ESC Grant application form - Project v2019 - A

Submission Date	2019-06-30 14:08:42
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A short CV of the applicant (or the principal investigator) should be provided here. (Max 250 words)	Patricia Lohr is an obstetrician and gynaecologist specialising in contraception and abortion care. Since 2007, she has been the Medical Director of British Pregnancy Advisory Service (BPAS), a non-profit organisation that performs approximately 1/3 of all abortions in England and Wales each year. Patricia has worked with the Royal College of Obstetricians and Gynaecologists (RCOG), the National Institute for Health and Care Excellence, Faculty of Sexual and Reproductive Healthcare (FSRH), and Society of Family Planning to develop clinical guidelines and is widely published in peer-reviewed journals. The focus of her current research includes quality in abortion care services and the use of a low-sensitivity pregnancy test to detect ongoing pregnancy after early medical abortion at 64-70 days of gestation. She has recently led on revisions to the RCOG curriculum on abortion care and is the Chair of a working group designing a national service specification for the management of women seeking abortion who are medically complex. Patricia received a Bachelor of Arts from the New School for Social Research, a Medical Doctorate from the University of Southern California, and a Masters of Public Health from the University of Pittsburgh. She completed her post-graduate training in obstetrics and gynecology at the Harbor-ULCA Medical Center and a Fellowship in Family Planning and Contraceptive Research at the University of Pittsburgh. Patricia is a co-founder and the current Treasurer of the British Society of Abortion Care Providers and Education Lead for the RCOG Abortion Task Force.
Submission date of this form	30-06-2019
Is the person responsible for the project different to the person named in box A	No
Title of the project	Women's opinions and experience of undergoing an ultrasound scan for gestational age before early medical abortion.

Please provide a comprehensive description of your project. The application will be assessed under the following headings: Background and hypothesis; Specific aims and objectives; a Needs Analysis with evidence of unmet need and Innovation; Approach and Methodology; ie numbers recruited, ethical approval. inclusion & exclusion criteria; Expected outcomes; Impact it will or may have in the field of contraception, sexual and reproductive health; Feasibility (1000 words)

Background and hypothesis: Medical abortion now accounts for 71% of terminations in England in Wales (DH 2018), and 86% in Scotland (ISD 2019). Most healthcare services in the UK perform ultrasonography to determine gestational age prior to medical abortion, despite guidance from the Royal College of Obstetricians and Gynaecologists (RCOG 2011) and the World Health Organization (WHO 2012) that routine use of ultrasound before abortions is unnecessary. Reasons for its persistent use are unclear but potentially include a desire to determine a precise gestational age so as not to exceed legal restrictions, to rule out extra-intrauterine pregnancy, and to document other findings such as multiple gestation or uterine fibroids.

A systematic review in 2014 reported on the accuracy of the last menstrual period (LMP) to determine gestational age up to 63 days of gestation (Schoenberg D et al. 2014). In the largest study in this review, only 1.6% of women had a gestational age by ultrasound in excess of 63 days of gestation when their LMP indicated the pregnancy was of a lower gestational age. This suggests that with the right screening criteria, early medical abortion without an ultrasound would be feasible for a large number of women. A recent demonstration project tested this hypothesis in 365 women and found that medical abortion without screening ultrasound or pelvic exam was acceptable to women and resulted in no serious adverse events that were likely to have been prevented by those tests (Raymond EG et al. 2018).

Removal of the need to obtain an ultrasound to before medical abortion increases the potential for telemedical models of abortion care, including direct-to-patient models that are delivered online. There are few studies that explore women's views on pre-abortion ultrasound. Most studies have focused on women's experiences or opinions on viewing the ultrasound before the abortion and the relationship between that activity and decision-making around abortion (Simpson JD et al. 2019; Weibe E and Adams L 2009). This qualitative study will explore the opinions and experiences of women undergoing routine ultrasound for gestational age dating prior to abortion care.

References

DHSC. Abortion Statistics, England and Wales: 2018: 13 June 2019

ISD Scotland. Termination of pregnancy Year ending December 2018: 28 May 2019

Raymond EG, Tan YL, Comendant R, Sagaidac I, Hodorogea S, Grant M, Sanhueza P, Van Pratt E, Gillespie G, Boraas C, Weaver MA, Platais I, Bousieguez M, Winikoff B. Simplified medical abortion screening: a demonstration project. Contraception. 2018 Apr;97(4):292-296.

RCOG. The care of women requesting induced abortion. London: Royal College of Obstetricians and Gynaecologists; 2011.

Schonberg D, Wang LF, Bennett AH, Gold M, Jackson E. The accuracy of using last menstrual period to determine gestational age for first trimester medication abortion: a systematic review. Contraception. Nov 2014;90(5):480-487.

Simpson JD, Brown A. Viewing ultrasound images in the abortion clinic: clients' and health care professionals' opinions. Eur J Contracept Reprod Health Care. 2019 Apr;24(2):130-133.

WHO. Safe abortion: technical and policy guidance for health systems, 2nd edition. 2012.

Wiebe ER, Adams L. Women's perceptions about seeing the ultrasound picture before an abortion. Eur J Contracept Reprod Health Care. 2009 Apr;14(2):97-102.

Specific aims and objectives:

The specific objectives of the study are to:

a. To understand women's experiences of having received an ultrasound as part of abortion care

b. To explore women's opinions on routine ultrasound in the context of abortion care

c. To examine women's views on removing ultrasound from the abortion care pathway including the potential for telemedical abortion care through online and direct-to-patient provision

d. To use qualitative findings to inform creation of a quantitative survey with which the views of a wider sample will be sought

Needs analysis (unmet need and innovation): It is unknown how women would react to provision of care without the need for an ultrasound beyond the study referred to above and how they experience the requirement for ultrasound as it is currently used. This study aims to explore women's opinions and experiences of the routine use of ultrasound for gestational age dating in the context of abortion care. The findings from this qualitative exploration will be used to generate a quantitative study to obtain feedback from a larger, more representative sample of women.

Approach and methodology: Semi-structured qualitative interviews will be undertaken in person or via telephone with approximately 24 women who have undergone an abortion at British Pregnancy Advisory Service. Using content analysis, we will analyze transcripts to explore how women experience ultrasonography in the context of abortion care, the positive and negative aspects of their experiences, and their views on removing ultrasound from the abortion care pathway. We will also explore participants interest in less-medicalised or self-sourced medical abortion through online and direct-to-patient models of care.

Ethical approval: We will seek ethical approval from the BPAS Research and Ethics Committee and NHS Research and Ethics Committee

1. Inclusion and exclusion criteria: Inclusion criteria for participants are as follows:

1. Women 18 years old and above
2. Able to give informed consent
3. Able to speak English
4. Obtained an early medical abortion at a BPAS clinic
5. Agrees to audio recording of interview

Exclusion criteria

1. Women having abortion for fetal anomaly or spontaneous fetal demise

Expected outcomes: Because this is qualitative research, we will not have preset outcomes. We anticipate potentially finding themes related to provider's treatment of women, barriers to access, desire to see or avoid ultrasound images, and dignity, among others.

Impact: Findings from this study will be used to inform the creation of a quantitative survey to obtain feedback from a wider group of women having undergoing abortion care. This study may also help other service providers and staff interested in providing medical abortion without an ultrasound to design care pathways that meet women's needs.

Feasibility: BPAS has successfully conducted qualitative research on women's views of fetal tissue disposal and is currently undertaking research on quality in abortion care. We have an experience team of researchers and internally funded staff to carry out this project. We have also accrued a database of women interested in undertaking projects with BPAS which will be used for recruitment.

Timeline: When will it start / finish? (Max 20 words)	1 September 2019-31 January 2020
Where will it take place – country / town, establishment? (Max 20 words)	We will recruit women who have had an abortion at a BPAS clinic in England or Wales.
Sector in the area of contraception, sexual and reproductive health:	Abortion Care
Is it a 'new' project?	Yes

Do you foresee any reasons (political, climatic, etc) why this project may be adversely affected? (Max 20 words)	No: we have successfully carried out research on more and less controversial topics. We have organisational support for such studies.
How much will this project cost?	16998.00 Euro
How much are you requesting from ESC?	6681.00 Euro
Are there other partners or organisations supporting this same project?	Yes
If YES - name the other partners who will support this project (Max 20 words)	British Pregnancy Advisory Service will provide salary support for research team members and all paper supplies, telephony, postage and equipment.
Have you already obtained any funding?	No

Budget

List each Item required for this project	Amount requested from ESC	Amount requested from additional partner	Name of partner	Any Comments
Consultant support for analysis	2786.00	0		5 days at 557 Euro (including VAT)
Dedoose software subscription	267.00	0		4 month subscription for 5 researchers
Remuneration for participants	528.00	0		20 Euro per person x 24
Travel for interviews	1320.00	0		Estimate 50 Euro per interview x 24
Transcription costs	1780.00	0		Estimate 89 Euro per x 24
Staffing	0	10094.00	BPAS	2 PIs (5% time), 1 research nurse (10% time), 1 research officer (10% time), 1 research assistant (10% time)
Postage, telephony, equipment, paper supplies		223.00	BPAS	

Total amount requested from ESC	6681.00 Euro
Total amount requested from partner(s)	10317.00 Euro
The ESC may not be in a position to fully fund all applications; you must indicate whether / how part funding may impact your project. (Max 100 words)	We will seek funding elsewhere and/or attempt to carry out the study with fewer staff, but will increase study duration.
Who will oversee the budget & keep accounts? Provide name, title, contact number and email address	Kirsty Reynolds, Accounts Officer, BPAS Head Office, 20 Timothy's Bridge Road, Stratford upon Avon CV37 9BF, Tel: +44(0)3454655050; kirsty.reynolds@bpas.org
If you or your department has received funding from ESC for a project or course before, please give details of the date of funding, contact person and title of project or course.	2009 First course on second and third trimester abortion, recipient Patricia Lohr 2010 Second course on second and third trimester abortion, recipient Patricia Lohr

I/We, as responsible agents for this project, agree to the following 10 points:

	yes
I/We agree that all monies will be spent appropriately	✔
I/We agree to work with the nominated Mentor	✔
I/We agree to advise you at the earliest time if this project is delayed or cannot be completed	✔
I/We agree to provide an interim report(s) part way through the project and a final report to the ESC within 6 months of the end of the project.	✔
I/We agree to provide the ESC with an interim budget(s) and a detailed budget at the end of the project. NOTE funding will be awarded in stages and will be dependent on appropriate reporting.	✔
I/We agree to provide receipts for monies spent if requested.	✔
I/We agree that if we need to make any significant changes to the duration, contents or funding of the project after it has been awarded, I/we will advise the nominated mentor.	✔
I/We agree that any unspent money will be returned to the ESC	✔
I/We (the applicant) agree to acknowledge the ESC as a donor in any publications, submission of abstracts and oral communications resulting from this project. Please inform the ESC Office where and when the data is to be presented and/or published and note that ideally any manuscript should be sent to the ESC journal in the first instance.	✔
I/We agree to remain fully paid up ESC member(s) until the final grant report is submitted	✔