SAGE Research Methods Cases

Medicine & Health

Submission for Consideration

Case Title

A Mixed Method Study of the views of Women, in a General Practice (primary) healthcare setting, regarding Intrauterine Contraception

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Contributor Biographies

Dr Susan Walker is an academic with a background of working in the NHS as a GP. She teaches in the field of contraception and sexual health at Anglia Ruskin University and is interested in the intersection of clinical and social factors, especially the effect of gender and sexuality on health behaviors and experiences. Her main research interest is attitudes and behavior in the area of contraception and sexual health.

Her PhD explored the effect of gendered body image on contraceptive outcomes, which she completed at the University of Cambridge in 2010.

Published Articles

Walker, S., Newton, V. L., Hoggart, L., & Parker, M. (2018). “I think maybe 10 years seems a bit long.” Beliefs and attitudes of women who had never used intrauterine contraception. *BMJ Sexual & Reproductive Health*. https://doi.org/10.1136/bmjsrh-2017-101798

Walker, S., Newton, V., Hoggart, L., & Parker, M. (2016). Predictors of non-use of intrauterine contraception among women aged 18–49 years in a general practice setting in the UK. *Open Access Journal of Contraception*, *Volume 7*, 155–160. https://doi.org/10.2147/OAJC.S116994

Abstract

Mixed methodology can be an appropriate methodology in healthcare settings, particularly where the focus of interest is on the opinions, feelings and experiences of healthcare users. This case outlines the use of a sequential exploratory mixed methods approach, used to examine the views of women, recruited in a primary care setting, regarding intra-uterine contraception. This case study will consider why a mixed-methods approach was chosen for this research. It will also describe the practical considerations involved in the recruitment and consent of participants, which are relevant in the healthcare context. It describes the gathering and analysis of both qualitative and quantitative data, and how each set of data can be used to answer the research problem. It will provide some tips for minimizing common research pitfalls, and highlight some areas for discussion and decision, for new researchers who are undertaking this kind of research for the first time.

Learning Outcomes

1. Understand when a mixed-method approach may be suitable for their own research problem
2. Anticipate some of the ethical challenges involved in healthcare research.
3. Formulate a practical approach to the gathering and analysis of both quantitative and qualitative data, and how these may be used together to address a research question

# Case Study

## Project Overview and Context

### Background – the research question

We were interested in why intra-uterine contraceptive methods (IUC), (methods where a copper or hormone containing device is inserted into the womb), are used by only a minority of women in the UK, despite being safe, effective and long-lasting methods (HSIC 2019).

Intra-uterine methods have many advantages over shorter acting oral methods of contraception, in that once they are fitted, they last from 3-5 years, but can be removed at any time, on request. They remove the need to remember to take a pill or use a condom, and so they are more effective than pills or condoms in typical use (Trussell 2011). They have fewer contraindications and risks than the combined oral contraceptive pill, because they do not contain estrogen, and so are suitable for many women for whom the combined pill is contra-indicated. This includes women who have had a clot, women with risk factors for cardiovascular disease, older or heavier smokers and women who suffer from migraine with aura (FSRH 2015).

Despite these advantages, previous research has shown that many women have anxieties about using intra-uterine contraception, and may encounter practical barriers to using the methods. We also knew, from previous research, that there were some persistent myths and misconceptions around intra-uterine contraception that were often cited by women as reasons for not choosing intrauterine contraception (Michie 2014). Since 2005, the UK Department of Health has encouraged the promotion of long-acting methods, including IUC over shorter acting methods like pills or condoms, because of their greater efficacy and cost-effectiveness (NICE 2005). This involves an emphasis on practitioners offering IUC and providing some information about it, to every women requesting contraception.

We designed the research to address the question of the acceptability of intrauterine methods to women, a decade after the initiation of this approach, and to explore the nature and prevalence of women’s concerns and opinions about IUC.

### Setting

In the UK, all UK citizens are eligible for care from a general practice (GP), and contraceptive methods are supplied free of charge, from both general practice and community clinic settings. Many quantitative and qualitative data, from the UK and elsewhere, are derived from community contraceptive clinics. However, these serve a somewhat different population to the general population of women who require contraception. French et al. (2018) and previous research, has shown that the majority of women in the UK obtain their contraception from their general practice (primary care provider), so we decided to base our research in this setting. This allowed us to understand the acceptability of IUC in a somewhat under-researched setting.

### Research Aim

Our primary research objective was to explore the acceptability or unacceptability of intrauterine contraception for women in a general practice context, and the reasons underlying their views on the method.

### Funding

We were funded for this project by Bayer PLC, who manufacture intra-uterine contraceptive devices.

## Methodology

### Strengths and Weakness of Qualitative Research

Research that seeks to understand the views and opinions of healthcare users typically uses a qualitative methodology, because this methodology is focused on the human experience. The more open responses allowed in qualitative methods allow the participants to nuance and explain their responses. Qualitative approaches are often said to provide a “rich and thick”, subjective description of the topic, from the participants’ points of view. Since we were interested in the acceptability of IUC, and the reasons for this, a qualitative approach was appropriate.

However, a limitation of a qualitative approach is that it is necessarily limited to a relatively small number of participants, typically 10-50, and usually in a delimited setting, such as a clinic or a discreet geographical area. These participants are rarely selected in a random manner from the larger population, and are often self-selecting, in a much as they respond to an invitation to take part. Researchers, in analyzing qualitative data, will compare accounts, looking for common themes, but also highlighting interesting or minority opinions. This means that qualitative research cannot provide strong evidence that the data gathered is representative of the wider population. It is not ‘generalizable’ in the way that quantitative data can be. In addition, it cannot give an indication of the prevalence of a view or opinion, even within the sample, let alone the wider population, unless every participant is asked a specific question about that particular theme. As healthcare research usually has a pragmatic aim of improving healthcare services, this shortcoming can limit its usefulness if the results are to be applied more generally.

### Rationale for Choosing a Mixed Method approach

We were interested, not only in women’s views and concerns about IUC, but also how common or prevalent these views were, in the wider general practice population in the area in which the research was carried out. For this reason, we decided to include quantitative data in our research design. We used qualitative interviews, carried out first, to gain insight into the views and concerns of our participants regarding IUC. Then we incorporated these themes, along with other questions from previous research projects, into a quantitative survey.

This survey was distributed more widely, and completed by over 1100 participants. It allowed us to demonstrate whether our qualitative findings were reflected in the wider population of women attending general practices in the area. This research design is known as a QUAL->quant (i.e. with qualitative approaches having priority), sequential, exploratory design. In other words, the qualitative data and quantitative data were gathered sequentially, rather than at the same time, and the quantitative data were used to further explore the prevalence of the qualitative themes (Cresswell & Plano-Clark 2011p.109).

####  Section summary

* We wanted to find out more about the attitudes of women towards intra-uterine contraception, in a general practice setting.
* We chose a mixed-method sequential exploratory approach because the qualitative first phase allowed us to hear women’s opinions, concerns and feelings, and the quantitative second phase allowed us to gauge how prevalent those views were in a larger population.

## Research Design

### Qualitative arm of the research – gathering the opinions of women

We were interested in why women might choose not to consider intra-uterine contraception (IUC) as a method for them, and we were also interested to find out whether the information given to women in the last decade, had helped to dispel some of the misinformation about the methods. For both these reasons, we chose to interview, for the qualitative arm of our research, women who were using contraception but had never used IUC. These women were recruited through primary care general practices.

### Recruiting the Sample

When carrying out research on National Health Service patients in the UK, it is imperative that personal or healthcare details are not seen by the researchers, unless the researchers themselves are members of the healthcare team. For this reason, the collaboration of a member of the healthcare team is needed to make the initial approach to potential participants.

We had sought approval from the local NHS ethics committee prior to starting the project, and this entailed outlining in some detail, in our application, the way we would contact potential interviewees, the incentives we would offer, the information sheets we would give to participants to help them decide whether or not to take part, and the means of consenting the participants.

For our project, we worked with practices who had an interest in conducting research, and were familiar with inviting patients to take part. These practices were known to the local clinical research network, which is a part of the government funded national infrastructure to support healthcare research in the UK, under the National Institute for Health Research (NIHR). We asked practices to to tell women about the study and to pass on contact forms, on which the women could supply their own contact details. We did not ask practices to fully explain the study or to take consent for interview, as this can be very time-consuming and requires training to take consent. Instead, the practice staff signposted the women to our research team, as described below. Ideally we would have reimbursed practices for the extra time it took to do this, but we were unable to offer this and were fortunate that these research-active practices were willing to help in this way.

One of our research team visited each of the practices who were willing to recruit participants for interview, and spoke to practice managers and staff, to explain the project, and to answer any queries. This personal contact is very important, and can influence whether or not recruitment is successful. Although we did this after gaining ethical approval, ideally, it should be done prior to making any application for ethical approval, because staff may have insight into what will work and what will not, and the research design may need to be altered as a result. Altering the design after ethical approval has been gained requires a notice of substantial amendment (NOSA) to the ethics committee, describing the requested change, and this is time-consuming and will cause delays.

Staff in the practices (nurses, doctors or other healthcare staff) told women about the project. The women were given an information sheet about the project, and a contact form on which they could fill in their details, if they wanted to be contacted by the research team. In this way the personal details of participants were kept completely unknown to the research team, unless the women herself decided to give them to us. The drawback of this method of recruitment is that some prospective interviewees do not respond to attempts by the research team to contact them subsequently.

The women were then contacted by the interviewer, and a time arranged for the interview, which could take place in person in the GP surgery or by telephone. In either case, the interviewer ensured that the participant was happy to take part, answered any questions and took consent from the participant. The women were given a £20 shopping voucher in recognition of their time spent taking part in the interview.

When budgeting for a project like this, it is essential to think about the incentives and reimbursement needed, for participants, and for the employers of healthcare staff who will be helping with recruitment. These costs need to be included in the initial budget when seeking funding.

### Data gathering

We developed the interview questions, based on previous literature and on our research question. We asked for comments and suggestions from an advisory group, which we assembled, who included doctors, nurses, commissioners and other researchers with experience in the field. Ideally, we would have included lay-people and service users in this advisory group but this proved very difficult in terms of finding service users willing to commit their time, and able to attend meetings. Ethics committees, funders and publishers are becoming more stringent in insisting on the inclusion of service users in research design, and if we were to repeat this project now, we would probably have to find a way to gain the views of service users before commencing.

Similarly, it would have been good for us to pilot the interview questions with some service users, who would not ultimately become research participants, to ensure that the questions were understood and allowed us to explore the topics appropriately. We did not do this, and fortunately, the interview questions worked well, in part due to the experience of the researcher who carried out the interviews.

The questions asked by the interviewer covered the following topics.

* What knowledge do women have of different types of contraception?
* Where is this knowledge obtained? i.e. their own experiences, the experiences of others, urban myths, other information sources
* What are women’s views on suitability of different types of contraception for women of different ages? With/without children? Different sexual relationships? Etc.
* What are women’s views on intrauterine contraception:
* What are their perceptions of the Intrauterine device (IUD) (copper device)?
* What are their perceptions of the Intra-uterine system (IUS) (hormone bearing device)?
* What anxieties might they have about IUC in general; IUD; IUS?

We collected data from 30 interviews, which was audio-recorded and transcribed to written form.

### Analysis of qualitative data

We conducted a thematic analysis of the qualitative data with the assistance of NVivo software. Thematic analysis is a form of analysis whose aim is to draw out the underlying themes (in our case concerns, opinions and feelings) expressed by the participants, about the topic being investigated (in our case, IUC). It has several clear steps and is described by Braun & Clarke (2006). It is a useful and appropriate form of analysis for researchers who want to explore opinions and experiences, and get an idea of which opinions are shared by the majority (dominant themes), and which are unusual or contradictory (divergent themes). This form of analysis is known as ‘inductive’ or ‘emergent’ because it works from the data up, without a pre-conceived analytical framework.

In truth, researchers who are familiar with their field often do have some pre-conceived ideas about what might emerge from the data. When analyzing qualitative data it is helpful to think about what you expect to find, and to note these as pre-conceived codes. For example, in our research we expected to find that women might feel that IUC was only suitable for women who had had a baby. Therefore, we were alert to this theme, and coded parts of the interview where views on this were expressed. It is perfectly acceptable to use a mixture of pre-conceived and emergent codes when analyzing qualitative data, but it helpful to be clear in your mind, and to make clear in your write-up, which is which. This aids the robustness of your analysis, and helps you to spot truly unexpected findings.

Thematic analysis allowed us to form a clear idea of which concerns and opinions were influencing whether or not the women in our sample considered IUC to be an acceptable form of contraception.

### Computer Assisted Qualitative Data An analysis Software (CAQDAS)

The use of software to help with qualitative analysis saves researchers much paper. There are various software programs to aid qualitative analysis, and all allow analysts to label sections of text from the interviews, with codes, which can then be further grouped into wider themes. These codes and themes can be retrieved easily, shared, examined, argued over, altered and finally agreed upon by the research team.

The final qualitative themes that emerged from our interviews were:

* the long-term nature of IUC
* adverse effects of IUC
* lack of control over starting and stopping the method
* concerns about fitting and removal
* the imagined size and shape of the device and its method of action
* the internal nature of the device
* the device moving, falling out or being felt by a partner
* ‘friend of a friend’ reports from other people.

### Constructing the quantitative survey

Having analyzed the themes from our qualitative interviews we wanted to see if these represented the views of a wider population of women who attended general practices in the region of the UK in which we carried out the research. This required a quantitative approach and was undertaken in the second phase of our research.

Using the themes from our first, qualitative phase, and drawing on questions used in other surveys examining attitudes towards IUC, we developed a survey with 29 questions. These included some demographic questions (age, ethnicity), questions about whether the respondent had ever used IUC, what they had heard from other people about IUC, questions about the concerns our interviewees had expressed, type of contraception used at present, and finally some more sensitive questions of pregnancy history.

The attitudinal questions were designed to be answered on a visual analogue scale or ‘Likert-type’ scale. This is a scale of five (or sometimes 7) responses ranging from e.g. “strongly disagree” to “strongly agree” or “very unlikely” to “very likely”. This allows an attitudinal response to be converted into a numerical value.

We piloted this survey extensively using two groups of students. We were interested in how long the survey took to complete, whether or not they were likely to return it if asked to fill it in, and on how easy it was to understand, and whether the topics or questions were too sensitive. The first group were nursing students, who had an age range similar to that of our intended respondents i.e. 18-40+ years. The second group were students with no health service background, who were able to comment on the acceptability of language used in the questionnaires, and on how easily (or otherwise) the questions were understood. These two pilots resulted in some rephrasing of questions and changes to language, but we were reassured that completing the questionnaire took only about 10 minutes, and it was not too arduous.

### Distributing the survey

We were helped to distribute our survey by the local clinical research network, who liaised with GP practices in the region. This already established contact between the clinical research network and the practices was very important to us, because we were unable to offer reimbursement to practices for distributing the surveys. It is best to consider how to reimburse practices for their time and effort, and in retrospect, it would have been helpful if we could have budgeted for this from the beginning.

Thirty-two practices agreed to distribute surveys, which meant that each practice had to return 30-50 surveys to allow us to achieve our intended target. We knew from piloting that the surveys could be completed quickly, and they were distributed in waiting areas, so that women could fill them in whilst waiting for their appointment. We distributed 4300 surveys and received just over 1200 back. Some of these were blank and were excluded from analysis but our response rate was 28%, which is average for a survey of this kind.

Women attending the practices were offered the survey, and an accompanying Participant Information Sheet, and invited to take part, by a member of the practice team. We had supplied posters, and notices of our survey that could be displayed on practice information screens, so in many practices, reception or other staff could simply point these out to women, and indicate where they could pick up and return a survey.

 Women who chose to complete the survey returned them in an envelope, to especially provided ‘drop-box’ placed on the premises. This ensured that the women could freely choose whether to take part, without having to explain their decision to a member of staff.

To minimize the workload of staff who were helping us, we designed the survey so that the first page contained information about IUC; so that women were clear what the survey was about, without staff having to explain. We also gained ethical approval to have ‘implied consent’ for the return of the anonymous survey. Participants gave their consent to take part through the act of returning the survey to the drop-box. This removed the need for written consent, and the loss of anonymity that would have entailed. The fact that implied consent was being given was stressed both in the information sheet, and at the end of the questionnaire itself.

### Quantitative sample

Ours was not a randomized survey, in that women who took part were self-selected. Nor was it a representative survey in that no attempt was made to mirror the population of the practices, in terms of the characteristics of the respondents. Given these limitations, power calculations (the ability of the data to detect a true difference between group responses), confidence intervals (the likelihood that the sample data reflects the population data) and statistical significance calculations (the likelihood that a difference between groups is not a result of chance) must be taken as indicative, rather than definitive. Nonetheless, we wanted to ensure that our sample size was large enough to give credibility to the data. Following consultation with a healthcare statistician, we aimed for a sample size of 1068 respondents. After excluding blank responses, we achieved a final sample of 1195 eligible responses from 32 GP practices. Consulting a statistician in this way is very helpful, because if a survey is underpowered, i.e. there are not enough returns for statistical analysis to be deemed significant, or even for descriptive analysis to be robust, then the research is of limited value, and may be difficult to publish. This is a waste of time, funding and the goodwill of those who took part.

### Analysis of Quantitative Data

We analyzed the data descriptively, looking at the responses of ever-users (those who used IUC now or in the past) and never-users separately. The never-users corresponded to the group we had interviewed in our qualitative arm. We found that the themes arising from the qualitative interviews with 30 women were well represented among the 873 never-users in the quantitative sample. The most commonly endorsed concern was that of the internal nature of the IUC devices, followed by concerns about fitting and removal. This added weight and credibility to our findings from the qualitative arm.

We were also able to show, by analyzing the responses of ever-users and never-users, that whilst only 6.2% of respondents viewed the long-acting nature of IUC negatively, this opinion was a strong predictor of non-use of IUC. Combined with the qualitative themes in the interview data, we were able to suggest that clinicians who were discussing IUC with women needed to be more nuanced about the long-acting nature of IUC. They needed to address the concerns women had about its long-term effects, and stress that the devices could be removed at any time, on request.

#### Section summary

* We undertook qualitative interviews first, and used the themes derived from these to construct a quantitative survey. This sequential exploratory approach allowed us to show that our quantitative findings were representative of the views expressed in a much larger sample.
* We had to design the research project with ethical values in mind. Specifically we had to design recruitment so that we did not impinge upon the confidentiality of health service records or the privacy of patients. For this, we needed help from the GP practices and their staff, who made the initial approach to women. In the UK, the help of the local clinical research network can be invaluable in this respect.

## Research Practicalities

### *Ethical considerations*

Before any research project involving humans can be undertaken, ethical approval must be obtained. We were seeking to recruit NHS patients and so our route of seeking ethical approval was via the NHS ethics committee system, overseen by the Health Research Authority (HRA). This is a time-consuming and meticulous process. It involves completing a very detailed application form, outlining the ethical considerations given below, and justifying the need for the research, the methods used and the means of avoiding harm. This must be done carefully and with much thought because once approval is given, the methods and research design cannot be changed, without seeking explicit permission to do so. In addition, in the UK, research governance permission must be sought from each organisation taking part in the research. It is wise to plan for at least three months, and often up to six months, to apply for the ethical and regulatory approvals required.

Once an application is submitted it is scrutinised by an ethics committee, who will usually ask for changes to documents, or practical procedures, in order to better inform and better protect participants. For example, our ethics committee questioned whether survey respondents would have time to decide whether to take part in the survey, and did not want them to feel pressurised. Our use of drop-boxes was a way of allowing women plenty of time to complete the survey and consider whether to return it, without feeling that staff were waiting for their response.

#### Informing participants

Ethics committees are concerned that participants are fully informed of the nature, risks and aims of the research, and of what will happen to their data and details. Participant Information Sheets, which outline these details in an accessible, comprehensible manner, must be supplied, and approved by the ethics committee. We had to ensure that these sheets were given to participants before they decided whether or not to take part.

#### Gaining consent

We had to think about who would take consent, and whether this consent would be written, verbal or implied. This is a balance between minimizing the burden to participants and healthcare staff who are enabling the research, and the need to ensure that consent is properly recorded, and that the method of obtaining consent is appropriate for the risks involved in the research. Ultimately, the ethics committee has to make a judgment on this but as researchers we have to show that we are aware of ethical issues.

#### Protecting Confidentiality during Recruitment

It is unlikely that ethical permission will be given for the research team to have access to the health records of patients, or to approach patient directly without their consent. When considering how to recruit our sample of participants, we needed to find gatekeepers and cooperating healthcare staff, to make the initial approaches to our participants.

### *Gaining ethical approval for a two-stage project*

In mixed-method research of a sequential design, it is sometimes not possible to know what form the second phase of the project will take, before the first phase is completed. We did not know what questions our quantitative survey would contain until we had analyzed our first phase, qualitative data. To address this we gained ethical approval for the first part of our project, and indicated that we would return to the ethics committee to seek further approval for the second phase, once the survey was developed. We did not have to make a resubmission but used a ‘Notice of Substantial Amendment’ (NoSA) to do this before starting the second phase.

#### Working with health service partners

Healthcare staff who help researchers with a project are usually doing so out of goodwill. We made every effort, in the design of our research, to minimize the inconvenience to healthcare staff, and to simplify the actions that we were asking them to make on our behalf. Where possible it is best to secure funds and to budget for reimbursement of staff time, since this makes it easier to persuade staff and their employers to become involved.

#### Collecting and transferring data

It is a disaster if interview recordings or completed patient surveys get lost in transit. Not only are data lost but also confidentiality is compromised. We had to think carefully about how data could be transferred safely and securely. In terms of completed paper surveys, this involved personally driving to collect the surveys in batches, rather than sending them through the post. This care to protect against loss of data was outlined in our application for ethical approval.

#### Section summary

* Gaining ethical permission can take considerable time. It is best to think carefully about ethical considerations at the very earliest stage of designing a project.
* When considering methodology and project design it is very useful to think concretely how the involvement and cooperation of healthcare staff, and the goodwill of participants, will affect what you are able to do. If an elegantly constructed research design proves too onerous for staff to implement, or for participants to take part in, it will fail.
* If data are to be transferred, it is important to do this safely and securely, to avoid breaching the confidentiality of participants. This may involve using encryption for electronic transfer.

## Method in Action

### What went well?

The recruitment of women who volunteered to be interviewed went well and we had a good response to our invitation, delivered via practice staff. This may have been due to the enthusiasm of practice staff, who approached the participants for interview. Visiting the practices beforehand to ensure that staff were happy with their role, and maintaining contact, so that queries could be quickly resolved, is helpful. Similarly, the recruitment of women to the quantitative survey went well, in large part due to the help given to us by research nurses from the local clinical research network, and staff in practices who invited participant to take part.

The women who were interviewed by our team understood the nature of our research question, and were able to express their opinions, and give us data that answered our question.

The majority of those who returned it, and appeared to be easy to understand completed the survey accurately and appropriately. This is likely to be because we piloted the survey extensively, and altered it according to the feedback that we received.

### What didn’t go to plan?

We received 1230 surveys in total. Some of these were excluded because the respondents indicated that they were outside the age range that we were interested in (18-49 years), and for whom we had ethical approval. This is because the survey was self-completed, without the oversight of a researcher, who would have been able to ensure the respondent was eligible. However, we had opted for this strategy because we could not meet the costs of situating a researcher in 32 separate practices for the duration of the survey.

### What would you do differently?

In the analysis of the quantitative survey, it would have been useful to know the income bracket, and the educational achievement of the women who responded. This is because some previous research has shown that these factors influence contraceptive choice. We decided against this because we considered this to be very sensitive information, and were concerned that women would refuse to answer the questions. We used the first part of the respondent’s postcode as a proxy for this, but this did not prove very useful because the areas covered were too large. In retrospect, we should have included these questions and allowed women to choose to skip them.

#### Section summary

* Time taken to explain the research to staff, who will help recruit participants, is time well spent.
* Piloting of surveys and of interview questions is very important to ensure that the methods work well in practice.
* Sometimes the ideal research design is not possible because of the limitations of cost or time. Good research is a compromise that produces the best possible results within these constraints.

## Practical Lessons Learned

1. When designing a healthcare related project, think about consent and health service confidentiality first, since these are likely to determine how the participants can be approached, and ethical approval obtained.
2. If the assistance of healthcare staff is needed to carry out the project, make time and effort to speak to the staff involved, and their managers and employers, before designing the project, to find out how your design will play out ‘in the real world’.
3. Take time to pilot both surveys questions and interview questions, with people who are as similar as possible to your proposed participants. This will save time and wasted responses later.
4. Consult a statistician before undertaking any kind of quantitative survey.
5. If working in England, make every effort to obtain the assistance of the local clinical research network in the area in which you will be working. Assistance and support from a clinical research network is only provided for research which meets NIHR criteria, including whether research funds have been awarded as a result of open national competition across England with high quality peer review; whether the research is of clear value to the NHS, social care or public health; and whether it takes appropriate account of the priorities, needs and realities of the NHS, social care or public health. These and other criteria can be found on the NIHR website (https://www.nihr.ac.uk/documents/eligibility-faqs/11636), and researchers apply to be considered for support as part of the application for ethical and research governance approval.
6. If you are not able to draw on assistance from the clinical research networks, then additional time must be spent networking, visiting and gaining the trust of healthcare staff and potential collaborators, before budgeting and research design takes place.

#### Section summary

* Good preparation is always worth the time it takes when designing a research project.
* Seek the advice of subject experts and stakeholders – including colleagues, healthcare staff and statisticians.
* Increasingly Public and Patient Involvement (PPI) in the design and conduct of the research, is a requirement of funders and some journals. At the time when we were designing our research, this was not such a strong requirement but if we repeated the project we would have to make efforts to include the opinions of service users from the beginning in the design and methods.

## Conclusion

Mixed-methodology can address some of the limitations of purely qualitative healthcare research, in terms of generalizability, and widening of the applicability of the research. Since healthcare research often has a pragmatic aim of improving services, this is important. We used qualitative interviews to develop a rich understanding of the concerns and attitudes of women about intrauterine contraception. The second phase quantitative survey allowed us to demonstrate that the findings from our qualitative arm where applicable to a wider population of similar women. This is known as a sequential, exploratory design.

The sequence of methods can be reversed, particularly if validated surveys exist which address your research topic. This is known as a sequential explanatory design, where the second phase qualitative data helps to explain the survey findings.

Our research was designed to answer our research problem concerning the acceptability of IUC to women, but we had also had to consider practical issues, and ethical issues, when deciding how concretely to carry out the project.

#### Section summary

* In designing our research project, we were guided by our research aim, i.e. to explore the acceptability of IUC, and the concerns and attitudes of women about IUC. This suggested a qualitative methodology. However we also had a pragmatic desire to explore whether the themes we elicited form our interviews were representative of the views of a wider population of similar women. The addition of a quantitative phase allowed us to do this, and made a mixed-methodology the most appropriate for our project.
* Practical and ethical concerns also shaped the concrete ways in which we gathered our data for this project. Thinking about these early in the design process saved time and effort later.

Classroom Discussion Questions

1. Why is a qualitative approach appropriate for investigating the attitudes and opinions of healthcare users? What are the limitations of this methodology? How can these be addressed by using mixed – methods?
2. To what extent can participants give fully informed consent to a project of this nature? Are there limitations to the principle of fully, informed consent in practice? What can researchers do to ensure, as much as possible, that participant fully understand what permission they are giving, and what will happen to them and their data?
3. Is healthcare research of this kind useful in the real world? Which groups potentially benefit from this kind of research? Is it a good use of public money to fund this kind of research?

Multiple Choice Quiz Questions

1. Our research design was sequential, exploratory mixed method. Does that mean that

A: We carried out a quantitative survey and then explained the results with qualitative interviews

B: We carried out qualitative interviews and a quantitative survey at the same time

C: We carried out qualitative interviews, and used them to construct a quantitative survey to further explore the themes (CORRECT)

1. Our survey was designed to be completed and returned without the intervention of healthcare staff. For this reason the type of consent for which we sought ethical approval was:

A: Implied (CORRECT)

B: Written

C: Verbal

1. We recruited women to take part in our interviews by asking healthcare staff to give women information about the research, and the women could then choose to allow their contact details to be passed on to us, because:

A: We did not want to waste time approaching women who would refuse to take part.

B: Our research team were not part of the healthcare team, which routinely cared for the women we hoped to interview, so we could not ask for access to their contact details from the practice registers because this would breach patient confidentiality. (CORRECT)

C: We were not properly trained to approach women and ask for their consent.

**Declaration of Conflicting Interests**

 Bayer, who manufacture several intra-uterine contraceptive devices, funded this research.

Further Reading

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Web Resources

* <https://digital.nhs.uk/data-and-information/publications/statistical/sexual-and-reproductive-health-services/2017-18>
* <https://www.nhs.uk/conditions/contraception/iud-coil/>
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* <https://www.nihr.ac.uk/explore-nihr/support/study-support-service.htm>

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