Research Protocol

Title: Evidence base to inform health service configuration for abortion provision

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ABSTRACT

Research question

How can health services be best configured in response to the decriminalisation, deregulation and de-medicalisation of abortion to provide quality, evidence-based care for women in the UK?

Background:

One in three women in the UK have an abortion at some point in their lives. Significant changes to the nature and context of abortion provision are taking place in the UK which will impact on patients, practitioners and policy makers. Challenges persist in relation to abortion provision, even in countries with few legal constraints, including insufficient human resources and suboptimal training, and for women, experience of stigma, delay in obtaining appointments and negative staff attitudes. [1][2][3][4]

Aims and objectives

Our aim is to provide an evidence base to inform optimal configuration of health services and systems in response to current and future changes in the legal and regulatory context of abortion provision in the UK. The objectives are to: i) collate, synthesise and summarise recent evidence for innovative models of abortion care with the potential to enhance access, quality of experience and cost-effectiveness; ii) explore the potential for beneficial and harmful consequences of current trends in abortion provision and identify implementation strategies to harness positive outcomes of current developments and mitigate adverse outcomes; iii) assess the potential of General Practitioners (GPs) and non-clinician providers in abortion provision, their education and training needs and their views on innovations in care; iv) elicit women's views on current experiences of abortion and on preferences for abortion techniques, models of care and sources of support; v) consult decision-makers on the range of innovative abortion practices and procedures and on the potential feasibility, acceptability and sustainability of their adoption in UK health services and systems.

Methods

The study will be guided by 'Diffusion of Innovation' theory [5][6] which focuses attention on the qualities of novel strategies, the characteristics of potential adopters, and their 'fit' with the context in which they might be introduced. A horizon-scanning study is planned with five integrated components: i) a realist review to generate evidence to guide the effective choice and implementation of novel approaches to abortion provision; ii) Country-based case studies (Canada, Australia and Sweden) identifying transferable lessons for UK policy and practice; iii) A survey exploring attitudes, receptivity to and preparedness for changes in abortion provision amongst healthcare practitioners; iv) Qualitative research with women with recent experience of different methods of abortion and

service delivery models to explore their views and experiences of abortion provision, care and support; v) Round table discussion groups with key stakeholders to generate/share expert knowledge on the optimal configuration of abortion services, and the feasibility and applicability of novel strategies and interventions in the UK.

Timelines for delivery: Two years

Anticipated impact and dissemination:

The proposed research has the potential to improve the health and well-being of women seeking abortion, cut NHS costs, improve NHS services and increase job-satisfaction amongst practitioners. Dissemination will be guided by the needs of different audiences, including the general public, healthcare professionals, academics, policy makers and commissioners, and non-government organisations.

Background

Improving access to safe abortion is an essential strategy in the provision of universal access to reproductive health care. An estimated one in three women in the UK have an abortion at some point in their lives. Significant changes to the nature and context of abortion provision are taking place in the UK. Firstly, changes to the legislative framework in which abortion is provided seem imminent.1 Pressure is mounting for the *decriminalisation* of abortion, on the grounds that the procedure should be treated in the same way as other routine medical procedures. Secondly, pharmacological and technological advances are contributing to the *demedicalisation* of abortion provision. [7] The advent of medical abortion, involving administration of mifepristone and misoprostol, has repositioned abortion as a health rather than a legal issue. Medical abortion now accounts for 70% of abortions carried out in Britain. Thirdly, there have been changes in the regulatory frameworks around abortion. By December 2018, the UK governments had approved *deregulation* of abortion, such that the second abortion medication, misoprostol, could be taken by women at home provided it had been prescribed in a clinic.

The moves are accompanied by new directions in thinking about abortion provision. Practitioners and policy makers are reconsidering clinical pathways and models of care for both surgical and non-surgical abortion. [1][8] Issues are being raised about, for example, the upper gestational limit for early medical abortion and the appropriate location for procedures.[9][10][11] Discussion is taking place about what support is needed by women managing their own abortions at home. The roles of other health professional cadres such as pharmacists, nurses and midwives as abortion providers are being reconsidered.[1][12][13][14] The discussions reflect broader trends within 21st century health systems: recognition of the need for patient-centred approaches, shared decision making in health care, and supported self-management. [15][16]

The changes taking place will impact on the way abortion services are provided in the UK. Medical abortion has radically altered the way in which women access and experience abortion, resulting in procedures occurring at increasingly earlier gestation. The recent change in the regulations about where the medication can be taken further transforms abortion from a medicalised procedure to a self-managed experience at home, with implications for provision of care and support for women. Decriminalisation would impact additionally on provision, accelerating the trend towards earlier abortions and creating the possibility that early medical abortion could be entirely delivered through self-management.

The potential benefits of current developments to women, practitioners and the NHS in terms of a safe, effective and positive abortion experience are considerable. De-medicalisation of abortion has advantages for health care and provision, increasing women's autonomy over the procedure, normalising abortion and reducing stigma, cutting costs through task-sharing by other providers, and

ensuring earlier abortion by removing obstacles in the care pathway. For the benefits to be realised, significant challenges need to be addressed. These include organisational barriers, the adequacy and preparedness of the workforce, equality of access, required support for women considering or opting for an abortion and the setting of standardised criteria for quality of care.

The planned study will compile the evidence base needed to address these challenges in the UK by reviewing the evidence on innovative strategies for provision and where and how they work; examining the impact of such changes elsewhere, consulting women and health care professionals, collating examples of good practice and mapping the views of stakeholders on their likely acceptability, applicability and feasibility. Comparisons of clinic-based administration of mifepristone and misoprostol with self-management (completing the medication at home) have shown no difference in rates of efficacy or major adverse events. [17][18] More is known, however, about bio-medical than psychosocial outcomes of different modes of abortion provision.
Whilst a significant body of research is building on novel approaches to abortion provision, there remain important gaps in the evidence base. A UK focus is needed in addressing shortfalls in evidence.

Objectives

The aim of the research is to provide an evidence base to inform measures to ensure the optimal configuration of health services and health systems in response to current and future changes in the legal and regulatory context of abortion provision in the UK.

The objectives are to: i) summarise recent evidence for innovative models of good practice in abortion provision; ii) explore the possible consequences of current trends in abortion provision and identify implementation strategies to harness positive outcomes and mitigate adverse outcomes; iii) assess the potential of non-specialist healthcare practitioners to provide abortion, together with the necessary education and training needs; iv) elicit women's views on current experiences of abortion and on preferences for abortion techniques, models of care and sources of support; v) consult decision-makers on the range of innovative approaches to abortion provision and their potential feasibility, acceptability and sustainability in the UK.

Design and theoretical framework

A descriptive 'horizon scanning' study will be carried out, drawing on existing literature, comparative evidence, and the views, experience and practice of policy makers, practitioners and women to ensure that services are optimally configured to adjust to upcoming changes.

The study will be guided by 'Diffusion of Innovation' theory which focuses attention on the qualities of novel strategies, the characteristics of those who might adopt them, and their 'fit' with the context into which they might be introduced. [6] In this context, innovation is defined as strategies

to drive transformational change in health systems and services, including novel ways of working, organisational reforms, and advances in clinical methods and technological approaches.

The study comprises five interlinking components:

i) A realist review to generate evidence to guide the effective choice and implementation of novel approaches to abortion provision.

ii) Qualitative research with women with recent experience of different abortion procedures and service delivery models exploring views and experiences of abortion provision, care and support;

iii) Survey exploring attitudes, receptivity to and preparedness for changes in abortion provision amongst healthcare practitioners;

iv) Round table discussion groups with key stakeholders to generate/share expert knowledge on the feasibility and applicability of novel strategies and interventions in the UK.

Plan of investigation

COMPONENT 1: REALIST REVIEW

We will carry out a systematic, theory-driven approach to evidence synthesis of published data to establish the design and outcomes of interventions, the mechanisms by which they are achieved and in which contexts.[6] Key questions are: 'What works, how and in what circumstances?' A realist review will allow us to take account of the fact that interventions, especially complex interventions, may be more effective in some contexts than others and that outcomes may be both intended and unintended. whose effect size is rarely constant but varies with setting, being crucially dependent on contextual factors such as institutional setting, health service and health system organisation, level of health care funding, workforce issues, public health traditions and cultural norms and values. The focus of the realist review on mechanism of action of interventions for specific populations, together with its ability to combine qualitative and quantitative evidence, is well suited to the pragmatic focus of our work on complex service delivery and policy development and will further our objective of exploring which innovative interventions documented in the literature might be applicable to the UK context.

Our review will follow the RAMESES quality and publication standards for realist reviews. [19][20]

Our plan of investigation consists of Pawson's five steps [21]:

Step 1: Locate existing theories. The aim of this step is to identify existing theories on how novel approaches to abortion delivery, particularly those that involve self-care, were expected to work, for whom, in what circumstances. We are also interested in when they are not effective and in any unintended outcomes that they might have. We will consult with key content experts, our collaborators on this grant, who bring together an exceptional group well qualified to support this

stage. In addition, we will informally search the literature to identify existing theories. From these we will build an initial programme theory for testing in the review. An example of a part of our programme theory might be 'women having abortions in the UK value being actively involved in their care and therefore they will engage in self-care opportunities as part of NHS abortion services'.

Step 2: Searching the literature. We will start with broad inclusion criteria and refine these as more data is needed for programme theory testing. We will focus on the literature that helps us to test the theories identified in step 1, for example, evaluations of home abortion services. We will develop, pilot and refine our search strategy with the input of a librarian. We will search for both published and grey literature and not exclude by study type.

Step 3: Document selection. Documents will be selected on the basis of relevance (whether data can contribute to theory building and/or testing) and rigour (whether the methods used to generate the relevant data are credible and trustworthy).

Step 4: Extracting and organising data. We will develop and pilot a data collection tool to enable us to extract the data in a standardised format. We will use a qualitative software analysis tool, NVivo to help us organise the data for retrieval and analysis.

Step 5: Synthesising the evidence and drawing conclusions. Data analysis will use a realist logic of analysist to make sense of our initial programme theory. We aim to test (that is confirm, refute or refine) aspects of the initial programme theory we identified in step 1 using the data from within included documents. We will use interpretive cross-case comparison to understand and explain the outcomes described in the literature. During the review we will move iteratively between the analysis of particular examples, refinement of our initial theories and further searching for data to test aspects of our programme theory.

By the end of this process we will have developed and refined our programme theory. Emerging themes are likely to include innovative approaches to: addressing workforce capacity (including expanding involvement in abortion provision, building capacity, meeting training needs, and influencing professional attitudes towards abortion); providing support to women in self-management and self-use of medical abortion; providing alternative models of abortion provision; tackling stigma as a barrier to service access; the use of digital technologies aimed at optimising abortion provision; and the creation of quality standards. For each of these themes, we will examine contextual influences that may have influenced the mechanisms to generate the outcomes of interest. We will take an iterative approach to this work. The evidence synthesis will shape the research instruments for subsequent research components and, conversely, as issues warranting

further exploration emerge from research within those components, new terms will be added to the review.

COMPONENT 2: COUNTRY-BASED CASE STUDIES

We will examine the experience of countries in which abortion has been decriminalised (Canada, Australia and Sweden) identifying transferable lessons for UK policy and practice. The focus will be on changes to health service configuration following decriminalisation; intended and unintended outcomes and innovative ways to address them. We will document strategies to increase equality of access, interventions to reduce stigma and to increase public and health professional awareness of changes in health policy and regulation; strategies for monitoring abortion where recording can no longer be mandated; training and professional education; support for shared care and self-management, including ehealth interventions; the role of primary care and other healthcare providers, management of conscientious objection to abortion and initiatives aimed at providing quality of care standards.

There are three strands to this component: i) a search of documentary sources including reports, grey literature, policy documents and guidelines, and peer-reviewed literature aimed at gathering country-specific evidence on the process of decriminalisation and deregulation. ii) Analysis of routine data to examine time trends and area-related differences in abortion rates, types of procedure, gestational age and demographic characteristics of women undergoing abortion and iii) interviews with key stakeholders, including service providers, policy makers, non-governmental organisations, government officials, including representatives from Health Ministries, surveillance agencies, national associations of key practitioners; policy and law makers; and academics (n=30 across each country). The aim of all strands of this component is to understand and contextualise unintended and intended consequences of decriminalisation, facilitators and barriers to implementation and novel approaches to abortion provision. Time series approaches will be used to analyse the routine data. Thematic analysis of the interview data will use NVIVO qualitative coding software.

COMPONENT 3 SURVEY OF HEALTHCARE PRACTITIONERS' VIEWS ON ABORTION PROVISION

We will survey attitudes towards decriminalisation, deregulation and de-medicalisation of abortion, and receptivity to and preparedness for changes in provision among health care practitioners.

Recruitment: The questionnaire-based postal survey will recruit practitioners who could have a role in providing abortion care and support: GPs, practice nurses, community midwives, Sexual and Reproductive Health (SRH) doctors and nurses and pharmacists. Services will be randomly identified in a two-stage process. First, local authorities will be randomly selected using probability proportional to (population) size sampling. Second, a random postcode generator

(www.doogal.co.uk) will be used to identify community-based services within the selected local authorities. Postcodes will be entered into the 'find a service' in the NHS website to identify the nearest general practice, SRH clinic, abortion provider and pharmacies to the randomly generated postcode. Practitioners within each service will be identified from website staff profiles and via contacting service managers and local Sexual Health Leads. For prevalence estimates of around 50% for the primary outcomes of interest, a final completed sample of 1200 will be needed to give precision of +/- 3% around this estimate. Using information from websites to obtain an idea of numbers likely to be achieved and from clinical experience, we anticipate recruiting around 40 practitioners for each postcode.

Data collection: The questionnaire, together with an information sheet explaining the purpose of the research will be posted to all identified practitioners within each service. To maximise response rates we will use strategies we [22] and others [23] have found effective in achieving this. They include: including an unconditional incentive (£10 book token) as a thank you in the first mail out; ii) following up with two mailings and two subsequent phone calls and iii) limiting the questionnaire to a maximum of two pages. Data collected will include professional role and demographic characteristics, attitudes towards decriminalisation, deregulation and demedicalisation of abortion and its integration into routine health care, their potential role in this and the implications for professional training and workload.. Survey questions will be guided by findings from the realist review and existing surveys of practitioner attitudes and practices. Responding to the survey will be taken as implied consent. No information will be collected which could be linked to personal identity; contact details will be kept securely and separately from survey responses.

Analysis: Data will be entered and analysed in Stata 16. Responses will be analysed by professional role, age, gender, religion and region (administrative and urban/rural). The analysis will take account of clustering within health service sites.

COMPONENT 4: IN-DEPTH INTERVIEWS WITH WOMEN WITH RECENT EXPERIENCE OF ABORTION

We will carry out qualitative research with women across the UK with recent experience of abortion to explore their experience of provision, care and support, on how this might be improved and on the likely effectiveness and acceptability of novel interventions.

Recruitment: A purposive sample of 30-40 women aged 16+ who have recently (last six months) undergone a medical or surgical abortion within the last 6 months for reasons other than fetal anomaly. Recruitment will take account of the need to represent different chronological and gestational ages, procedures and site (home or clinic-based). Recruitment strategies will reflect abortion method. Within facilities (BPAS and Marie Stopes), clinical staff will direct clients to the on-

site team researchers for further discussion and study consent. In addition, project information and contact details will be placed in clinical units and women interested in participating will contact the researchers. Women self-using abortion medication will be recruited with the help of women's services, including Women on Web and Women Help Women. Those having hospital-based abortions will be recruited at initial assessment from Chalmers, Edinburgh, where 80% of women requesting abortion in the region are seen, and through the academic gynaecology department at Imperial College, London. PPI collaborators will help with recruitment strategies and design of materials.

Settings: i) The main independent-sector providers commissioned by the NHS to deliver abortion care in England and Wales: British Pregnancy Advisory Service (BPAS) and Marie Stopes; ii) Sexual Health in Northern Ireland iii) NHS abortion services in Edinburgh and London; iv) on-line services facilitating self-sourcing of abortion medication.

Data collection: In depth interviews using semi-structured interview guides will be carried out face-to-face or by video-conferencing software according to participant's preference. The interviews guide will be informed by themes emerging from Components 1 and 2, but is likely to include reflections on the abortion experience, quality of care; perceptions of different methods of abortion and models of provision; influences on method choice; experience of self-management; and extent and adequacy of support received; views on the involvement of GPs and non-clinician providers in abortion provision; and views on novel interventions and models of service provision drawn from C1 & 2.

Thematic analysis using NVIVO qualitative coding software, concurrently with data collection allowing modification of the interview schedule to take account of emerging themes. The analysis framework will be developed using a priori research questions but will also be conducted inductively from the data collected to capture unanticipated themes, agreed jointly between team members and PPI collaborators.

RESEARCH COMPONENT 5: CONSULTATION WITH KEY STAKEHOLDERS

Design: 'Round table' discussions will be carried out, triangulating the views of diverse groups of policy makers, providers, PPIs and researchers to gauge the feasibility and applicability in the UK context of novel interventions and to guide necessary next steps to ensure readiness for new directions in provision.

Participants: ≥ 8 stakeholders from different sectors and with different professional roles will attend 'Round table' discussion groups attended aimed at obtaining and triangulating multiple perspectives and viewpoints on aspects of abortion provision. Participants will include policy makers, commissioners, service providers, PPI representatives and researchers across the UK with a

responsibility or interest in abortion. Recruitment will be purposive via professional colleges and associations, government and third sector agencies and academic institutions.

Data collection: Each group will be asked to discuss the implications of one of the themes of the evidence syntheses summaries: Provider Training; Expansion of HCP roles; Support for Self-Management in Medical Abortion, the Role of Digital Interventions, and Creating Quality of Care Standards. The composition of the groups will reflect the topic of the themed evidence syntheses. Two of the participants at each round table discussion will be PPIs.

Data collection: Summaries of the evidence syntheses drawing on research components 1-4 (Table 1, page 12), each focussing on one of the key themes identified and selected to match participants' area of expertise and role, will be mailed to participants in advance of the consultation process. Participants will be invited to discuss the feasibility and acceptability in the UK context of the novel approaches to abortion provision on which we have collated evidence, and of factors helping and hindering their adoption. Key attributes of Diffusion of Innovation Theory will be used to structure discussions: ie. relative advantage: whether benefits over current practice are seen in the suggested innovations; complexity: how straightforward implementation is likely to be; what contextual features might help or hinder their adoption and sustainability in the UK; whether the innovations lend themselves to experimental evaluation; and the extent to which the innovation provides tangible results. Discussions will be recorded with the permission of participants. Each group will be convened by two members of the research team, one guiding discussion the other taking notes. The roundtable discussions will take place at the LSHTM with participants attending in-person, or by Zoom, depending on COVID-19 public health guidelines current at the time.

Data analysis: Data will be analysed using a Framework approach, charting the data and paying attention to differences in perspectives, preferences and priorities between participants. Data from this and previous components will be used to generate hypotheses about the feasibility and acceptability of adoption in the UK of a range of novel approaches to abortion provision.

Integration of research components

The study is designed so that each research component draws on, and adds to, knowledge gained in the previous one. (Figure 1) To compile the evidence syntheses which will form the basis of discussion in Component 5, the Stakeholder Consultation, we will draw on the evidence from all previous components. The final stage, the compilation of themed evidence syntheses from all five components, incorporating the reflections of key stakeholders, will represent the collective knowledge gained through the entire process. Thus, though the scheduling of different components is largely sequential it is also iterative, enabling reciprocity of perspectives.

Figure 1 Inter-relationships between research components

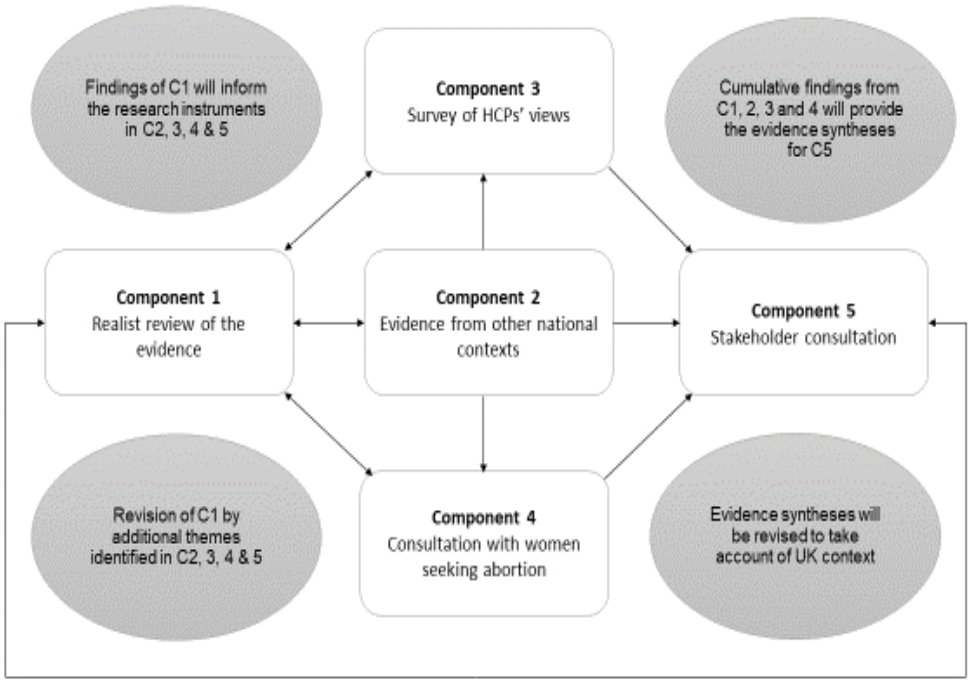

Table 1 Summary of peer-reviewable and policy-related outputs from the study

Themed evidence syntheses					Research Components	Egs of component-specific papers for peeriew
Provider Training	Expansion of HCP roles	Support for self-management	Digital interventions	Quality standards		
↓	↓	↓	↓	↓	Component 1 -> *Realist review*	*eg. Innovative approaches to optimal abortion provision: the findings of a realist review*
					Component 2 -> *International perspective*	*eg. Abortion provision post-decriminalisation; lessons from Canada, Australia and Sweden*
					Component 3 -> *HCP survey*	*egs. HCP's views on extending their role in abortion provision . HCP's views of on training needs in abortion provision*
					Component 4 -> *Women's views*	*egs. Women's preferences for abortion methods in the UK Women's views on support for self-management in the UK*
Draft summaries for consultation with stakeholders					Component 5 -> *Stakeholder consultation*	*eg. Improving abortion provision in the UK: the views of key stakeholders*
Final summary documents and papers incorporating stakeholder views, for wider dissemination; final papers for peer-review						

NB. *Themes listed are indicative and component-specific papers for peer review provisional examples; a definitive list will be informed by the scoping exercise (Component 1)*

Analysis and interpretation of data from all components: Data from Components 1-4 will be analysed discretely and reported at the relevant time points throughout the study. The process of using the accumulated evidence from all components to answer specific questions of relevance to the study will

occur not at the stage of initial analysis but at the stage of interpretation. It will involve a further level of data synthesis, in the 'triangulation protocol'. [24] This will consist in constructing a "convergence coding matrix" to display findings emerging from each component of the study to compare findings across the different components. Each matrix will represent a different key theme, we envisage around 5-6, to examine the degree of convergence, complementarity, and divergence across the findings. This work will be done by small groups of team members each devoted to one specific theme.

Outputs and dissemination

Research outputs will be guided by the needs of different audiences, including the general public, healthcare professionals, academics, policy makers and commissioners, and non-government organisations. Primary audiences are policy makers, regulatory agencies and professional bodies. The main output will be a policy and service relevant review of evidence to facilitate the modernisation of abortion services in responses to changes in legislation, regulation and clinical innovation, exemplifying approaches and strategies to abortion provision, what features promote or hinder their use and success, and an understanding of the contextual factors which may influence their adoption in the UK.

Papers reporting on the study will be published open-access in peer-review journals. Authorship will be on the basis of meeting the criteria recommended by the International Committee of Medical Journal Editors. After the publication of our main findings, and within three years of the start of the study, the data set will be available on request from the corresponding authors.

Discussion: Impact of the research

The proposed research has the potential to improve the health and well-being of women seeking abortion, cut NHS costs, improve NHS services and increase the job-satisfaction of health care professionals. As the legal and regulatory barriers change, the study findings will have a direct impact on clinical policy and practice by setting out the options for innovation that these changes afford, collating the evidence to support innovation in improving abortion provision, predicting the barriers and facilitators to their adoption and suggesting strategies to mitigate hindrances. The findings will help professional bodies, regulatory agencies and commissioners to create guidance for health care practice, criteria for establishing quality control and frameworks for monitoring and surveillance.

Evidence on the feasibility of involvement of non-specialist providers in surgical and non-surgical methods of abortion and their training needs is, in the short term, likely to inform new curricula to equip health care professional for a possible expansion of their role. In the longer term it is likely to address shortfalls in the service workforce by enabling a wider range of practitioners to carry out procedures. In so doing it is likely to simplify, and so shorten, care pathways, increasing the likelihood of an early abortion and so reducing the risks of complications, pain and distress which increase with gestational age. Benefits for

practitioners include increased levels of confidence and the opportunity to be more involved in provision, greater job satisfaction. For all practitioners, shorter care pathways will ease qualms relating to later abortion and, for those with ethical concerns about abortion provision, the opportunity to delegate to other colleagues.

In the context of home completion of medical abortion, a better understanding of the merits of different models of provision and care is likely to increase patient satisfaction by widening the choice as to how, where and by whom care is provided. Increasing uptake of self-managed medical abortion is likely to save time and money; increase patient satisfaction and produce efficiencies. Greater understanding of women's support and counselling needs will lessen the chances of adverse outcomes such as infection, incomplete pregnancy and repeat abortion. The identification of a wider range of effective interventions and their potential suitability to the UK context could, in the short term, lead to the development and testing of interventions to mitigate barriers to preferred care, and in the longer term increase women's autonomy. Increased understanding of women's needs may also inform how to improve clinic-based or surgical services in restricted settings, lessening the stigma around abortion by treating it as other health issues and so normalising the procedure.

Benefits for the NHS include expansion of the workforce by extending the range of providers and cost savings through shared care and greater involvement in routine procedures by GP and non-clinician practitioners. Identifying interventions which increase uptake of self-managed medical abortion will result in savings in staff costs, as will increasing opportunities for shared care and task sharing, since procedures previously exclusively carried out by more highly paid clinical staff may be carried out by other providers. Increasing the uptake of digital-first and other aids to shared care will also result in efficiencies. Interventions to shorten care pathways would result in significant cost savings; it has been estimated that a reduction of one day in the average waiting time would save the NHS £1.6 million per year.

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