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The importance of pilot studies

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Summary

The term 'pilot studies' refers to mini versions of a full-scale study (also called 'feasibility' studies), as well as the specific pre-testing of a particular research instrument such as a questionnaire or interview schedule. Pilot studies are a crucial element of a good study design. Conducting a pilot study does not guarantee success in the main study, but it does increase the likelihood of success. Pilot studies fulfil a range of important functions and can provide valuable insights for other researchers. There is a need for more discussion among researchers of both the process and outcomes of pilot studies.

THE TERM 'PILOT study' is used in two different ways in social science research. It can refer to so-called feasibility studies, which are 'small scale version[s], or trial run[s], done in preparation for the major study' (Polit *et al* 2001). A pilot study can also be the pre-testing or 'trying out' of a particular research instrument (Baker 1994). One of the advantages of conducting a pilot study is that it can give advance warning about where the main research project could fail, where research protocols might not be followed, or whether proposed methods or instruments are inappropriate or too complicated. In the words of De Vaus (1993): 'Do not take the risk. Pilot test first.' These are important reasons for undertaking a pilot study, but there are additional reasons, such as convincing funding bodies that your research proposal is worth funding. Thus pilot studies are conducted for a range of different reasons (Box 1).

Pilot studies can be based on quantitative and/or qualitative methods and large-scale studies might employ a number of pilot studies before the main

survey is conducted. Therefore, researchers might start with 'qualitative data collection and analysis on a relatively unexplored topic, using the results to design a subsequent quantitative phase of the study' (Tashakkori and Teddlie 1998).

The first phase of a pilot might involve using in-depth interviews or focus groups to establish the issues to be addressed in a large-scale questionnaire survey. Next the questionnaire could be piloted, for example, the wording and order of the questions, or the range of answers on multiple-choice questions could be tested. A final pilot could be conducted to test the research process, such as the different ways of distributing and collecting the questionnaires. A recent study exploring nurses' and midwives' attitudes to research followed this pattern: in this study, focus groups were used to identify key issues from which a questionnaire could be developed, and this was then piloted before the study proper (Hundley *et al* 2000).

On a bigger scale, the largest decennial survey in the UK, the Census (April 29 2001), tested methodological and other changes to the 1991 Census questionnaire on more than 100,000 households in 1997. This 1997 Census test 'provided essential information on public reaction to new questions and form style, as well as assessing the success of collection and processing methods' (Office for National Statistics, General Register Office for Scotland, Northern Ireland Statistical and Research Agency 1999).

Pilot studies might also try to identify potential practical problems in following the research procedure. For example, in a recent Scottish study of maternity care the pilot phase demonstrated that the proposed means of distributing the questionnaires would not be adhered to (van Teijlingen *et al* 2001). Without consulting the research team, the person responsible for distributing the questionnaires from

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■ Interviews and interviewing

■ Research methods

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Box 1. Reasons for conducting pilot studies

- Developing and testing adequacy of research instruments
- Assessing the feasibility of a full-scale study or survey
- Designing a research protocol
- Assessing whether the research protocol is realistic and workable
- Establishing whether the sampling frame and technique are effective
- Assessing the likely success of proposed recruitment approaches
- Identifying logistical problems which might occur using proposed methods
- Estimating variability in outcomes to help determining sample size
- Collecting preliminary data
- Determining what resources, such as finance or staff, are needed for a planned study
- Assessing the proposed data analysis techniques to uncover potential problems
- Developing a research question and research plan
- Training a researcher in as many elements of the research process as possible
- Convincing funding bodies that the research team is competent and knowledgeable
- Convincing funding bodies that the main study is feasible and worth funding
- Convincing other stakeholders that the main study is worth supporting

the hospital records department decided that it was better to distribute them through the community midwives. This was despite the fact that the hospital itself had suggested the records department as a means of distribution. Other problems such as poor recording and response rates can also be identified and precautionary procedures or safety nets can be devised.

The steps used to pilot a questionnaire on a small group of volunteers, who are as similar as possible to the target population, are listed in Box 2.

Pilot studies can also uncover local politics or problems that might affect the research process. In the study described above, the managers of maternity services had different perceptions of what the forthcoming changes in the Data Protection Act 1998 allowed them to do about the involvement of their clients in research. In the above mentioned Scottish study of maternity care, one head of midwifery voiced ethical concerns about the use of follow-up or reminder letters. She pointed out a previous local incident where parents of an ill baby had been sent a questionnaire that was felt to be inappropriate as a result of changes to the UK Data Protection Act. Consequently, reminders were sent out via the head of midwifery in case there were any problems with the newborn.

Problems of pilot studies

Pilot studies can have a number of limitations. These include the possibility of making inaccurate predictions or assumptions on the basis of pilot data, problems arising from contamination and problems related to funding. These issues are now discussed in turn.

Completing a pilot study successfully is not a guarantee of the success of the full-scale survey. Although pilot study findings might offer some indication of the likely size of the response rate in the main survey, they cannot guarantee this because they do not have a statistical foundation and are nearly always based on small numbers. Furthermore, other problems might not become obvious until a larger scale study is conducted.

A further concern is that of contamination. This might arise in two ways:

- Where data from the pilot study are included in the main results.
- Where pilot participants are included in the main study, but new data are collected from these people.

Social scientists engaged in predominantly quantitative research are likely to argue that: 'an essential feature of a pilot study is that the data are not used to test a hypothesis or included with data from the actual study when the results are reported' (Peat *et al* 2002). The obvious concern is that if there were problems with the research tool and modifications had to be made in the light of the findings from the pilot study, data could be flawed or inaccurate. However, where an established and validated tool is being used and the pilot study is determining other methodological aspects such as recruitment rates, it could be argued that such data might be of value.

A more common problem is deciding whether to include pilot study participants or sites in the main study. Here the concern is that they have already been exposed to an intervention and, therefore, might respond differently from those who have not previously experienced it. This might be

Box 2. Pilot study procedures to improve the internal validity of a questionnaire

- Administer the questionnaire to pilot subjects in exactly the same way as it will be administered in the main study
- Ask the subjects for feedback to identify ambiguities and difficult questions
- Record the time taken to complete the questionnaire and decide whether it is reasonable
- Discard all unnecessary, difficult or ambiguous questions
- Assess whether each question gives an adequate range of responses
- Establish that replies can be interpreted in terms of the information that is required
- Check that all questions are answered
- Re-word or re-scale any questions that are not answered as expected
- Shorten, revise and, if possible, pilot again

(Peat *et al* 2002)

positive, for example, the participants might become more adept at using a new tool or procedure. However, it might also be negative with participants showing a decline in following a protocol because it is no longer novel. Both changes in behaviour have long been recognised and a 'run in' period, where an intervention is introduced before a study, is often used for these reasons.

The concern about including participants from the pilot study in the main study arises because only those involved in the pilot, and not the whole group, will have had the experience. In some cases, however, it is simply not possible to exclude these pilot-study participants because to do so would result in too small a sample in the main study. This problem arises in particular where the samples are clusters, for example, schools, prisons or hospitals. In such cases one can conduct a sensitivity analysis (or sub-group analysis) to assess to what extent the process of piloting influences the size of the intervention effect.

Contamination is less of a concern in qualitative research, where researchers often use some or all of their pilot data as part of the main study. Qualitative data collection and analysis is often progressive and a second or subsequent interview in a series is often more effective than the previous one: the interviewer might have gained insights from previous interviews that are used to improve interview schedules and specific questions. Some have, therefore, argued that in qualitative approaches separate pilot studies are not necessary (for example, Holloway 1997). A qualitative interviewer conducting 15 focus group interviews will listen to the recordings or read through the transcripts of the first three or four to improve the questions, the way of introducing the issues into the group interview, or even to add new topics. Therefore, although there is no specific pilot study, analysis of the earlier focus groups might help improve the later ones.

However, Frankland and Bloor (1999) argue that piloting provides the qualitative researcher with a

'clear definition of the focus of the study', which in turn helps the researcher to concentrate data collection on a narrow spectrum of projected analytical topics. Piloting of qualitative approaches can also be carried out if 'the researcher lacks confidence or is a novice, particularly when using the interview technique' (Holloway 1997).

Problems might also arise where a pilot study requires a significant investment of resources, making it difficult for the study team to call a halt to the research after an unsuccessful pilot study. Researchers might be tempted to make considerable changes in the main study rather than deciding that the proposed study is not possible with the available resources, time, population and so on. In contrast, funding bodies might be reluctant to fund a further study if the pilot has been substantial as they might view the research as no longer original, especially if results from the pilot study are published.

Why are pilot studies not reported?

Publication bias might occur because of a tendency for journals to accept only papers that have statistically significant results and not to report non-significant effects (Chann 1982, Dickersin 1990, Mahoney 1977). A recent study exploring research on passive smoking found a difference of two years in the median time to publication between findings from significant and non-significant studies (Misakian and Bero 1998). It follows that papers reporting methodological issues, such as those identified during the pilot phase of a study, will also be less attractive to publishers.

Selective publication of research results has been recognised as a problem. It might lead to an over-estimation of the effectiveness of interventions, exposing patients to useless or harmful treatments, while over-estimation of adverse effects might mean that patients are denied effective forms of care (Oxman *et al* 1994). In the past, editors have recognised the dangers of publication bias with respect

to clinical trials and have offered 'an amnesty for unpublished trials' in an attempt to overcome these problems (Smith and Roberts 1997).


However, it is equally important to ensure that lessons learnt with respect to the research method are shared, otherwise patients might be subjected to poorly developed tools or money might be wasted because methods of recruitment failed. A consistent selection bias favouring reports of primary research over papers on research methods, theoretical thinking or secondary analysis, can lead to many researchers re-inventing the wheel without having had the opportunity to learn from other people's experience.

Conclusion

It has been said that pilot studies are likely to be 'under-discussed, underused and under-reported' (Prescott and Soeken 1989). Full reports of pilot studies are rare in the research literature (Lindquist 1991, Muoio *et al* 1995, van Teijlingen *et al* 2001). When reported, they often only justify the research methods or particular research tool used. Too often research papers only refer to one element of the pilot study, for example, to the 'pre-testing' or 'pilot testing' of a questionnaire (De Vaus 1993). Such papers simply state: 'the questionnaire was tested for validity and reliability'.

When pilot studies are mentioned in more detail

in academic papers and reports, researchers regularly comment that they learnt from the pilot study and made the necessary changes, without offering the reader details about what exactly was learnt. Some of these processes and outcomes from both successful and failed pilot studies might be useful to others embarking on projects using similar methods and instruments. This is particularly important because pilot studies can be 'time-consuming, frustrating and fraught with unanticipated problems, but it is better to... deal with them before investing a great deal of time, money, and effort in the full study' (Mason and Zuercher 1995). It has also been argued that the current research climate demands accountability from researchers, which means that there is a need to ensure the best possible use of research results (Crosswaite and Curtice 1994). We would like to go one step further and argue that researchers have an ethical obligation to make the best use of their research experience by reporting issues arising from all parts of a study, including the pilot phase.

Well-designed and well-conducted pilot studies can inform us about the best research process and occasionally about likely outcomes. Therefore, investigators should be encouraged to report their pilot studies, and in particular to report in more detail the actual improvements made to the study design and the research process .

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