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Group Pregnancy Care for refugee background women: a co-designed, multi-method evaluation protocol applying a community engagement framework and an interrupted time series design

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Abstract

Introduction Pregnancy and early parenthood are key opportunities for interaction with health services and connecting to other families at the same life stage. Public antenatal care should be accessible to all, however barriers persist for families from refugee communities to access, navigate and optimise health care during pregnancy. Group Pregnancy Care is an innovative model of care co-designed with a community from a refugee background and other key stakeholders. Group Pregnancy Care aims to provide a culturally safe and supportive environment for women to participate in antenatal care in a language they understand, to improve health literacy and promote social connections and inclusion. This paper outlines the Group Pregnancy Care program and provides details of the evaluation framework.

Methods and analysis This is a multi-site, multi-phase, quasi-experimental study using community-based participatory research methods and an interrupted time series design to evaluate a complex intervention. Process and cost effectiveness measures will be incorporated into quality improvement cycles. Evaluation measures are underpinned by partnerships, community engagement and capacity building.

Ethics and dissemination Ethics and dissemination protocols are informed by co-design and participatory principles. All measures are piloted to refine research processes and ensure appropriateness and meaningfulness to community members, bicultural researchers and partners.

Strengths and limitations of this study

- The study's conceptual framework is underpinned by recognition of the diverse experiences of families of refugee background and the need for trauma informed approaches in health care and research
- Comprehensive, multi-method evaluation framework including interrupted time series, process measures and cost effectiveness
- Partnerships and community engagement set the foundation for co-design of the study methods
- Capacity building and employment of refugee background staff is central to the conduct of the evaluation to enable community support for the study and women's participation
- Staffing and resource constraints coupled with the COVID-19 pandemic have limited the capacity of health services to implement the intervention and hampered the evaluation as planned

Introduction

Women from refugee backgrounds giving birth in Australia have high rates of stillbirth and perinatal mortality.[1 2] These women also have a high risk of physical, mental and social health problems related to experiences of hardship, stress, and experience of persistent disadvantage in the high-income countries in which they settle.[3-5] The loss of family members through death, detention or separation is common, with pervasive and long term consequences for mental health, family functioning and social cohesion.[6 7] In addition, the psychological and social impacts of torture and other traumatic events can often be experienced intergenerationally.[7-9] This is particularly significant given the accumulating evidence that exposure to stress and trauma preceding, during, and after pregnancy contributes to a range of adverse outcomes (for example infants born preterm, small for gestational age or with low birthweight), with the potential to affect health across the life course.[8-15]

The provision of effective high quality care during pregnancy is critical for healthy mothers and babies.[16] In this paper, we outline the evaluation framework for an innovative model of Group Pregnancy Care (GPC) for women of refugee background that is currently being implemented in Melbourne, Australia. Group Pregnancy Care aims to provide a culturally safe and supportive environment for women to actively participate in their health care.[17] The program aims to improve maternal and child health outcomes by increasing engagement with antenatal care, providing early postnatal care, overcoming language and health literacy barriers and decreasing social isolation.

The United Nations estimates there are approximately 70 million forcibly displaced people globally.[18] Each year, the Australian Government sets the number of visas that may be granted to those in humanitarian need. This quota has been around 13,750 places annually, with some variation. In 2017, an additional 12,000 places were provided for people displaced from Syria and Iraq. In the state of Victoria, Australia, 40% of all women giving birth are born overseas, with the majority of migrant women coming from a country where English is not the main language.[19] This equates to over 31,000 women of non-English speaking background giving birth in Victoria each year. In Victoria's largest metropolitan maternity hospitals around 10% of all women giving birth are of refugee background.[20]

Well provided pregnancy care should provide an opportunity to identify and attend to potentially modifiable social risk factors (e.g. social isolation, stress, trauma, low health literacy, family violence, smoking).[21-26] However the evidence regarding the effectiveness of antenatal interventions addressing social risk factors is mixed. For example, Kiely et al found that a relatively brief psychosocial intervention in pregnancy resulted in a reduction of intimate partner violence (IPV) and improved pregnancy outcomes among African-American women.[27] In contrast, a systematic review pooling evidence from nine Randomised Controlled Trials (RCTs) evaluating pregnancy interventions for IPV concluded that stronger, high quality research evidence is needed to clarify which interventions should be adopted.[28]

Families of refugee background encounter significant barriers accessing and utilising public maternity services and early maternal and child health services.[29 30] Within these systems of care, failure to identify and address clinical and social risks for poor maternal and infant outcomes places mothers and unborn babies at significant risk of adverse outcomes.[16 31] Supporting women to develop health literacy by tailoring antenatal and postnatal care to

address their specific needs for information and build social connections for support has been shown to improve both health care access and engagement, and to enhance women's ability to make health decisions for themselves and their children.[32-34]

Group Pregnancy Care for women and their families from a refugee background

The World Health Organization identified Group Pregnancy Care as having the potential to meet the complex needs of populations vulnerable to poor outcomes,[16] with the Australian antenatal care guidelines identifying potential benefits to women from refugee backgrounds.[35] Group-based pregnancy models typically involve a midwife providing antenatal care and education to a number of women at the same time. The group setting provides an avenue for sharing information and developing supportive social networks. The premise of the model is that women learn best from each other's experience, with facilitated discussion focusing on what women want to know.

The evidence in this field is building, with studies indicating improvements in preterm birth and low birthweight,[36] maternal knowledge and patient satisfaction,[37-39] social support[40] and reduced costs of health care provision.[41] However, a Cochrane systematic review including four randomised and quasi-randomised controlled trials (n=2350, English speaking women) evaluating group antenatal care found no clear evidence of improvement in rates of preterm birth, low birthweight, small-for-gestational age infants or perinatal mortality comparing group based models of antenatal care with one to one antenatal care.[42] The authors concluded that the number of women included in the review was too small to provide adequate power for meaningful comparisons, and further research was needed. Since this review, there has been a rapid emergence of new evidence supporting group-based models of pregnancy care. A systematic review of group prenatal care in high-risk populations identified a range of improved outcomes for women identified as having a 'high-risk' pregnancy.[43] This included decreased preterm birth for low-income and African American women, increased care attendance for women with opioid addiction, adolescents and low-income groups. Other American studies involving African American and Medicaid (public health insurance in the USA) eligible women have identified a reduction in low birthweight, caesarean birth, low 5 minute Apgar scores, and neonatal intensive care unit admission for women who attended the group model compared to standard care.[44-46] However, none of these studies have specifically focussed on women from refugee backgrounds.

Co-design and implementation of a new model of Group Pregnancy Care

All Australian residents have access to free pregnancy care at public hospitals, free care from public maternal and child health (and other community health) services, and subsidised care from community-based general practitioners and other medical providers through Australia's universal public health insurance scheme (Medicare).[47] Depending on visa type, some people from refugee backgrounds will be ineligible for Medicare.[48] Pregnancy care in Australia can be accessed in either the public or private sector. Public pregnancy care is offered through public hospital antenatal clinics or in shared care arrangements between a community-based general practitioner and hospital antenatal clinic. Most women in Australia give birth in a public hospital.

The *Bridging the Gap Partnership* (2014-2016) co-designed and pilot tested a new model of Group Pregnancy Care for families of refugee background living in the outer western region

of Melbourne, Australia.[17] This is the first program of its kind in Australia and involves inter-agency collaboration between public maternity hospitals, refugee support services and publicly funded maternal and child health (MCH) services.

The key program elements are outlined in Table 1. In brief, the model involves multifaceted, culturally appropriate preventive and health promoting health care, information and support for women of refugee background during and after pregnancy in a community setting. The model of care is delivered by a multidisciplinary team of five staff. Fortnightly group information sessions are co-facilitated by a midwife, MCH nurse and bicultural worker. Clinical antenatal care is provided by a second midwife and an on-site interpreter alongside the group sessions. The program is cost-free for clients; provides pregnancy care and information that is woman-directed, culturally appropriate and in women's language; and facilitates referrals, e.g. social work, housing services. Women can enrol to attend the fortnightly group information sessions at any stage of pregnancy.

Table 1: Key program elements of the new model of *Group Pregnancy Care*

Key elements:

- local partnerships between public maternity hospitals, maternal and child health services and multicultural agencies. Partnership meetings are held quarterly and both managers and staff are invited to attend.
- community and stakeholder engagement in the co-design of each local program
- establishment of a multidisciplinary team including two midwives, a maternal and child health nurse, a professional interpreter and a community and language specific bicultural worker; with the same team delivering the program each session, with designated back-up staff available if needed.
- women invited to participate by general practice referral, hospital booking or through community networks
- women-directed group information sessions with women from early to late pregnancy, co-facilitated by a midwife, maternal and child health nurse and a bicultural worker
- pregnancy care (as per standard hospital schedule of visits) with a midwife and professional interpreter held at the same time as the group information session
- home visits by the same maternal and child health nurse and bicultural worker up to 4 months postpartum (if needed)
- locating the program in a community setting close to where families live (e.g. MCH centre)
- flexibility to embed the model in ways that work for communities and health services.

Figure 1 outlines the program logic for GPC. The program is underpinned by the trauma and recovery framework developed by the Victorian Foundation for the Survivors of Torture (Foundation House).[49] The family context and promoting positive outcomes for the whole family are central to the program. A fundamental premise of the program is that by creating culturally safe places for women to connect, access information and strengthen health literacy and self-efficacy, the program will contribute to improved birth and family health outcomes. We expect that should the program be able to change individual behaviors (e.g.

self-efficacy, health literacy) these determinants are on the pathway to improved birth and family health outcomes. We hypothesise that GPC will initially increase access and engagement with prenatal services (primary outcome for evaluation), and that subsequent changes in individual behaviors (e.g. self-efficacy, health literacy) will be determinants on the pathway to improved birth and family health outcomes.

[Insert Figure 1 about here]

A qualitative evaluation of the pilot program found that GPC provides a space for women to feel like they belong, connect with their community networks and find a sense of kinship, family and community in Melbourne.[17] A key finding was the pivotal role of the bicultural worker in leveraging her own community networks for women to find out about the program, and enabling trust and understanding between healthcare providers. The bicultural worker also played a valuable role building the knowledge and skills of other team members in culturally appropriate and sensitive ways of working with women and families of refugee background.[46] Based on the positive findings of this preliminary evaluation, the Victorian Government supported scale-up and a robust evaluation across several sites.

Scaling up Group Pregnancy Care

Partnership and governance

The Murdoch Children's Research Institute (MCRI) is the lead agency and oversees the program in partnership with Foundation House. Foundation House is the major state-wide provider of counselling and advocacy services for people of refugee background. A team of study investigators with expertise in refugee health, community engagement, perinatal mental health, midwifery, implementation science, biostatistics and health economics are responsible for the evaluation. Thirteen agencies have come together to enable the implementation and evaluation of Group Pregnancy Care, including: eight health services; two refugee agencies; and three Victorian government department and peak governmental bodies. In addition, Local Partnership Groups have been formed comprising key managers and staff from the services involved to oversee site-specific co-design and implementation.

Partnerships for sustainability

The context for implementing and evaluating GPC is complex. The programs are all situated in large public hospitals with competing demands for acute care resources. The implementation of GPC requires substantial investment from all stakeholders into the partnership relationship. All aspects of design, system readiness and workforce development have been developed within the existing resources of each partner agency. The partner agencies have provided a substantial investment of time, energy and enthusiasm for trying out GPC to improve care and outcomes for refugee families. This approach was adopted as a strategy to support program sustainability within health services.

Pressures on the health agencies taking part include rising birth rates and changing demographics (i.e. population growth, new refugee populations) in the regions served by participating hospitals, coupled with organisational restructuring and fluctuations in workforce supply. In addition, national and state refugee and asylum seeker health service eligibility policies compound the challenges for services in meeting the needs of women and

families newly arrived in Australia. Despite these systemic challenges, the investment in partnerships is anticipated to promote direct and sustained translation into practice.[50]

GPC Program staffing

GPC staff (e.g. midwives, MCH nurses, bicultural workers, interpreters) have been identified by service managers or via internal Expression of Interest pathways. Bicultural workers were drawn from staff already employed by one of the partner agencies (Victorian Cooperative on Children's Services for Ethnic Groups, known as VICSEG New Futures). All GPC staff participated in tailored professional development provided by the Foundation House[51] and the Groupwork Centre.[52] Training included trauma-informed approaches to care,[49] skills development in group co-facilitation, creating group safety, self-care and reflective practice.

Communities participating in Group Pregnancy Care

The partner agencies committed to expanding the program with four refugee background communities: Karen (from Burma), Afghan, Assyrian Chaldean (from Iraq and Syria) and Vietnamese communities. Priority for these populations was based on:

(i) evidence of poor maternal, perinatal and child health outcomes and under utilisation/lack of engagement with services (based on service data);

(ii) >100 births per annum in the country/language group at partner hospitals

(iii) social risks within communities as identified by partner agencies (access issues, isolation, family violence, low health literacy, requirement for interpreters)

Drawing on learnings from the pilot study, women are invited to participate in the program when they book in for pregnancy care or may be referred through community/social networks and other services (e.g. GP clinics).

Study Aims

The specific aims of the evaluation are to:

1. Evaluate the effectiveness of the GPC program in improving timely access and engagement with preventive health care
2. a) Identify program attributes (intensity, frequency, acceptability, sustainability) that are associated with health care access and engagement and improved maternal and child outcomes and b) monitor adverse maternal, perinatal and infant health outcomes of women participating in the GPC program.
3. Examine mothers' progression in health literacy, social and emotional well-being and experience of care associated with participation in the GPC program.
4. Estimate the potential cost-offsets from improved maternal and child health outcomes relative to the costs of implementing the program, and program cost-effectiveness.

Patient and Public (community) Involvement

Community engagement and capacity building

For the past nine years MCRI and Foundation House have been working in partnership to develop and implement a program of collaborative, community-based, participatory research with refugee families focusing on social health and wellbeing of the whole family. Our commitment to respect, reciprocity and capacity building are fundamental to the way in which this study has been designed. Community engagement is a key strategy for ensuring that services are responsive to the needs of the communities which they serve.

The employment of linguistically and culturally matched bicultural research staff and provision of mentoring and training to build research capacity are central to this study. Drawing upon the bicultural researchers' cultural knowledge, language skills and community networks is critical for establishing cultural safety.[53] These participatory strategies aim to alleviate the unequal relationships between researchers and research participants that characterize traditional research approaches. [54]

Role of bicultural researchers

In addition to the four bicultural staff appointed to work with GPC implementation teams, four bicultural researchers have been employed as part of the MCRI evaluation team. The bicultural researchers speak the language of the communities participating in GPC and have extensive community knowledge and networks to support consultation and other research activities. Specific training for the bicultural researchers has included: skills building in research activities (recruitment, informed consent, data collection, data security); processes for supporting participants experiencing distress; and opportunities to practice and receive feedback with research team members on facilitating discussion groups and conducting interviews.

Community Advisory Groups

Following principles of cultural safety,[53] Community Advisory Groups (CAGs) have been established for each refugee community. Our previous research with refugee background communities has established effective community engagement methodologies involving the employment of bicultural staff and the establishment of Community Advisory Groups.[59] Our methodology is inclusive, flexible and aims to build capacity and support ongoing community participation.

Recruitment of Community Advisors was undertaken by the bicultural researchers, with support from partner agencies. The aim of the CAGs is to involve women (and men where appropriate) from refugee backgrounds with a range of experiences (e.g. new parents, Elders, religious leaders). Community consultation was conducted by the bicultural community researchers to identity appropriate community advisors. The CAGs meet at key points relevant to the evaluation. The role of community advisors has been to: (i) provide community perspectives to ensure the evaluation methods are appropriate and meaningful; (ii) contribute to problem solving, interpretation and dissemination of the evaluation findings; (iii) facilitate wider community engagement; and (iv) provide a conduit between the MCRI research team and the community.

Study design and evaluation framework

This is a multi-site, multi-phase, quasi-experimental study using community-based participatory research methods and an interrupted time series design to evaluate a complex intervention (GPC). The time series design uses routinely collected hospital data to compare health service use and maternal and infant outcomes preceding and over the period of implementation of GPC.

To explore the program inputs and attributes, a prospective cohort of mothers participating in the GPC program across all sites is being recruited. Interviews are conducted at 30 weeks' gestation and at 4 months postpartum. To further enhance understanding of scale-up and implementation, we are conducting focus groups with participating women and service providers implementing the model of care. Finally, an assessment of cost effectiveness of the GPC program is being undertaken (Figure 2).

Scaling-up complex interventions

Scaling 'up' and scaling 'out' is a challenging process and involves changing systems, institutions, policies, practices and the culture of people, organisations and systems.[55-57] Not all elements are in the control of those wanting to implement the program. To determine what enables the capacity of systems to scale-up innovation (or not) requires a flexible and multi-faceted approach to evaluation. The Group Pregnancy Care study incorporates methods designed to answer questions that arise during implementation, enabling timely feedback to support scalability and sustainability.

Our approach to scaling up draws upon implementation science, complexity theory and social science – that is, scale-up as structured improvement.[57] To study the ecological properties of GPC as a complex intervention[63] addressing socially determined health inequalities, multiple methods and data sources, including both qualitative and quantitative data are being used. Rather than demonstrating success of the scale-up of GPC by measuring fidelity of its replication alone, we seek to generate a nuanced understanding of what changed during implementation, why and how. We will draw upon: 1) implementation science which takes a structured approach to developing, replicating and evaluating interventions in multiple sites; 2) complexity science which encourages a flexible and adaptive approach to change in dynamic systems; and 3) social science which aims to consider why people act in the way they do, encompassing the organisational and wider social forces that shape and constrain people's actions.[57] These approaches will be used in combination to understand the challenges of spread and scale-up of a complex intervention. Our model of GPC as a complex intervention has been co-designed with each community, as we know that culturally adapting interventions can increase salience, acceptability and uptake.[58] Currently, there is insufficient evidence on the clinical effectiveness or cost-effectiveness of such an approach. We hope to contribute to this evidence base with learnings that can be translated to other settings, and more broadly, to policy and practice guidance. [59]

[Insert Figure 2 about here]

Methods and analysis

Setting

We will evaluate seven GPC programs at four sites involving six different refugee background communities (See Figure 3). The sites include public maternity hospitals in Melbourne's west, north and south east suburbs, all areas of high cultural diversity and increasing refugee settlement.

[Insert Figure 3 about here]

Program Effectiveness (Aim 1)

Data extraction from the Birthing Outcomes System

To facilitate the interrupted time-series analysis, all partner hospitals are extracting data from the electronic Birthing Outcomes System (BOS) for all women giving birth at each site for a 12-month period prior to commencement of GPC (baseline) and at 6 monthly intervals from implementation of GPC until completion. The BOS is a database collecting routine data including demographic information, service contact, screening results and maternal and neonatal outcomes (Table 2). We will categorise women according to whether they are Australian born or born overseas in an English-speaking country or non-English speaking country. In addition, we will identify all women from the cultural backgrounds of women participating in GPC, identified by county of birth and language spoken. Women enrolled in GPC will be identified in the BOS by a code in the data set.

Table 2 Data to be extracted from hospital Birthing Outcomes System

PRIMARY OUTCOME
Number of women attending ≥ 7 antenatal clinic visits
SECONDARY OUTCOMES
Pregnancy care: First antenatal visit <14 weeks, ultrasound scan <14 weeks, number of visits with a professional interpreter involved, screening/diagnostic tests for gestational diabetes at < 30 weeks
Maternal pregnancy medical conditions and complications: hypertension, anaemia, pre-eclampsia, antepartum haemorrhage, gestational diabetes, threatened preterm labour, emergency department attendance
Pregnancy and birth events: induction of labour, method of birth, 3rd or 4th degree tear
Maternal morbidity and mortality: intrapartum or post-partum haemorrhage, wound infection, admission to intensive care, post-discharge readmission, maternal death
Infant outcomes: preterm birth (<37 weeks), low birthweight (<2500 grams), small/large for gestational age (<10th/90th centile), admission to neonatal/special care nursery for >12 hours, unplanned home birth, birth on way to hospital, stillbirth, neonatal death

Covariates

Demographics

Maternal country of birth, year of arrival in Australia, interpreter required, language(s) spoken, place of residence, maternal age at time of birth (years), relationship status,

Reproductive history: parity; plurality; gravidity, pre-existing medical conditions

Medical record data abstraction

Non-routinely collected items such as referral pathways will be collected from the hospital records of women participating in GPC. Information will be abstracted on screening, referral and follow-up of medical and psychosocial issues including: high blood pressure, gestational diabetes, suspected intra-uterine growth restriction, maternal mental health and family violence. Data collection will be undertaken by a research midwife following a protocol using a standardised form. De-identified data will be entered into the Research Electronic Data Capture (REDCap) online software.[60]

Comparative study populations, sample size and study power

Based on the pilot program, we anticipated that 4 sites would implement 7 programs, providing an average of 74 women per group to participate in the evaluation. Allowing for an average loss of 4 women per group (5%), our projected comparison is based on 490 women participating over the period of provision of GPC. Comparisons will be made with i) 490 women receiving antenatal care in the 12 months preceding introduction of GPC; and ii) 490 women contemporaneously enrolled in other models of care. These comparative populations will include women from the same cultural/language background receiving antenatal care at the same hospitals, selecting the most closely matched woman in regards to age and parity for each woman participating in GPC.

As the level of intragroup correlation in attendance is unknown but expected to be low, we will include an intra-class correlation in attendance by hospital for women not participating in GPC, ICC 0.001, and an ICC of 0.005 within groups for women participating in GPC. A level of 5% is considered significant for all comparisons. Using the hospital data as the basis for estimates, the comparisons would each provide 94% power to detect a minimum absolute difference in attendance at 7 or more antenatal visits of 10% (from the current 76% to 86%). Seven visits are considered the minimum for a healthy pregnancy without complications.[35]

Statistical analysis

i) All statistical analyses will be performed using STATA 15.[61] An interrupted time-series comparison[62 63] will be used to investigate the difference in the primary outcome - proportion of mothers attending the recommended number of antenatal visits - associated with the introduction of GPC. This comparison will be made using multilevel regression models accounting for clustering of mothers within hospitals/pregnancy groups, autocorrelation of the observed primary outcome over time and potential period effects (e.g. changes in the percentage of families of refugee background in the hospital service area). Models will thus

include whether the timing of pregnancy was pre or post introduction of the GPC; and an additional item reflecting trend in antenatal attendance over the course of the evaluation to account for any contemporaneous patterns of attendance. Maternal characteristics specified *a priori* will be controlled for including: age; reproductive history and pregnancy complications (e.g. parity, prior preterm birth, prior stillbirth); gestation at program enrolment; country of birth; year of arrival; and other sociodemographic characteristics – this accounting for changes in the eligible population over the study period.

ii) Comparisons between women contemporaneously participating in GPC and other models of care will be conducted using congruent modelling strategies replacing the comparator of whether the timing of pregnancy was pre or post introduction of the GPC with the comparator of participating in GPC versus other models of care.

Program Implementation (Aim 2)

An approach using iterative continuous quality improvement cycles will apply the Plan Do Study Act method (PDSA)[64] for collecting and analysing data and feeding it back to the Local Partnership Groups to refine GPC and continue to improve it.[65] This feedback aims to support and strengthen potential for intervention sustainability. Specifically, we will utilise the PDSA method to (i) conduct an initial assessment of the key elements of the model from the perspective of women/families and staff; (ii) identify barriers and enablers for implementation, and (iii) refine program elements and implement strategies to minimise barriers and maximise opportunities to achieve objectives. The researchers have used this method successfully in other maternity initiatives.[66] Three data sources will be used to gather data.

1. Data will be abstracted from hospital records of women participating in GPC to inform improvement (as described above in Program Effectiveness).

2. Focus groups with women will be used to explore experiences of: accessibility and program content and relevance. A semi-structured discussion guide will be developed in consultation with the bicultural researchers. A nested purposive sample of 5-8 women from each GPC program who have completed the 16-week postpartum interview will be recruited (4 groups, n=20-30). Invited women will have a variety of experiences related to: time in Australia, English language fluency and group attendance. Focus groups will be conducted in women's preferred language co-facilitated by the MCRI bicultural researchers and will be audio recorded (with informed consent), transcribed verbatim, translated to English and analysed using thematic analysis.[67]

3. Midwives, MCH nurses, interpreters, bicultural workers and management involved in delivery of the new model (n=35-45 participants) will be invited to participate in focus groups/interviews. Discussions will explore process evaluation measures including staff experiences of program implementation, cross-sector collaboration, capacity building, skill development, multidisciplinary team work, organisational and systems change, and program/workforce sustainability.

Women's experiences (Aim 3)

All women enrolled in GPC will be invited to complete an interview with a bicultural researcher at approximately 28-32 weeks' gestation and 3-4 months postpartum. The interviews will ask about their health, health literacy, their social connections and their experiences of GPC. The MCRI bicultural researchers will recruit women and conduct the interviews.

Design and translation of structured interview

Standardised measures were used where possible, subject to pre-testing to ensure cultural acceptability. To optimise data quality, all study materials were translated into required languages by a professional agency and with the assistance of the bicultural researchers, translated back into English to ensure high quality and accurate translations.[68] Maternal interviews were audio recorded (with participant consent) and transcribed into English by bicultural staff.

Parent mental health was measured using the Hopkins Symptom Checklist and Harvard Trauma Questionnaire, developed for refugee populations.[69] Working with the MCRI bicultural researchers and the CAGs, we pilot tested the Edinburgh Postnatal Depression Scale,[70] [71] and the Composite Abuse Scale (measures experiences of physical and psychological abuse within intimate partner relationships) to determine acceptability, or not, by all communities participating in GPC.[72] Other domains include: general demographics, health literacy, social connections and experiences of care.

Recruitment of nested prospective pregnancy cohort

The bicultural researchers attended the GPC site corresponding to their community, where they explain their role in the evaluation. Eligible women are enrolled in GPC and ≥ 18 years. Women were not eligible to take part if they were too unwell to participate, had an intellectual disability or medical condition precluding them from giving informed consent (e.g. psychotic illness).

Participant details are all stored on a REDCap database which produced a report based on women's estimated due date to notify the research team when a woman is due to be contacted to schedule the postnatal interview.

Data Analysis

After the completion of each interview, the bicultural researchers transcribed the audio-recording to provide a comprehensive interview transcript in English. All data collected in the interview is manually entered by research team staff into REDCap. Quantitative data will be exported to Stata 15 for scoring and analysis. Qualitative data will be exported to and managed in NVivo[73] for thematic analysis. Four steps for thematic data analysis will be followed: immersion, coding, categorising and developing themes.[67]

Cost effectiveness (Aim 4)

Data on resources used to deliver the intervention will be collected including time commitments of paid staff and participating women. These will be valued ($AUD) at standard

unit costs (e.g. salary scales, interpreter costs, travel) to calculate intervention costs specific to each site. Intervention costs will be combined with potential cost-offsets and outcomes data (Table 2) in an economic evaluation that compares additional costs associated with GPC to changes in health outcomes (cost-consequences analysis).[74] Potential cost-offsets from improved maternal and child health outcomes will be estimated by partner hospitals based on routine perinatal data and hospital financial systems data on in-hospital care costs. As part of the qualitative data collection with GPC staff and stakeholders, information will be collected to inform the economic evaluation.

Progress to date

Implementation of Group Pregnancy Care

Planning for expansion of GPC to three new sites commenced in 2017. However, due to staffing and resource constraints at two of these sites, only the initial pilot program and one new program remain part of the evaluation (involving the Karen and Assyrian Chaldean communities). Additional funding was secured in late 2019 to conduct consultation with two additional communities (Sudanese/South Sudanese and Iraqi/Syrian Muslim) with a view to establishing two new GPC programs and joining the overall evaluation.

Implications of COVID-19 pandemic

In response to the global COVID-19 pandemic, Australia initiated strict internal lockdown policies to reduce the risk of community transmission in late March 2020. As a result, the two established GPC programs paused provision of group sessions, and planning for the two new GPC programs was put on hold. The two established programs transitioned to virtual platforms for clinical and group-based information sessions between March-November 2020. Group sessions using an online platform were initiated in response to the ongoing need for women and families to connect to services and peers for information and support.

The evaluation has also continued, adapting to telephone/video interviews with women and staff/stakeholders. The abrupt disruption to GPC services flowing from the COVID-19 pandemic mean the numbers of women participating in GPC and available for the interviews will be lower than planned.

Given these circumstances, the intended sample size will not be achieved within the intended study completion period. At this point, interim analyses will be conducted and preliminary findings will be shared with the study partners and funders. Interim analyses will provide substantial outputs in regard to process and implementation learnings (Aim 2) and participant experiences (Aim 3) as well as preliminary exploration of responses in the primary outcome (proportion of women attending ≥7 antenatal clinic visits – Aim 1). Extension of the study with the two additional communities at the new sites for which funding has been secured plus continuation of the program at the existing sites where feasible, will provide the opportunity to extend evaluation to achieve the intended sample size for the full comparisons (Aim 1) and economic evaluation (Aim 4).

Ethics and dissemination

Ethical considerations

Human Research Ethics Committee approvals have been provided by all six relevant authorities through the Australian National Mutual Acceptance scheme, where permitted. Ethical amendments were sought for each stage of the study following community and partner organisation consultation to finalise each stage. This staged approach enables piloting and reflection on the cultural safety[53] of the research activities and flexibility to refine research processes to ensure appropriateness and meaningfulness to community members, bicultural researchers and partners. At the time of submitting this protocol, HREC approval had been granted for all stages of the study with a modification for data abstraction pending at one partner site.

In Australia, there are specific ethical guidelines for conducting research with Aboriginal and Torres Strait Islander Communities.[75] However, an equivalent national approach to mandatory ethical research guidelines for the engagement of refugee background communities does not exist. We are mindful of the ethical issues to consider when conducting research with people of refugee background.[76 77] As the concepts of research and ethics may be unfamiliar to some participants, we acknowledge the possibility that participants may feel anxious about their involvement. Concerns may be provoked when issues such privacy, trust and confidentiality, audio recording of interviews etc. are not clear or comfortable for the participant. The bicultural researchers will clarify the voluntary nature of research participation and encourage participants to ask questions to alleviate any concerns, as per our previous research.[78] A study distress protocol developed in partnership with Foundation House and used in our previous research studies will guide the researchers in situations where participants become distressed, require support or disclose issues related to mental health, family violence or participant/child safety.

HREC approvals: The Royal Children's Hospital 37025, HREC/17/RCHM/66, MCRI SSA/17/RCHM/97, Monash Health 17-424X, HREC/16/MONH/65, SSA/17/MonH/362, Northern Health HREC/17/RCHM/66, SSA/17/NH/104, Western Health HREC/17/RCHM/66, SSA/AU/5/C@E0314, Mercy Health 2017-017, Victorian Department of Health and Human Services HHSD/19/174035.

Dissemination

We have developed a comprehensive knowledge translation and dissemination plan in line with our values of reciprocity and collaboration. Including: sharing study findings with communities in accessible ways (via bicultural researchers at Community Advisory Groups), presentations at community forums, partnership meetings, conferences, policy and practice briefs and publication of journal articles. All outputs will be available on the study website.

Conclusion

Group Pregnancy Care for women and their families from refugee backgrounds is an innovative, complex intervention that aims to provide an equitable approach to pregnancy and early postnatal care addressing the health and social inequalities experienced by refugee families. This multi-component evaluation will provide insights into what it takes to

implement innovative, collaborative, culturally-safe, co-designed and sustainable models of care within the constraints of existing resources.

Authors' contributors

ER is the study Principal Investigator and drafted this protocol based on the project proposal and other planning documents involving many people as outlined in the author contribution and acknowledgements. JY, FM, LG, JS, IK, RS, PM, CE, CH, JB, JO, LH, DC and SB are study investigators who contributed to the development of the project proposal and project planning. FM conducted sample size estimate calculations for the interrupted time series design. AK, EM, LB are employed on the project and have contributed to development of planning documents, conceptual framework, ethics submissions which involve many of the components outlined in this protocol, and drafting the manuscript. All authors contributed to drafting and finalising the manuscript.

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Competing interests

None declared.

Data availability statement

Data sharing not applicable as no data sets generated and/or analysed for this study

Participant consent for publication

Not required.

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Figure legends

Figure 1 Conceptual model of Group Pregnancy Care to improve outcomes

Figure 2 Evaluation overview

Figure 3 Planned Group Pregnancy Care Sites and Programs

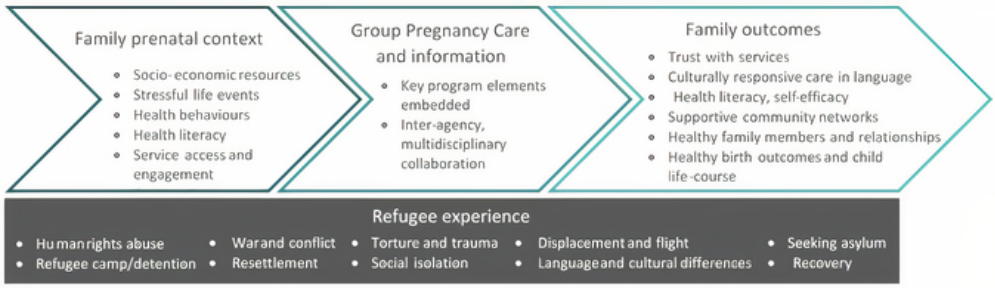

Figure 1 Conceptual model of Group Pregnancy Care to improve outcomes

Program Effectiveness *Aim 1*	Method: Interrupted time-series using routinely collected hospital data supplemented by data on referral pathways obtained from hospital medical records
Program Implementation *Aim 2*	Method: Plan Do Study Act cycles, using 1) data from medical records 2) structured interviews with women 3) focus groups with women, staff, and stakeholders
Women's Experiences *Aim 3*	Method: Community consultation and structured interviews with women in a nested cohort
Cost Effectiveness *Aim 4*	Method: Economic costings using data collected via staff/stakeholder interviews/focus groups

Figure 2. Evaluation overview

Figure 3. Planned Group Pregnancy Care Sites and Programs

Reporting checklist for quality improvement in health care.

Based on the SQUIRE guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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		Reporting Item	Page Number
Title			
	#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
Abstract			
	#02a	Provide adequate information to aid in searching and indexing	3
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	3
Introduction			
Problem description	#3	Nature and significance of the local problem	4

Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	4-6
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	5-9
Specific aims	#6	Purpose of the project and of this report	8-9
Methods			
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	11
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	11-15
Intervention(s)	#08b	Specifics of the team involved in the work	13-14
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	11-15
Study of the Intervention(s)	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	11?
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	p13?
Measures	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	13
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Group Pregnancy Care for refugee background women: a co-designed, multi-method evaluation protocol applying a community engagement framework and an interrupted time series design

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Group Pregnancy Care for refugee background women: a co-designed, multi-method evaluation protocol applying a community engagement framework and an interrupted time series design

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Abstract

Introduction Pregnancy and early parenthood are key opportunities for interaction with health services and connecting to other families at the same life stage. Public antenatal care should be accessible to all, however barriers persist for families from refugee communities to access, navigate and optimise health care during pregnancy. Group Pregnancy Care is an innovative model of care co-designed with a community from a refugee background and other key stakeholders in Melbourne, Australia. Group Pregnancy Care aims to provide a culturally safe and supportive environment for women to participate in antenatal care in a language they understand, to improve health literacy and promote social connections and inclusion. This paper outlines Group Pregnancy Care and provides details of the evaluation framework.

Methods and analysis The evaluation uses community-based participatory research methods to engage stakeholders in co-design of evaluation methods. The study is being conducted across multiple sites and involves multiple phases, use of quantitative and qualitative methods, and an interrupted time series design. Process and cost effectiveness measures will be incorporated into quality improvement cycles. Evaluation measures will be developed using co-design and participatory principles informed by community and stakeholder engagement and will be piloted prior to implementation.

Ethics and dissemination Ethics approvals have been provided by all six relevant authorities. Study findings will be shared with communities and stakeholders via agreed pathways including community forums, partnership meetings, conferences, policy and practice briefs and journal articles. Dissemination activities will be developed using co-design and participatory principles.

Strengths and limitations of this study

- The conceptual framework for Group Pregnancy Care is informed by recognition of the diverse experiences of families of refugee background and the need for trauma informed approaches in health and social care and research.
- The evaluation involves a comprehensive, multi-method evaluation framework including interrupted time series, process measures and cost effectiveness analysis.
- Partnerships and community engagement have informed the co-design of the evaluation methods.
- Capacity building and employment of refugee background staff is central to conduct the evaluation and to support women's participation.
- Staffing and resource constraints coupled with the COVID-19 pandemic have limited the capacity of health services to implement the intervention. Pandemic social distancing measures also limited the capacity to implement some elements of the evaluation.

Introduction

The United Nations estimates there are approximately 70 million forcibly displaced people globally.[1] Each year, the Australian Government sets the number of visas that may be granted to those in humanitarian need. This quota has been around 13,750 places annually, with some variation. In 2017, an additional 12,000 places were provided for people displaced from Syria and Iraq. In the state of Victoria, Australia, 40% of all women giving birth in 2017 were born overseas, with the majority of migrant women coming from a country where English is not the main language.[2] This equates to over 31,000 women of non-English speaking background giving birth in Victoria each year. In Victoria's largest metropolitan maternity hospitals around 10% of all women giving birth are of refugee background.[3]

Women from refugee backgrounds have high rates of stillbirth and perinatal mortality.[4 5] They also have a high risk of physical, mental and social health problems related to experiences of hardship, stress, and experience of persistent disadvantage in the high-income countries in which they settle.[6-8] The loss of family members through death, detention or separation is common, with pervasive and long term consequences for mental health, family functioning and social cohesion.[9 10]

There is accumulating evidence that exposure to stress and trauma preceding, during, and after pregnancy contributes to a range of adverse outcomes (for example infants born preterm, small for gestational age or with low birthweight), with the potential to affect health across the life course.[11-18] Further, the psychological and social impacts of torture and other traumatic events can often be experienced intergenerationally.[10 12 15]

The provision of effective high quality care during pregnancy is critical for healthy mothers and babies.[19] Pregnancy care should provide an opportunity to identify and attend to potentially modifiable social risk factors (e.g. social isolation, stress, trauma, low health literacy, family violence, smoking).[20-25] However the evidence regarding the effectiveness of antenatal interventions addressing social risk factors is mixed. For example, Kiely et al found that a relatively brief psychosocial intervention in pregnancy resulted in a reduction of intimate partner violence (IPV) and improved pregnancy outcomes among African-American women.[26] In contrast, a systematic review pooling evidence from nine Randomised Controlled Trials (RCTs) evaluating pregnancy interventions for IPV concluded that stronger, high quality research evidence is needed to clarify which interventions should be adopted.[27]

Families of refugee background encounter significant barriers accessing and utilising public maternity services and early maternal and child health services.[28 29] Within these systems of care, failure to identify and address clinical and social risks for poor maternal and infant outcomes places mothers and unborn babies at significant risk of adverse outcomes.[19 30] Supporting women to develop health literacy by tailoring antenatal and postnatal care to address their specific needs for information and build social connections for support has been shown to improve both health care access and engagement, and to enhance women's ability to make health decisions for themselves and their children.[31-33]

In this paper, we outline the evaluation framework for an innovative model of Group Pregnancy Care (GPC) for women of refugee background that is currently being implemented in Melbourne, Australia. Group Pregnancy Care aims to provide a culturally safe and supportive environment for women to actively participate in their health care.[34] GPC aims to improve maternal and child health outcomes by increasing engagement with antenatal care,

providing early postnatal care, overcoming language and health literacy barriers and decreasing social isolation.

Group Pregnancy Care for women and their families from a refugee background

The World Health Organization identified Group Pregnancy Care as having the potential to meet the complex needs of populations vulnerable to poor outcomes,[19] with the Australian antenatal care guidelines outlining the potential benefits to women from refugee backgrounds.[35] Group-based pregnancy models typically involve a midwife providing antenatal care and education to a number of women at the same time. The group setting provides a forum for sharing information and developing supportive social networks. The premise of the model is that women learn best from each other's experience, with facilitated discussion focusing on what women want to know.

The evidence in this field is building, with studies indicating improvements in preterm birth and low birthweight,[36] maternal knowledge and patient satisfaction,[37-39] social support[40] and reduced costs of health care provision.[41] However, a Cochrane systematic review including four randomised and quasi-randomised controlled trials (n=2350, English speaking women) evaluating group antenatal care found no clear evidence of improvement in rates of preterm birth, low birthweight, small-for-gestational age infants or perinatal mortality comparing group based models of antenatal care with one to one antenatal care.[42] The authors concluded that the number of women included in the review was too small to provide adequate power for meaningful comparisons, and further research was needed. Since this review, there has been a rapid emergence of new evidence supporting group-based models of pregnancy care. A systematic overview of group prenatal care in high-risk populations identified a range of improved outcomes for women identified as having a 'high-risk' pregnancy.[43] This included a 33-41% decrease in preterm birth for low-income and African American women, and increased antenatal care attendance for women with opioid addiction, adolescents and low-income groups observed in a number of studies in the review. The purpose of this review was to summarise the state of the evidence, yet pooled analyses were not attempted. Other American studies involving African American and Medicaid (public health insurance in the USA) eligible women have identified a reduction in low birthweight, caesarean birth, low 5 minute Apgar scores, and neonatal intensive care unit admission for women who attended the group model compared to standard care.[44-46] However, none of these studies have specifically focussed on women from refugee backgrounds.

Co-design and implementation of a new model of Group Pregnancy Care

All Australian residents have access to free pregnancy care at public hospitals, and from public maternal and child health (and other community health) services, and subsidised care from community-based general practitioners through Australia's universal public health insurance scheme (Medicare).[47] Three quarters of women in Australia give birth in a public hospital and around a quarter of women give birth in a private hospital.[48]

The *Bridging the Gap Partnership* (2014-2016) was a consortium comprising 13 agencies, who came together with a shared goal of reducing disparities in maternal and child health outcomes among families of refugee background living in Melbourne's south eastern and western suburbs. The Partnership implemented a series of quality improvement initiatives over a 4-year period.[3 49] One of these initiatives involved the co-design and piloting of Group

Pregnancy Care for Karen families (from Burma) living in an outer western region of Melbourne, Australia.[34] This was the first program of its kind in Australia, involving inter-agency collaboration between public maternity hospitals, refugee support services and publicly funded maternal and child health (MCH) services. The pilot was evaluated in 2016 and details of the co-design process and qualitative evaluation have been published elsewhere.[34]

The key elements of GPC are outlined in Table 1 and described on the study website.[50] In brief, the model involves multifaceted, culturally appropriate preventive and health promoting health care, information and support for women of refugee background during and after pregnancy in a community setting. The model of care is delivered by a multidisciplinary team of five staff. Fortnightly group information sessions are co-facilitated by a midwife, MCH nurse and bicultural worker. Clinical antenatal care is provided by a second midwife and an on-site interpreter alongside the group sessions. GPC is cost-free for clients; provides pregnancy care and information that is woman-directed, culturally appropriate and in women's language; and facilitates referrals, e.g. social work, housing services. Women can enrol to attend the fortnightly group information sessions at any stage of pregnancy.

Table 1: Key elements of *Group Pregnancy Care* for refugee background women

Key elements:

- Local partnerships between public maternity hospitals, maternal and child health services and multicultural agencies. Partnership meetings are held quarterly and both managers and staff are invited to attend.
- Community and stakeholder engagement in the co-design of each new local program. GPC is tailored to meet the needs of a specific cultural group
- Establishment of a multidisciplinary team including two midwives, a maternal and child health nurse, a professional interpreter and a community and language specific bicultural worker; with the same team delivering GPC each session, with designated back-up staff available if needed.
- Women are invited to participate by general practice referral, hospital booking or through community networks
- Women-directed group information sessions with women from early to late pregnancy, co-facilitated by a midwife, maternal and child health nurse and a bicultural worker
- Pregnancy care (as per standard hospital schedule of visits) with a midwife and professional interpreter held at the same time as the group information session
- Home visits by the same maternal and child health nurse and bicultural worker up to 4 months postpartum (if needed)
- Locating GPC in a community setting close to where families live (e.g. MCH centre)
- Flexibility to embed the model in ways that work for communities and health services.

Figure 1 outlines the program logic for GPC. GPC is underpinned by the Trauma Recovery Framework developed by the Victorian Foundation for Survivors of Torture (Foundation House).[51] The family context and promoting positive outcomes for the whole family are central to GPC. A fundamental premise of GPC is that by creating culturally safe places for

women to connect, access information and strengthen health literacy and self-efficacy, the key elements of GPC will contribute to improved birth and family health outcomes. We expect that GPC should be able to change individual behaviors (e.g. self-efficacy, health literacy). As outlined in figure 1, these determinants are on the pathway to improved birth and family health outcomes.

We have defined some key terms here:

Self-efficacy - refers to an individual's confidence in their ability to complete a task or achieve a goal or be able to cope with a given situation based on the skills they have and the circumstances they face.

Health literacy - is about how people access health and health care information, understand the information, and how they apply that information to their lives by making decisions and acting on it.

Cultural safety - seeks to achieve better care through being aware of cultural difference, giving consideration of power relationships, implementing reflective practice, and makes systems and organisations responsible to ensure that service environments are safe for everyone—regardless of their expressed or assumed culture.

[Insert Figure 1 about here]

Nineteen women participated in a qualitative evaluation of the GPC pilot. Results showed that that GPC provides a space for women to feel like they belong, connect with their community networks and find a sense of kinship, family and community in Melbourne.[34] A key finding was the pivotal role of the bicultural worker in leveraging her own community networks for women to find out about GPC, and enabling trust and understanding between healthcare providers. The bicultural worker also played a valuable role building the knowledge and skills of other team members in culturally appropriate and sensitive ways of working with women and families of refugee background.[46] Based on the positive findings of this preliminary evaluation, the Victorian Government supported scale-up and a robust evaluation across several sites.

Scaling up Group Pregnancy Care

Partnership and governance

The Murdoch Children's Research Institute (MCRI) is the lead agency and oversees the GPC study in partnership with Foundation House. Foundation House is the major state-wide provider of counselling and advocacy services for people of refugee background. Building on community, research and health service partnerships established by the Bridging the Gap Partnership, the Lead Investigator brought together a team of study investigators with expertise in refugee health, community engagement, perinatal mental health, midwifery, implementation science, biostatistics and health economics to oversee the evaluation. The original partnership expanded to include eight health services; two refugee agencies; and three Victorian government department and peak governmental bodies. In addition, Local Partnership Groups have been formed comprising key managers and staff from the services involved to oversee site-specific co-design and implementation.

Partnerships for sustainability

The context for implementing and evaluating GPC is complex. Each GPC site involves a public hospital with competing demands for acute care resources. The implementation of GPC requires substantial investment from all stakeholders into the partnership relationship. All aspects of design, system readiness and workforce development have been developed within the existing resources of each partner agency. The partner agencies have provided a substantial investment of time, energy and enthusiasm for trying out GPC to improve care and outcomes for refugee families. This approach was adopted as a strategy to support sustainability of GPC within health services.

Pressures on the health agencies taking part include rising birth rates and changing demographics (i.e. population growth, new refugee populations) in the regions served by participating hospitals, coupled with organisational restructuring and fluctuations in workforce supply. In addition, national and state refugee and asylum seeker health service eligibility policies compound the challenges for services in meeting the needs of women and families newly arrived in Australia. Despite these systemic challenges, the investment in partnerships is anticipated to promote direct and sustained translation into practice.[52]

GPC staffing

GPC staff (e.g. midwives, MCH nurses, bicultural workers, interpreters) have been identified by service managers or via internal Expression of Interest pathways. Bicultural workers were drawn from staff already employed by one of the partner agencies (Victorian Cooperative on Children's Services for Ethnic Groups, known as VICSEG New Futures). All GPC staff participated in tailored professional development provided by the Foundation House[53] and the Groupwork Centre.[54] Training included trauma-informed approaches to care,[51] skills development in group co-facilitation, creating group safety, self-care and reflective practice.

Communities participating in Group Pregnancy Care

The partner agencies committed to expanding GPC with four refugee background communities: Karen (from Burma), Afghan, Assyrian Chaldean (from Iraq and Syria) and Vietnamese communities. Priority for these populations was based on:

(i) evidence of poor maternal, perinatal and child health outcomes and under utilisation/lack of engagement with services (based on service data);

(ii) >100 births per annum in the country/language group at partner hospitals

(iii) social risks within communities as identified by partner agencies (access issues, isolation, family violence, low health literacy, requirement for interpreters)

Drawing on learnings from the pilot study, women are invited to participate in Group Pregnancy Care when they book in for pregnancy care at the participating hospital or they may be referred through community/social networks and other health and social care services (e.g. GP clinics).

Study Aims

The specific aims of the evaluation are to:

1. Evaluate the effectiveness of GPC in improving timely access and engagement with preventive health care
2. a) Identify attributes of GPC (i.e. frequency of attendance at the group sessions, acceptability of GPC) that are associated with health care access and engagement and improved maternal and child outcomes and b) monitor adverse maternal, perinatal and infant health outcomes of women participating in GPC.
3. Examine mothers' progression in health literacy, social and emotional well-being and experience of care associated with participation in GPC.
4. Estimate the potential cost-offsets from improved maternal and child health outcomes relative to the costs of implementing GPC, and cost-effectiveness.

We hypothesise that GPC will increase access and engagement with prenatal care (primary outcome for evaluation), and that participation in GPC will result in subsequent changes in individual health behaviors (e.g. self-efficacy, health literacy) that are on the pathway to improved birth and maternal health outcomes.

Study design and evaluation framework

The evaluation framework has been developed using community-based participatory research methods to engage stakeholders in co-deign of the evaluation methods. The study is being conducted across multiple sites and involves multiple phases, use of quantitative and qualitative methods, including an interrupted time series design. The time series design uses routinely collected hospital data to compare health service use and maternal and infant outcomes preceding and over the period of implementation of GPC.

To explore GPC inputs and attributes, a prospective cohort of mothers participating in GPC across all sites is being recruited. Interviews are conducted at 30 weeks' gestation and at 4 months postpartum. To further enhance understanding of scale-up and implementation, we are conducting focus groups with participating women and service providers implementing the model of care. Finally, an assessment of cost effectiveness of GPC is being undertaken (Figure 2).

Scaling-up complex interventions

Scaling 'up' and scaling 'out' is a challenging process and involves changing systems, institutions, policies, practices and the ethos of people, organisations and systems.[55-57] Not all elements are in the control of those wanting to implement the initiative. To determine what enables the capacity of systems to scale-up innovation (or not) requires a flexible and multi-faceted approach to evaluation. The Group Pregnancy Care study incorporates methods designed to answer questions that arise during implementation, enabling timely feedback to support scalability and sustainability.

Our approach to scaling up draws upon implementation science, complexity theory and social science – that is, scale-up as structured improvement.[57] To study the ecological properties of GPC as a complex intervention[58] addressing socially determined health inequalities, multiple methods and data sources, including both qualitative and quantitative data are being used. Rather than demonstrating success of the scale-up of GPC by measuring fidelity of its

replication alone, we seek to generate a nuanced understanding of what changed during implementation, why and how. We will draw upon: 1) implementation science which takes a structured approach to developing, replicating and evaluating interventions in multiple sites; 2) complexity science which encourages a flexible and adaptive approach to change in dynamic systems; and 3) social science which aims to consider why people act in the way they do, encompassing the organisational and wider social forces that shape and constrain people's actions.[57] These approaches will be used in combination to understand the challenges of spread and scale-up of a complex intervention. Our model of GPC as a complex intervention has been co-designed with each community, as we know that culturally adapting interventions can increase salience, acceptability and uptake.[59] Currently, there is insufficient evidence on the clinical effectiveness or cost-effectiveness of such an approach. We hope to contribute to this evidence base with learnings that can be translated to other settings, and more broadly, to policy and practice guidance. [60]

[Insert Figure 2 about here]

Methods and analysis

Patient and Public (community) Involvement

The priorities of the study partner agencies and the experiences of the women participating in the pilot study have been critical to the design of this study, in particular the research questions, outcome measures and translation strategies. Study findings will be shared via bicultural researchers at Community Advisory Groups and presentations at community forums. The following sections details the community involvement in the conduct of all aspects of the evaluation.

Partnerships, community engagement and capacity building underpin this study. For the past nine years MCRI and Foundation House have been working in partnership to develop and implement a program of collaborative, community-based, participatory research with refugee families focusing on social health and wellbeing of the whole family. Our commitment to respect, reciprocity and capacity building are fundamental to the way in which this study has been designed. Community engagement is a key strategy for ensuring that services are responsive to the needs of the communities which they serve.

The employment of linguistically and culturally matched bicultural research staff and provision of mentoring and training to build research capacity are central to this study. Drawing upon the bicultural researchers' cultural knowledge, language skills and community networks is critical for establishing cultural safety.[61] These participatory strategies aim to alleviate the unequal relationships between researchers and research participants that characterise traditional research approaches. [62]

Role of bicultural researchers

In addition to the four bicultural staff appointed to work with GPC implementation teams, four bicultural researchers have been employed as part of the MCRI evaluation team. The bicultural researchers speak the language of the communities participating in GPC and have extensive community knowledge and networks to support consultation and other research

activities. Specific training for the bicultural researchers has included: skills building in research activities (recruitment, informed consent, data collection, data security); processes for supporting participants experiencing distress; and opportunities to practice and receive feedback with research team members on facilitating discussion groups and conducting interviews.

Community Advisory Groups

Following principles of cultural safety,[61] Community Advisory Groups (CAGs) have been established for each refugee community. Our previous research with refugee background communities has established effective community engagement methodologies involving the employment of bicultural staff and the establishment of Community Advisory Groups.[63] Our methodology is inclusive, flexible and aims to build capacity and support ongoing community participation.

Recruitment of Community Advisors was undertaken by the bicultural researchers, with support from partner agencies. The aim of the CAGs is to involve women (and men where appropriate) from refugee backgrounds with a range of experiences (e.g. new parents, Elders, religious leaders). Community consultation was conducted by the bicultural community researchers to identity appropriate community advisors. The CAGs meet at key points relevant to the evaluation. The role of community advisors has been to: (i) provide community perspectives to ensure the evaluation methods are appropriate and meaningful; (ii) contribute to problem solving, interpretation and dissemination of the evaluation findings; (iii) facilitate wider community engagement; and (iv) provide a conduit between the MCRI research team and the community.

Setting

We planned to evaluate seven GPC programs at four sites (in Melbourne Australia) involving six different refugee background communities (See Figure 3). The sites include public maternity hospitals and maternal and child health services in Melbourne's west, north and south east suburbs, all areas of high cultural diversity and increasing refugee settlement.

[Insert Figure 3 about here]

Effectiveness (Aim 1)

Data extraction from the Birthing Outcomes System

To facilitate the interrupted time-series analysis, all partner hospitals are extracting data from the electronic Birthing Outcomes System (BOS) for all women giving birth at each site for a 12-month period prior to commencement of GPC (baseline) and at 6 monthly intervals from implementation of GPC until completion. The BOS is a database collecting routine data including demographic information, service contact, screening results and maternal and neonatal outcomes (Table 2). We will categorise women according to whether they are Australian born or born overseas in an English-speaking country or non-English speaking country. In addition, we will identify all women from the cultural backgrounds of women participating in GPC, identified by county of birth and language spoken. Women enrolled in GPC will be identified in the BOS by a code in the data set.

Table 2 Data to be extracted from hospital Birthing Outcomes System

PRIMARY OUTCOME
Number of women attending ≥ 7 antenatal clinic visits
SECONDARY OUTCOMES
Pregnancy care: First antenatal visit <14 weeks, ultrasound scan <14 weeks, number of visits with a professional interpreter involved, screening/diagnostic tests for gestational diabetes at < 30 weeks
Maternal pregnancy medical conditions and complications: hypertension, anaemia, pre-eclampsia, antepartum haemorrhage, gestational diabetes, threatened preterm labour, emergency department attendance
Pregnancy and birth events: induction of labour, method of birth, 3rd or 4th degree tear
Maternal morbidity and mortality: intrapartum or post-partum haemorrhage, wound infection, admission to intensive care, post-discharge readmission, maternal death
Infant outcomes: preterm birth (<37 weeks), low birthweight (<2500 grams), small/large for gestational age (<10th/90th centile), admission to neonatal/special care nursery for >12 hours, unplanned home birth, birth on way to hospital, stillbirth, neonatal death
Covariates
Demographics
Maternal country of birth, year of arrival in Australia, interpreter required, language(s) spoken, place of residence, maternal age at time of birth (years), relationship status
Reproductive history: parity; plurality; gravidity, pre-existing medical conditions

Medical record data abstraction

Non-routinely collected items such as referral pathways will be collected from the hospital records of women participating in GPC. Information will be abstracted on screening, referral and follow-up of medical and psychosocial issues, including: high blood pressure, gestational diabetes, suspected intra-uterine growth restriction, maternal mental health and family violence. Data collection will be undertaken by a research midwife following a protocol using a standardised form. De-identified data will be entered into the Research Electronic Data Capture (REDCap) online software.[64]

Comparative study populations, sample size and study power

Based on attendance at the GPC pilot, we anticipated that 4 sites would implement 7 GPC programs, providing an average of 74 women per group to participate in the evaluation. Allowing for an average loss of 4 women per group (5%), our projected comparison is based on a total sample size of 490 women participating over the period of provision of GPC. Comparisons will be made with i) 490 women receiving antenatal care in the 12 months

preceding introduction of GPC; and ii) 490 women contemporaneously enrolled in other models of care. These comparative populations will include women from the same cultural/language background receiving antenatal care at the same hospitals, selecting the most closely matched woman in regards to age and parity for each woman participating in GPC.

As the level of intragroup correlation in attendance is unknown but expected to be low, we will include an intra-class correlation in attendance by hospital for women not participating in GPC, ICC 0.001, and an ICC of 0.005 within groups for women participating in GPC. A level of 5% is considered significant for all comparisons. Using the hospital data as the basis for estimates, the comparisons would each provide 94% power to detect a minimum absolute difference in attendance at 7 or more antenatal visits of 10% (from the current 76% to 86%). Seven visits are considered the minimum for a healthy pregnancy without complications.[35]

Statistical analysis

i) All statistical analyses will be performed using STATA 15.[65] An interrupted time-series comparison[66 67] will be used to investigate the difference in the primary outcome - proportion of mothers attending the recommended number of antenatal visits - associated with the introduction of GPC. This comparison will be made using multilevel regression models accounting for clustering of mothers within hospitals/pregnancy groups, autocorrelation of the observed primary outcome over time and potential period effects (e.g. changes in the percentage of families of refugee background in the hospital service area). Models will thus include whether the timing of pregnancy was pre or post introduction of the GPC; and an additional item reflecting trend in antenatal attendance over the course of the evaluation to account for any contemporaneous patterns of attendance. Maternal characteristics specified *a priori* will be controlled for including: age; reproductive history and pregnancy complications (e.g. parity, prior preterm birth, prior stillbirth); gestation at GPC enrolment; country of birth; year of arrival; and other sociodemographic characteristics – this accounting for changes in the eligible population over the study period.

ii) Comparisons between women contemporaneously participating in GPC and other models of care will be conducted using congruent modelling strategies replacing the comparator of whether the timing of pregnancy was pre or post introduction of GPC with the comparator of participating in GPC versus other models of care.

Implementation (Aim 2)

We will use an approach to iterative, continuous quality improvement cycles called the Plan Do Study Act (PDSA) method [68]. This will involve collecting and analysing data and feeding it back to the Local Partnership Groups to refine GPC and continue to improve it.[69] This feedback aims to support and strengthen potential for intervention sustainability. The partnership adopted the PDSA framework as a pragmatic method for implementing and testing changes through small rapid cycles of improvement, with flexibility to adapt change according to feedback and engage GPC staff/managers in each PDSA cycle. The PDSA method aims to provide a supportive process to trial new ideas, allowing for small failures without compromising overall standards of care.

Specifically, we will utilise the PDSA method to: (i) conduct an initial assessment of the key elements of the model from the perspective of women/families and staff taking part; (ii) identify barriers and enablers for implementation, and (iii) refine GPC elements and implement strategies to minimise barriers and maximise opportunities to achieve objectives. The researchers have used this method successfully in other maternity initiatives.[70] Three data sources will be used to gather data.

1. Data will be abstracted from hospital records of women participating in GPC to inform improvement (as described above in Effectiveness).

2. Focus groups with women will be used to explore experiences of: GPC accessibility, content and relevance. A semi-structured discussion guide will be developed in consultation with the bicultural researchers. A purposive sample of 5-8 women from each GPC program who have completed the 16-week postpartum interview will be recruited (4 groups, n=20-30). Invited women will have a variety of experiences related to: time in Australia, English language fluency and group attendance. Focus groups will be conducted in women's preferred language co-facilitated by the MCRI bicultural researchers and will be audio recorded (with informed consent), transcribed verbatim, translated to English and analysed using thematic analysis.[71]

3. Midwives, MCH nurses, interpreters, bicultural workers and management involved in delivery of the new model (n=35-45 participants) will be invited to participate in focus groups/interviews. Discussions will explore process evaluation measures including staff experiences of GPC implementation, cross-sector collaboration, capacity building, skill development, multidisciplinary teamwork, organisational and systems change, and sustainability.

Women's experiences (Aim 3)

All women enrolled in GPC will be invited to complete two interviews with a bicultural researcher at approximately 28-32 weeks' gestation and again 3-4 months postpartum. The MCRI bicultural researchers will recruit women and conduct the interviews.

Design and translation of structured interview

Standardised measures have been used where possible, and pre-tested to ensure cultural acceptability. All study materials were translated into required languages by a professional agency and with the assistance of the bicultural researchers, translated back into English to ensure high quality and accurate translations.[72] Maternal interviews will be audio recorded (with participant consent) and transcribed into English by bicultural staff.

Parent mental health will be measured using the Hopkins Symptom Checklist and Harvard Trauma Questionnaire, developed for refugee populations.[73] Working with the MCRI bicultural researchers and the CAGs, we pilot tested the Edinburgh Postnatal Depression Scale,[74 75] and the Composite Abuse Scale[76] (measures experiences of physical and psychological abuse within intimate partner relationships) to determine acceptability, or not, by all communities participating in GPC. Other domains include: general demographics, health literacy, social connections and experiences of GPC.

Recruitment of prospective pregnancy cohort

The bicultural researchers will attend the GPC site corresponding to their community and explain their role in the evaluation. Eligible women are enrolled in GPC and ≥ 18 years old. Women are not eligible to take part if they are too unwell to participate, have an intellectual disability or medical condition precluding them from giving informed consent (e.g. psychotic illness).

Participant details will be stored on a REDCap database which produces a report based on women's estimated due date to notify the research team when a woman is due to be contacted to schedule the postnatal interview.

Data Analysis

After the completion of each interview, the bicultural researchers will transcribe the audio-recording to provide a comprehensive interview transcript in English. All data collected in the interview will be manually entered by research team staff into REDCap. Quantitative data will be exported to Stata 15 for scoring and analysis. Qualitative data will be exported to and managed in NVivo[77] for thematic analysis. Four steps for thematic data analysis will be followed: immersion, coding, categorising and developing themes.[71]

Cost effectiveness (Aim 4)

Data on resources used to deliver the intervention will be collected, including time commitments of paid staff and participating women. These will be valued ($AUD) at standard unit costs (e.g. salary scales, interpreter costs, travel) to calculate intervention costs specific to each site. Intervention costs will be combined with potential cost-offsets and outcomes data (Table 2) in an economic evaluation that compares additional costs associated with GPC to changes in health outcomes (cost-consequences analysis).[78] Potential cost-offsets from improved maternal and child health outcomes will be estimated by partner hospitals based on routine perinatal data and hospital financial systems data on in-hospital care costs. As part of the qualitative data collection with GPC staff and stakeholders, information will be collected to inform the economic evaluation.

Progress to date

Implementation of Group Pregnancy Care

Planning for expansion of GPC to three new sites commenced in 2017. However, due to staffing and resource constraints at two of these sites, only the initial GPC pilot and one new GPC program remain part of the evaluation (involving the Karen and Assyrian Chaldean communities). Additional funding was secured in late 2019 to conduct consultation with two

additional communities (Sudanese/South Sudanese and Iraqi/Syrian Muslim) with a view to establishing two new GPC programs to join the overall evaluation.

Implications of COVID-19 pandemic

In response to the global COVID-19 pandemic, Australia initiated strict internal lockdown policies to reduce the risk of community transmission in late March 2020. As a result, the two established GPC programs paused provision of group sessions, and planning for the two new GPC programs was put on hold. The two established programs transitioned to virtual platforms for clinical and group-based information sessions from March 2020. Group sessions using an online platform were initiated in response to the ongoing need for women and families to connect to services and peers for information and support.

The evaluation has also continued, adapting to telephone/video interviews with women and staff/stakeholders. The abrupt disruption to GPC services flowing from the COVID-19 pandemic mean the numbers of women participating in GPC and available for the interviews will be lower than planned.

Given these circumstances, the intended sample size will not be achieved within the funded study period. At this point, interim analyses will be conducted and preliminary findings will be shared with the study partners and funders. Interim analyses will provide substantial outputs in regard to process and implementation learnings (Aim 2) and participant experiences (Aim 3) as well as preliminary exploration of responses in the primary outcome (proportion of women attending ≥7 antenatal clinic visits – Aim 1). Extension of the study with the two additional communities at the new sites for which funding has been secured plus continuation of GPC at the existing sites where feasible, will provide the opportunity to extend evaluation to achieve the intended sample size for the full comparisons (Aim 1) and economic evaluation (Aim 4).

Ethics and dissemination

Ethical considerations

Human Research Ethics Committee (HREC) approvals have been provided by all six relevant authorities through the Australian National Mutual Acceptance scheme, where permitted. Ethical amendments were sought for each stage of the study following community and partner organisation consultation to finalise each stage. This staged approach enables piloting and reflection on the cultural safety[61] of the research activities and flexibility to refine research processes to ensure appropriateness and meaningfulness to community members, bicultural researchers and partners. At the time of submitting this protocol, HREC approval had been granted for all stages of the study with a modification for data abstraction pending at one hospital.

In Australia, there are specific ethical guidelines for conducting research with Aboriginal and Torres Strait Islander Communities.[79] However, an equivalent national approach to mandatory ethical research guidelines for the engagement of refugee background communities does not exist. We are mindful of the ethical issues to consider when conducting research with people of refugee background.[80 81] As the concepts of research and ethics may be unfamiliar to some participants, we acknowledge the possibility that participants may feel anxious about their involvement. Concerns may be provoked when issues such privacy, trust and confidentiality, audio recording of interviews etc. are not clear or comfortable for the

participant. The bicultural researchers will clarify the voluntary nature of research participation and encourage participants to ask questions to alleviate any concerns, as conducted in our previous research.[63] A study distress protocol developed in partnership with Foundation House and used in our previous research studies will guide the researchers in situations where participants become distressed, require support or disclose issues related to mental health, family violence or participant/child safety.

HREC approvals: The Royal Children's Hospital 37025, HREC/17/RCHM/66, MCRI SSA/17/RCHM/97, Monash Health 17-424X, HREC/16/MONH/65, SSA/17/MonH/362, Northern Health HREC/17/RCHM/66, SSA/17/NH/104, Western Health HREC/17/RCHM/66, SSA/AU/5/C@E0314, Mercy Health 2017-017, Victorian Department of Health and Human Services HHSD/19/174035.

Dissemination

We have developed a comprehensive knowledge translation and dissemination plan in line with our values of reciprocity and collaboration. Including: sharing study findings with communities in accessible ways (via bicultural researchers at Community Advisory Groups), presentations at community forums, partnership meetings, conferences, policy and practice briefs and publication of journal articles. All outputs will be available on the study website.

Authors' contributions

ER is the study Principal Investigator and drafted this protocol based on the project proposal and other planning documents involving many people as outlined in the author contribution and acknowledgements. JY, FM, LG, JS, IK, RS, PM, CE, CH, JB and SB are study investigators and NN is a key stakeholder from a partner agency who have contributed to the study conceptualisation, development of the evaluation proposal and project planning. FM conducted sample size estimate calculations for the interrupted time series design. AK, EM, LB are employed on the project and have contributed to development of planning documents, conceptual framework, ethics submissions which involve many of the components outlined in this protocol, and drafting the manuscript. All authors contributed to drafting and finalising the manuscript.

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Competing interests

None declared.

Data availability statement

Data sharing not applicable as no data sets generated and/or analysed for this study

Participant consent for publication

Not required.

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Figure legends

Figure 1 Conceptual model of Group Pregnancy Care to improve outcomes

Figure 2 Evaluation overview

Figure 3 Planned Sites for Group Pregnancy Care

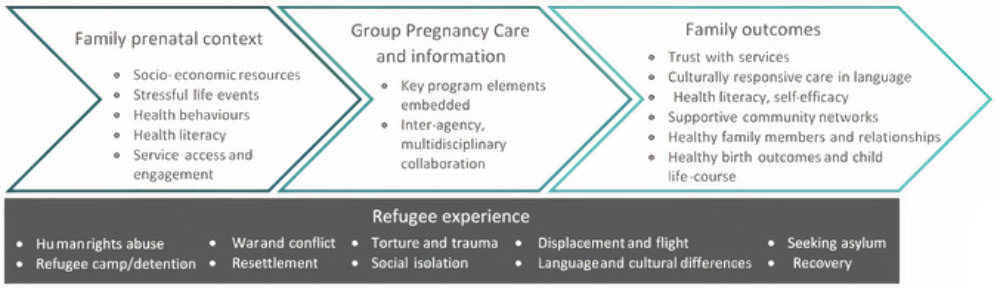

Figure 1 Conceptual model of Group Pregnancy Care to improve outcomes

Effectiveness *Aim 1*	Method: Interrupted time-series using routinely collected hospital data supplemented by data on referral pathways obtained from hospital medical records
Implementation *Aim 2*	Method: Plan Do Study Act cycles, using 1) data from medical records 2) structured interviews with women 3) focus group with women, staff, and stakeholders
Women's Experiences *Aim 3*	Method: Community consultation and structured interviews with women
Cost Effectiveness *Aim 4*	Method: Economic costings using data collected via staff/stakeholder interviews/focus groups

Figure 2. Evaluation overview

Figure 3. Planned Group Pregnancy Care Sites and Programs