

BMJ Open Protocol for a multicentre prospective observational study of families with full-term infants on postnatal wards and in the community to capture feeding practices across the first year of life: the Mother Infant Lactation Questionnaire (MILQ) study

Jacqueline F Gould ^{1,2}, Lisa N Yelland,^{1,3} Robert A Gibson,^{1,4} Andrew J McPhee,^{1,5} Jojoy Varghese,⁶ Rosalie Grivell,^{7,8} Maria Makrides^{1,9}

To cite: Gould JF, Yelland LN, Gibson RA, *et al.* Protocol for a multicentre prospective observational study of families with full-term infants on postnatal wards and in the community to capture feeding practices across the first year of life: the Mother Infant Lactation Questionnaire (MILQ) study. *BMJ Open* 2022;**12**:e066355. doi:10.1136/bmjopen-2022-066355

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-066355>).

Received 05 July 2022
Accepted 20 September 2022



© Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to

Dr Jacqueline F Gould;
jacqueline.gould@sahmri.com

ABSTRACT

Introduction Breastmilk is considered the gold standard for infant nutrition. Breast feeding is recommended as the sole source of nutrition between birth until around 6 months of age and should be continued beyond this age as complementary foods are introduced. While breast feeding initiation is generally high in developed countries, continuation of breast feeding appears to drop rapidly. This is a prospective observational study of life that aims to characterise a current picture of infant feeding practices across the first year, and motivations for feeding practices, and to identify barriers and enablers for breast feeding.

Methods and analysis Caregivers with newborn singleton infants of normal birth weight are approached on the postnatal units of three hospitals in South Australia, or through targeted online advertising campaigns promoting the study. Caregivers are asked to complete surveys when their infant reaches 3, 5 and 7 weeks', and at 3, 4, 5, 6, 9 and 12 months of age. Initially, baseline characteristics, intentions and preferences for infant milk feeds, as well as reasons for preferences are captured. Latter surveys query how infants are being fed, difficulties or barriers to breast feeding, as well as any enablers (if breast feeding). Once infants reach 5 months of age, surveys capture complementary feeding. A large opportunistic sample from the Adelaide community with a minimum of 1000 mother–infant pairs will be enrolled. The data will be analysed descriptively and using regression models.

Ethics and dissemination Women's and Children's Health Network Human Research Ethics Committee reviewed and approved the study (approval no HREC/19/WCHN/140, approval date: 22 November 2019). Study results will be disseminated through academic meetings, peer-reviewed journals, in-services for postnatal healthcare services, results letters for participants and social media.

Trial registration number ACTRN12620000529943.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Breastfeeding barriers, enablers and preferred sources of infant feeding support are reported regularly over the first 12 months of life.
- ⇒ Recruitment for this study may be subject to bias from self-selection.
- ⇒ Online recruitment of infants up to 7 weeks of age may miss detecting some key early challenges or enablers for exclusive breast feeding.
- ⇒ Lost to follow-up across the 12 months study period may introduce attrition bias.

INTRODUCTION

Nutrition in early life is one of the most influential, non-genetic, determinants of healthy development.^{1–6} Breastmilk is the natural and gold-standard source of nutrients, preformed in their bioavailable state, for infants.^{7–10} The WHO recommends that infants commence breast feeding within the first hour of being born,¹¹ and are exclusively breastfed until 6 months of age¹² with ongoing breast feeding until or beyond 24 months of age.^{12 13} At around 6 months, parents are encouraged to introduce complementary feeding to the infants diet while continuing breast feeding.^{12 13} In Australia, the National Health and Medical Research Council recommends that breast feeding be exclusive until 6 months of age, and continuing to 12 months of age or beyond, with complementary foods introduced around 6 months of age.^{14 15}

The Australian Institute of Health and Welfare conducted the first nationwide survey of infant feeding practices in Australia; the

2010 Australian National Infant Feeding Survey.¹⁶ The cross-sectional survey captured the prevalence and duration of breast feeding, attitudes towards breast feeding, barriers to breast feeding and timing of introduction of complementary feeds. Caregivers of 28 759 infants less than 24 months of age self-reported that breast feeding was initiated for 96%.¹⁶ However, breast feeding decreased with age so that by 4 months only 69% were breastfed, and between seven and 12 months only 42% of infants were breast feeding.¹⁶ A recent cross-sectional nationwide survey of 1140 families with infants under 24 months of age, the OzFits study,¹⁷ found breastfeeding initiation was still high at 98% and that 44% of infants were breastfed at 12 months of age.¹⁷ The 2010 Australian National Infant Feeding Survey and the OzFits study provide critical nationwide snapshots of infant feeding practices that suggest that breastfeeding trends have not improved over the last decade. However, both surveys were cross-sectional and relied on recall, which may be subject to inaccuracies and bias, so that changes within individual families across time are still unknown.^{16 17} In addition, facilitators or enablers of breast feeding were not addressed in either survey and hence are not available to inform postnatal support services.^{16 17}

Contemporary information about facilitators and barriers to breast feeding could be used to better inform interventions to promote breastfeeding practices. We propose to conduct a prospective observational study that follows infants across the first 12 months of life through repeated surveys to measure infant feeding practices, and factors that influence them.

Aims and objectives

The aim of the Mother Infant Lactation Questionnaire (MILQ) study is to document the current feeding practices of South Australian mothers with full-term infants, with particular interest in the prevalence of exclusive breast feeding. Objectives of the MILQ study include describing the prevalence and duration of breast feeding, barriers and enablers of breast feeding, feeding support received, as well as timing and type of complementary feeds. Preferences, intentions and motivations for feeding and satisfaction with breast feeding duration are described. Additional objectives are to explore characteristics associated with breastfeeding intentions, initiation and continuation.

METHODS

Study design and management

This is a prospective observational study of infant feeding practices across the first year of life. Once screened and enrolled, families are sent regular surveys. There is no reimbursement for participation. Recruitment commenced on 27 February 2020 and is expected to be completed in June 2022, with the last follow-up survey due June 2023.

The MILQ study is managed through a study-specific web-based management system built by the South Australian Health and Medical Research Institute (SAHMRI) using Research Electronic Data Capture (REDCap) and hosted on SAHMRI's secure servers. Surveys are built in REDCap where questions are mainly multiple choice with built-in logic to display or hide specific questions or response options depending on previous responses.

The MILQ study survey is designed by the investigative team, based on the 2010 Australian National Infant Feeding Survey.¹⁶ Study investigators give permission for other researchers to use the questionnaire (see online supplemental material), or any subset of the questions in their own research, with appropriate acknowledgement of the source.

Study population

Families residing in metropolitan South Australia with a newborn infant. Only one caregiver can be enrolled per infant.

Inclusion criteria

Caregivers are eligible if they have a singleton infant under 49 days of age born full-term (37 to 41 weeks' gestation) at an appropriate birth weight for their gestational age (birth weight >5th and <95th percentile; males 2604 \geq to \leq 4215 g, females 2532 \geq to \leq 4041 g). Caregivers can enrol before their infant reaches 49 days' (7 weeks) of age. The caregiver or legally authorised representative must be at least 16 years of age at enrolment and able to provide informed consent.

Recruitment

Caregivers are recruited from postnatal units of three maternity hospitals within South Australia, and from the community through online targeted advertising of the MILQ study. Information about the MILQ study is available to the public through the SAHMRI website with the MILQ study email address and contact number. Study information materials with links to the SAHMRI MILQ Study website are displayed on the SAHMRI Facebook page, the SAHMRI Women and Kids Facebook page and at local perinatal exhibitions.

Nurses, midwives and lactation consultants on the postnatal wards of the Women's and Children's Hospital, the Flinders Medical Centre and the Lyell McEwin Hospital in Adelaide, South Australia screen and approach caregivers with newborn infants and provide verbal and/or written information about the study. If eligible and interested, caregivers can complete a hard-copy information sheet and consent form or be emailed or texted an individualised link to the online information sheet and consent form. Alternatively, caregivers can request a follow-up phone call from study staff.

Face-to-face recruitment on the postnatal wards was paused on the 24 March 2020 during the initial months of the severe acute respiratory syndrome coronavirus disease 2019.¹⁸ In order to safely continue recruitment, a digital

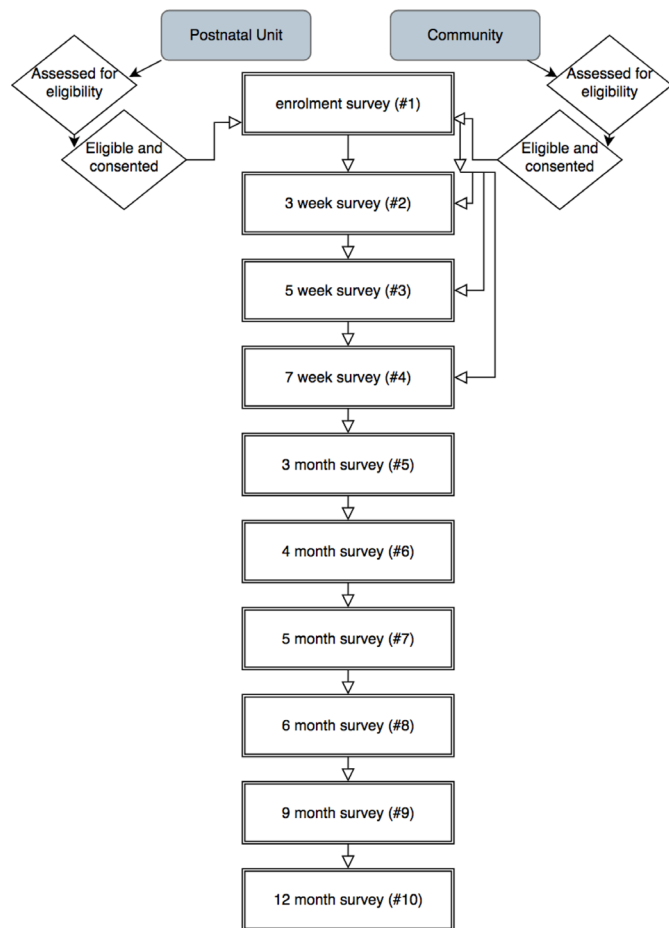


Figure 1 Flow of participants from multiple sources of recruitments into and through the MILQ study. MILQ, Mother Infant Lactation Questionnaire.

media recruitment campaign targets caregivers in South Australia with a new infant with study advertisements on platforms such as Google, Instagram and Facebook (based on proprietary algorithms). The advertisement links to an information page and online prescreening where individuals book a virtual appointment to complete screening with study staff.

Study procedures

Participants provide informed consent either through hard-copy or e-version of the information sheet and consent form prior to being enrolled. On enrolment, caregiver–infant pairs are allocated a unique participant identification code (study ID) in REDCap. Screening questions are completed by study staff and all other questions are self-completed by caregivers, or can be completed via phone interview with study staff. Individualised survey links are automatically sent via text message or email to the nominated caregiver by REDCap as the infant reaches the specific ages (calculated using their date of birth). There are (up to) 10 surveys designed to be completed shortly after enrolment and when the target infant is 3, 5 and 7 weeks', and at 3, 4, 5, 6, 9 and 12 months of age (see online supplemental material). All families are asked to complete the baseline survey but are

not asked to retrospectively complete surveys due prior to enrolment (see the figure 1 for study flow). Any caregiver of an enrolled infant can complete surveys.

Sample characteristics

Demographics and baseline characteristics are collected during screening and an enrolment survey. Sociodemographic details such as level of education and maternal age are captured, along with pregnancy details including mode of birth and support with feeding during hospitalisation. At each subsequent survey, caregivers are asked if the mother has returned to work (see online supplemental material).

Feeding intentions and preferences

At enrolment, caregivers are asked their feeding intentions and preferences, with some subsequent questions depending on the option selected. If breastmilk only is selected, they are prompted to indicate the reason(s) why from a series of possible reasons. If formula only is selected, an alternate list of possible motivations is provided.

First feeding practices

Initial feeding practices captured at enrolment include the first milk fed to the infant, and all milks fed while in hospital and at home, with possible reason(s) for exclusive breast feeding, or no breast feeding. Possible reason(s) are displayed as a list, and options are dependent on the mode of infant feeding indicated.

Current feeding practices

After the enrolment survey, subsequent surveys ask about current milk feeds and reason(s) for feeding choice if exclusively breast feeding, or not breast feeding. Options for feeding choice reason(s) are dependent on the mode of infant feeding indicated.

If infants are breastfed, caregivers will be prompted with questions about challenges and enablers for breast feeding and need for feeding support. If breast feeding has ceased, caregivers are asked the date and their degree of satisfaction with their duration of breast feeding, with the option of leaving a free-text comment. If breast feeding has ceased, subsequent surveys hide questions about breast feeding. Once infants reach 5 months of age, surveys include questions about the introduction and provision of complementary foods.

Sample size

We aim to enrol at least 5% of the live births in metropolitan South Australia over the anticipated 26-month enrolment period. The birth rate in South Australia is estimated to be 11.6 per 1000,¹⁹ meaning a minimum of 1000 mother–infant pairs need to be enrolled in MILQ. This sample size will enable estimates of categorical (dichotomous) characteristics (such as prevalence of breast feeding) with a precision of at least $\pm 3\%$, with precision defined as the width of a 95% CI.



Statistical analysis and data management

The data collected is a mixture of categorical, continuous, dichotomous and some free text. Data are entered into a REDCap database, which uses a MySQL database through a secure web interface. Data are stored on secure servers within SAHMRI for a minimum of 30 years, with access granted only to authorised SAHMRI study personnel.

All analyses will be undertaken according to a prespecified statistical analysis plan. Descriptives of sample characteristics will be reported and compared with characteristics of all births in South Australia over the same period to determine generalisability of the sample. Analyses of feeding practices and motivations will primarily be descriptive. Feeding intentions and preferences, as well as first feeding practices, and the mother's return to work will be reported descriptively and will be explored as predictors of breast feeding (initiation, duration and exclusive breast feeding) in linear and logistic regression models. Results will be presented both overall and by subgroups defined by recruitment source (online or hospital recruitment) and participation in other studies conducted by SAHMRI Women and Kids (yes or no), as these factors may be related to responses. The number and pattern of missing responses will be reviewed for the key variables of interest and missing data techniques, such as multiple imputation, will be used to address missing data as appropriate.

Ethical considerations and dissemination of results

This study is carried out in accordance with the Australian National Statement on Ethical Conduct in Research Involving Humans,²⁰ which builds on the ethical codes of the Declaration of Helsinki and the Principles of International Conference on Harmonisation²¹ Good Clinical Practice (as adopted in Australia).²² The MILQ study is conducted in compliance with the current version of the Protocol. All study procedures, the protocol and study materials have been reviewed and approved by the Women's and Children's Health Network Human Research Ethics Committee prior to the study commencing (HREC/19/WCHN/140; approval date: 22 November 2019). The MILQ study is registered on the Australia and New Zealand Clinical Trial Registry (ANZCTR: ACTRN12620000529943).

Families are provided with detailed written information about the study. Either a caregiver or legally authorised representative must provide informed consent, in the form of either e-consent or a hard copy written form, prior to study participation. Participants are free to decline any aspect of the study, or decline to complete any surveys or survey questions, or withdraw from the study at any time without prejudice.

The results of this study will be presented to practising clinicians and in-services for postnatal healthcare facilities (such as postnatal units and lactation consultants), at academic conferences, and published in multiple peer-reviewed journal manuscripts. Participants and participating centres will be provided with a report of the study

results, and results may be presented on social media. No participants will be identified in the dissemination of study results.

Access to data

Deidentified individual participant data, with data dictionaries, may be shared on reasonable request to the study investigators. Proposals to access the data must be scientifically and methodologically sound and must be reviewed and approved by the MILQ Study Steering Committee and by the Women's and Children's Health Network Human Research Ethics Committee. To gain access, data requestors will need to sign a data access agreement. Proposals should be directed to Jacqueline Gould through email (Jacqueline.gould@sahmri.com).

Patient and public involvement

SAHMRI Women and Kids research nurses, assistants, and academics who are mothers reviewed the questions and provided feedback prior to study commencement. Caregivers from the public were not involved in the development of the research question, the questionnaires or design of this study.

DISCUSSION

There are numerous benefits of breast feeding for both mother and infant,²³ and breastfeeding facilitates national economic growth through reductions in morbidity, and mortality, coupled with improvements to IQ and subsequent adult working and social capacity.²⁴ Breast feeding also has the advantage of lower environmental costs than breast milk substitutes due to absence of manufacturing, packaging, transport and production costs.²⁵ Hence breastfeeding promotion is an intervention with one of the highest health and economic impacts.^{24 25} Furthermore, breastfeeding practices are highly responsive to breastfeeding intervention,²⁵ and as breast feeding is available to most families at no cost, breastfeeding interventions promote equity by allowing all children a nutritionally optimal start to life.²⁴ The MILQ survey will provide an indication of barriers and enablers for breast feeding and when they occur during the first 12 months of life that can be used to better support and promote exclusive breast feeding.

Strengths and limitations

While eligibility for the MILQ study is restricted to caregivers with full-term infants born at a normal birth weight, which represents most infants born within Australia, findings may not reflect or be directly applicable to some subpopulations, such as those born preterm or at a low birth weight. The MILQ study targets families living within metropolitan South Australia, and although it is debatable as to whether infant feeding practices differ rural vs urban locations. The three postnatal wards recruiting for the MILQ study are Baby Friendly Hospital Initiative accredited, meaning they support

and promote exclusive breast feeding.²⁶ As only 26% of maternity facilities around Australia are accredited,²⁷ families recruited from the community likely birthed in hospitals that are not accredited and may have different experiences for feeding support and education. Participants are approached shortly after birth and can enrol any time before 7 weeks of age. Challenges with breast feeding that commonly occur within the first 6 weeks may not be adequately captured in some families enrolling older infants. Recruitment for the MILQ study, as with any breastfeeding study, may be subject to bias from self-selection, where women with positive attitudes towards breast feeding, and/or confidence in breast feeding may be more likely to enrol and complete each of the surveys. Following the recommendations of the Australia National Health and Medical Research Council to continue breast feeding to 12 months of age or beyond,¹⁴ the MILQ study surveys cease once the infant reaches 12 months of age. Future research would be necessary to determine the prevalence of breast feeding beyond 12 months of age, and whether challenges or enablers differ to those reported for infants less than 12 months of age. The MILQ study does not capture reasons for mixed feeding or for timing of complementary feeding. Future research is needed to determine motivations for mixed feeding, preferably using open ended questions. The MILQ study commenced recruitment immediately prior to the COVID-19 outbreak reaching Australia, which may have impacted infant feeding practices and/or support available to new families. Findings from the MILQ survey may be applicable to other countries, as results of the Australian National Infant Feeding and OzFits surveys are similar to the results of other breastfeeding studies around the world.²³

Conclusion

The MILQ study will provide a contemporary, prospective indication of the prevalence and duration of exclusive breast feeding across the first 12 months of life. Reporting of barriers and enablers of breast feeding and the timing of these is a critical step towards better supporting families with newborn infants.

Author affiliations

¹Women and Kids, South Australian Health and Medical Research Institute, Adelaide, South Australia, Australia

²School of Psychology & Discipline of Paediatrics, Faculty of Health and Medical Sciences, The University of Adelaide, Adelaide, South Australia, Australia

³School of Public Health, The University of Adelaide, Adelaide, South Australia, Australia

⁴FOODplus Research Centre, University of Adelaide School of Agriculture Food and Wine - Waite Campus, Glen Osmond, South Australia, Australia

⁵Neonatal Medicine, Women's and Children's Hospital, North Adelaide, South Australia, Australia

⁶Dept. of Paediatrics, Lyell McEwin Hospital, Elizabeth Vale, South Australia, Australia

⁷Department of Obstetrics and Gynaecology, Flinders University, Adelaide, South Australia, Australia

⁸College of Medicine and Public Health, Flinders University, Bedford Park, South Australia, Australia

⁹Discipline of Paediatrics, Faculty of Health and Medical Sciences, University of Adelaide, Adelaide, South Australia, Australia

Acknowledgements We would like to thank the families who generously participate in the MILQ Study, the Investigative Team, the study coordinators Beth Kean, Kimberly Hamlyn and Lauren Williams, the postnatal midwives and nurses who recruited for this study, and Thomas R. Sullivan for statistical advice. The MILQ Steering Committee is composed of Chair Gould, and members Makrides, Yelland, Gibson, Varghese, McPhee and Grivell.

Contributors JFG and MM conceptualised and designed the study. LNY provided statistical expertise for the study design and manuscript. JFG, MM and RAG obtained funding for the study. JFG drafted the manuscript, with significant input from MM, LNY and RAG. JFG, MM, RAG, LNY, AM, JV and RG refined the manuscript and approved the final manuscript for submission. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Funding This work is supported by a research grant from Fonterra Co-Operative Group, Palmerston North, New Zealand and a Centres of Research Excellence grant from the National Health and Medical Research Council in Australia ID: GNT1135155. MM is supported by an Australian National Health and Medical Research Council Principal Research Fellowship ID: GNT1154912.

Disclaimer The contents of the published material are solely the responsibility of the authors and do not reflect the views of Fonterra Co-Operative Group or the National Health and Medical Research Council.

Competing interests Honoraria have been paid to JFG's institution to support conference travel by the Nestle Nutrition Institute. No other authors reported any financial disclosures.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iD

Jacqueline F Gould <http://orcid.org/0000-0003-2810-6870>

REFERENCES

- 1 Cusick S, Georgieff MK. The first 1,000 days of life: the brain's window of opportunity. Secondary The first 1,000 days of life: the brain's window of opportunity. Available: <https://www.unicef-irc.org/article/958/>
- 2 Save the Children. *Nutrition in the first 1,000 days; state of the world's mothers*. London: Save the Children, 2012.
- 3 US Agency for International Development. The 1,000-day window of opportunity: technical guidance brief secondary the 1,000-day window of opportunity: technical guidance brief, 2017. Available: <https://www.usaid.gov/what-we-do/global-health/nutrition/1000-day-window-opportunity>
- 4 Gould JF, Feeding C. Micronutrients and Developmental Outcomes of Children. In: Black RE, Makrides M, Ong K, eds. *Complementary feeding: building the foundations for a healthy life (Nestle nutrition Institute workshop series 87)*. Switzerland: Karger, 2017.



- 5 Cheatham CL. Nutritional factors in fetal and infant brain development. *Ann Nutr Metab* 2019;75 Suppl 1:20–32. doi:10.1159/000508052
- 6 Colombo J, Gustafson KM, Carlson SE. Critical and sensitive periods in development and nutrition. *Ann Nutr Metab* 2019;75 Suppl 1:34–42. doi:10.1159/000508053
- 7 Lönnerdal B. Bioactive proteins in human milk: mechanisms of action. *J Pediatr* 2010;156:S26–30. doi:10.1016/j.jpeds.2009.11.017
- 8 Horta B, CG V. Long-Term effects of breastfeeding: a systematic review and meta-analysis 2013. doi:10.1111/apa.13139
- 9 Kramer MS, Aboud F, Mironova E, et al. Breastfeeding and child cognitive development: new evidence from a large randomized trial. *Arch Gen Psychiatry* 2008;65:578–84–84. doi:10.1001/archpsyc.65.5.578
- 10 Anderson JW, Johnstone BM, Remley DT. Breast-Feeding and cognitive development: a meta-analysis. *Am J Clin Nutr* 1999;70:525–35.
- 11 World Health Organisation (WHO), UNICEF. *Protecting, promoting and supporting breast-feeding: the special role of maternity services*. in: *statement AJWU*. Geneva: World Health Organisation (WHO), 1989.
- 12 World health organisation (who). Breastfeeding. secondary breastfeeding. Available: https://www.who.int/maternal_child_adolescent/topics/child/nutrition/breastfeeding/en/
- 13 World Health Organisation (WHO). *Guiding principles for complementary feeding of the breastfed child*. World Health Organisation (WHO), 2003.
- 14 NHMRC. Infant Feeding Guidelines: information for health workers. In: DoHa A, ed. *Canberra National health and medical Research Council*, 2012.
- 15 NHMRC. Eat for Health; Infant Feeding Guidelines: Summary. In: *National health and medical Research Council*. DoHaACanberra, Australia: National Health and Medical Research Council, 2013.
- 16 AIHW. Australian National Infant Feeding Survey: indicator results. In: AIHW C, ed. *Welfare AloHa*. 2011, 2010.
- 17 Netting MJ, Moumin NA, Knight EJ, et al. The Australian feeding infants and toddler study (OzFITS 2021): breastfeeding and early feeding practices. *Nutrients* 2022;14. doi:10.3390/nu14010206. [Epub ahead of print: 03 Jan 2022].
- 18 Gould JF, Best K, Netting MJ, et al. New methodologies for conducting maternal, infant, and child nutrition research in the era of COVID-19. *Nutrients* 2021;13. doi:10.3390/nu13030941. [Epub ahead of print: 15 Mar 2021].
- 19 Unit PO. *Pregnancy Outcome in South Australia 2016*. In: *Prevention and population health branch SH*. Government of South Australia, 2018.
- 20 National Health and Medical Research Council, Australian Research Council, Australia U. *The National statement on ethical conduct in human research 2007 (updated 2018) Australian government*, 2018.
- 21 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). *ICH Harmonised guideline; integrated addendum to ICH E6 (R1): guideline for good clinical practice E6 (R2): international Council for harmonisation of technical requirements for Pharmaceuticals for human use ICH*, 2016.
- 22 Administration TG. Australian clinical trial handbook: Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods. In: Government A, ed. *Health do*, 2018.
- 23 Victora CG, Bahl R, Barros AJD, et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. *The Lancet* 2016;387:475–90. doi:10.1016/S0140-6736(15)01024-7
- 24 Hansen K. Breastfeeding: a smart investment in people and in economies. *The Lancet* 2016;387. doi:10.1016/S0140-6736(16)00012-X. [Epub ahead of print: Online First: Epub Date].
- 25 Rollins NC, Bhandari N, Hajeerhoy N. Why invest, and what it will take to improve breastfeeding practices? *The Lancet* 2016;387:504.
- 26 Australia B. Baby friendly health Initiative Australia. secondary baby friendly health Initiative Australia, 2020. Available: <https://bfhi.org.au/about/>
- 27 Councils of Australian Governments. Australian National breastfeeding strategy: 2019 and beyond secondary Australian National breastfeeding strategy: 2019 and beyond, 2019. Available: https://bfhi.org.au/wp-content/uploads/2019/11/australian_national_breastfeeding_strategy_-_final_.pdf