

2-18-2022

Developing a Sexual Health Consent Strategy for Refugees: A Qualitative Approach

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Recommended APA Citation

Tuteja, A., Riggs, E., Sancı, L., Mascarenhas, L., Power, A., VanVliet, D., Sangster, K., McGuinness, K., & Temple-Smith, M. (2022). Developing a Sexual Health Consent Strategy for Refugees: A Qualitative Approach. *The Qualitative Report*, 27(2), 509-538. <https://doi.org/10.46743/2160-3715/2022.5158>

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Developing a Sexual Health Consent Strategy for Refugees: A Qualitative Approach

Abstract

We report the development of a strategy for obtaining a truly voluntary and informed consent for sexual and reproductive health (SRH) research with Burma-born refugees settled in Australia. Using a qualitative descriptive research design, we interviewed 29 providers of refugee services (PRS) including health care professionals (doctors, nurses, midwives), bilingual supporting staff (interpreters, social workers, settlement workers, community liaison officers) and administrative staff (practice managers, reception staff) who provide primary care services to refugees. Interviews were audio recorded, transcribed, and subjected to thematic analysis. Four themes emerged: (a) unique values of Burma-born people, (b) unfamiliarity with Western concepts of research, (c) usefulness of individual consent discussions with potential participants, and (d) need for verification of voluntary participation prior to research interview. Results were used to develop a three-stage process of research consent. The first stage comprises of community information sessions to introduce concepts of research including explanations of voluntary participation and informed consent. Secondly, consent discussions for interested participants are undertaken with their preferred interpreter. Finally, voluntary participation is confirmed just prior to the interview. This three-stage process of research consent will serve as a useful tool for PRS to support cross cultural SRH research interactions involving interpreters and participants.

Keywords

consent, sexual health research, reproductive health research, refugees, migrants, Burma, Myanmar, qualitative descriptive research

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Acknowledgements

The authors profoundly thank and acknowledge the significant contribution of Melbourne Social Equity Institute, in funding the PhD student in her research initiatives. A special thanks is due to Dr Phyllis Lau and Dr Vasudha Iyengar for supporting the PhD student in her research journey. Mr. Krishan Kumar Tuteja's vision of inclusive health is the drive behind developing a robust consent strategy before interviewing the refugee participants.

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Developing a Sexual Health Consent Strategy for Refugees: A Qualitative Approach

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We report the development of a strategy for obtaining a truly voluntary and informed consent for sexual and reproductive health (SRH) research with Burma-born refugees settled in Australia. Using a qualitative descriptive research design, we interviewed 29 providers of refugee services (PRS) including health care professionals (doctors, nurses, midwives), bilingual supporting staff (interpreters, social workers, settlement workers, community liaison officers) and administrative staff (practice managers, reception staff) who provide primary care services to refugees. Interviews were audio recorded, transcribed, and subjected to thematic analysis. Four themes emerged: (a) unique values of Burma-born people, (b) unfamiliarity with Western concepts of research, (c) usefulness of individual consent discussions with potential participants, and (d) need for verification of voluntary participation prior to research interview. Results were used to develop a three-stage process of research consent. The first stage comprises of community information sessions to introduce concepts of research including explanations of voluntary participation and informed consent. Secondly, consent discussions for interested participants are undertaken with their preferred interpreter. Finally, voluntary participation is confirmed just prior to the interview. This three-stage process of research consent will serve as a useful tool for PRS to support cross cultural SRH research interactions involving interpreters and participants.

Keywords: consent, sexual health research, reproductive health research, refugees, migrants, Burma, Myanmar, qualitative descriptive research

Women from migrant and refugee backgrounds may experience poor sexual and reproductive health (SRH) outcomes post settlement in western countries. This can be explained by a multitude of factors including their underutilization of sexual health services, lack of knowledge, and unique cultural values associated with sexuality (Kingsbury & Chatfield, 2019; Multicultural Centre for Women's Health, 2016; Ussher et al., 2017). Research is needed to develop a better understanding of the socio-cultural, behavioral, and environmental determinants of refugee SRH needs post settlement in Western countries (Boyle et al., 2018; Burke, 2011; Kingsbury & Chatfield, 2019; Mengesha et al., 2018). Social and cultural norms sometimes make open discussion about sex and sexuality difficult (Dehlendorf & Rinehart, 2010; Howard et al.,

2008). Research with refugee communities is often labelled as too hard because of the multiple complexities and uncertainties around issues such as obtaining informed consent, waiver of written consents for the illiterate, confidentiality, management of power imbalances between participants and researchers, and legal standpoints of governments (Hugman, Pittaway, et al., 2011).

Negotiating consent for SRH research with participants who are in unequal or dependent relationships with the researchers is listed as highly sensitive research in most ethics committee approval applications. Institutional review boards and ethics committees request information on how the research team plans to ensure voluntary participation (Hugman, Bartolomei, et al., 2011; National Health and Medical Research Council, 2007; Seagle et al., 2020). However, there are few guidelines to support refugee rights about participation in sensitive research (Perry, 2011). In addition, the literature offers no advice regarding levels of agency among different refugee communities (Afolabi et al., 2014; Nakkash et al., 2009), frameworks to ensure voluntary participation (Childress & Thomas, 2018), or verification of genuine understanding of the research objectives (Hugman, Bartolomei, et al., 2011). Few researchers provide details of how they negotiated obtaining informed consent from participants, or how specific refugee communities responded to the process of obtaining informed consent (Block et al., 2013; Flicker & Guta, 2008; Hirani et al., 2019; Limbu, 2009; Mackenzie et al., 2007; Maiter et al., 2008; Santelli et al., 2017; Zhang et al., 2019).

There is a common assumption that informed consent is achieved when research participants sign a form that serves as documentary evidence of consent (Barsky, 2010; Humpage et al., 2019; Pranati, 2010). However, refugees may have second thoughts about signing, a concern that raises the issues of “vulnerability” of this group of study participants (Block et al., 2013; Obijiofor et al., 2018). This vulnerability arises from the fact that refugees have survived traumatic migration journeys and now need to negotiate unfamiliar Western systems without, often, full proficiency in the host country’s language (Gifford, 2013). It is of utmost importance to realize that vulnerability does not mean lacking autonomy. It is not that the experience of seeking refuge and associated trauma necessarily takes away people’s capacity to understand and to exercise their own good judgement. Instead, the context and hierarchy of individuals involved in the process of consent may have an impact on understanding choices and making decisions (Mackenzie et al., 2007).

Therefore, autonomy is a capacity that is socially acquired and can be enhanced or undermined in the way we engage with the refugee communities (Hugman, Pittaway, et al., 2011). For instance, refugee and asylum seekers may perceive research consent forms as a part of government documentation or legal formalities they need to complete in order to live in the new country of settlement. Their willingness to comply with expectations in their new country can leave researchers doubting whether true informed consent has been given (Childress & Thomas, 2018; Skinner, 2014). When research objectives are clearly explained or translated in culturally appropriate ways, refugees may be empowered with a sense of agency to decide for themselves in the new environment (Block et al., 2013). In contrast, when researchers are unsuccessful in obtaining a truly voluntary informed consent, they reinforce themselves as a dominant party. This may leave the refugee participants feeling threatened and result in coercive participation (Day, 2014; Pittaway & Bartolomei, 2003). On top of that, the research process may precipitate distress by reawakening traumatic memories and experiences (Hirani et al., 2019).

Very little is known about how to effectively engage in research with refugee families from Burma, particularly SRH research (Krumtum, 2014; LaMancuso et al., 2016; McCleary, 2017; McGinnis, 2012). Anthropology studies reveal that the people from Burma have lived under military dominance for decades, followed by prolonged stays in refugee camps (Fink, 2009). Consequently, refugees have minimal exposure to Western concepts of decision-making, voluntary participation, informed consent, and research before migrating to high-income and English-speaking countries (Hugman, Pittaway, et al., 2011).

Respecting and acknowledging community values is essential in cross-cultural research, especially when working on sensitive subjects such as SRH (Shirmohammadi et al., 2018; Afolabi et al., 2014; Nakkash et al., 2009; Zhang et al., 2019). Our study is a part of a doctoral thesis aimed to understand the patient and provider perspectives about the SRH needs of refugees from Burma. The thesis research was conceived and guided by an ongoing partnership between the providers of refugee services (PRS) based at a community health center located in the settlement area of refugees from Burma and the Department of General Practice at the University of Melbourne, which is involved in teaching next generation doctors and conducting research in the primary care setting. The partnership supplied doctors, nurses, and primary care researchers with expertise in refugee health and SRH (Figure 1). This research aimed to develop a deeper understanding of the cultural traditions and beliefs surrounding SRH to inform interventions appropriate to improve the health of this vulnerable community.

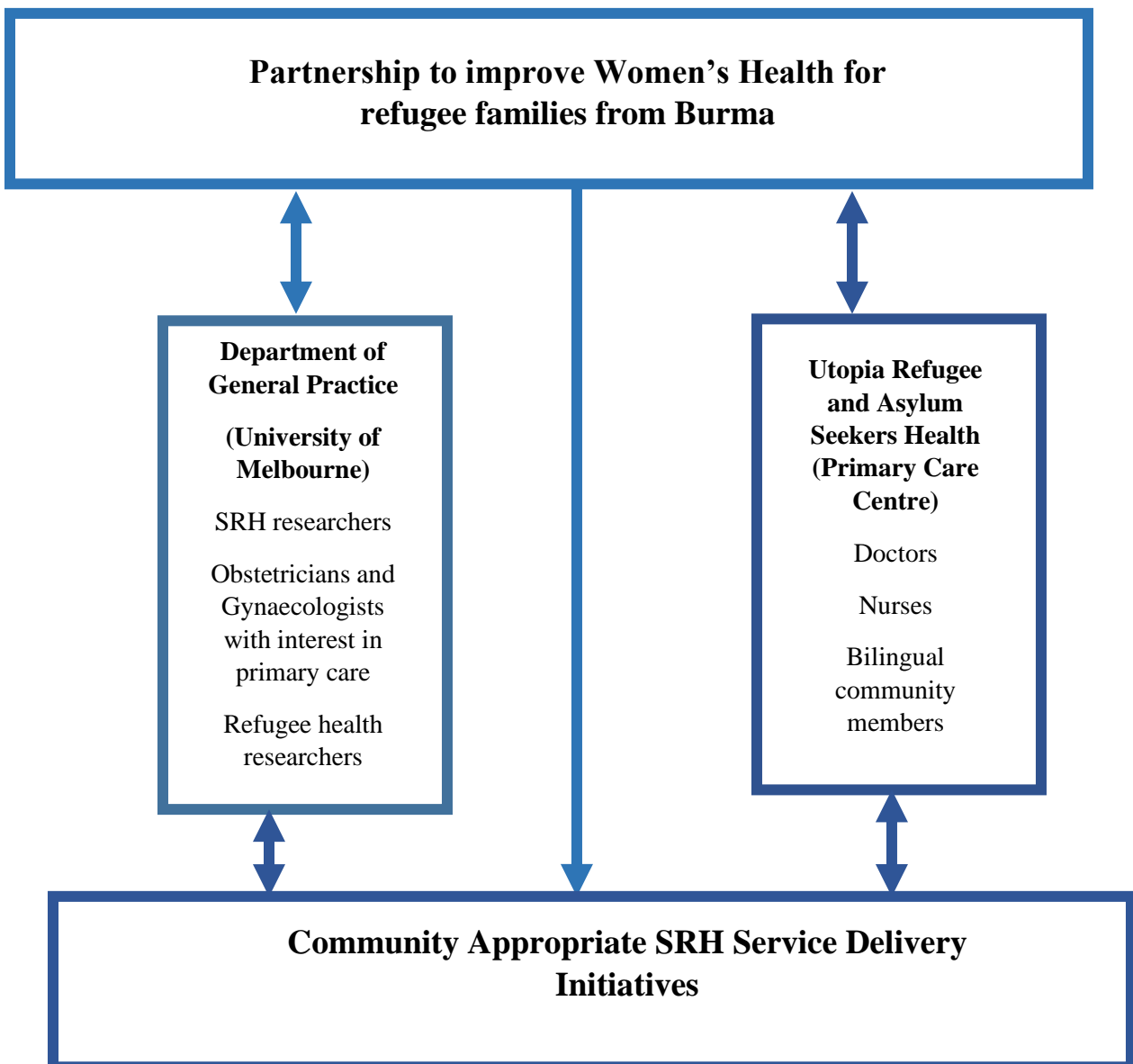


Figure 1

Working partnership for improving SRH services for refugees from Burma

Obtaining truly voluntary and informed consent for SRH research was a challenging proposition; the research participants had recently arrived in Australia, spoke little or no English, had had no contact with Western medicine, and might have experienced sexual violence. It was evident that we would need to consider a culturally appropriate strategy to obtain consent before determining the SRH needs of this community. In this paper, we focus on the complexities involved in obtaining consent for SRH research with refugees from Burma. Considerations, examples, and potential solutions are presented in the hope of advancing consent-related ethics, policies, and practice in SRH initiatives for refugees.

Methods

Settings

The City of Wyndham is a rapidly growing area in Melbourne's outer south-west (12 to 45 kilometers from the Melbourne City Centre) (*Wyndham Snapshot (Quarter 2)*, 2020). Wyndham residents are diverse, with 66.2 % of residents having at least one parent born overseas (Australian Bureau of Statistics, 2016). In addition, 54% of refugees settling in Wyndham are from Burma or Thai-Burma border refugee camps (*Communities of Interest: Humanitarian arrivals*, 2016). The SRH services need to be responsive to meet the needs of this growing population of refugees from Burma.

Ethics

Ethics approvals and permissions for the study protocol, informed consent forms, information sheets, and community organization support letters were approved by the University of Melbourne Human Research Ethics Committee.

Study Design

We utilized a qualitative descriptive research design (Sandelowski, 2000, 2010) to study the SRH needs of refugees from Burma. This method was particularly suited to this research as it is neither theory-driven nor based on high interpretation; rather, it aims to provide a straight description of events or topics of investigation (Bradshaw et al., 2017; Kim et al., 2017). This pragmatic approach offered us flexibility to conduct broad-scoped interviews with diverse PRS for maximal variation and collect rich descriptions of events in their natural clinical settings. These PRS were the best resource from which to seek information about the needs of the community (Ulin, 2002). In addition, qualitative description enabled us to stay closer to the data during analysis and provide a description of events in participants' own languages (Neergaard et al., 2009). Using this low-inference, rich description of events (Colorafi & Evans, 2016), we were able to achieve consensus easily and report our findings in a straightforward application-based, ready-to-use style. The study was set up in two phases; the first phase involved interviewing the PRS to understand their perspectives on the SRH needs of the refugees from Burma. The results of this first phase will inform the development of a suitable methodology for the second phase, which will involve community recruitment and participation. Here, we present relevant findings of phase one, which was conducted between 2015 and 2016.

This is an ongoing study, and in 2020-2021, we used the study results to recruit mono-lingual Burma-born refugee participants for SRH research initiatives (Tuteja et al., 2020). The interviews are ongoing, and preliminary findings confirm that the themes identified are very relevant for refugee communities. In recent discussions with community members, they have reflected that little has changed in their circumstances in the last 5 years. In fact, the problems of

accessing SRH services have been exacerbated by the current pandemic situation. Further, community members are worried about the worsening situation in Burma and emphasized that the return of military junta will result in a global increase in refugees (Cuddy, 2021, April 1). Besides, many pointed out that because of the massive exodus of Rohingyas to Burma Bangladesh border camps (UNHCR: The UN Refugee Agency, 2019), a large number of refugees are awaiting re-settlement.

Participant Recruitment

We recruited the participants through the community-based organizations based in the city of Wyndham. Invitation emails were sent to staff members of community centres explaining the premise of the study, the interview process, and the confidentiality clause with our contact information. Those interested were required to contact the first author and were subsequently sent the study plain language statement and the informed consent form. Interested participants returned the signed, scanned consent forms to the research team through email. Further, participants were recruited via snowballing and personal contacts of the research team.

Interviews

We conducted semi-structured interviews using a guided conversation style (Chenail, 1997; Rabionet, 2011) to gather information relevant to the research question. The first author, who is a PhD student and an obstetrician and gynaecologist, conducted the interviews at the participants' places of work. The interviews lasted 60-90 minutes and were audiotaped and conducted over 1-2 sessions. Phase one of the study covered broader questions about the interaction of PRS with refugees from Burma, including specific problems with communication, working with interpreters, experience regarding acceptance and utilization of contraception, and cervical smear tests. True to the tenets of qualitative interviewing, open questions prompted PRS to discuss unique challenges of informed consent in SRH consultations with refugees from Burma.

Although the intention of this research was to interview participants objectively to explore provider perspectives of SRH needs of refugees from Burma, researcher bias should not be overlooked. As an obstetrician and gynecologist with a keen interest in refugee health issues, the interviewer's (first author) innate perspective is a combination of "emic" and "etic" perspectives. Her medical training contributed to the emic provider perspectives and migration to Australia was also emic, but the cultural traditions of Burma and interaction with a health care system in an unfamiliar language was etic to her. Although these personal characteristics ideally do not influence this research significantly, it is important to acknowledge the possibility of researcher bias and to recognize the lens through which this research is viewed.

In the present analysis we focus on responses to two questions: (a) tell me about your experience of obtaining consent in SRH consultations with refugee women from Burma, and (b) please suggest a strategy which would be ideal to negotiate meaningful informed consent for SRH research with refugee women from Burma. These questions were followed by clarifications to aid in understanding the nuances of the responses. Field notes included nonverbal cues highlighted during conversation, including facial expressions, body language, tone of voice, the underlying emotions noted at the conversation, researcher reflections of the interview process, and other contextual factors (Mulhall, 2003; Muswazi & Nhamo, 2013; Phillippi & Lauderdale, 2018). The process of data collection and analysis is illustrated in Figure 2.

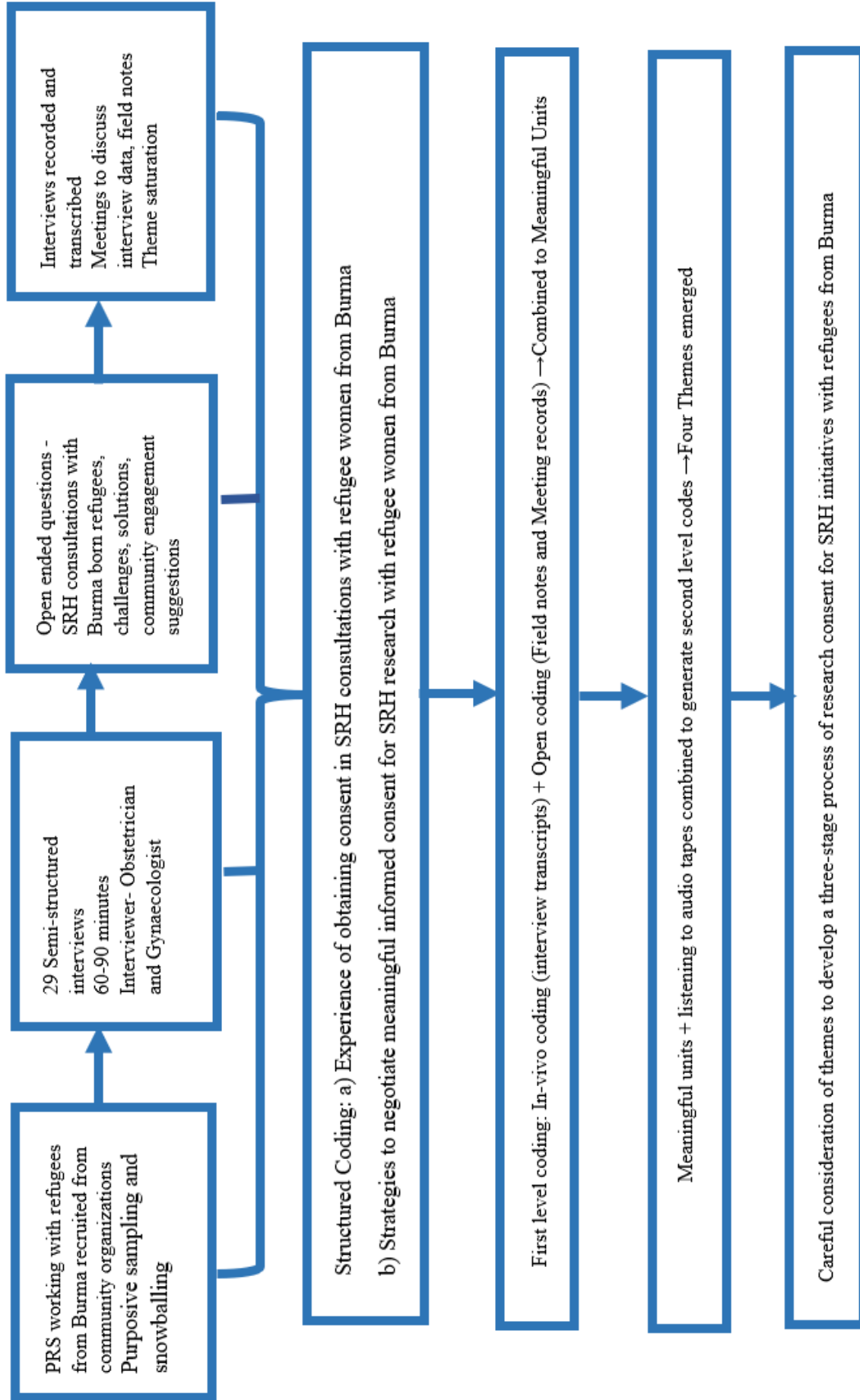


Figure 2: Steps of data collection and analysis

Data Analysis

We drew on interview transcripts, field notes, and meeting records of the research team to analyse the ethical strategies for obtaining consent for interviewing Burma-born refugee women (Chatfield, 2020). Firstly, the PhD student (first author), her principal supervisor (last author) and co-supervisors (second, third and fourth authors) reviewed the listed research material to identify potential ethical tensions in negotiating consent in the local context of the study. In this process, the core team of five (first, second, third, fourth and last author) followed a structured coding and collected answers of the two specific consent-related questions from the interview transcripts. After 29 interviews were complete, we reviewed the interview transcripts and decided that no further themes were arising from the data, and saturation had been met. In the second step, we drew empirical data on ethical issues and practical strategies about how to meet these ethical challenges from the documents. We used a combination of in-vivo and open coding in this step. We summarized participant quotations with in-vivo coding, and thus relied on participants themselves to give meaning to the data (first level codes). Similarly, we employed open coding to field notes and meeting records to create additional first level codes. Next, we sorted through the first level codes to identify similar phrases and patterns to determine meaningful units of analysis (Chenail, 2012). We spent a considerable amount of time with these units of analysis to integrate manifest and latent content adequately. Even though our focus was on description, a great degree of interpretation occurred naturally in describing meaningful units. In the third step, we read these meaningful units and listened to the audio tapes again and combined them to generate second level codes. We focussed on commonalities and differences among these coded sections and finalized four themes. We achieved consensus on the final four themes and resolved minor discrepancies by discussion. During the whole process, we stayed close to what the data said and how it was said, creating an inducting coding within the world of data. In the final step, all the authors read the four themes to check if they worked in relation to the coded extracts and the entire data set. This final step of reviewing the data and refining the specifics of each theme to generate an overall story from the themes increased the rigor of the analysis process.

Once the coding process was completed, we integrated these themes to create a three-stage process of negotiating informed consent for research with Burma-born refugees. All the authors reviewed the practical applicability of this three-stage consent process in light of existing knowledge and agreed on its utility for refugees from Burma. To ensure that the study findings are valid and transferable to clinical and research settings, we took multiple steps. We have explicitly documented the evolution of our research and our records create an audit trail for future collaborators. We maintained consistency in data collection by using the same interviewer and asking the same questions in the same order. We preserved authenticity by purposefully selecting expert participants and allowing them to freely articulate their felt needs. In addition, we faithfully reported their lived experiences of SRH consultations. To preserve criticality, we derived meaningful units of analysis rather than conducting a line-by-line coding. During this process we reflected on our dual roles of clinicians and researchers and acknowledged our biases. Finally, we have developed a trusting relationship with the community. The detailed steps of thematic analysis are enclosed in Appendix 1.

Results

Twenty-nine providers of refugee services participated in one-to-one interviews, including six general practitioners (GP), nine nurses, three practice managers, six social practitioners (social workers, community access workers, bilingual support persons, settlement workers) and five interpreters (Table 1). The sample included men (n=5) and women (n=24) from large and small organizations, younger and older practitioners, and with different levels of experience. Some were

proficient in native languages of Burma and others were English-speaking practitioners, and to ensure maximal variation, they had diverse roles in refugee health services.

Table 1:
Participant Demographics

	GPs N=6	Nurses N=9	Practice managers N=3	Social practitioners N=6	Interpreters N=5
Gender	3 female 3 male	All female	All female	All female	3 female 2 male
Mean Age (Range)	48 years (35-64)	55 years (43-66)	51 years (38-66)	37 years (30-45)	34 (28-44)
Ethnic background (self- defined)	3 Australian 1 Indian 1 Burmese 1 Anglosaxon	4 Australian 1 Anglosaxon 1 Indian 1 Dutch 1 Italian 1-British	1 Australian 2 Anglosaxon	3 Australian 2 Karen 1-Chin/ Burmese	3 Karen 1 Chin/ Burmese 1 Karen Burmese
Language Proficiency (First Language) ¹	5 English 1 Burmese	9 English	3 English	4 English 3 Burmese 2 Karen 1 Thai 1 Chin	2 English 2 Karen 1 Chin 1 Burmese
Language Proficiency (Second Language) ¹	1 Burmese 1 Hindi	Nil	1 French	2 English 2 Karen 1 Korean	2 English 1 Karen 2 Burmese
Experience in health care Mean (Range)	26 years (12-40)	31 years (20-48)	31 years (21-33)	5 years (0-10) ²	7 years (5-8) ³
Experience in refugee health Mean (Range)	10 years (10-18)	9 years (1-15)	7 years (3-10)	4 years (0-10) ²	7 years (5-8) ³
Proportion of Burmese refugees seen in practice Mean % (Range %)	75 (50-90)	55 (5-90)	83 (80-90)	80 (60-80) ⁴	100 ⁵
Designated roles in services for	Primary care physicians	Refugee health nurses	Practice managers	Bilingual workers	Interpreters

refugee community		Mother and Child Health nurses Women's health nurses Care plan nurses	Client service Officers	Social workers Community access workers Settlement practitioners	
<p>¹ Some participants have proficiency in more than one language and have identified with more than one first and second language(s).</p> <p>² One social practitioner worked in a non-governmental refugee organization and helped mothers with young children in education and day to day work, and occasionally worked in health promotion groups. Therefore, she felt that she had no direct experience in health care.</p> <p>³ All the interpreters had always worked in refugee health organizations and had no experience of other settings.</p> <p>⁴ Social practitioners worked with all refugee groups who presented to community health centres and children's play groups, but as the area had predominantly people from Burma, the majority of them worked with Burma born families.</p> <p>⁵ Interpreters participating in the study were selected by purposive sampling and all of them worked with people from Burma.</p>					

Following data analysis, four themes were identified: a) unique cultural values of Burma borne people, b) unfamiliarity with Western concepts of research, c) usefulness of individual consent discussions with potential participants, and d) need for verification of voluntary participation prior to research interview. Quotes have been selected to capture the experiences and perceptions shared by many of the participants regarding ethical aspects of obtaining truly informed voluntary consent.

Unique Values of Burma-Born People

The participants used words such as "gentle" [GP 1], "considerate" [Nurse 3], "modest" [GP 3], "polite" [Nurse 4], "good natured" [GP 5], and "patient" [Nurse 9] to describe refugees from Burma. All nurses and GPs shared their common initial perceptions of working with refugees from Burma where they felt that medical appointments with this community were very easy because the patients were highly agreeable and consented to everything. "For the first six months of joining the refugee health practice, I thought to myself, 'this is easy, they agree to everything'. I hardly ever had any questions, no arguments and simply no fuss people" [GP 1].

It was also emphasized that a response of "yes" from Burma-born people may not always mean "yes." While responses are often made in agreement, they may be saying what they think you want to hear, rather than what they mean, to avoid friction.

Our people will keep nodding, but they may not be getting a word in the appointment. It is very difficult for our people to speak up and say that they have not followed anything. Say, if a lady comes for a 6 week [postnatal] check, and this is usually a long appointment, but the lady will hardly speak and will let the doctor talk and talk. She will keep nodding out of politeness. But the lady will not be able to decide her preferred birth control method as she may not have understood a large

portion of the doctor's advice. She will, however, refrain from asking any questions. [Social Practitioner 1]

People will keep saying yes, yes, yes, yes...but only to be polite. Patients will not know what to do next and will want us, the interpreters, to explain everything as soon as the appointment is over [Interpreter 3].

The bilingual practitioners who are also community insiders also emphasized that indirect communication is inherent to Burma-born communities. People from Burma generally take a roundabout way to making their point known to not offend the other person in the conversation.

During an initial refugee health assessment, a patient appeared to be thinking about something else. This couple had just arrived in the country, so I was not sure what was happening. I was worried and took the liberty of asking her on my own without letting the nurse know if she was okay. She informed me that she is pregnant after her husband left the room. She was raped in the camp about a month ago and she has not told it to her husband about the rape. She is not sure what to do and does not want to make anyone upset...least of all her husband. Imagine: she had been suffering so much but is worried about upsetting the husband, the nurse, or me [Interpreter 2].

In addition, people from Burma show deep respect for their elders and will not contradict, criticize, or disagree with them. Any disagreement with elders is considered socially inappropriate and a person can lose their reputation.

The rule is to agree to everything said by your parents, teachers, government and doctors. This is a cultural value that runs across all ethnic groups. So, if a lady has to tell the doctor that she does not want a particular birth control method, it will be almost impossible for her to say it [Interpreter 4].

Additional views were that "people from Burma have experienced the military junta where speaking up against the wrongs was difficult" [Social practitioner 3], "camps also create a loss of control over one's own life and that stays with the person for a long time" [Interpreter 1], and "spending time as undocumented migrants" [Nurse 2] or "years of waiting for visas before migration" [Nurse 5] makes the community extremely apprehensive of speaking up against any government formalities or advice.

Unfamiliarity with Western Concepts of Research

All PRS unanimously noticed that refugees from Burma were unfamiliar with the Western concepts of research. They cited examples to illustrate different clinical situations where concepts of voluntary participation, informed consent, shared decision-making, and evidence-based research took a long time to explain to the refugee families. Of concern was the fact that even after putting in extra efforts, PRS were still not sure if these concepts had been clarified sufficiently.

So, what will you like to do next? This simple question made one of my newly arrived refugee patients cry out aloud, like really loud. I got worried if I had said something wrong. The interpreter clarified that "no one has ever asked him or his wife what they would like to do". People just kept telling them what to do all the time [GP 5].

I hear this all the time, “Doctor can you tell me what is the best for me? I am not sure how to decide. In the camp they just told us what to do”. This is so common in the post-natal check-ups, that I worry how will they respond to your research request about finding out their sexual and reproductive health needs [GP 5].

PRS contended that most refugees from Burma had makeshift or no schooling and will need some time to build their capacity for comprehending complex medical research concepts. A bilingual GP said that “People who have not been to schools, and have focussed on staying alive, finding food, do not know much about research. So, if you want my advice, I think spend some time in health education and building community capacity before asking them to enrol in your research” [GP5].

Leaving the task of participant recruitment solely to the community leaders was not advised. Instead, PRS specifically mentioned that we should aim to use multiple channels of participant recruitment for a fair representation of the community views.

Community advocates or leaders have their own time constraints, agendas and particular sub-groups who they associate with in their own community. If they tell these people to take part in your research, they will say yes. They cannot afford to offend these powerful figures. So, spend some time in explaining voluntary participation and informed consent, even if they have already agreed to take part in the study [Nurse 6].

PRS suggested that researchers may begin recruitment with community leaders but should expand community engagement by attending “festivals, cultural events and community picnics” [Interpreter 4], “health care practices frequented by the community” [Nurse 7], or “play groups” [Social Practitioner 1] for recruitment independent from community leaders. Often, interviewees will suggest “friends and family members who they believe will have additional information to contribute to the research topics” [Social Practitioner 2].

Another aspect highlighted was low levels of health literacy of the community. Many people do not read and write in their own native language.

My people are not allowed to learn Chin and did not learn Burmese because they did not want to. There are so many people like that in our village in the Chin state. These are simple people who have never heard of anything about research. Spend some time with them so that they can trust you and then start explaining these facts such as risks and benefits of research, consent, they have a choice to say no and to clear their doubts before they agree. So, don't expect them to know all this straightaway [Social Practitioner 2].

Usefulness of Individual Consent Discussions with Potential Participants

Participants reported in refugee settings, informed consent is better thought of as a process rather than an event, where participants may have their rights explained not only at the initiation of research, but as many times as deemed appropriate by the researcher to ensure genuine understanding of consent.

Please don't think of consent as a mere event of signing a paper. To me, this paper is a protection for the researchers more than the refugee. Some people may be able to grasp research issues quickly, and others may have no previous experience about

research and do not understand easily. So, instead of this consent signing, plan it more like a discussion [Nurse 4].

All the social practitioners and interpreters agreed that the people from refugee backgrounds would benefit from consent discussions where the researcher not only talks about the research aims and objectives, but also spends extra time in pointing out participant rights.

Our people from Chin state will know nothing about these research activities. So, if you are thinking of this sexual research, it will be better to spend one full session only to explain the whole thing. You will find that people will agree to you and be better aware of what is going to happen next [Interpreter 1].

Karen ladies will first agree and then if you ask private questions, they will be shocked and may feel very embarrassed inside. I will suggest that you try and explain to them what is going to happen next. What kind of questions will you ask during the research interview? Take your time and sit and go over everything two, three times slowly so that they not only hear you but also absorb it [Social Practitioner 4].

Need for Verification of Voluntary Participation Prior to Research Interview

All PRS were of the view that for ensuring truly voluntary and well-informed participation, it will be essential to objectively verify participants' understanding of the research process.

When the patients present for cervical smear tests, I try and spend extra time to explain the whole process as much as I can. I have a model of reproductive organs and I try to demonstrate what is going to happen using the model. I will ask the lady after I am reasonably sure that she has understood the process a few questions. Simply to check if I should go ahead. "What will happen if you decide not to do the Pap test?" and I will not proceed till I am reassured that they understand their rights well. [Nurse 4]

Most PRS were concerned that many refugees from Burma may agree to participate in the research study and think of it as a part of government activities of immigrating to Australia. The PRSs felt that simply explaining research objectives, benefits, risks etc. will not be sufficient.

I would suggest that on the day you are scheduled for the interview, spend some time in making the participants comfortable. Then, ask them a few questions about your research to find out what they have grasped from your prior discussions. At least, you can spend some time to clarify their misunderstandings before you proceed further. [GP 1].

Back questioning will be my suggestion. I do that in my clinics, especially when I know I am explaining difficult topics. It's not to put the patient on the spot but to find out if they have missed on crucial information. I may simply ask them to repeat my explanation. You could perhaps have some "yes/no" kind of questions in your consent form itself [Nurse 7].

Three-Stage Process of Research Consent

Following on from the identification of these four themes, we developed a three-stage process of research consent. To assist in this process, we applied the four ethical principles developed by Gombert et al. (2016) to improve communication while working with homeless young people in Scotland. These include *communication* (determining the appropriate language that suits each particular group of participants), *trust between researchers and participants*, *trust among participants*, and *power relations between researchers and participants* (Gombert et al., 2016). This three-stage process of research consent comprises of: (a) community information sessions to introduce concepts of research, voluntary participation, and informed consent, (b) subsequent consent discussions for interested participants without community leaders but with the interpreter of the potential participant's choice, and (c) verification of consent and research understanding just prior to the interview.

Community Information Sessions

We integrated the first three themes and proposed that the first stage of recruiting refugees from Burma should be community health information sessions (Appendix 2: Invite to Health Information Session). We planned to jointly conduct these community health information sessions with other PRS, professional interpreters working with the research team, and bicultural liaison workers from social support organizations. We mapped out separate sessions for men and women. We made provision for joint sessions for men and women in a family setting if requested. We will brief the interpreters and bicultural workers about the issues planned to be discussed and their role in translating between researchers and community information session attendees. The interpreters would be gender matched for open communication (Tuteja et al., 2021).

The community information sessions would start with an introduction of modern concepts of research, such as informed consent, voluntary participation, shared decision-making, and evidence-based research. This would be followed by a discussion of SRH issues selected by attendees themselves or community leaders. This will provide the community members a chance to ask any questions or clear their doubts and dilemmas about any SRH-related issues. In the end, all the community information session attendees would be provided with translated information leaflets and consent forms to explain the research objectives and methodology. We would invite all community information session attendees to participate in individual "consent discussions" with the research team (Appendix 3: Invite to participate in research interviews).

"Consent Discussions"

We merged all the four themes to create the concept of "consent discussions" for potential research participants from refugee backgrounds. The team reflected on the first three themes and derived that flexibility would be key for consent discussions. There may be adults who would like to participate as a group, or friends or couples who may want to be interviewed together. Therefore, we will allow people to participate together as per their wishes or hold separate consent discussions for men and women. We will provide translated plain language statements and consent forms again prior to starting the consent discussion. We will gender match the interpreters for the consent discussion for greater support, comfort, and communication.

As per the recommendations of PRS (in theme three), extra time needs to be available for participants to read the information leaflets and consent forms to refresh their memories. During consent discussions, we will go over each point of the information leaflet. In theme four, PRS suggested that comprehension and effective communication should be intermittently verified to avoid one-sided discussion. Hence, we may ask participants to explain the meaning of important

points in the information leaflet and consent forms. Interpreters will help in translating and conveying the correct meaning of the information provided. We will provide small silences in the discussion to create room for questions. Those who want to take some time to think about the study can come back with questions for clarification before study enrolment. The option of verbal consent will be offered to people who do not read and write in their own language. This verbal consent will be audio-recorded with the participants' permission.

Verification of Consent and Research Understanding Just Prior to the Interview

We put together the third stage of the consent process based on the recommendations of PRS in theme four. Nurse 4 talked about her experience of obtaining consent prior to performing cervical smear tests. We adopted her ideology of enquiring from the patient about the consequences of refusing the cervical smear examination, proceeding only when she was satisfied that the participants knew that the examination was voluntary. Next, Nurse 7 discussed back questioning and proposed that we should include a few yes/no questions to verify the participant's understanding. We reflected on the lived experience of the PRS and incorporated two questions in the consent process. We believed that these two questions would verify that the potential participants understand the research process, consent and that their participation is voluntary. We would raise these two questions prior to signing the consent formally or recording the verbal consent.

Q1) What will happen if you decide not to participate in the study?

Q2) Once you sign up for the study you must go ahead and participate in the study.

(True/False)

The answers will generate an insight into the participants' real understanding of voluntary participation and the effectiveness of the delivery of consent information. If the answers suggest lack of real understanding, then more clarification is needed. We will evaluate the situation for each consent discussion and schedule a second consent discussion after an interval of time if needed. This gap will provide participants with some time to think on the research objectives and form questions. We will try to provide further clarifications in the subsequent "Consent Discussion" session. The two questions will serve as a checkpoint to decide if the participant has a clear understanding of the research aims and processes.

Discussion

In this paper we re-affirm that the conventional thinking and protocols regarding informed consent may not hold true when researching with settling refugees, particularly for sensitive subjects such as SRH; the reasons for this are manifold. Refugees may have low general literacy, and the standard format of printed information leaflets and consent forms (even if they are translated in native language) will have limited utility in these settings (Chuah et al., 2018; Riggs et al., 2016; Wångdahl et al., 2015). Refugee communities have lived in an atmosphere of dominance with minimal sense of agency. Therefore, they may agree to everything said by the researchers (Gillam, 2013; Obijiofor et al., 2018). Moreover, refugees are more likely to suffer from other societal problems such as racism, poverty, isolation, and so on, which will perpetuate their vulnerable stance despite a new country with refugee-friendly policies (Dominelli & Campling, 2002). This vulnerability will place the researchers in a higher hierarchical power position where the refugee participants are more likely to agree to participate without fully comprehending the implications of participation (Hugman, Pittaway, et al., 2011; Marmo, 2013). In addition, obtaining consent with the help of community leaders may impact the decision to

enroll in a research study. Despite education sessions with the community leaders, they may exert undue control over the right of some to be heard or coerce others to participate and thus produce skewed data (Jan-Khan, 2006; Leck, 2014). Finally, the cultural norms which impact discussions regarding SRH are different for every ethnic group, and thus, the consent forms cannot be made within a framework of Western values of individual choice and freedom (Afolabi et al., 2014; Nakkash et al., 2009; Shirmohammadi et al., 2018).

The need for methodological innovation (Block et al., 2012) while obtaining meaningful informed consent is also emphasized by other researchers who state that standardized research protocols may be invalid when applied to different cultural groups (Hugman, Bartolomei, et al., 2011; Humpage et al., 2019; Mackenzie et al., 2007; McLaughlin & Alfaro-Velcamp, 2015). However, very few publish their innovations or modifications which could be practical for future researchers for effective engagement with refugee communities. This study used data collected from interviews with 29 PRS to develop a strategy for obtaining a truly voluntary and informed consent for sexual and reproductive health (SRH) research with Burma-born refugees settled in Australia. Four themes arose from the data which highlighted the vulnerabilities of Burma-born refugees but may be true of refugees of many origins. Using these themes alongside the four ethical principles of Gombert et al. (2016), we developed a three-stage process of research consent for recruiting monolingual refugees from Burma for further SRH research.

Three studies in the literature have similarly attempted to design a research consent protocol to meet the needs of a specific refugee community. Block et al. (2012), published a methodological reflection of ethical engagement with newly arrived youth of refugee backgrounds. They engaged with students attending English language classes to explore the role of social network and support systems on the resettlement experiences. However, the consent forms bewildered the refugee students. The research team was focusing on social network mapping exercises, and this was also a small component of the English language program. At the end of this social network mapping exercise, the research team sought permission from the students to use these maps for research purposes. As explicit consent was gained before using information provided by any member of the group, the institutional review board readily gave its permission.

In a second example, Obijofor et al. (2018) made special efforts to document methodological and ethical challenges in refugee engagement. They reported that despite providing a plain language statement and multiple reassurances about confidentiality, participants seemed very uneasy about giving information in the presence of an “industry partner”. The industry partners were described as “strangers” and participants were apprehensive of talking in their presence. Participants were concerned that their responses may be disclosed to other governmental agencies. These issues were solved by negotiating consent in the presence of community insiders who tried to allay concerns as much as possible. Obijofor et al. advise researchers to plan extra time to explain research aims and objectives to community leaders to then work together to explain the study to research participants. Parallel findings are reported by Nakkash et al. (2009), who worked with impoverished Palestinian youth and children.

Hugman and Pittaway et al. (2011) in their landmark paper on ethics of research with refugees and vulnerable groups reinforce reciprocal research, a notion of equal exchange between researchers and participants. Reciprocal research draws from the growing concept of community-based participatory research but adds that refugees should be equal partners in every step of the research process. Humpage et al. (2019) reported their experience with institutional ethical review boards regarding photovoice projects with refugees and concluded that labelling of refugees as vulnerable is no solution to difficult ethical questions. Instead, they recommended working with a layered approach which accounts for people’s agency, aspirations, and capacity to recover from adversity. In this layered approach, vulnerability is not fixed but a dynamic concept. Context, culture, and power dynamics all become relevant in the process of meaningful consent. Post settlement, these new concepts of ethical research can be introduced to the refugees, and we can

partner with them to create substantial improvements in an ethical and culturally appropriate way. With this approach, refugee participants can be empowered to suggest the best way to proceed with the process of consent for any research activities. With increasing settlement of refugees in the Western world, we should be moving towards a culture of respect for refugees rather than only labelling vulnerabilities. Therefore, consent should not be viewed as a hindrance to research but a process of respecting the participant, providing them with the confidence to decline participation and if they proceed to speak up and express their genuine views.

In summary, these studies have re-envisioned “informed consent” as a meaningful process which allows a degree of flexibility in how the research aims and objectives are conveyed to the participant. Instead of focusing on the formalities, attention is shifted to having a meaningful exchange of information between the participants and the research team. This has been endorsed by other researchers who report that oral consent may be preferred to written consent even for the participants who are literate (Humpage et al., 2019). The opportunity to discuss the information leaflets and consent forms provides room for clearing doubts and raising questioning and information exchanges which may be missed in written signings. In pursuit of more meaningful consent, many social scientists have proposed an idea of consent discussions in refugee research (Block et al., 2013; Hopkins, 2008; Hugman, Bartolomei, et al., 2011; Mackenzie et al., 2007; Redwood & Todres, 2006). According to them, this will enable more worthwhile conversations around consent, compared to a one-off signature gaining exercise. Further, they advise that consent can be re-visited multiple times in the research process to keep at par with the evolving research project.

There are three limitations to our proposed consent process. Firstly, we did not interview any monolingual refugees from Burma to find out their views on how a more meaningful consent should be obtained. However, we did interview 11 bilingual participants who we believe have functioned as community insiders and provided cultural insights. In the second phase of our study, we will pilot our three-stage process of research consent with monolingual participants and modify it as per their feedback. Additionally, we plan to keep this as a flexible protocol which we can modify as the research progresses. Secondly, this protocol is developed for refugees from Burma and may not be valid for other refugee communities. Research teams may adapt this to suit their local context. Finally, although this approach has not been trialed with the community, we believe that our experience of developing this protocol is valuable for other researchers working with refugee groups post settlement in Western countries. In future, we will report our experience of implementing this process.

Conclusion

SRH research can positively impact quality of life by improving sexual and reproductive health of the individual, the community, and the populations. For effective SRH research, it is crucial to achieve meaningful involvement of refugee communities in the design and implementation of SRH research and intervention programs. It is essential to ensure that research design, methods, analysis, results, and implementation are congruent with empowering the study participants and do not reinforce the hierarchical differences between the researchers and study participants. In addition, account for the culture and traditions which surround SRH issues of any community.

Therefore, to explore the SRH needs of refugees from Burma, we began our research with developing an ethically and culturally appropriate consent strategy for SRH research. We present a customized three-stage process of research consent especially targeting refugees from Burma post settlement in Australia. With this, we add to the growing pool of data documenting problems with the standard informed consent and bring forth community solutions. This three-stage process of research consent is a constructive contribution to deepening researcher engagement with negotiating informed consent with refugees post settlement. Most importantly, we advocate for

greater cultural customization in research designs. This will ultimately improve study participation and present a greater community voice in research outcomes.

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Appendix 1

Steps followed in thematic analysis

Step 1: Accounting for personal biases which may influence research findings

- Research team members prior to analysis recorded their opinions, thoughts, prejudices in relation to the research subject “sexual and reproductive health (SRH) needs of migrants from Burma”.
- PhD student (first author) did “bracketing sessions” with her principal supervisor (last author). The fourth author participated in reflection sessions with the last and first author to document his clinical practice-based opinions.

Step 2: Continued data collection, ongoing critical reflection of methods & evolving analysis

- We held regular discussion meetings to interpret the data collected. This was a continuing process where previous analysis was used to understand newer data collected.
- We used this preliminary analysis to develop the perspectives of interview participants and revise the sampling frame.
- We modified the interview schedule and analysis according to the ongoing thematic analysis.
- We subjected the emerging themes with existing data and new themes emerged as data collection continued.

Step 3: Meticulous record keeping, demonstrating a clear decision trail

- The first author documented detailed field notes after every interview session.
- Field notes included nonverbal cues highlighted during conversation including facial expressions, body language, tone of voice and the underlying emotions noted at the conversation. She also noted “Off record information” (with the participants permission) in the field diaries.
- The first author added observational memos to the field notes. These memos included her impressions of the participants workplace, waiting areas of the practice, displayed SRH brochures and pamphlets.
- We included the field notes and observational memos in critical reflections and analysis.
- We recorded the discussions in the margins of transcripts. These helped us in careful selection of subsequent sampling frames. We also directed our literature searches to understand global contexts of the questions raised in the discussions.
- Theme saturation was apparent after first 20 interviews. However, we proceeded to complete 9 more interviews which had already been scheduled before theme saturation.

Step 4: Establishing a comparison case/seeking out similarities and differences across accounts to ensure different perspectives are represented

- We initiated coding consensus meetings after completing transcription.
- In the first step, first and last author independently read the transcripts without attempting to identify codes.
- During the second reading, the first, second, third, fourth and last author noted any significant impressions or unanswered questions in the margins of the text.
- They re-read their marked texts and identified first level codes (in-vivo coding in participant transcripts and open coding for field notes). Then, discussed these codes to extract meaningful units of analysis.

- All the authors read these meaningful units and listened to the audio tapes again and combined them to generate second level codes.
- We combined the second level codes to derive themes.
- We followed inductive coding and achieved a clear consensus in the themes and resolved minor discrepancies by discussion.
- All the authors read through the marked excerpts, codes and the final four themes. All verified theme saturation.
- We combined the four themes and constructed a three-stage process of research consent. This was designed for practical application in the second phase of research which would involve recruitment of monolingual community members..

Step 5: Including rich and thick verbatim descriptions of participants' accounts to support findings

- The most representative excerpts, quotes were noted in the trails for verification by all team members.
- The quotations, reflections and stories that were representative of divergent views were also trail marked.
- After theme saturation was achieved, we re-visited the four themes to check if they worked in relation to the coded extracts and the entire data set.

Step 6: Demonstrating clarity in terms of thought processes during data analysis and subsequent interpretation

- The analysis was reviewed for confirmation of coding process, clarity of codes and re-evaluation of themes and sub-themes by taking a "pause" in analysis.
- The first author re-evaluated the audio recordings and re-read the transcripts after a "leave of absence" from PhD studies.
- In this period, she gained experience of working in Obstetrics and Gynaecology in the Australian multi-cultural society.
- The first author re-discussed the data with her principal supervisor (last author) and believed that work experience improved her interpretation of latent data.

Step 7: Engaging with other researchers to reduce research bias

- The original research article submitted was read by all members of the research team and feedback was included to ensure correct representation of our thought process and analysis.

Step 8: Trustworthiness and verification of quality of research

- We have explicitly documented the evolution of our research. The records create an objective audit trail for future collaborators.
- We maintain consistency in data collection by using the same interviewer and asking the same questions in the same order.
- We preserve authenticity by purposefully selecting expert participants and allowing them free speech about their felt needs. In addition, we portrayed true perspectives of their lived experience of SRH consultations.
- To preserve criticality, we derived meaningful units of analysis rather than conduct a line-by-line coding. During this process we reflected on our dual roles of clinicians and researchers and acknowledged our biases.
- The rich thick descriptions to illustrate the final themes increase our credibility.

- Finally, we have developed a trusting relationship with the community for prolonged engagement. For the last 5 years, our team has been working on deepening community based participatory projects.
- Despite, all the above steps we agreed that the findings were both a process and a product in which we were deeply and intricately involved at every step. The findings were therefore a subjective construction in which the knowledge, beliefs and activities of our team played a significant role.
- The findings were ‘meaningful social interactions’ and, for this reason, our qualitative research can never be truly ‘generalisable’. The research and its reported product will be useful to other providers of refugee services, policy makers and social scientists according to their own subjective criteria.

Appendix 2

INVITATION LETTER

“Understanding Women’s Health in families from Burma”

Dear Friends from Burma

You are cordially invited to attend women’s health information sessions being held jointly by Refugee Health Care Organization and the University.

Women are the essence of our family. Healthy women ensure a happy family. We want to join hands with families from Burma to improve women’s health in the community.

You may be Burman, Chin, Kachin, Karen, Karenni, Mon, Rakhine, Rohingya, Shan or simply from Burma, you are all cordially invited to attend the health information sessions on women’s health and wellbeing.

I am a women’s health doctor and I will be holding health information sessions to help people understand these less discussed but very important health issues better.

EXAMPLE TOPICS

Caring for growing up daughters

Healthy marital life and relationships

Caring in pregnancy, childbirth and after delivery of the baby

We don’t have a child...Do we have any hope?

Can we do anything to decide the number of children we have?

I would like to invite you to participate in the women’s health information sessions. I will try and speak the same language you speak at home. Sessions are available on the phone or online depending on your convenience. If you want to talk in person, we will have to wait till it is safe to do so.

We believe that with knowledge the families from Burma can take better care of their mothers, wives and daughters.

The session will be followed by details of our research study and an invitation to join it. Please feel free to contact us with any questions. The session will be in [language] and interpreters will be present.

Contact information: Research Team

I will be
online/or on phone
but if you want to meet
me in person, I can only
organize this after the
lockdown is over.

Appendix 3

INVITATION LETTER

Women's health project for people from Burma settled in Australia

Dear Friends from Burma

We are seeking your help for a research project on the women's health issues of people from Burma who have settled in Australia. We are interested in talking to anyone who is from Burma, whether you are Burman, Karen, Chin, Karenni, Mon, Shan, Rakhine, Wa, Kachin, Rohingya or belong to any other group. Your thoughts and feelings are important to us.

Who are we?

We are reproductive health specialists from the University and doctors from Refugee Health Organization who are jointly doing this study.

Why are we doing this study?

In families from Burma women play a central role in raising children, caring for everyone, earning income, cooking and feeding the family. Therefore, having good women's health is very important to have healthy happy families. We are keen to improve women's health conversations in the clinic which happen with the interpreter and improve service delivery.

Why have you been approached?

We are asking you to take part because you are from Burma and you will be the expert in telling us more about your cultural traditions, and the needs and the improvements that can be made in the Australian health system.

What will I be asked to do?

We want you to participate in interviews and share information about your culture and traditions associated with marriage, pregnancy and childbirth. Your stories of growing up in Burma, leaving home and settling in Australia are very important to us. However, our focus is to understand how this change affected your personal life, marriage and relationships. We would like you to tell us about the social and medical problems surrounding the marital life of the community in a new country with a different culture. We want to know your idea of family, the number of children you want to have and what is the best way to help you have your ideal family. Finally, we want to explore your views on the problems in accessing women's health services and your suggestions to improve them.

How will the interview be done?

The information will be collected online or via telephone with the researcher, who is a women's health doctor.

She will contact you at your preferred time to schedule the interview that may last for up to 1 hour. The interview will be audiotaped with your permission so that we do not miss anything.

The conversation will be in the language of your choice. As the researcher speaks only English, we will work with an interpreter of your choice if you prefer. We are happy to work with qualified interpreters present online or on telephone and even family or friends if you are more comfortable with them.

You will receive a gift card for taking time to participate in the interview.

Do I have to take part?

You don't have to participate if you don't want to. If you decide to take part and later change your mind, you can stop taking part in the project without giving a reason why. Whether you decide to take part or not, or change your mind later and leave the study, it will not affect any services or support you receive at any health centre.

Will my identity and the information provided be kept confidential?

We will not identify you in the research. Your name and the information provided will be known only to the research team and will not be mentioned in any reports or publications. Your confidentiality is our top priority. Information arising from interviews will be kept confidential subject to legal limitations.

What are the benefits associated with participation?

This research will find out about your views related to women's health conversations in the presence of an interpreter. We will use what we learn to help health services give better services and care to families.

What will we do with the information?

The information provided by the participants in the study will be collected together and studied without including details which could identify you. Should you wish to see a copy of the results we are very happy to send these to you. The information from the study will be shared with your community via a newsletter and community forums. The results will also be shared with health services that provide women's health services to refugee. Results will also be published in reports and journals.

Are there any other things that I need to know before I say yes?

You don't have to be alone-We are happy to gather your opinion whether you are single or in a group. If you feel more comfortable with your friends and family, we can talk to you together.

We will be there for you-In the unlikely event that talking to us reminds you of your past experiences with health services, and upsets you, we will be there for you. The community workers and researcher will listen and support you in getting assistance from services. We will provide you with our phone numbers in case you need help before or after the interview.

You can call us any time?

If you have any questions and would like to speak to someone you can call
Research Team (Ph xxxxxxxxx)

However, if you have any concerns or complaints and would like to talk to someone not directly related to the research you can call.

Executive Officer, Human Research Ethics

The University

An interpreter can be arranged for the discussion.

How will we keep you COVID 19 Safe?

We will do everything online or on phone to keep you safe.

Will you share your views?

To join hands with us in our mission to make services better for women's health for families from Burma you can fill in your name on the form attached and return it to us at any of the information sessions. A member of the research team will contact you to arrange the discussion. If you decide later, you can call the researcher on the phone number (xxxx) and we will try to get in touch with you along with an interpreter. Alternatively, please contact the reception at Refugee health Organization and express your interest to participate and we will get in touch with you.

I would like to take part in the discussion regarding "Improving women's health conversations for people from Burma settled in Australia"

Name:

My telephone number is:

The best day for me is:

The best time for me is:

Author Note

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Acknowledgements: The authors profoundly thank and acknowledge the significant contribution of Melbourne Social Equity Institute, in funding the PhD student in her research initiatives. A special thanks is due to Dr. Phyllis Lau and Dr. Vasudha Iyengar for supporting the PhD student in her research journey. Mr. Krishan Kumar Tuteja's vision of inclusive health is the drive behind developing a robust consent strategy before interviewing the refugee participants.

Declaration of Interest Statement: We have no conflicts of interest, or any disclosures related to the research. The University of Melbourne (Melbourne Social Equity Institute) awarded the PhD student (AT) with the Melbourne International Fee Remission Scholarship and Melbourne International Research Scholarship and is the prime contributor towards funding of research.

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Article Citation

Tuteja, A., Riggs, E., Sancı, L., Mascarenhas, L., Power, A., VanVilet, D., Sangster, K., McGuinness, K., & Temple-Smith, M. (2022). Developing a sexual health consent strategy for refugees: A qualitative approach. *The Qualitative Report*, 27(2), 509-538. <https://doi.org/10.46743/2160-3715/2022.5158>
