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TITLE PAGE

Title

Protocol for ACCESS: a qualitative study exploring barriers and facilitators to accessing the emergency contraceptive pill from community pharmacies in Australia

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morning-after pill; emergency contraception; emergency contraceptive pill; postcoital contraception; access.

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ABSTRACT

Introduction: The rate of unplanned pregnancy in Australia remains high, which has contributed to Australia having the third highest abortion rate of developed countries with 1 in 5 women having an abortion. The emergency contraceptive pill (ECP) offers a safe way of preventing unintended pregnancy after unprotected sex has occurred. While the ECP has been available over-the-counter in Australian pharmacies for over a decade, its use has not significantly increased. This paper presents a protocol for a qualitative study that aims to identify the barriers and facilitators to accessing the emergency contraceptive pill (ECP) from community pharmacies in Australia.

Methods and analysis: Data will be collected through one-on-one interviews that are semi-structured and in-depth. Partnerships have been established with two pharmacy groups and two women's health organisations to aid with the recruitment of women and pharmacists for data collection purposes. Interview questions explore domains from the Theoretical Domains Framework in order to assess the factors aiding and/or hindering access to ECP from community pharmacies. Data collected will be analysed using deductive content analysis. The expected benefits of this study are that it will help develop evidence-based workforce interventions to strengthen the capacity and performance of community pharmacists as key ECP providers.

Ethics and dissemination: The findings will be disseminated to the research team and study partners, who will brainstorm ideas for interventions that would address barriers and facilitators to access identified from the interviews. Dissemination will also occur through presentations and peer-reviewed publications and the study participants will receive an executive summary of the findings. The study has been evaluated and approved by the Monash Human Research Ethics Committee.

STRENGTHS AND LIMITATIONS

- Contribution of new knowledge to the limited literature on barriers to ECP access in the Australian context that will help inform the development and implementation of interventions in community pharmacy to enhance access.
- Use of the Theoretical Domains Framework that includes constructs from 33 behaviour change theories, to conduct and analyse the interviews and ultimately inform the interventions.
- Recruitment challenge is an anticipated problem due to the sensitive nature of the research topic and the fear of disclosure or privacy concerns, potentially delaying the study timeline.

INTRODUCTION

The rate of unplanned pregnancy in Australia remains high and nearly half of all Australian women of reproductive age have experienced an unplanned pregnancy.[1] Australia also has the third highest abortion rate of developed countries with 1 in 5 women having an abortion.[2] An estimated 80,000 abortions performed annually have serious health service impacts along with physical and emotional impacts on the individual. The emergency contraceptive pill (ECP) offers a way of preventing unintended pregnancy after unprotected sex has occurred. While the ECP is safe and has no medical contraindications, there are significant barriers to pharmacy access in Australia and overseas.[3]

The levonorgestrel containing ECP in Australia has been available since 2004 through community pharmacies as a 'Pharmacist Only Medicine' without a prescription. In Australia, Pharmacist Only Medicines must be stored in a part of the pharmacy not accessible to the public and supplied only for a therapeutic need after the pharmacist has personally taken reasonable steps to ensure that such a need exists. The Pharmaceutical Society of Australia (PSA) released the first protocol to guide pharmacists' supply of the ECP in 2003[4] and released an updated version in 2006.[5] In 2011 the PSA revised the 2006 protocol and released another updated practice guideline for levonorgestrel provision that contains the latest scientific evidence regarding its use.[6] The revisions address several factors including the time frame that levonorgestrel can be used within, which was changed to allow use up to 96 hours after intercourse, compared with the product information that indicated use within 72 hours. The revision also established that advance supply does not negatively impact on sexual and reproductive health. Lastly, there was an acknowledgement that there is limited data regarding the use of the ECP in females aged 14–16 years, and the pharmacist needs to refer to a general practitioner (GP) where advisable; however, the guideline highlighted that there was no reason for ECP use to be restricted on the basis of age.

Pharmacists' practices in Australia are variable, commonly not meeting evidence-based recommendations in the PSA guideline and resulting in women being unnecessarily declined ECP supply.[7 8] Women's experiences of obtaining the ECP from pharmacies are both positive and

negative.[3] Some positive experiences reported by women include faster and more direct access, convenient location, and feeling of more control over their reproductive health, while some negative experiences reported include lack of privacy, judgmental or indifferent pharmacist attitude, cost of ECP and so on. Compounding this is the unexplained paradox between unplanned pregnancy rates and ECP availability.[9]

Access to emergency contraception, especially the ECP, is essential as it helps prevent unwanted pregnancies – an important public health goal. If the ECP is refused by a pharmacist or GP, women are placed at risk of having an unwanted pregnancy that may result in an abortion or be carried to term with long term implications for the woman and her partner. This study seeks to understand the underpinning reasons for refusal of supply that make access to this medicine unnecessarily complex.

The ECP was made available over-the-counter (OTC) in Australia with the view that it would allow women to access the ECP more quickly than from a GP, and therefore lead to a decrease in the unplanned pregnancy rate in Australia. A focus group study suggested that Australian women aged 16-30 years were in favour of pharmacy availability of the ECP, as faster and more direct access is afforded, particularly on Sundays and for women living in rural and remote locations.[10] However, a decade later, despite pharmacy availability of the ECP, it seems that Australian women's use of the ECP has neither significantly increased nor has the rate of unplanned pregnancies significantly decreased. A study conducted in Sydney that surveyed 718 women on ECP use, concluded that OTC availability and access to the ECP increased women's awareness but did not significantly increase ECP use among abortion seekers.[11]

A research study examining the attitudes and practices of pharmacists in Australia in relation to their increased role in ECP provision following the policy change to OTC availability, found that pharmacists' attitudes and beliefs play a major role in ECP dispensing.[8] Australian pharmacists had stronger and more conservative views than overseas pharmacists and 22% of the pharmacists surveyed felt it was reasonable for a pharmacist's religious faith to influence ECP supply. This seems

stark compared to the survey response of pharmacists in Nova Scotia, Canada where only 1.6% of pharmacists indicated that they had not provided the ECP due to moral, religious or ethical objections.[12] In addition, pharmacists' decision to decline ECP provision in Australia is because of incorrect beliefs regarding advance prescription, the responsible use of ECP and its impact on sexual reproductive health.[8] Pharmacists also noted a number of problems with the number of differing written protocols used to dispense the ECP. In another study examining attitudes of pharmacy assistants in Northern Queensland, 22% of those interviewed felt it was reasonable for a pharmacists' religious faith to influence EC supply, while 65% of pharmacists interviewed identified young age as the most common reason for refusing to dispense EC.[13]

The first random population-based study of Australian women's ECP knowledge, attitudes and use since its availability without a prescription surveyed 632 Australian women aged 16-35 years.[3] This study found that less than half were aware that ECP was available from pharmacies without a prescription and 57% did not think they were at risk of getting pregnant. While most women felt the ECP was effective at preventing pregnancy, less than half believed that is was safe or very safe for the health of women. Of the women surveyed, 32% thought that the ECP was an abortifacient, when in fact, it delays ovulation. In addition, more than half the women reported feeling somewhat or very uncomfortable when asking for the ECP at a pharmacy and less than half thought it was the role of the pharmacist to give women advice about contraception and sexually transmissible infections at the time the ECP is obtained. Although Australian women have a high awareness of the ECP, their knowledge about how and when to use it and where to obtain it is inadequate, thus increasing their risk of becoming pregnant.[3]

A comprehensive barriers analysis to determine pharmacist- and patient-related barriers to ECP provision has not been done in Australia or overseas, although some light has been indirectly thrown onto this issue in a previous mystery caller study of a sample of pharmacies in Victoria, Australia.[7] In this study, 515 pharmacists were randomly allocated one of three scenarios when supplying the ECP and these scenarios exemplified the three major areas of change in the revised PSA guideline:

outside the licensed 72-h time frame (Scenario 1); by a woman under 16 years (Scenario 2); and for future use (Scenario 3). These scenarios tested actual performance in situations for which pharmacists' self-reported responses in a previous study were inappropriate.[8] It was found that 55.4% of pharmacists tested for scenario 1 declined supply and most referred to the doctor; and 46.1% and 40% denied supply for scenarios 2 and 3, respectively. The study concluded that Victorian pharmacists' practices in relation to ECP provision are not always in line with the recommendations in the PSA guideline.

These findings are mirrored by a recent review of workforce interventions that facilitate increased access to ECP in low and middle income countries, revealing that in these countries too, provider knowledge gaps, less than favourable attitudes and practice issues impact access to ECP. The review also highlighted the need to further examine provider performance to inform the development of appropriate workforce interventions.[14]

We therefore recommend that a formal analysis is required to understand how services such as community pharmacy should be reoriented to ensure they meet the sexual and reproductive health needs of women in Australia. Hence, in-depth interview with key stakeholders – women and pharmacists – is the proposed method to undertake the barriers analysis in this Australian based study that we have named ACCESS (ACcessing Contraception for Emergency Supply Study). In-depth interviewing will be used to develop an understanding of both individual (attitudinal, knowledge-based, skills-related, risk assessment) and organizational barriers and facilitators. Key informant interviews with pharmacists as well as key informant interviews with women living in Australia will be conducted over a two month period. The interview questions have been developed based on the Theoretical Domains Framework[15] and seek information pertaining to women's interactions with pharmacists when obtaining the ECP, attitudes and beliefs of pharmacists and women, as well as characteristics of those interviewed (gender, age, highest education level, country of birth, primary language spoken, place of residence, employment status, type of health insurance, marital status and other relevant characteristics).

The major significance of ACCESS will be the evidence that it will provide to help inform workforce interventions in community pharmacy that will address barriers to ECP access, promote increased adherence with the PSA national guideline and therefore increase supply of, and enhance access to, the ECP by women. A key focus of the study is to evaluate practice against national guideline evidence in order to facilitate ECP supply. The data from this study will be used to develop and pilot evidence-based interventions that will strengthen the capacity of pharmacists to play a more effective role in reducing unwanted pregnancies and the abortion rate in Australia.

METHODS AND ANALYSIS

Design

Exploratory qualitative study.

Scope

The study will be carried out in collaboration with 10 pharmacy sites located in Victoria, Australia. We will work with our partners to include pharmacies from various different locations/regions within Victoria as well as pharmacists from differing religious affiliations and genders. The pharmacist interview will take place at the pharmacy where they work and the women interviewees will be asked to nominate a mutually agreeable place such as the Monash University Parkville campus where the Chief Investigator is based or over the phone. The study will be carried out over a period of 12 months where after gaining ethics approval, 3 months will be designated for recruitment and 4 months toward conducting the interviews which will be followed by a few months of data analysis.

Sample size

The sample size of pharmacists we seek to interview is anywhere between 10-50 participants. The sample size of women participants we seek to interview is anywhere between 20-70 participants. The reason for such a wide range in sample size is due to the fact that since this is an exploratory

qualitative study, the number of interviews is dependent on whether saturation of themes is reached and is dictated by resources.

Tool

Participants will be interviewed for between thirty minutes to one and a half hours and they will be asked open-ended questions focusing on the barriers and facilitators to accessing ECP from community pharmacies. The interview questions were formulated based on Michie's Theoretical Domains Framework[15 16] described in detail below.

Pharmacists will be encouraged to talk about internal beliefs and attitudes that may hinder them from freely providing the ECP. The 21 interview questions explore the following ten behavioural constructs in order to assess pharmacist-related barriers to ECP provision: Knowledge; skills; social/professional role and identity; beliefs about capabilities; memory, attention and decision processes; beliefs about consequences; behavioural regulation; social influences; environmental context and resources; and nature of behaviour (Table 1).

Table 1: Interview Guide for Pharmacists according to Michie's theoretical domains

Theoretical domains	Interview prompts
Knowledge	Are you aware of the PSA guideline for providing the ECP? What is your understanding of this guideline?
Skills	Have you had any training to use the PSA guideline? What kind of training? What skills are required to supply ECP to someone? Are there any specific areas of difficulty?
Social/professional role and identity	Why do you provide the ECP in your pharmacy? What are your views about the PSA guideline in general? Do you think it is an appropriate part of your role to be following this guideline? Does your ethical position affect your practice with regard to the ECP? How do you reconcile this with your duty of care?
Beliefs about capabilities	Do you find it difficult to apply the information in the PSA guideline to assess whether someone should receive the ECP? What problems have you encountered? What would help you to overcome these problems? Do you think you have the skills to provide the ECP? Do you fear that you might miss something when assessing whether someone should receive the ECP?
Memory, attention and decision processes	What thought processes might guide your decision to provide the ECP to someone?
Beliefs about consequences	In your experience of providing the ECP, have you come across problems in your population? What do you think about the evidence behind the ECP? Are there any advantages or disadvantages in trying to access the ECP via a pharmacy instead of a health clinic or doctor?
Behavioural regulation	Are there any procedures or ways of working that encourage or discourage you to provide the ECP?
Social influences	To what extent do social influences of peers, managers etc. facilitate or hinder you in… providing the ECP? applying the PSA guideline?
Environmental context and resources	Are there any environmental or resource factors that facilitate or hinder you in… providing the ECP? applying the PSA guideline? Does your pharmacy use any checklists or tools when providing the ECP?
Nature of the behaviours	What do pharmacies have to do differently to… improve awareness and access of the ECP? increase the application of the PSA guideline?

PSA: Pharmaceutical Society of Australia; ECP: Emergency contraceptive pill

Women will be encouraged to talk about the social pressures, judgements and prior experiences that may hinder them from accessing the ECP from pharmacies. The 14 interview questions regarding consumer-related barriers to ECP provision explore all the same behavioural constructs mentioned above except for one: memory, attention and decision processes (Table 2).

Table 2: Interview Guide for Women according to Michie's theoretical domains

Theoretical domains	Interview prompts
Knowledge	What is the ECP? How long after unprotected sex can you take the ECP? Where would you get the ECP from? Did you know the ECP is available without a prescription from a pharmacy?
Skills	Have you ever taken the ECP? From where? When? (Note: If they got it from pharmacy – then the question is complete. If they got it from somewhere else, and didn't know about pharmacy access - then ask would they if they could?)
Beliefs about capabilities	What can be done to increase someone's capability to access the ECP from a pharmacy?
Beliefs about consequences	Are there any advantages or disadvantages in trying to access the ECP via a pharmacy instead of a health clinic or doctor?
Behavioural regulation	We want women to know that it is easy, convenient and fast to get the ECP from pharmacies. What factors are important to you if you had to get the ECP from a pharmacy? (Prompt: Good factors include convenient location, fast service, avoidance of doctor's visit and so on; Bad factors include lack of privacy, fear of judgement and so on).
Social/professional role and identity	What skills do you think a pharmacist should have when providing the ECP? Who do you think has the skills to provide the ECP?
Environmental context and resources	Is there anything about the pharmacy environment that concerns you? What information do you think a pharmacist should be able to provide you with?
Social influences	Do you know people who have accessed the ECP from a pharmacy? What problems did they encounter? Have their experiences facilitated or hindered you in accessing the ECP?
Nature of the behaviours	What do pharmacies have to do differently to improve awareness of and access to the ECP?

Theoretical Domains Framework

Behaviour change is key to increasing the uptake of evidence into healthcare practice and improving health outcomes. A variety of psychological theories have been used to explain health care professional behaviours and cognitions across a range of behaviours and settings. However, the large number of theories and overlapping constructs presents a challenge for knowing how to select and apply theories when exploring specific behaviours. The Theoretical Domains Framework (TDF), which includes constructs from 33 behaviour change theories, was developed to make theories more accessible for implementation researchers.[16 17] TDF consists of 14 theoretical domains and exemplar questions for each to use in interviews or focus groups to provide a comprehensive theoretical assessment of implementation problems. This framework has been used by research teams across several healthcare systems to explain implementation problems and inform implementation interventions. The TDF has proved useful across a number of healthcare systems and for stronger explanatory and predictive power, and therefore increased usefulness in informing interventions to improve implementation and bring about other behaviour change.[16]

In a brief review to assess the extent of TDF-based research, 133 papers that cite the framework were identified.[16] Of these, 17 used the TDF as the basis for empirical studies to explore health professionals' behaviour. The identified papers provide evidence of the impact of the TDF on implementation research. Two major strengths of the framework are its theoretical coverage and its capacity to elicit beliefs that could signify key mediators of behaviour change. The TDF has been applied in many implementation studies.[15] Specifically, qualitative studies have concluded that the TDF was useful for the comprehensive exploration of possible explanations for suboptimal implementation behaviour and for the identification of suitable theories to further investigate those behaviours.[18] Another study documenting the development and use of the TDF stated that the TDF is arguably the most comprehensive framework for designing implementation interventions as it offers a broad coverage of potential change pathways.[19] An example of a study utilizing TDF to inform the design of its intervention is the Healthy Kids Check (HKC). The authors of this study concluded that TDF was able to classify which barriers needed to be targeted to improve

implementation of HKC services.[20] The study reported here aims to do the same by using the TDF to identify those behavioural constructs that will need to be targeted in order to increase pharmacy performance in ECP provision and ultimately women's access to the ECP.

Recruitment

The pharmacy organisations involved in this research – Australian Pharmaceutical Industry (API)/Priceline Pharmacy Group whose main clientele are women and Quality Pharmacy Group (QPG) who is focused on professional service delivery – will nominate five pharmacies each in their group as the sampling frame i.e. total of 10 pharmacies in Victoria.

Every pharmacist working at the nominated pharmacies of both pharmacy groups will be given an information pack by their organisation that will contain information about the study. Pharmacists interested in participating in the study will contact the researchers to enrol in the study.

Women participants will be recruited by API/Priceline Pharmacy Group by advertising the study in an in-store leaflet that will be provided to consumers (e.g. placed in store bags, placed on counters for consumers to self-select). QPG will select women participants from their database of approximately 70,000 pharmacy consumers. This database contains both demographic and medication-related information i.e. prescription and non-prescription medicines purchased by consumers.

Additional recruitment methods will be employed if recruiting women participants through the two pharmacy groups mentioned above generate a low response. These additional recruitment strategies will be carried out by the Policy and Health Promotion Manager from Women's Health Victoria and the Marketing and Communications Director from Marie Stopes International (partner institutions). Women's Health Victoria will recruit through their networks statewide by sending the recruitment flyer to all the managers and staff in their network of Victorian Women's Health Programs and School Nursing Programs. Marie Stopes International will aid in recruitment by posting the recruitment flyer on the "Morning After Pill" webpage on the Marie Stopes International website. Lastly, Fernwood

fitness clubs, which have exclusively female membership, will be approached to aid in recruitment by displaying the recruitment flyer at selected locations in the gym such as the reception area and women's changing rooms. Fernwood fitness managers will be incentivised with a $75 voucher for recruiting at least four women participants.

The Research Assistant (A.G., MPH, female, has experience in conducting and analysing interviews) will contact women who are selected for the study after they have been screened for the inclusion/exclusion criteria, to determine the date, time and interview location that suits them. Similarly, pharmacists selected for the study will also be contacted in order to determine a suitable date and time for the interview. No prior knowledge or characteristics about the Research Assistant were shared with the participants, or relationship with her was established, prior to the interviews.

Inclusion criteria

In order to participate in the study, pharmacists should be over the age of 18 and English should be their primary language. The women participating in the study should be between the ages 15 to 44 and English should also be their primary language.

Exclusion criteria

Pharmacists who have never refused supply of the ECP will be excluded from the study. The reason we included this criterion is because the majority of our interview questions aim at eliciting answers to situations where a pharmacist has refused ECP access. In addition, women who have not tried to access the ECP within the past year will be excluded from the study. This is because we want our participants to be able to describe in detail (with minimal recall bias) their prior experience of accessing the ECP.

Compensation

A $75 gift voucher will be given to pharmacist and women interviewees.

Data analysis

All interviews will be tape-recorded and conducted by the Research Assistant who does not intend to make field notes during or after. No one else besides the Research Assistant and interviewee will be present and repeat interviews will not be conducted. Interview data will be transcribed. Participants will receive a copy of their transcript for approval. Data from the interviews will be de-identified so that no participant names or other identifying features will appear in any form of data reporting. Instead, codes will be used to identify who the comment or quote was made by in the interview. Transcripts will be read and coded by the Research Assistant, then checked by the Chief Investigator and one other Investigator. The coding process will be deductive with the selected theoretical domains as an organising framework. If the codes validate the TDF domains they will be used to inform appropriate workforce interventions for a pilot randomised controlled trial in selected API/Priceline and QPG community pharmacies.

NVivo (version 10) will be used to manage data and code this data into TDF domains. Data will be retained in the Centre for Medicine Use and Safety at Monash University, Parkville for at least five years. Hard copies of data will be kept in a locked filing cabinet, in a locked room at the Centre. All electronic data will be stored in password-protected computers. Only the study team will have access to the data.

Possible outcome of the analysis and benefits of the study

A study on barriers and facilitators to accessing the ECP from community pharmacy in Australia has never been undertaken before. We hope the data from this study will help develop evidence-based workforce interventions to strengthen the capacity and performance of community pharmacists as key ECP providers.

Possible benefits are that the study will contribute new knowledge to the limited literature on barriers to ECP access in the Australian context and will help inform the development of evidence-based interventions in community pharmacy that will achieve the following: address barriers to ECP access,

promote increased adherence with a national practice guideline for pharmacists that benchmarks best practice in the area, and therefore increase the supply of, and enhance access to, the ECP by women.

ETHICS AND DISSEMINATION

ACCESS was approved by the Monash University Human Research Ethics Committee (CF14/3551 – 2014001868).

Participants will be assured of their anonymity and that the primary purpose of the research is to identify the barriers and facilitators to accessing the ECP from community pharmacies in Australia. Written informed consent will be taken from all pharmacists and women interviewed. All study participants will be provided with an Explanatory Statement containing information about the study, what participation involves and the contact details of the Monash University Ethics Committee so that they are able to report any concerns or complaints about the study. All respondents have the right to refuse to answer any question posed by the interviewer, and can withdraw from the study prior to having approved the interview transcript.

The risk of physical or psychological harms from participation in the study will be negligible. The study only involves interviews with participants; however, given the potentially sensitive nature of the topic, the questions in both have been designed to be as objective as possible and have been worded carefully. Participants will not be identified by name in any report or publication resulting from the study data. There are no risks for the researchers.

The results from the study will be disseminated to all researchers and organisational partners associated with this study, who will brainstorm ideas for interventions that would address barriers and facilitators to access identified from the interviews. The study participants will receive an executive summary of the research findings. In addition, the findings will be written up for publication in peer-reviewed journals in specialist, general, national or international journals.

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AUTHORS' CONTRIBUTIONS

SH is the Chief Investigator whose role is to supervise the Research Assistant, communicate with other investigators and study partners, establish partners, draft papers and disseminate findings as well as seek funding. AG is the Research Assistant and is employed for 2 days/week to manage the study by organising team meetings, preparing the ethics application, conducting all one-on-one participant interviews, drafting papers, collating findings and analysing data from the interviews. All other authors are Investigators who have contributed to the study design. SH and AG drafted the first version of this manuscript and all other authors revised it. All authors approved the submitted version.

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COMPETING INTERESTS

None.

NB: Our paper is a protocol for a qualitative research study, however, there was no relevant checklist for it & we have thus completed this one! Some of the questions are not applicable & we have indicated this below.

Table I Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No	Item	Guide questions/description
Domain 1: Research team and reflexivity		
Personal Characteristics		
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group? ✓
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD* ✓
3.	Occupation	What was their occupation at the time of the study? ✓
4.	Gender	Was the researcher male or female? ✓
5.	Experience and training	What experience or training did the researcher have? ✓
Relationship with participants		
6.	Relationship established	Was a relationship established prior to study commencement? ✓
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research* ✓
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic* ✓
Domain 2: study design		
Theoretical framework		
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis* ✓
Participant selection		
10.	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball* ✓
11.	Method of approach	How were participants approached? e.g. *face-to-face, telephone, mail, email* ✓
12.	Sample size	How many participants were in the study? ✓
13.	Non-participation	How many people refused to participate or dropped out? Reasons? N/A as study not conducted yet
Setting		
14.	Setting of data collection	Where was the data collected? e.g. *home, clinic, workplace* ✓
15.	Presence of non-participants	Was anyone else present besides the participants and researchers? ✓
16.	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date* ✓
Data collection		
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested? ✓
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many? ✓
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data? ✓
20.	Field notes	Were field notes made during and/or after the interview or focus group? ✓
21.	Duration	What was the duration of the interviews or focus group? ✓
22.	Data saturation	Was data saturation discussed? ✓ N/A
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction? ✓
Domain 3: analysis and findingsz		
Data analysis		
24.	Number of data coders	How many data coders coded the data? ✓
25.	Description of the coding tree	Did authors provide a description of the coding tree? ✓
26.	Derivation of themes	Were themes identified in advance or derived from the data? ✓
27.	Software	What software, if applicable, was used to manage the data? ✓
28.	Participant checking	Did participants provide feedback on the findings? ✓
Reporting		
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number* N/A
30.	Data and findings consistent	Was there consistency between the data presented and the findings? N/A
31.	Clarity of major themes	Were major themes clearly presented in the findings? N/A
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes? N/A

(ii) Participant selection: Researchers should report how participants were selected. Usually purposive sampling is used which involves selecting participants who share particular characteristics and have the potential to provide rich, relevant and diverse data pertinent to the research question [13, 17]. Convenience sampling is less optimal because it may fail to capture important perspectives from difficult-to-reach people [16]. Rigorous attempts to recruit participants and reasons for non-participation should be stated to reduce the likelihood of making unsupported statements [18].

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Protocol for ACCESS: a qualitative study exploring barriers and facilitators to accessing the emergency contraceptive pill from community pharmacies in Australia

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TITLE PAGE

Title

Protocol for ACCESS: a qualitative study exploring barriers and facilitators to accessing the emergency contraceptive pill from community pharmacies in Australia

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ABSTRACT

Introduction: The rate of unplanned pregnancy in Australia remains high, which has contributed to Australia having one of the highest abortion rates of developed countries with an estimated 1 in 5 women having an abortion. The emergency contraceptive pill (ECP) offers a safe way of preventing unintended pregnancy after unprotected sex has occurred. While the ECP has been available over-the-counter in Australian pharmacies for over a decade, its use has not significantly increased. This paper presents a protocol for a qualitative study that aims to identify the barriers and facilitators to accessing the emergency contraceptive pill (ECP) from community pharmacies in Australia.

Methods and analysis: Data will be collected through one-on-one interviews that are semi-structured and in-depth. Partnerships have been established with two pharmacy groups and two women's health organisations to aid with the recruitment of women and pharmacists for data collection purposes. Interview questions explore domains from the Theoretical Domains Framework in order to assess the factors aiding and/or hindering access to ECP from community pharmacies. Data collected will be analysed using deductive content analysis. The expected benefits of this study are that it will help develop evidence-based workforce interventions to strengthen the capacity and performance of community pharmacists as key ECP providers.

Ethics and dissemination: The findings will be disseminated to the research team and study partners, who will brainstorm ideas for interventions that would address barriers and facilitators to access identified from the interviews. Dissemination will also occur through presentations and peer-reviewed publications and the study participants will receive an executive summary of the findings. The study has been evaluated and approved by the Monash Human Research Ethics Committee.

STRENGTHS AND LIMITATIONS

- Contribution of new knowledge to the limited literature on barriers to ECP access in the Australian context that will help inform the development and implementation of interventions in community pharmacy to enhance access.
- Use of the Theoretical Domains Framework that includes constructs from 33 behaviour change theories, to conduct and analyse the interviews and ultimately inform the interventions.
- Recruitment challenge is an anticipated problem due to the sensitive nature of the research topic and the fear of disclosure or privacy concerns, potentially delaying the study timeline.

INTRODUCTION

The rate of unplanned pregnancy in Australia remains high and nearly half of all Australian women of reproductive age have experienced an unplanned pregnancy.[1] Australia is reported to have one of the highest abortion rates of developed countries with an estimated 1 in 5 women having an abortion.[2] Abortions can have serious health effects/implications. One comprehensive study of 400 international studies into the psychological risks associated with abortion concluded that 20-30% of women who had an abortion suffered from serious, prolonged, negative consequences.[3]

The emergency contraceptive pill (ECP) offers a way of preventing unintended pregnancy after unprotected sex has occurred. It is important to note that many of the previous randomized controlled trials[4-7] demonstrating no association between ECP access or its advanced provision and unintended pregnancy or abortion rates, have mostly been conducted in post-partum or family management clinics or hospitals, and thus targeted women who were already accessing specialized forms of care. However, one trial has demonstrated that increasing access to the ECP can reduce unintended pregnancy rates during breastfeeding,[8] highlighting the importance of the culture, setting and context of such trials. Women in general health settings such as community pharmacy may have different attitudes, needs and health seeking behaviors, and the care they receive may not be as systematic or evidence-based. It is therefore critical to study these populations in greater depth than what has already been investigated,[5 9] i.e. in several countries and different cultural contexts, both to determine an effect of enhanced ECP access on unintended pregnancy rates and on the mental health and wellbeing of the women involved.

While the ECP is safe and has no medical contraindications, there are significant barriers to pharmacy access in Australia and overseas.[10] Barriers such as suboptimal acceptance by healthcare providers and the public, and multiple financial and healthcare system barriers to use,[11] are preventing the ECP's potential for reducing unintended pregnancies and abortion rates to be realized. The only ECP in Australia, containing levonorgestrel, has been available since 2004 through community pharmacies as a 'Pharmacist Only Medicine' without a prescription. In Australia, Pharmacist Only Medicines

must be stored in a part of the pharmacy not accessible to the public and supplied only for a therapeutic need after the pharmacist has personally taken reasonable steps to ensure that such a need exists. The Pharmaceutical Society of Australia (PSA) released the first protocol to guide pharmacists' supply of the ECP in 2003[12] and released an updated version in 2006.[13] In 2011 the PSA revised the 2006 protocol and released another updated practice guideline for levonorgestrel provision that contains the latest scientific evidence regarding its use.[14] The revisions address several factors including the time frame that levonorgestrel can be used within, which was changed to allow use up to 96 hours after intercourse, compared with the product information that indicated use within 72 hours. The revision also established that advance supply does not negatively impact on sexual and reproductive health. Lastly, there was an acknowledgement that there is limited data regarding the use of the ECP in females aged 14–16 years, and the pharmacist needs to refer to a general practitioner (GP) where advisable; however, the guideline highlighted that there was no reason for ECP use to be restricted on the basis of age.

Pharmacists' practices in Australia are variable, commonly not meeting evidence-based recommendations in the PSA guideline and resulting in women being unnecessarily declined ECP supply.[15 16] Women's experiences of obtaining the ECP from pharmacies are both positive and negative.[10] Some positive experiences reported by women include faster and more direct access, convenient location, and feeling of more control over their reproductive health, while some negative experiences reported include lack of privacy, judgmental or indifferent pharmacist attitude, cost of ECP and so on. Compounding this is the unexplained paradox between unplanned pregnancy rates and ECP availability.[17]

Access to emergency contraception, especially the ECP, is essential as it helps prevent unwanted pregnancies – an important public health goal. If the ECP is refused by a pharmacist or GP, women are placed at risk of having an unwanted pregnancy that may result in an abortion or be carried to term with long term implications for the woman and her partner. This study seeks to understand the underpinning reasons for refusal of supply that make access to this medicine unnecessarily complex.

The ECP was made available over-the-counter (OTC) in Australia with the view that it would allow women to access the ECP more quickly than from a GP, and therefore lead to a decrease in the unplanned pregnancy rate in Australia. A focus group study suggested that Australian women aged 16-30 years were in favour of pharmacy availability of the ECP, as faster and more direct access is afforded, particularly on Sundays and for women living in rural and remote locations.[18] However, a decade later, despite pharmacy availability of the ECP, it seems that Australian women's use of the ECP has neither significantly increased nor has the rate of unplanned pregnancies significantly decreased. A study conducted in Sydney that surveyed 718 women on ECP use, concluded that OTC availability and access to the ECP increased women's awareness but did not significantly increase ECP use among abortion seekers.[19]

A research study examining the attitudes and practices of pharmacists in Australia in relation to their increased role in ECP provision following the policy change to OTC availability, found that pharmacists' attitudes and beliefs play a major role in ECP dispensing.[16] Australian pharmacists had stronger and more conservative views than overseas pharmacists and 22% of the pharmacists surveyed felt it was reasonable for a pharmacist's religious faith to influence ECP supply. This seems stark compared to the survey response of pharmacists in Nova Scotia, Canada where only 1.6% of pharmacists indicated that they had not provided the ECP due to moral, religious or ethical objections.[20] In addition, pharmacists' decision to decline ECP provision in Australia is because of incorrect beliefs regarding advance prescription, the responsible use of ECP and its impact on sexual reproductive health.[16] Pharmacists also noted a number of problems with the number of differing written protocols used to dispense the ECP. In another study examining attitudes of pharmacy assistants in Northern Queensland, 22% of those interviewed felt it was reasonable for a pharmacists' religious faith to influence EC supply, while 65% of pharmacists interviewed identified young age as the most common reason for refusing to dispense EC.[21]

The first random population-based study of Australian women's ECP knowledge, attitudes and use since its availability without a prescription surveyed 632 Australian women aged 16-35 years.[10] This study found that less than half were aware that ECP was available from pharmacies without a prescription and 57% did not think they were at risk of getting pregnant. While most women felt the ECP was effective at preventing pregnancy, less than half believed that is was safe or very safe for the health of women. Of the women surveyed, 32% thought that the ECP was an abortifacient, when in fact, it delays ovulation. In addition, more than half the women reported feeling somewhat or very uncomfortable when asking for the ECP at a pharmacy and less than half thought it was the role of the pharmacist to give women advice about contraception and sexually transmissible infections at the time the ECP is obtained. Although Australian women have a high awareness of the ECP, their knowledge about how and when to use it and where to obtain it is inadequate, thus increasing their risk of becoming pregnant.[10]

A comprehensive barriers analysis to determine pharmacist- and patient-related barriers to ECP provision has not been done in Australia or overseas, although some light has been indirectly thrown onto this issue in a previous mystery caller study of a sample of pharmacies in Victoria, Australia.[15] In this study, 515 pharmacists were randomly allocated one of three scenarios when supplying the ECP and these scenarios exemplified the three major areas of change in the revised PSA guideline: outside the licensed 72-h time frame (Scenario 1); by a woman under 16 years (Scenario 2); and for future use (Scenario 3). These scenarios tested actual performance in situations for which pharmacists' self-reported responses in a previous study were inappropriate.[16] It was found that 55.4% of pharmacists tested for scenario 1 declined supply and most referred to the doctor; and 46.1% and 40% denied supply for scenarios 2 and 3, respectively. The study concluded that Victorian pharmacists' practices in relation to ECP provision are not always in line with the recommendations in the PSA guideline.

These findings are mirrored by a recent review of workforce interventions that facilitate increased access to ECP in low and middle income countries, revealing that in these countries too, provider

knowledge gaps, less than favourable attitudes and practice issues impact access to ECP. The review also highlighted the need to further examine provider performance to inform the development of appropriate workforce interventions.[22]

We therefore recommend that a formal analysis is required to understand how services such as community pharmacy should be reoriented to ensure they meet the sexual and reproductive health needs of women in Australia. Hence, in-depth interview with key stakeholders – women and pharmacists – is the proposed method to undertake the barriers analysis in this Australian based study that we have named ACCESS (ACcessing Contraception for Emergency Supply Study). In-depth interviewing will be used to develop an understanding of both individual (attitudinal, knowledge-based, skills-related, risk assessment) and organizational barriers and facilitators. Key informant interviews with pharmacists as well as key informant interviews with women living in Australia will be conducted over a two month period. The interview questions have been developed based on the Theoretical Domains Framework[23] and seek information pertaining to women's interactions with pharmacists when obtaining the ECP, attitudes and beliefs of pharmacists and women, as well as characteristics of those interviewed (gender, age, highest education level, country of birth, primary language spoken, place of residence, employment status, type of health insurance, marital status and other relevant characteristics).

The major significance of ACCESS will be the evidence that it will provide to help inform workforce interventions in community pharmacy that will address barriers to ECP access, promote increased adherence with the PSA national guideline and therefore increase supply of, and enhance access to, the ECP by women. A key focus of the study is to evaluate practice against national guideline evidence in order to facilitate ECP supply. The data from this study will be used to develop and pilot evidence-based interventions that will strengthen the capacity of pharmacists to play a more effective role in reducing unwanted pregnancies and the abortion rate in Australia.

METHODS AND ANALYSIS

Design

Exploratory qualitative study.

Scope

The study will be carried out in collaboration with 10 pharmacy sites located in Victoria, Australia. We will work with our partners to include pharmacies from various different locations/regions within Victoria as well as pharmacists from differing religious affiliations and genders. The pharmacist interview will take place at the pharmacy where they work and the women interviewees will be asked to nominate a mutually agreeable place such as the Monash University Parkville campus where the Chief Investigator is based or over the phone. The study will be carried out over a period of 12 months where after gaining ethics approval, 3 months will be designated for recruitment and 4 months toward conducting the interviews which will be followed by a few months of data analysis.

Sample size

The sample size of pharmacists we seek to interview is anywhere between 10-50 participants. The sample size of women participants we seek to interview is anywhere between 20-70 participants. The reason for such a wide range in sample size is due to the fact that since this is an exploratory qualitative study, the number of interviews is dependent on whether saturation of themes is reached and is dictated by resources.

Tool

Participants will be interviewed for between thirty minutes to one and a half hours and they will be asked open-ended questions focusing on the barriers and facilitators to accessing ECP from community pharmacies. The interview questions were formulated based on Michie's Theoretical Domains Framework[23 24] described in detail below.

Pharmacists will be encouraged to talk about internal beliefs and attitudes that may hinder them from freely providing the ECP. The 21 interview questions explore the following ten behavioural constructs in order to assess pharmacist-related barriers to ECP provision: Knowledge; skills; social/professional role and identity; beliefs about capabilities; memory, attention and decision processes; beliefs about consequences; behavioural regulation; social influences; environmental context and resources; and nature of behaviour (Table 1).

Table 1: Interview Guide for Pharmacists according to Michie's theoretical domains

Theoretical domains	Interview prompts
Knowledge	Are you aware of the PSA guideline for providing the ECP? What is your understanding of this guideline?
Skills	Have you had any training to use the PSA guideline? What kind of training? What skills are required to supply ECP to someone? Are there any specific areas of difficulty?
Social/professional role and identity	Why do you provide the ECP in your pharmacy? What are your views about the PSA guideline in general? Do you think it is an appropriate part of your role to be following this guideline? Does your ethical position affect your practice with regard to the ECP? How do you reconcile this with your duty of care?
Beliefs about capabilities	Do you find it difficult to apply the information in the PSA guideline to assess whether someone should receive the ECP? What problems have you encountered? What would help you to overcome these problems? Do you think you have the skills to provide the ECP? Do you fear that you might miss something when assessing whether someone should receive the ECP?
Memory, attention and decision processes	What thought processes might guide your decision to provide the ECP to someone?
Beliefs about consequences	In your experience of providing the ECP, have you come across problems in your population? What do you think about the evidence behind the ECP? Are there any advantages or disadvantages in trying to access the ECP via a pharmacy instead of a health clinic or doctor?
Behavioural regulation	Are there any procedures or ways of working that encourage or discourage you to provide the ECP?
Social influences	To what extent do social influences of peers, managers etc. facilitate or hinder you in… providing the ECP? applying the PSA guideline?
Environmental context and resources	Are there any environmental or resource factors that facilitate or hinder you in… providing the ECP? applying the PSA guideline? Does your pharmacy use any checklists or tools when providing the ECP?
Nature of the behaviours	What do pharmacies have to do differently to… improve awareness and access of the ECP? increase the application of the PSA guideline?

PSA: Pharmaceutical Society of Australia; ECP: Emergency contraceptive pill

Women will be encouraged to talk about the social pressures, judgements and prior experiences that may hinder them from accessing the ECP from pharmacies. The 14 interview questions regarding consumer-related barriers to ECP provision explore all the same behavioural constructs mentioned above except for one: memory, attention and decision processes (Table 2).

Table 2: Interview Guide for Women according to Michie's theoretical domains

Theoretical domains	Interview prompts
Knowledge	What is the ECP? How long after unprotected sex can you take the ECP? Where would you get the ECP from? Did you know the ECP is available without a prescription from a pharmacy?
Skills	Have you ever taken the ECP? From where? When? (Note: If they got it from pharmacy – then the question is complete. If they got it from somewhere else, and didn't know about pharmacy access - then ask would they if they could?)
Beliefs about capabilities	What can be done to increase someone's capability to access the ECP from a pharmacy?
Beliefs about consequences	Are there any advantages or disadvantages in trying to access the ECP via a pharmacy instead of a health clinic or doctor?
Behavioural regulation	We want women to know that it is easy, convenient and fast to get the ECP from pharmacies. What factors are important to you if you had to get the ECP from a pharmacy? (Prompt: Good factors include convenient location, fast service, avoidance of doctor's visit and so on; Bad factors include lack of privacy, fear of judgement and so on).
Social/professional role and identity	What skills do you think a pharmacist should have when providing the ECP? Who do you think has the skills to provide the ECP?
Environmental context and resources	Is there anything about the pharmacy environment that concerns you? What information do you think a pharmacist should be able to provide you with?
Social influences	Do you know people who have accessed the ECP from a pharmacy? What problems did they encounter? Have their experiences facilitated or hindered you in accessing the ECP?
Nature of the behaviours	What do pharmacies have to do differently to improve awareness of and access to the ECP?

Theoretical Domains Framework

Behaviour change is key to increasing the uptake of evidence into healthcare practice and improving health outcomes. A variety of psychological theories have been used to explain health care professional behaviours and cognitions across a range of behaviours and settings. However, the large number of theories and overlapping constructs presents a challenge for knowing how to select and apply theories when exploring specific behaviours. The Theoretical Domains Framework (TDF), which includes constructs from 33 behaviour change theories, was developed to make theories more accessible for implementation researchers.[24 25] TDF consists of 14 theoretical domains and exemplar questions for each to use in interviews or focus groups to provide a comprehensive theoretical assessment of implementation problems. This framework has been used by research teams across several healthcare systems to explain implementation problems and inform implementation interventions. The TDF has proved useful across a number of healthcare systems and for stronger explanatory and predictive power, and therefore increased usefulness in informing interventions to improve implementation and bring about other behaviour change.[24]

In a brief review to assess the extent of TDF-based research, 133 papers that cite the framework were identified.[24] Of these, 17 used the TDF as the basis for empirical studies to explore health professionals' behaviour. The identified papers provide evidence of the impact of the TDF on implementation research. Two major strengths of the framework are its theoretical coverage and its capacity to elicit beliefs that could signify key mediators of behaviour change. The TDF has been applied in many implementation studies.[23] Specifically, qualitative studies have concluded that the TDF was useful for the comprehensive exploration of possible explanations for suboptimal implementation behaviour and for the identification of suitable theories to further investigate those behaviours.[26] Another study documenting the development and use of the TDF stated that the TDF is arguably the most comprehensive framework for designing implementation interventions as it offers a broad coverage of potential change pathways.[27] An example of a study utilizing TDF to inform the design of its intervention is the Healthy Kids Check (HKC). The authors of this study concluded that TDF was able to classify which barriers needed to be targeted to improve

implementation of HKC services.[28] The study reported here aims to do the same by using the TDF to identify those behavioural constructs that will need to be targeted in order to increase pharmacy performance in ECP provision and ultimately women's access to the ECP.

Recruitment

The pharmacy organisations involved in this research – Australian Pharmaceutical Industry (API)/Priceline Pharmacy Group whose main clientele are women and Quality Pharmacy Group (QPG) who is focused on professional service delivery – will nominate five pharmacies each in their group as the sampling frame i.e. total of 10 pharmacies in Victoria.

Every pharmacist working at the nominated pharmacies of both pharmacy groups will be given an information pack by their organisation that will contain information about the study. Pharmacists interested in participating in the study will contact the researchers to enrol in the study.

Women participants will be recruited by API/Priceline Pharmacy Group by advertising the study in an in-store leaflet that will be provided to consumers (e.g. placed in store bags, placed on counters for consumers to self-select). QPG will select women participants from their database of approximately 70,000 pharmacy consumers. This database contains both demographic and medication-related information i.e. prescription and non-prescription medicines purchased by consumers.

Additional recruitment methods will be employed if recruiting women participants through the two pharmacy groups mentioned above generates a low response. These additional recruitment strategies will be carried out by the Policy and Health Promotion Manager from Women's Health Victoria and the Marketing and Communications Director from Marie Stopes International (partner institutions). Women's Health Victoria will recruit through their networks statewide by sending the recruitment flyer to all the managers and staff in their network of Victorian Women's Health Programs and School Nursing Programs. Marie Stopes International will aid in recruitment by posting the recruitment flyer on the "Morning After Pill" webpage on the Marie Stopes International website. Lastly, Fernwood

fitness clubs, which have exclusively female membership, will be approached to aid in recruitment by displaying the recruitment flyer at selected locations in the gym such as the reception area and women's changing rooms. Fernwood fitness managers will be incentivised with a $75 voucher for recruiting at least four women participants.

The Research Assistant (A.G., MPH, female, has experience in conducting and analysing interviews) will contact women who are selected for the study after they have been screened for the inclusion/exclusion criteria, to determine the date, time and interview location that suits them. Similarly, pharmacists selected for the study will also be contacted in order to determine a suitable date and time for the interview. No prior knowledge or characteristics about the Research Assistant were shared with the participants, or relationship with her was established, prior to the interviews.

Inclusion criteria

In order to participate in the study, pharmacists should be over the age of 18 and English should be their primary language. The women participating in the study should be between the ages 15 to 44 and English should also be their primary language.

Exclusion criteria

Pharmacists who have never refused supply of the ECP will be excluded from the study. The reason we included this criterion is because the majority of our interview questions aim at eliciting answers to situations where a pharmacist has refused ECP access. In addition, women who have not tried to access the ECP within the past year will be excluded from the study. This is because we want our participants to be able to describe in detail (with minimal recall bias) their prior experience of accessing the ECP.

Compensation

A $75 gift voucher will be given to pharmacist and women interviewees.

Data analysis

All interviews will be tape-recorded and conducted by the Research Assistant who does not intend to make field notes during or after. No one else besides the Research Assistant and interviewee will be present and repeat interviews will not be conducted. Interview data will be transcribed. Participants will receive a copy of their transcript for approval. Data from the interviews will be de-identified so that no participant names or other identifying features will appear in any form of data reporting. Instead, codes will be used to identify who the comment or quote was made by in the interview. Transcripts will be read and coded by the Research Assistant, then checked by the Chief Investigator and one other Investigator. The coding process will be deductive with the selected theoretical domains as an organising framework. If the codes validate the TDF domains they will be used to inform appropriate workforce interventions for a pilot randomised controlled trial in selected API/Priceline and QPG community pharmacies.

NVivo (version 10) will be used to manage data and code this data into TDF domains. Data will be retained in the Centre for Medicine Use and Safety at Monash University, Parkville for at least five years. Hard copies of data will be kept in a locked filing cabinet, in a locked room at the Centre. All electronic data will be stored in password-protected computers. Only the study team will have access to the data.

Possible outcome of the analysis and benefits of the study

A study on barriers and facilitators to accessing the ECP from community pharmacy in Australia has never been undertaken before. We hope the data from this study will help develop evidence-based workforce interventions to strengthen the capacity and performance of community pharmacists as key ECP providers.

Possible benefits are that the study will contribute new knowledge to the limited literature on barriers to ECP access in the Australian context and will help inform the development of evidence-based interventions in community pharmacy that will achieve the following: address barriers to ECP access,

promote increased adherence with a national practice guideline for pharmacists that benchmarks best practice in the area, and therefore increase the supply of, and enhance access to, the ECP by women.

ETHICS AND DISSEMINATION

ACCESS was approved by the Monash University Human Research Ethics Committee (CF14/3551 – 2014001868).

Participants will be assured of their anonymity and that the primary purpose of the research is to identify the barriers and facilitators to accessing the ECP from community pharmacies in Australia. Written informed consent will be taken from all pharmacists and women interviewed. All study participants will be provided with an Explanatory Statement containing information about the study, what participation involves and the contact details of the Monash University Ethics Committee so that they are able to report any concerns or complaints about the study. All respondents have the right to refuse to answer any question posed by the interviewer, and can withdraw from the study prior to having approved the interview transcript.

The risk of physical or psychological harms from participation in the study will be negligible. The study only involves interviews with participants; however, given the potentially sensitive nature of the topic, the questions in both have been designed to be as objective as possible and have been worded carefully. Participants will not be identified by name in any report or publication resulting from the study data. There are no risks for the researchers.

The results from the study will be disseminated to all researchers and organisational partners associated with this study, who will brainstorm ideas for interventions that would address barriers and facilitators to access identified from the interviews. The study participants will receive an executive summary of the research findings. In addition, the findings will be written up for publication in peer-reviewed journals in specialist, general, national or international journals.

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AUTHORS' CONTRIBUTIONS

SH is the Chief Investigator whose role is to supervise the Research Assistant, communicate with other investigators and study partners, establish partners, draft papers and disseminate findings as well as seek funding. AG is the Research Assistant and is employed for 2 days/week to manage the study by organising team meetings, preparing the ethics application, conducting all one-on-one participant interviews, drafting papers, collating findings and analysing data from the interviews. All other authors are Investigators who have contributed to the study design. SH and AG drafted the first version of this manuscript and all other authors revised it. All authors approved the submitted version.

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COMPETING INTERESTS

No, there are no competing interests.

NB: Our paper is a protocol for a qualitative research study, however, there was no relevant checklist for it & we have thus completed this one! Some of the questions are not applicable & we have indicated this below.

Table 1 Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No	Item	Guide questions/description
Domain 1: Research team and reflexivity		
Personal Characteristics		
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*
3.	Occupation	What was their occupation at the time of the study?
4.	Gender	Was the researcher male or female?
5.	Experience and training	What experience or training did the researcher have?
Relationship with participants		
6.	Relationship established	Was a relationship established prior to study commencement?
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research*
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*
Domain 2: study design		
Theoretical framework		
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*
Participant selection		
10.	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*
11.	Method of approach	How were participants approached? e.g. *face-to-face, telephone, mail, email*
12.	Sample size	How many participants were in the study?
13.	Non-participation	How many people refused to participate or dropped out? Reasons? N/A as study not conducted yet
Setting		
14.	Setting of data collection	Where was the data collected? e.g. *home, clinic, workplace*
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?
16.	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*
Data collection		
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?
20.	Field notes	Were field notes made during and/or after the interview or focus group?
21.	Duration	What was the duration of the interviews or focus group?
22.	Data saturation	Was data saturation discussed? N/A
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?
Domain 3: analysis and findingsz		
Data analysis		
24.	Number of data coders	How many data coders coded the data?
25.	Description of the coding tree	Did authors provide a description of the coding tree?
26.	Derivation of themes	Were themes identified in advance or derived from the data?
27.	Software	What software, if applicable, was used to manage the data?
28.	Participant checking	Did participants provide feedback on the findings?
Reporting		
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number* N/A
30.	Data and findings consistent	Was there consistency between the data presented and the findings? N/A
31.	Clarity of major themes	Were major themes clearly presented in the findings? N/A
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes? N/A

(ii) Participant selection: Researchers should report how participants were selected. Usually purposive sampling is used which involves selecting participants who share particular characteristics and have the potential to provide rich, relevant and diverse data pertinent to the research question [13, 17]. Convenience sampling is less optimal because it may fail to capture important perspectives from difficult-to-reach people [16]. Rigorous attempts to recruit participants and reasons for non-participation should be stated to reduce the likelihood of making unsupported statements [18].

BMJ Open

Protocol for ACCESS: a qualitative study exploring barriers and facilitators to accessing the emergency contraceptive pill from community pharmacies in Australia

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TITLE PAGE

Title

Protocol for ACCESS: a qualitative study exploring barriers and facilitators to accessing the emergency contraceptive pill from community pharmacies in Australia

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ABSTRACT

Introduction: The rate of unplanned pregnancy in Australia remains high, which has contributed to Australia having one of the highest abortion rates of developed countries with an estimated 1 in 5 women having an abortion. The emergency contraceptive pill (ECP) offers a safe way of preventing unintended pregnancy after unprotected sex has occurred. While the ECP has been available over-the-counter in Australian pharmacies for over a decade, its use has not significantly increased. This paper presents a protocol for a qualitative study that aims to identify the barriers and facilitators to accessing the emergency contraceptive pill (ECP) from community pharmacies in Australia.

Methods and analysis: Data will be collected through one-on-one interviews that are semi-structured and in-depth. Partnerships have been established with two pharmacy groups and two women's health organisations to aid with the recruitment of women and pharmacists for data collection purposes. Interview questions explore domains from the Theoretical Domains Framework in order to assess the factors aiding and/or hindering access to ECP from community pharmacies. Data collected will be analysed using deductive content analysis. The expected benefits of this study are that it will help develop evidence-based workforce interventions to strengthen the capacity and performance of community pharmacists as key ECP providers.

Ethics and dissemination: The findings will be disseminated to the research team and study partners, who will brainstorm ideas for interventions that would address barriers and facilitators to access identified from the interviews. Dissemination will also occur through presentations and peer-reviewed publications and the study participants will receive an executive summary of the findings. The study has been evaluated and approved by the Monash Human Research Ethics Committee.

STRENGTHS AND LIMITATIONS

- Contribution of new knowledge to the limited literature on barriers to ECP access in the Australian context that will help inform the development and implementation of interventions in community pharmacy to enhance access.
- Use of the Theoretical Domains Framework that includes constructs from 33 behaviour change theories, to conduct and analyse the interviews and ultimately inform the interventions.
- Recruitment challenge is an anticipated problem due to the sensitive nature of the research topic and the fear of disclosure or privacy concerns, potentially delaying the study timeline.

INTRODUCTION

The rate of unplanned pregnancy in Australia remains high and nearly half of all Australian women of reproductive age have experienced an unplanned pregnancy.[1] Australia is reported to have one of the highest abortion rates of developed countries with an estimated 1 in 5 women having an abortion.[2] The emergency contraceptive pill (ECP) offers a way of preventing unintended pregnancy after unprotected sex has occurred. It is important to note that many of the previous randomized controlled trials[3-6] demonstrating no association between ECP access or its advanced provision and unintended pregnancy or abortion rates, have mostly been conducted in post-partum or family management clinics or hospitals, and thus targeted women who were already accessing specialized forms of care. However, one trial has demonstrated that increasing access to the ECP can reduce unintended pregnancy rates during breastfeeding,[7] highlighting the importance of the culture, setting and context of such trials. Women in general health settings such as community pharmacy may have different attitudes, needs and health seeking behaviors, and the care they receive may not be as systematic or evidence-based. Further, relationships between women and community pharmacists, and women and general practitioners, may also be different, with pharmacy being challenged by the consumer's power in the commercial transaction and perceived expertise in the management of minor illness. It is therefore critical to study these populations in greater depth than what has already been investigated,[4 8] i.e. in several countries and different cultural contexts, to determine an effect of enhanced ECP access on unintended pregnancy rates.

While the ECP is safe and has no medical contraindications, there are significant barriers to pharmacy access in Australia and overseas.[9] Barriers such as suboptimal acceptance by healthcare providers and the public, and multiple financial and healthcare system barriers to use,[10] are preventing the ECP's potential for reducing unintended pregnancies and abortion rates to be realized. The only ECP in Australia, containing levonorgestrel, has been available since 2004 through community pharmacies as a 'Pharmacist Only Medicine' without a prescription. In Australia, Pharmacist Only Medicines must be stored in a part of the pharmacy not accessible to the public and supplied only for a therapeutic need after the pharmacist has personally taken reasonable steps to ensure that such a need

exists. The Pharmaceutical Society of Australia (PSA) released the first protocol to guide pharmacists' supply of the ECP in 2003[11] and released an updated version in 2006.[12] In 2011 the PSA revised the 2006 protocol and released another updated practice guideline for levonorgestrel provision that contains the latest scientific evidence regarding its use.[13] The revisions address several factors including the time frame that levonorgestrel can be used within, which was changed to allow use up to 96 hours after intercourse, compared with the product information that indicated use within 72 hours. The revision also established that advance supply does not negatively impact on sexual and reproductive health. Lastly, there was an acknowledgement that there is limited data regarding the use of the ECP in females aged 14–16 years, and the pharmacist needs to refer to a general practitioner (GP) where advisable; however, the guideline highlighted that there was no reason for ECP use to be restricted on the basis of age.

Pharmacists' practices in Australia are variable, commonly not meeting evidence-based recommendations in the PSA guideline and resulting in women being unnecessarily declined ECP supply.[14 15] Women's experiences of obtaining the ECP from pharmacies are both positive and negative.[9] Some positive experiences reported by women include faster and more direct access, convenient location, and feeling of more control over their reproductive health, while some negative experiences reported include lack of privacy, judgmental or indifferent pharmacist attitude, cost of ECP and so on. Compounding this is the unexplained paradox between unplanned pregnancy rates and ECP availability.[16]

Access to emergency contraception, especially the ECP, is essential as it helps prevent unwanted pregnancies – an important public health goal. If the ECP is refused by a pharmacist or GP, women are placed at risk of having an unwanted pregnancy that may result in an abortion or be carried to term with long term implications for the woman and her partner. This study seeks to understand the underpinning reasons for refusal of supply that make access to this medicine unnecessarily complex.

The ECP was made available over-the-counter (OTC) in Australia with the view that it would allow women to access the ECP more quickly than from a GP, and therefore lead to a decrease in the unplanned pregnancy rate in Australia. A focus group study suggested that Australian women aged 16-30 years were in favour of pharmacy availability of the ECP, as faster and more direct access is afforded, particularly on Sundays and for women living in rural and remote locations.[17] However, a decade later, despite pharmacy availability of the ECP, it seems that Australian women's use of the ECP has neither significantly increased nor has the rate of unplanned pregnancies significantly decreased. A study conducted in Sydney that surveyed 718 women on ECP use, concluded that OTC availability and access to the ECP increased women's awareness but did not significantly increase ECP use among abortion seekers.[18]

A research study examining the attitudes and practices of pharmacists in Australia in relation to their increased role in ECP provision following the policy change to OTC availability, found that pharmacists' attitudes and beliefs play a major role in ECP dispensing.[15] Australian pharmacists had stronger and more conservative views than overseas pharmacists and 22% of the pharmacists surveyed felt it was reasonable for a pharmacist's religious faith to influence ECP supply. This seems stark compared to the survey response of pharmacists in Nova Scotia, Canada where only 1.6% of pharmacists indicated that they had not provided the ECP due to moral, religious or ethical objections.[19] In addition, pharmacists' decision to decline ECP provision in Australia is because of incorrect beliefs regarding advance prescription, the responsible use of ECP and its impact on sexual reproductive health.[15] Pharmacists also noted a number of problems with the number of differing written protocols used to dispense the ECP. In another study examining attitudes of pharmacy assistants in Northern Queensland, 22% of those interviewed felt it was reasonable for a pharmacists' religious faith to influence EC supply, while 65% of pharmacists interviewed identified young age as the most common reason for refusing to dispense EC.[20]

The first random population-based study of Australian women's ECP knowledge, attitudes and use since its availability without a prescription surveyed 632 Australian women aged 16-35 years.[9] This

study found that less than half were aware that ECP was available from pharmacies without a prescription and 57% did not think they were at risk of getting pregnant. While most women felt the ECP was effective at preventing pregnancy, less than half believed that is was safe or very safe for the health of women. Of the women surveyed, 32% thought that the ECP was an abortifacient, when in fact, it delays ovulation. In addition, more than half the women reported feeling somewhat or very uncomfortable when asking for the ECP at a pharmacy and less than half thought it was the role of the pharmacist to give women advice about contraception and sexually transmissible infections at the time the ECP is obtained. Although Australian women have a high awareness of the ECP, their knowledge about how and when to use it and where to obtain it is inadequate, thus increasing their risk of becoming pregnant.[9]

A comprehensive barriers analysis to determine pharmacist- and patient-related barriers to ECP provision has not been done in Australia or overseas, although some light has been indirectly thrown onto this issue in a previous mystery caller study of a sample of pharmacies in Victoria, Australia.[14] In this study, 515 pharmacists were randomly allocated one of three scenarios when supplying the ECP and these scenarios exemplified the three major areas of change in the revised PSA guideline: outside the licensed 72-h time frame (Scenario 1); by a woman under 16 years (Scenario 2); and for future use (Scenario 3). These scenarios tested actual performance in situations for which pharmacists' self-reported responses in a previous study were inappropriate.[15] It was found that 55.4% of pharmacists tested for scenario 1 declined supply and most referred to the doctor; and 46.1% and 40% denied supply for scenarios 2 and 3, respectively. The study concluded that Victorian pharmacists' practices in relation to ECP provision are not always in line with the recommendations in the PSA guideline.

These findings are mirrored by a recent review of workforce interventions that facilitate increased access to ECP in low and middle income countries, revealing that in these countries too, provider knowledge gaps, less than favourable attitudes and practice issues impact access to ECP. The review

also highlighted the need to further examine provider performance to inform the development of appropriate workforce interventions.[21]

We therefore recommend that a formal analysis is required to understand how services such as community pharmacy should be reoriented to ensure they meet the sexual and reproductive health needs of women in Australia. Hence, in-depth interview with key stakeholders – women and pharmacists – is the proposed method to undertake the barriers analysis in this Australian based study that we have named ACCESS (ACcessing Contraception for Emergency Supply Study). In-depth interviewing will be used to develop an understanding of both individual (attitudinal, knowledge-based, skills-related, risk assessment) and organizational barriers and facilitators. Key informant interviews with pharmacists as well as key informant interviews with women living in Australia will be conducted over a two month period. The interview questions have been developed based on the Theoretical Domains Framework[22] and seek information pertaining to women's interactions with pharmacists when obtaining the ECP, attitudes and beliefs of pharmacists and women, as well as characteristics of those interviewed (gender, age, highest education level, country of birth, primary language spoken, place of residence, employment status, type of health insurance, marital status and other relevant characteristics).

The major significance of ACCESS will be the evidence that it will provide to help inform workforce interventions in community pharmacy that will address barriers to ECP access, promote increased adherence with the PSA national guideline and therefore increase supply of, and enhance access to, the ECP by women. A key focus of the study is to evaluate practice against national guideline evidence in order to facilitate ECP supply. The data from this study will be used to develop and pilot evidence-based interventions that will strengthen the capacity of pharmacists to play a more effective role in reducing unwanted pregnancies and the abortion rate in Australia.

METHODS AND ANALYSIS

Design

Exploratory qualitative study.

Scope

The study will be carried out in collaboration with 10 pharmacy sites located in Victoria, Australia. We will work with our partners to include pharmacies from various different locations/regions within Victoria as well as pharmacists from differing religious affiliations and genders. The pharmacist interview will take place at the pharmacy where they work and the women interviewees will be asked to nominate a mutually agreeable place such as the Monash University Parkville campus where the Chief Investigator is based or over the phone. The study will be carried out over a period of 12 months where after gaining ethics approval, 3 months will be designated for recruitment and 4 months toward conducting the interviews which will be followed by a few months of data analysis.

Sample size

The sample size of pharmacists we seek to interview is anywhere between 10-50 participants. The sample size of women participants we seek to interview is anywhere between 20-70 participants. The reason for such a wide range in sample size is due to the fact that since this is an exploratory qualitative study, the number of interviews is dependent on whether saturation of themes is reached and is dictated by resources.

Tool

Participants will be interviewed for between thirty minutes to one and a half hours and they will be asked open-ended questions focusing on the barriers and facilitators to accessing ECP from community pharmacies. The interview questions were formulated based on Michie's Theoretical Domains Framework[22 23] described in detail below.

Pharmacists will be encouraged to talk about internal beliefs and attitudes that may hinder them from freely providing the ECP. The 21 interview questions explore the following ten behavioural constructs

in order to assess pharmacist-related barriers to ECP provision: Knowledge; skills; social/professional role and identity; beliefs about capabilities; memory, attention and decision processes; beliefs about consequences; behavioural regulation; social influences; environmental context and resources; and nature of behaviour (Table 1).

Table 1: Interview Guide for Pharmacists according to Michie's theoretical domains

Theoretical domains	Interview prompts
Knowledge	Are you aware of the PSA guideline for providing the ECP? What is your understanding of this guideline?
Skills	Have you had any training to use the PSA guideline? What kind of training? What skills are required to supply ECP to someone? Are there any specific areas of difficulty?
Social/professional role and identity	Why do you provide the ECP in your pharmacy? What are your views about the PSA guideline in general? Do you think it is an appropriate part of your role to be following this guideline? Does your ethical position affect your practice with regard to the ECP? How do you reconcile this with your duty of care?
Beliefs about capabilities	Do you find it difficult to apply the information in the PSA guideline to assess whether someone should receive the ECP? What problems have you encountered? What would help you to overcome these problems? Do you think you have the skills to provide the ECP? Do you fear that you might miss something when assessing whether someone should receive the ECP?
Memory, attention and decision processes	What thought processes might guide your decision to provide the ECP to someone?
Beliefs about consequences	In your experience of providing the ECP, have you come across problems in your population? What do you think about the evidence behind the ECP? Are there any advantages or disadvantages in trying to access the ECP via a pharmacy instead of a health clinic or doctor?
Behavioural regulation	Are there any procedures or ways of working that encourage or discourage you to provide the ECP?
Social influences	To what extent do social influences of peers, managers etc. facilitate or hinder you in… providing the ECP? applying the PSA guideline?
Environmental context and resources	Are there any environmental or resource factors that facilitate or hinder you in… providing the ECP? applying the PSA guideline? Does your pharmacy use any checklists or tools when providing the ECP?
Nature of the behaviours	What do pharmacies have to do differently to… improve awareness and access of the ECP? increase the application of the PSA guideline?

PSA: Pharmaceutical Society of Australia; ECP: Emergency contraceptive pill

Women will be encouraged to talk about the social pressures, judgements and prior experiences that may hinder them from accessing the ECP from pharmacies. The 14 interview questions regarding consumer-related barriers to ECP provision explore all the same behavioural constructs mentioned above except for one: memory, attention and decision processes (Table 2).

Table 2: Interview Guide for Women according to Michie's theoretical domains

Theoretical domains	Interview prompts
Knowledge	What is the ECP? How long after unprotected sex can you take the ECP? Where would you get the ECP from? Did you know the ECP is available without a prescription from a pharmacy?
Skills	Have you ever taken the ECP? From where? When? (Note: If they got it from pharmacy – then the question is complete. If they got it from somewhere else, and didn't know about pharmacy access - then ask would they if they could?)
Beliefs about capabilities	What can be done to increase someone's capability to access the ECP from a pharmacy?
Beliefs about consequences	Are there any advantages or disadvantages in trying to access the ECP via a pharmacy instead of a health clinic or doctor?
Behavioural regulation	We want women to know that it is easy, convenient and fast to get the ECP from pharmacies. What factors are important to you if you had to get the ECP from a pharmacy? (Prompt: Good factors include convenient location, fast service, avoidance of doctor's visit and so on; Bad factors include lack of privacy, fear of judgement and so on).
Social/professional role and identity	What skills do you think a pharmacist should have when providing the ECP? Who do you think has the skills to provide the ECP?
Environmental context and resources	Is there anything about the pharmacy environment that concerns you? What information do you think a pharmacist should be able to provide you with?
Social influences	Do you know people who have accessed the ECP from a pharmacy? What problems did they encounter? Have their experiences facilitated or hindered you in accessing the ECP?
Nature of the behaviours	What do pharmacies have to do differently to improve awareness of and access to the ECP?

Theoretical Domains Framework

Behaviour change is key to increasing the uptake of evidence into healthcare practice and improving health outcomes. A variety of psychological theories have been used to explain health care professional behaviours and cognitions across a range of behaviours and settings. However, the large number of theories and overlapping constructs presents a challenge for knowing how to select and apply theories when exploring specific behaviours. The Theoretical Domains Framework (TDF), which includes constructs from 33 behaviour change theories, was developed to make theories more accessible for implementation researchers.[23 24] TDF consists of 14 theoretical domains and exemplar questions for each to use in interviews or focus groups to provide a comprehensive theoretical assessment of implementation problems. This framework has been used by research teams across several healthcare systems to explain implementation problems and inform implementation interventions. The TDF has proved useful across a number of healthcare systems and for stronger explanatory and predictive power, and therefore increased usefulness in informing interventions to improve implementation and bring about other behaviour change.[23]

In a brief review to assess the extent of TDF-based research, 133 papers that cite the framework were identified.[23] Of these, 17 used the TDF as the basis for empirical studies to explore health professionals' behaviour. The identified papers provide evidence of the impact of the TDF on implementation research. Two major strengths of the framework are its theoretical coverage and its capacity to elicit beliefs that could signify key mediators of behaviour change. The TDF has been applied in many implementation studies.[22] Specifically, qualitative studies have concluded that the TDF was useful for the comprehensive exploration of possible explanations for suboptimal implementation behaviour and for the identification of suitable theories to further investigate those behaviours.[25] Another study documenting the development and use of the TDF stated that the TDF is arguably the most comprehensive framework for designing implementation interventions as it offers a broad coverage of potential change pathways.[26] An example of a study utilizing TDF to inform the design of its intervention is the Healthy Kids Check (HKC). The authors of this study concluded that TDF was able to classify which barriers needed to be targeted to improve

implementation of HKC services.[27] The study reported here aims to do the same by using the TDF to identify those behavioural constructs that will need to be targeted in order to increase pharmacy performance in ECP provision and ultimately women's access to the ECP.

Recruitment

The pharmacy organisations involved in this research – Australian Pharmaceutical Industry (API)/Priceline Pharmacy Group whose main clientele are women and Quality Pharmacy Group (QPG) who is focused on professional service delivery – will nominate five pharmacies each in their group as the sampling frame i.e. total of 10 pharmacies in Victoria.

Every pharmacist working at the nominated pharmacies of both pharmacy groups will be given an information pack by their organisation that will contain information about the study. Pharmacists interested in participating in the study will contact the researchers to enrol in the study.

Women participants will be recruited by API/Priceline Pharmacy Group by advertising the study in an in-store leaflet that will be provided to consumers (e.g. placed in store bags, placed on counters for consumers to self-select). QPG will select women participants from their database of approximately 70,000 pharmacy consumers. This database contains both demographic and medication-related information i.e. prescription and non-prescription medicines purchased by consumers.

Additional recruitment methods will be employed if recruiting women participants through the two pharmacy groups mentioned above generates a low response. These additional recruitment strategies will be carried out by the Policy and Health Promotion Manager from Women's Health Victoria and the Marketing and Communications Director from Marie Stopes International (partner institutions). Women's Health Victoria will recruit through their networks statewide by sending the recruitment flyer to all the managers and staff in their network of Victorian Women's Health Programs and School Nursing Programs. Marie Stopes International will aid in recruitment by posting the recruitment flyer on the "Morning After Pill" webpage on the Marie Stopes International website. Lastly, Fernwood

fitness clubs, which have exclusively female membership, will be approached to aid in recruitment by displaying the recruitment flyer at selected locations in the gym such as the reception area and women's changing rooms. Fernwood fitness managers will be incentivised with a $75 voucher for recruiting at least four women participants.

The Research Assistant (A.G., MPH, female, has experience in conducting and analysing interviews) will contact women who are selected for the study after they have been screened for the inclusion/exclusion criteria, to determine the date, time and interview location that suits them. Similarly, pharmacists selected for the study will also be contacted in order to determine a suitable date and time for the interview. No prior knowledge or characteristics about the Research Assistant were shared with the participants, or relationship with her was established, prior to the interviews.

Inclusion criteria

In order to participate in the study, pharmacists should be over the age of 18 and English should be their primary language. The women participating in the study should be between the ages 15 to 44 and English should also be their primary language.

Exclusion criteria

Pharmacists who have never refused supply of the ECP will be excluded from the study. The reason we included this criterion is because the majority of our interview questions aim at eliciting answers to situations where a pharmacist has refused ECP access. In addition, women who have not tried to access the ECP within the past year will be excluded from the study. This is because we want our participants to be able to describe in detail (with minimal recall bias) their prior experience of accessing the ECP.

Compensation

A $75 gift voucher will be given to pharmacist and women interviewees.

Data analysis

All interviews will be tape-recorded and conducted by the Research Assistant who does not intend to make field notes during or after. No one else besides the Research Assistant and interviewee will be present and repeat interviews will not be conducted. Interview data will be transcribed. Participants will receive a copy of their transcript for approval. Data from the interviews will be de-identified so that no participant names or other identifying features will appear in any form of data reporting. Instead, codes will be used to identify who the comment or quote was made by in the interview. Transcripts will be read and coded by the Research Assistant, then checked by the Chief Investigator and one other Investigator. The coding process will be deductive with the selected theoretical domains as an organising framework. If the codes validate the TDF domains they will be used to inform appropriate workforce interventions for a pilot randomised controlled trial in selected API/Priceline and QPG community pharmacies.

NVivo (version 10) will be used to manage data and code this data into TDF domains. Data will be retained in the Centre for Medicine Use and Safety at Monash University, Parkville for at least five years. Hard copies of data will be kept in a locked filing cabinet, in a locked room at the Centre. All electronic data will be stored in password-protected computers. Only the study team will have access to the data.

Possible outcome of the analysis and benefits of the study

A study on barriers and facilitators to accessing the ECP from community pharmacy in Australia has never been undertaken before. We hope the data from this study will help develop evidence-based workforce interventions to strengthen the capacity and performance of community pharmacists as key ECP providers.

Possible benefits are that the study will contribute new knowledge to the limited literature on barriers to ECP access in the Australian context and will help inform the development of evidence-based interventions in community pharmacy that will achieve the following: address barriers to ECP access,

promote increased adherence with a national practice guideline for pharmacists that benchmarks best practice in the area, and therefore increase the supply of, and enhance access to, the ECP by women.

ETHICS AND DISSEMINATION

ACCESS was approved by the Monash University Human Research Ethics Committee (CF14/3551 – 2014001868).

Participants will be assured of their anonymity and that the primary purpose of the research is to identify the barriers and facilitators to accessing the ECP from community pharmacies in Australia. Written informed consent will be taken from all pharmacists and women interviewed. All study participants will be provided with an Explanatory Statement containing information about the study, what participation involves and the contact details of the Monash University Ethics Committee so that they are able to report any concerns or complaints about the study. All respondents have the right to refuse to answer any question posed by the interviewer, and can withdraw from the study prior to having approved the interview transcript.

The risk of physical or psychological harms from participation in the study will be negligible. The study only involves interviews with participants; however, given the potentially sensitive nature of the topic, the questions in both have been designed to be as objective as possible and have been worded carefully. Participants will not be identified by name in any report or publication resulting from the study data. There are no risks for the researchers.

The results from the study will be disseminated to all researchers and organisational partners associated with this study, who will brainstorm ideas for interventions that would address barriers and facilitators to access identified from the interviews. The study participants will receive an executive summary of the research findings. In addition, the findings will be written up for publication in peer-reviewed journals in specialist, general, national or international journals.

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AUTHORS' CONTRIBUTIONS

SH is the Chief Investigator whose role is to supervise the Research Assistant, communicate with other investigators and study partners, establish partners, draft papers and disseminate findings as well as seek funding. AG is the Research Assistant and is employed for 2 days/week to manage the study by organising team meetings, preparing the ethics application, conducting all one-on-one participant interviews, drafting papers, collating findings and analysing data from the interviews. All other authors are Investigators who have contributed to the study design. SH and AG drafted the first version of this manuscript and all other authors revised it. All authors approved the submitted version.

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COMPETING INTERESTS

No, there are no competing interests.

DATA SHARING

No additional data available.

NB: Our paper is a protocol for a qualitative research study, however, there was no relevant checklist for it & we have thus completed this one! Some of the questions are not applicable & we have indicated this below.

Table 1 Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No	Item	Guide questions/description
Domain 1: Research team and reflexivity		
Personal Characteristics		
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*
3.	Occupation	What was their occupation at the time of the study?
4.	Gender	Was the researcher male or female?
5.	Experience and training	What experience or training did the researcher have?
Relationship with participants		
6.	Relationship established	Was a relationship established prior to study commencement?
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research*
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*
Domain 2: study design		
Theoretical framework		
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*
Participant selection		
10.	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*
11.	Method of approach	How were participants approached? e.g. *face-to-face, telephone, mail, email*
12.	Sample size	How many participants were in the study?
13.	Non-participation	How many people refused to participate or dropped out? Reasons? N/A as study not conducted yet
Setting		
14.	Setting of data collection	Where was the data collected? e.g. *home, clinic, workplace*
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?
16.	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*
Data collection		
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?
20.	Field notes	Were field notes made during and/or after the interview or focus group?
21.	Duration	What was the duration of the interviews or focus group?
22.	Data saturation	Was data saturation discussed? N/A
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?
Domain 3: analysis and findingsz		
Data analysis		
24.	Number of data coders	How many data coders coded the data?
25.	Description of the coding tree	Did authors provide a description of the coding tree?
26.	Derivation of themes	Were themes identified in advance or derived from the data?
27.	Software	What software, if applicable, was used to manage the data?
28.	Participant checking	Did participants provide feedback on the findings?
Reporting		
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number* N/A
30.	Data and findings consistent	Was there consistency between the data presented and the findings? N/A
31.	Clarity of major themes	Were major themes clearly presented in the findings? N/A
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes? N/A

(ii) Participant selection: Researchers should report how participants were selected. Usually purposive sampling is used which involves selecting participants who share particular characteristics and have the potential to provide rich, relevant and diverse data pertinent to the research question [13, 17]. Convenience sampling is less optimal because it may fail to capture important perspectives from difficult-to-reach people [16]. Rigorous attempts to recruit participants and reasons for non-participation should be stated to reduce the likelihood of making unsupported statements [18].