialty health service provider is beneficial for the health professionals of WA , having access to pharmacists working within the specialty and

[i] The Women and Newborn Health Service provides clinical care to women and families. It comprises of King Edward Memorial Hospital, the Maternity Unit at Osborne Park Hospital and other specialist health services.

who have access to a medical expertise on site as mentioned in Section 3.2, in reference to MFAU.

As previously stated, the KEMH OMIS, during business hours, rostered a pharmacist as part of their additional duties. This mechanism provided, for the most part, efficient access to a pharmacist to provide a response to the enquirer. However, during the course of the day or on the weekends, accessibility to a pharmacist was less efficient due to the limited resources available, and call-backs were required. Call-backs may not be ideal, particularly for health professionals who may have the patient with them at the time, and in the case of the health consumer, there can be a risk of elevated anxiety if a query could not be immediately answered.[69]

Indeed, timeliness was noted in the literature as a key component of user satisfaction when using a helpline or telephone service.[76] Timely responses, as determined by the users, were mostly achieved by the KEMH OMIS pharmacists. From a service provider perspective, however, the sensitivity and clinical significance of enquiries takes precedence over provision of a rapid response. According to the service protocols adapted from the *SHPA Handbook*,[27] pharmacists must ensure information is current and appropriate resources have been consulted to provide evidence-based advice. Given that the majority of participants stated their intention to use the service again if the need arose, this was considered indicative of satisfaction with the quality and timeliness of the advice they received.

Medicines information in pregnancy and breastfeeding is a complex area with difficulties in accessing and/or interpreting information from variable sources that may contradict each other. As such, there were instances where the KEMH OMIS pharmacists, as perceived by the survey participants, were unable to provide definitive information, which was not to the users' satisfaction, or was unable to fully alleviate the user's concerns. During training, the KEMH OMIS pharmacists are trained to ensure a clinical assessment of each enquiry is conducted that will allow for tailored advice within the evidence-based limits, this allowed for sufficiently detailed information being provided to users. This was showcased in the results, where all but one user agreed to the information being provided being sufficiently detailed. Provision of advice over a telephone line is consistent with the nature of medicines

information services across Australia;[26] however, the ability to summarise information and provide written information is a useful tool, particularly for health professionals to have a reference point to assist with clinical decision making. The need for written information is driven by the complexity of the enquiry and summation of multiple references to construct an adequate and useful (tailored) response.

Feedback from the audience of the KEMH OMIS provided useful insight into the needs of the clientele and how these needs could shape enhancements to the service. Consumer participation in quality improvement provides 'lived experience' insights that complement the health professionals' or researchers' expertise for service development.[110] The use of the internet and online resources is a common means of accessing information for users, and the predominant theme emerging from user feedback within the survey, was the establishment of an online resource to facilitate convenient access to appropriate and relevant advice, with the repute of the service verifying the resources utilised. Adapting to this landscape of accessing information online, and provision of the information in a user-friendly, evidence-based manner, can assist users in navigation of valuable and useful information.[20]

Survey respondents identified a number of alternatives they would use to access information if the KEMH OMIS was not available. This encompassed 16 varying resources and access pathways for information. This variability in resources is consistent with the approach, that multiple resources are reviewed to attain safety information for medicines in pregnancy and breastfeeding, due to conflicting information between resources.[51, 73]

Health professionals identified a reliance on *MIMS* and *AusDI* as alternatives for seeking independent advice. Both platforms utilise manufacturer product information as their source of evidence. The ease of access and availability of these online resources allows for timely access of information for health professionals. However, the information provided is known to provide conflicting information.[66, 70, 73] This could contribute to the need for health professionals to contact the KEMH OMIS, to alleviate any concerns that could be exacerbated by conflicting information.

Almost half of the consumers (47%) identified they would contact their health professional and 17% contacting a different medicines information service, which included the Breastfeeding Centre[d] and the Poisons Information Centre[f]. These responses were reassuring that the public were accessing health professionals or designated consumer helplines to access their information. The 3% of consumers that identified they would Google® the information posed the ongoing risk of accessing misleading or conflicting information on the internet that could potentially lead to confusion and anxiety in a woman, knowing that her child may become the unintended recipient of the medicine should there be any transfer for the medicine from mother to child, either via the placenta or the breast milk.[75]As previously mentioned, relevant indexing of the KEMH OMIS, or direction to the KEMH Pregnancy and Breastfeeding Information Hub, within common internet search engines will allow for adequate information sources to be visible by users when searching terms that include medicines use in pregnancy or breastfeeding.

The response rate was high from those approached agreeing to participate in the telephone-survey. The comprehensive responses indicate a strong level of interest in the topic, which may guide future research (See Section 6.3.4).

Enhancing access to information in pregnancy and breastfeeding was a dominant theme from the feedback responses. Information access included online access, after-hours access, a greater social media presence, and access to expertise facilitated by training and education. Health professionals surveyed, highlighted this as an avenue to better understand how to evaluate and interpret medicines information in pregnancy and breastfeeding. Provision of medicines information in pregnancy and breastfeeding requires analytical skills to compare data sources and provide a succinct and tailored response for patient care.[5] Expertise can be developed by information seminars conducted by the KEMH OMIS pharmacists to engage health professionals and health consumers, increasing awareness and understanding around navigating available information and utilising peer-review, evidence-based avenues to access and interpret information. This information can be provided within the forums and resources that were described in the survey when users were asked how they located the contact details for the KEMH OMIS.

Chapter 6: General Discussion

6.1 Interpretation of Key Findings

This research is the first detailed analysis of the WA KEMH OMIS, which has been available to the community of WA as a free telephone-based service providing current, evidence-based information regarding the safe use of medicines in pregnancy and breastfeeding. The database analysis reported in Chapter 4 presents a broad overview of the types of enquiries and utilisation of the service over 20 years, informed by research questions drawn from the literature and priorities for review of the OMIS. The subsequent user survey reported in Chapter 5 presents deeper analysis of the experiences of a sample of consumers (health professionals and the public). While the database of nearly 50,000 enquiries will facilitate a wealth of ongoing multivariate analyses, together the current descriptive findings provide valuable insights into trends over 20 years and the user experience, to inform ongoing development of the service.

The number of enquiries received by the service identifies the need and value of the service to continue to be operational within WA. One key finding was an increasing trend for health professionals to access the service. Factors including health professionals being time poor, managing increasingly complex patients, and satisfaction and trust in the KEMH OMIS, all contribute to the ongoing use of the service by health professionals. By comparison, researchers analysing Mothersafe data identified a decline in health professional queries over 7 years to 2007, and suggested that an increase in health professionals' education could have been the reason for the decline in calls.[4] The ongoing educational needs of health professionals in the specialty area of medicines information in pregnancy and breastfeeding should be prioritised for KEMH OMIS development. Indeed, the requirement for education in this area was confirmed during the user survey (Chapter 5).

Health consumers comprised nearly half of the callers over the 20 years of OMIS data, albeit in a declining trend. As with health professionals, engagement with health consumers is required to understand their information requirements and determine the reasons for the decline. The user survey identified high satisfaction with the service

amongst health consumers. Interestingly, 47.0% (n=71) of the 150 health consumers who provided feedback indicated they would access their primary care health professionals should the KEMH OMIS be unavailable, further cementing the need for ongoing collaboration between the OMIS and health professionals to address health consumers' needs.

The rise in medicine use, including prescribed medicines, over-the-counter medicines, complementary medicines and recreational substances, within the general population will likely be reflected in their increased use in pregnancy and/or breastfeeding. With this rise comes the continual need for accessible, current and evidence-based information. Importantly, the information (advice) should be tailored to the user and appropriately documented. It was beyond the scope of the current research to investigate the quality of the advice provided, and therefore the degree to which it was tailored to each enquiry. However, commentary is provided on the documentation of enquiries (Section 4.8), with recommendations to improve the completeness and utility of the resulting data.

Stakeholder engagement should be a focus for the ongoing development and recognition of the KEMH OMIS, particularly to ensure validity, accessibility and sustainability of the service. This theme arose throughout the research. The literature promotes collaboration with custodians of medicines information databases and other reference sources to ensure broad and deep collation of information that can be disseminated to promote education.[4] This focus is important in embedding the KEMH OMIS service within obstetric care, affording it to sit alongside obstetric care as an integral part of patient service delivery. The service providers (rostered pharmacists) should also be considered stakeholders, whose experiences should be considered to ensure deliverables can be met and the service is sustainable.

The KEMH OMIS exists to educate as well as answer specific enquiries, and health professionals surveyed highlighted the KEMH OMIS as an avenue to better understand how to evaluate and interpret medicines information in pregnancy and breastfeeding. Indeed, provision of medicines information in pregnancy and breastfeeding requires analytical skills to compare data sources and provide a succinct and tailored response for patient care.[5] Education can be achieved on a broad level via seminars conducted

by the KEMH OMIS pharmacists to engage health professionals and health consumers. This education will facilitate increasing awareness and understanding around navigating available information and utilising peer-reviewed, evidence-based avenues to access and interpret information. While the current study did not explore the education provided by OMIS, the requirement for education was clearly identified in the user survey with 22.0% (n=26) of the 118 respondents requesting further training and education.

Users also requested online access, after-hours access, a greater social media presence, and access to expertise, via an interactive, tailored experience facilitated by training and education provided by the KEMH OMIS pharmacists. Development of an online platform to receive and manage enquiries would open valuable opportunities to provide written evidence-based educational resources for users, as well as the accessibility and interactivity expected by users. An online platform would also enable publicity to increase awareness of the service, if advertised in relevant online forums and health-related services. Based on current services provided within Australia, no medicines information service provides an interactive online model, with most online models encompassing an email interaction. SafeMotherMedicine in Norway, established in 2011 as an online-model only, appears to be the only medicines information service for pregnancy and breastfeeding that allows consumers to interact with their online service to provide information regarding their query. [43] The service was designed to empower pregnant and breastfeeding women in accessing information. Although the time taken for a response may take one to 48 hours, an online platform was utilised due to familiarity amongst women, with 90% of Norwegian women using the internet on a daily basis. [43]

The current research did not review the cost-effectiveness of the OMIS, nor the staffing levels required to meet demand. This is the domain of the KEMH management. However, the deficiencies in the quality and completeness of the documentation of enquiries suggest staff workload and training should be reviewed. Furthermore, improvements in the documentation platform are recommended (Section 6.3). The current documentation of enquiries poses a clinical risk if enquiries and their associated responses are not recorded in a timely manner. Adequate quality assurance is required to ensure this clinical risk can be mitigated

The specialist role of KEMH OMIS pharmacists in providing tailored advice to the community regarding the safe use of medicines in pregnancy and breastfeeding is an asset to the service. This is supported by overwhelmingly positive feedback in the user survey. A 2013 study conducted in South Australia, investigated the opinions of 41 obstetricians and hospital pharmacists on the approved product information providing medicines safety information. [119] These health professionals reported the product information to be cautious and conservative which could lead confusion for the health professional and/or women which could potentially affect the health care professionals credibility.[119] Health professionals admitted to finding it difficult to navigate the plethora of information that is available in published literature or across the internet that can be conflicting to both the health professional and the consumer.[20] For the public, being able to seek information regarding the use of medicines in pregnancy and breastfeeding allows the health consumer to become an active participant in their medical treatment. The same information can be utilised by health professionals to assist in decision making in clinical care.[52]

Analysis of the 20 years of KEMH OMIS data has provided insight into the exposures that pregnant and breastfeeding women experience. When trends in medicines enquiries are identified, this can inform interventions to respond to emerging patterns and medicines of concern. The current research identified 18 medicines for which concerns, or warnings had been published during the 20-year period for use in pregnancy and breastfeeding. In four of these cases, increases were noted in the number of enquiries received by the OMIS (Section 4.7.4). Of particular interest were the enquiries regarding sodium valproate following upgraded information warning of the effect of sodium valproate on the fetus and the potential for known fetal malformations.[84, 86] This analysis does not infer causality between published warnings and the volume of enquiries. However, it confirms the need for KEMH OMIS pharmacists to have access to current resources to respond to enquiries.

6.2 Limitations

This was the first WA study that analysed a medicines information service specialising in pregnancy and breastfeeding which reported both analysis of enquiry data and

consumer feedback across a 20-year period. The documentation of the data within the Microsoft Access® database was deficient in many call records, due to the limitations of the database itself and the predominance of 'free-text' fields that did not force data entry. From the original Microsoft Access® extract of 49,811 records, 2.7% (n=1,353) enquiries were excluded due to missing data.

The medicine enquiries data were predominantly categorical, and the limitations of the Microsoft Access® database meant considerable data coding was required. A single coder (the researcher) performed all coding. This offers advantages in terms of consistency, but the final database could have contained coding errors. This could be addressed in the future by including a second coder to check a sample of the coded data or, where resources permitting, transition from Microsoft Access® to an alternative platform with forced-response variables, inbuilt menu selections and predictive suggestions for auto-coding.

The identity of the attending pharmacist was excluded from this analysis. Deidentifying the pharmacist assumes the detail and accuracy of medicines enquiry answers provided by pharmacists was consistent. It also assumes documentation of the enquiry was completed by the pharmacist who responded to the query; it was not possible to identify if this was indeed the case. In the event of an error or resultant harm from incomplete, inaccurate or inappropriate advice, this deidentification of the pharmacist did not allow further investigation of the case. However, this approach was considered appropriate to explore feedback about the service (the user experience and utility of the advice received), given that consumers are not expected to assess the clinical appropriateness of the advice.

The study was not a quality audit, and the appropriateness of responses to enquiries was not assessed. As such, analysis presented here was limited to descriptive reporting of key trends, supplemented by user feedback. A quality audit would be most beneficial if details of the attending pharmacist were included, in order to identify the strengths and limitations of pharmacists in answering particular types of enquiries, and to inform educational and staffing requirements (e.g. referral process for less-experienced pharmacists).

The user survey sampled consumers of the service over 3 months. This window represented 1.3% of the 20 years of electronically documented enquiries. To facilitate the telephone survey, a limited number of questions and response options were provided. This is standard practice for feedback surveys.[110] Deeper insights would be obtained from focus groups or qualitative interviews.[116] However, the telephone survey invited participants to suggest improvements, in line with Objective 1 of the research. Focus groups might be used for detailed feedback about specific improvements to the service.

The user survey also only interviewed consumers of the service (health professionals and health consumers). It was beyond the scope of this study to interview providers of the service. This stakeholder engagement is recommended to inform implementation of improvements to the service and changes to the workflow.

As per the analysis of similar services,[76, 80, 81] the current data excluded demographic characteristics of the users. A useful variable would have been the caller's postcode, as a proxy for socio-demographic characteristics of health consumers accessing the service, and geographical reach of the service for targeted education or engagement.

6.3 Recommendations

Evaluation of the database and the results of the user survey have informed recommendations to promote development of the KEMH OMIS for ongoing delivery of the service.

6.3.1 Database Recommendations

The Microsoft Access® platform for recording enquiries requires refinement to recognise and/or prevent duplicate enquiries and incomplete records. The number of free-text entry fields created an overabundance of data requiring coding prior to analysis. Without this functionality, the current analysis is unlikely to be repeated in the future. A medicines database should be linked into the platform to ensure accurate spelling and classification of medicines. Also recommended is the introduction of multi-service telephone operating system with call recognition and recording software,

to capture the caller's details electronically and once consent was obtained, these details could be recorded more efficiently. This would require a disclaimer that all enquiries will be recorded and consent required for details to be stored within the KEMH OMIS database

6.3.2 Service Delivery Recommendations

With appropriate resourcing and their own continuing professional development, OMIS pharmacists could provide seminars and study days to health professionals, featuring up-to-date medicines information in pregnancy and breastfeeding. Reliance by health professionals on product information supplied by manufacturers, in platforms such as *MIMS* and *AusDI*, may result in overly conservative patient management on account of manufacturers' concerns about liability in pregnancy and/or breastfeeding.[70] Ambiguity in these resources can lead to misinterpretation of the information and cessation of medicine use in pregnancy or breastfeeding. This highlights the ongoing need for the KEMH OMIS, and ongoing access to a broad range of current reference material.

A key theme from the user survey was the lack of advertising of the KEMH OMIS across online and social media platforms. Engagement with WA Health or external marketing agencies would identify potential for rebranding of the OMIS to improve its name recognition with the public, and therefore utilisation.

To further increase visibility of the service, public awareness could be enhanced through repeated messaging, given the time-bound nature of pregnancy and breastfeeding. The service would benefit from improved positioning alongside the plethora of readily accessible online resources, the limitations of which have been discussed in Section 2.2.

Engagement with users via focus groups or scheduled interviews is recommended on a periodic basis to assess consumers' needs. Similarly, opinions of providers of the service (the OMIS pharmacists) are required to understand shortcomings in the current

service delivery model, including the workflow, and how the service can be developed to better benchmark internationally.

The Poisons Information Centre at Westmead Hospital in New South Wales is the only centre that provides a national service 24 hours per day for information relating to poisons or toxicology. The centre liaises with other state-based Poisons Information Centre to cover the hotline across Australia.[49,50] This approach could be used for a similar nationwide obstetric service for medicines information in pregnancy and breastfeeding.

6.3.3 Funding and Resource Recommendations

Continuation of this unfunded service with no dedicated staff position(s) has logistical, human resource and financial implications for maintenance of the OMIS. The current analysis provides evidence of utilisation and acceptability of the service. These can be considered proxy measures of impact and value in a business case for sustained resourcing, and ideally, dedicated staffing.

Maintaining the service, along with the expertise of the pharmacists, is paramount to the ensuring the provision of evidence-based, current medicines information in pregnancy and breastfeeding for Western Australians. Ongoing education of these pharmacists should be a priority to ensure the service continues to deliver quality within the current financial, human and operational constraints.

It is also recommended that the WNHS Executive Management team recognises the KEMH OMIS as a state-wide service within the organisational structure of the health service provider. This recognition will be in line with the current TGA recommendation for consumers to contact their local obstetric medicines information centre as the "TGA does not provide advice on the use of medicines in pregnancy for specific cases".

6.3.4 Further Research

This research is the first analysis of the KEMH OMIS data, and provides a template for further analysis, firstly, using the current dataset, and prospectively on a periodic basis.

The increasing number of enquiries from medical practitioners, particularly since 2009, was not noted amongst other health professionals (pharmacists, nurses and midwives). Further research into this trend is warranted to understand differences in medicines information needs between health professionals, and perceived liability in patient management.

A converse trend of declining enquiries was observed for both pregnancy- and breastfeeding-related calls from members of the public. Further research to engage with these users is warranted to understand their information access needs and how a telephone-based service meets these needs. This research is recommended to be conducted via focus groups or real-time inbuilt survey methods at the time of an enquiry.

With the unborn child or infant potentially exposed to the mother's medication, it is understandable why women seek natural medicines. However, as established in Section 2.5, natural medicines are not risk free in these situations. Research into consumers' motivations for self-prescribing of, and self-medication with, complementary medicines would be beneficial to inform how OMIS pharmacists can optimally and sensitively manage related enquiries.

Specific analysis of enquiries relating to COVID-19 vaccinations is recommended, both retrospectively (commencing in 2020) and prospectively. Given the multitude of information regarding the general use of the COVID-19 vaccines and the approved use of mRNA COVID-19 vaccines in pregnancy and breastfeeding,[120] analysis of related enquiries will be important to assess users' concerns about immunisation in pregnancy and breastfeeding.

A quality review of the KEMH OMIS responses is highly recommended to ensure optimal patient care and clinical training within the service. There are numerous options for this type of audit; all would require careful sampling and a feedback loop to the attending pharmacist for continuous quality improvement.

A service such as OMIS could utilise artificial intelligence to streamline responses in real time and increase efficiency. This type of development, reducing the need for a human interface, carries significant risk. As such, it would require careful design and research. Furthermore, the volume of data associated with this type of service could be utilised for real-time analysis of call statistics to measure clinical and operational outcomes.

The KEMH OMIS recognised some similarities and differences when compared to other services. Engagement and collaboration with these services to benchmark services would be recommended. This collaboration can promote collaborated research adding to the global body of knowledge regarding medicines use in pregnancy and breastfeeding and the value of obstetric medicines information services.

Prevalence data of medicines use in pregnancy in Australia is commonly cited using the results of the MAP study conducted in Adelaide in 1999. A repeat study similar in nature, and including breastfeeding, would be useful to identify the current prevalence rate of medicines use in pregnancy and breastfeeding within Australia.

Chapter 7: Conclusion

This research aimed to evaluate the database of medicine information enquiries received by the KEMH OMIS between 2001 and 2020, inclusive by identifying patterns in enquiries received by the service during this time This analysis was supplemented by a user survey to explore knowledge of and experience with the service and provide quality improvement recommendations.

In addressing Objective 1, the analysis identified that the majority of the 48,458 enquiries related to medicines used in pregnancy (48.2% of calls), while breastfeeding enquiries comprised 42.1% of calls. Health professionals were the dominant users, with medical practitioners submitting most of the pregnancy-related enquiries. Annual fluctuations in the number of enquiries received by the service may have reflected operational changes and the workload of the KEMH pharmacists. The range of enquiries per year ranged from as low as 1,262 enquiries to as high as 3,339 enquiries.

Enquiries by members of the public decreased over the 20 years, potentially due to increased accessibility of lay sources of information online, utilising freely available internet search engines, also colloquially known as ‘Dr Google’. This poses a risk to both the consumer and OMIS. Improved public recognition of the OMIS, and accessibility online, are key recommendations from this research.

The medicines of concern by callers were similar to those reported from similar services in other jurisdictions; and included antimicrobials, antidepressants, analgesics and complementary medicines. However, the OMIS remains unique in its antihistamine, hormonal and chemical enquiries. With the current analysis being a 20-year overview, prospective analysis is recommended to capture emerging medicines such as vaccines. Benchmarking with similar services internationally would be useful to share and draw upon best practice.

The user survey addressed Objective 2 by utilising the insights and feedback from users and providers of the KEMH OMIS provided valuable insights to inform optimal and sustainable service delivery model that can continue to provide quality healthcare to the people of WA. Further insights into the value of the service by users were gained

during the user survey with most participants finding the information useful and having the ability to alleviate their concerns. In addition, users identified that they would reuse the service when the time arose and ranked the service highly when reflecting on the service provided.

The user survey identified that the majority of consumers were satisfied with the service and usefulness of the information received. Similarly, the majority indicated they would utilise the service again, which reinforced the need for the service to continue and provide useful, timely and relevant information to the users. A significant proportion of the feedback highlighted the minimal promotion and public awareness of the service, leading to a key recommendation to develop an online and social media presence and thus improve accessibility and improved functionality.

At the time of writing this thesis, the Hunter medicines information service in New South Wales, which had been operational since 1979, closed in early 2022. The closure of medicines information services in Australia is concerning, with the TAIS service closing previously in 2010. These services should be prioritised to assist health professionals in the provision of evidence-based, and up-to-date clinical advice. This research has identified the value of medicines information services to both health consumers and health care professionals.

The KEMH OMIS provides an integral model of care for health professionals and the public of WA, providing a service that is important and valuable to its users. This research provided valuable insights into the current service delivery model, what was working well and aspects for further development. The current research identified that this specialist information service is, and should remain, a highly valued model of holistic, safe and evidence-based patient care.

Appendices

Appendix 1: List of Medicines Information Services in Australia [44]

Drug Information Centre	Contact Number	State /Territory
Poisons Information Centre	13 11 26	Nationwide
Specialised drug information centres		
Canberra Health Services	02 5124 3333	Australian Capital Territory
Hunter Drug Information Service Calvary Mater Newcastle Hospital	02 4014 3695	New South Wales
Royal North Shore Hospital	02 9463 1135	
Royal Prince Alfred Hospital Medicines Information Unit	02 9515 8145	
Westmead Hospital Medicines Information Unit	02 8890 6619	
Royal Darwin Hospital	08 8922 7488	Northern Territory
Queensland Medicines Advice & Information Service	07 3646 7098	Queensland
SA Pharmacy Medicines Information Service Women's and Children's Hospital	08 8161 7555	South Australia
Royal Hobart Hospital	03 6166 8667	Tasmania
Alfred Hospital	03 9496 5668	
Monash Medicines Information	03 9594 2361	
Peter MacCallum Cancer Centre	03 8559 5204	
Psychotropic Drug Advisory Service	03 9076 8036	
Royal Women's Hospital	03 8345 3190	
St Vincent's Hospital	03 9231 4359	
The Royal Children's Hospital	03 9345 5208	
Obstetric Medicines Information Service King Edward Memorial Hospital	08 6458 2723	Western Australia
Perth Children's Hospital	08 6456 0190	
Royal Perth Hospital	08 9224 2087	
Statewide Psychotropic Drug Information Centre Graylands Hospital	08 6159 6400	
Pregnancy Drug Information Centres		
Canberra Health Services	02 5124 3333	Australian Capital Territory
MotherSafe at Royal Hospital for Women	02 9382 6539 1800 647 848	New South Wales
Queensland Medicines Advice & Information Service Royal Brisbane and Women's Hospital	07 3646 7098	Queensland
SA Pharmacy Medicines Information Service Women's and Children's Hospital	08 8161 7555	South Australia
Monash Medicines Information	03 9594 2361	Victoria
Royal Women's Hospital	03 8345 3190	
Obstetric Medicines Information Service King Edward Memorial Hospital	08 6458 2723	Western Australia

Appendix 2: TGA ADEC Categories

Category	Description
Category A	Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.
Category B1	Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have not shown evidence of an increased occurrence of foetal damage.
Category B2	Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage.
Category B3	Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have shown evidence of an increased occurrence of foetal damage, the significance of which is considered uncertain in humans
Category C	Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human foetus or neonate without causing malformations. These effects may be reversible. Accompanying texts should be consulted for further details
Category D	Drugs which have caused, are suspected to have caused or may be expected to cause, an increased incidence of human foetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects. Accompanying texts should be consulted for further details.
Category X	Drugs which have such a high risk of causing permanent damage to the foetus that they should not be used in pregnancy or when there is a possibility of pregnancy.

Appendix 3: Excerpt of KEMH OMIS References Documented between 2001 and 2020

American Society of Health System Pharmacists® Patient Medication Information™
Australian Immunisation Handbook
Australian Injectable Drugs Handbook (Society of Hospital Pharmacists Australia)
Australian Medicines Handbook (AMH)
Australian Pharmaceutical Formulary
Australian Pharmacy Practice Manual
Australian Therapeutic Guidelines Limited®
British National Formulary
Don't Rush to Crush (Society of Hospital Pharmacists Australia)
Drugs and Lactation Database (LactMed)
Drugs in Pregnancy and Lactation (Briggs)
eLactancia®
Gullebaurd Contraception
Herbs and Natural Supplements (Authors: Lesley Braun, Matt Cohen)
KEMH Clinical Guidelines
KEMH Medical Consultant
Manufacturer Product Information
Martindale: The Complete Drug Reference
Micromedex IBM®
Mills and Bone: A Herbal Guide
MIMS Australia ®
Mosby's Handbook of Herbs and Natural Supplements (Author: Linda Skidmore-Roth)
Mothersafe: The Royal Hospital for Women
MothertoBaby®
Neofax IBM®
OMIS Pharmacist
Pediatric Dosage Handbook
Previous KEMH OMIS Record
Published Literature
Reprotox IBM®
Search Engine
The Organisation of Teratology Information Specialists (OTIS)
The Royal Womens Hospital: Pregnancy and Breastfeeding Medicines Guide
Therapeutic Goods Administration (TGA)
Thomas Hale: Medicines and Mothers Milk (HalesMed.com)
Trissels Handbook of Injectable Drugs®
Western Australian Health Department Policy

Appendix 4: Participant Information Statement

Government of **Western Australia**
Department of **Health**
North Metropolitan Area Health Service
Women and Newborn Health Service

WNHS P.I.S. (2018)

User Survey of the KEMH Obstetric Medicines Information Service

PARTICIPANT INFORMATION SHEET *(To be Read over the Phone)*

What is the study about?

The pharmacist-initiated and -operated King Edward Memorial Hospital Obstetric Medicines Information Service (KEMH OMIS) has been managing enquiries from health professionals and the public about medication use in pregnancy and lactation. This study aims to survey users of the service to understand their experience.

Who is carrying out the study?

My name is Nabeelah Mukadam and I am a Senior Pharmacist at KEMH. I will be conducting this study in collaboration with Curtin University and the KEMH Pharmacy Department.

What is required from you for this study?
Yesterday / on [date], you spoke with a pharmacist regarding information about whether [medicine/s] can be used in [pregnancy/breastfeeding].

I would like to ask you some questions about your enquiry to the service yesterday. This will take about 10 to 15 minutes. Your involvement in this survey is entirely up to you and voluntary. If you say no or pull out, this won't affect any future service you receive from the hospital. What you tell me will be treated with the strictest confidence and your answers will remain anonymous.

What will happen to information I provide??

Information you provide will be de-identified and only used for the purpose of this research. By signing the consent form you agree to the study team obtaining the information provided in the study group. It is anticipated that the results of **this research project will be published and/or presented in a** variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Who has approved the study?

Women and Newborn Health Service Governance Ethics and Knowledge, Outcomes Committee and Curtin University Ethics Committee.

Who to contact for more information about this study:

If you would like any more information about this study, please do not hesitate to contact myself. I am very happy to answer your questions.

Who to contact if you have any concerns/complaints about the study or its organisation?

If you have any concerns or complaints regarding this study, you can contact The Women and Newborn health Service Ethics Committee (Telephone No: (08) 6458 2222). Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

What to do next if you would like to take part in this research?

If you would like to take part in this research study, do you confirm you would like to proceed. I will confirm your consent to participate.

THANK YOU FOR YOUR TIME AND CONSIDERATION

Appendix 5: User Survey for KEMH OMIS


OMIS Survey

Q0.1 Enquiry Number

_____

Q1 Caller Details

- ○ Health Professional (1)
- ○ Public (2)

Q2 Health Professional

- ○ Doctor (1)
- ○ Nurse (2)
- ○ Midwife (3)
- ○ Pharmacist (4)
- ○ Other (5) _____

Q3 How did you find out about the Medicines Information Service?

- ○ From my Health professional (1) _____
- ○ Google® Search (2)
- ○ Purple Neonatal Book (3)
- ○ Poisons Information Centre (4)
- ○ Ngala Mia (5)
- ○ Breastfeeding Centre (6)
- ○ AMH (7)
- ○ Other (8) _____

Q5 Had you used this service prior to the call you made previously?

- ○ Yes (1)
- ○ No (2)

Q6 If Yes - how often do you use the service?

- ○ At least Once a Month (1) _____
- ○ Quarterly – every 3 months(2) _____
- ○ 1-2 times per Year (3) _____

Q7 With a calls based centre - with regards to being transferred to a pharmacist to answer your query , how easily did that occur for your call?

- ○ Within 5 minutes (1)
- ○ Between 5 and 15 Minutes (2)
- ○ Receive a Call Back (3)

Q8 If a call back was received, was there a reason this occurred?

_____

Q9 How long did the pharmacist take to provide you with a suitable response?

- ○ Within 5 minutes (1)
- ○ Between 5 and 15 Minutes (2)
- ○ Receive a Call Back (3)

Q10 With regards to the answer you received - how useful was this information

- ○ Not Useful (1)
- ○ Slightly useful (2)
- ○ Neutral (3)
- ○ Very Useful (4)
- ○ Extremely Useful (5)

Q11 If not useful - what could be altered to change the response to suit your needs?

_____

Q12 The answer provided by our pharmacist are usually verbal - was this the case for you?

- ○ Yes (1)
- ○ No (2) _____

Q13 If yes, was a verbal answer sufficient ?

- ○ Yes (1)
- ○ No what other forms would you require? (2) _____

Q14 Did the pharmacist provide enough detail for you?

- ○ Yes (1) _____
- ○ No (2) _____

Q15 How well did the response alleviate your concerns regarding the medication's safety in Pregnancy or Breastfeeding?

- ○ Extremely well (1)
- ○ Very well (2)
- ○ Moderately well (3)
- ○ Slightly well (4)
- ○ Not well at all (5)

Q16 Would you use this service again?

- ○ Yes (1)
- ○ Maybe (2)
- ○ No (3) _____

Q17 If the service as unavailable - what would you have done or who would you contact?

- [ ] Doctor (1)
- [ ] Pharmacist (2)
- [ ] Poisons Information Centre (3)
- [ ] Royal Womens (4)
- [ ] AMH (5)
- [ ] MIMS (6)
- [ ] Midwife (7)
- [ ] Nothing (8)
- [ ] Other (9) _____

Q18 Do you have any suggestions for the service?

_____

Q19 On a scale of 1 to 5 where one is Poor and 5 excellent, how would you rate the service?

- ○ 1 Poor (1) _____
- ○ 2 (2) _____
- ○ 3 (3)
- ○ 4 (4)
- ○ 5 Excellent (5)

Q20 Is there any information you would like in regards to your previous call?

_____

End of Survey – thank you for your time.

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