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# Reconceptualising the objectives of a pilot study for clinical research

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## Abstract

This is a methodological study in which a case report is used to retrospectively analyse the link between a successful pilot study and stalled main study to identify potential methodological weaknesses in the planning process. The analysis identified unanticipated influences related to hospital processes and discipline boundaries that adversely influenced participant recruitment and retention for a clinical trial. The findings of the study demonstrate that, whilst the pilot is an important step in research planning to confirm the design and operational processes for a study, a thorough analysis of the relevant health service environment is an important additional objective for the pilot study.

Author Keywords: Pilot study; Research methodology; Postoperative pain

## 1. Introduction

All researchers, both experienced and inexperienced, know the challenges of setting up a research project. The obvious goal of all clinical research is that it achieves the aims and objectives of the inquiry. Integral to this are the requirements of scholarship, ethics and funding, and accountability in the conduct of research. Good scholarship in research for example is dependent upon the rigour of the research findings and there are ethical issues related to involving participants in a study when the quality of the research design may compromise the efficacy of the findings. Furthermore, clinical research is expensive and funding bodies need assurance that research funds are gainfully expended. All of these factors rely upon meticulous planning and preparation before embarking upon clinical research. The pilot study is vital to this preparation.

Notwithstanding the primacy of the pilot study to the success of the research process the literature is limited in terms of providing guidance and rationale for conducting a pilot study. This paper will report on a specific pilot study and discuss the contribution that the pilot made to the larger study. Further to this, the paper will

demonstrate that researchers need to be open to the value of both the expected and unintended findings of a pilot study to research planning.

## 2. Background

There is agreement in the literature that pilot studies are important for a range of specific reasons. These reasons however are mostly related to trialing a study design and/or testing a new instrument ([Koch and Rowell (1997)]; [Roberts and Taylor (1997)]; [Summers (1993)]) and establishing that data collectors fully understand the research protocol and are consistent in data collection processes ([Baird (2000)]). However, while the term pilot study is frequently mentioned in research reports, the specific reasons for the inclusion of a pilot study and the contributions it made to the eventual study are not always explicit.

Pilot studies serve a range of functions additional to the above, that relate to the success of a research project. Publication of a pilot study can establish the credibility of the researcher and provide information to funding bodies and ethics committees about the skills of the investigating team. Additionally, whilst not contributing in a statistical or theoretical capacity, publication of a pilot study can contribute to the advancement of nursing research knowledge. A researcher undertaking a project or program of study in a specific field can use a pilot study and its publication to inform other nurses and researchers of the author's research interest and may encourage sharing of information and promote research collaboration.

However, one of the most valuable outcomes of the pilot study comes from those studies that identify the potential breakdown of a research plan. Publication of the pilot phase of those studies that fail to proceed is useful because it alerts other researchers to potential pitfalls ([Read and George (1994)]), and generates additional and important questions that need addressing prior to conducting a research study ([Ratzan (1982)]). It may be considered that this pilot study outcome is a valuable source of information to advance the nursing research agenda.

The beginning researcher is often guided by research text books, the primary focus of which are the descriptions and instructions relating to research design and methods. Most research texts devote scant, and in some cases, no attention to the topic of pilot studies ([Prescott and Soeken (1989)]) and the role they play in a project. These texts therefore underplay for the novice the centrality of the pilot to a successful research outcome. A scan of research textbooks has revealed ([Hinds & Gattuso, 1991 (1991)]) that the definitions of the pilot study give promise of a tightly controlled small-scale study that is driven by the research question or research objectives of the main study. This message belies the true nature of a working pilot; that is, a project with objectives that are related less to the research question than they are to the research process.

A search of the journal literature databases reinforces the notion of the pilot as a small-scale version of the main study. There are extensive publications relating to pilot studies but the main focus of this literature is reporting the results of pilot studies in terms of research outcomes (e.g. [Anderson (2001)]; [Cowan et al (2002)]; [Lupton and Fenwick (2001)]; [Wojner et al (2002)]). This indicates that pilots are often used as an early or surrogate 'results' publication. This type of publication does inform and provide important knowledge, albeit with acknowledged statistical and/or theoretical

limitations, but it does not necessarily report on the intended outcomes of a pilot—that is, to inform on the design, operational aspects and readiness of a full study. A pilot study report that informs the reader of modifications and adjustments made to the main study based on the results of the pilot provides an important body of knowledge for the nursing research community.

This is particularly relevant to the contemporary health service environment. Clinical research is at the best of times difficult to conduct, particularly when seeking to use experimental methods. Research designs that require prediction and control and a renewable flow of potential research participants make very specific demands of the research environment. However, this is an environment that is subject to the continual flux and change that is characteristic of contemporary health service and consequently can have a major impact on a research project. The pilot study is therefore increasingly playing a vital role in research planning in this environment that is subject to ongoing technological innovation, practice change and variability in models of care delivery. Both novice and experienced researchers need to be receptive to the findings of a pilot study and prepared to utilise these findings to influence and modify relevant aspects of the main project. The following study is used to illustrate this claim.

### 3. Prelude to a pilot study

The topic of interest for the research team was post-operative pain management. As an innovative method of combating post-operative pain, the application of local anaesthetic directly to the wound site has frequently proven to be highly flexible in terms of possible routes of administration, and effective in reducing post-operative pain scores and narcotic use ([Partridge and Stabile (1990)]; [Enneking et al (1997)]; [Oakley et al (1998)]). Additionally, there was, in the context of this study, an increasing interest from surgical teams in the use of local anaesthetic wound infusions for management of post-operative pain. However, there was scant evidence in the international literature to indicate that a standard system of continuous local anaesthetic delivery has greater clinical efficacy than current practice with intermittent or patient controlled analgesia. Therefore, there was a need to contribute to an evidence base to inform practice in this area of health care.

Following an extensive literature search and critique the investigating team decided to conduct a clinical trial of a specific elastometric system (On-QTM) intended to provide continuous infusion of a local anaesthetic directly into intra-operative sites for post-operative pain management. The local anaesthetic agent ropivacaine was to be used in the main study. Ropivacaine has been shown to be as effective as bupivacaine for sensory block, but to have less intense and shorter duration motor block effects, and less toxicity than bupivacaine ([McClure (1996)]). A randomised controlled trial was the methodology of choice due to the absence of any generalisable research into this topic. Additionally the investigating team was interested in providing an evidence base to inform a proposed change to established practice. The aim of the study, therefore, was to conduct a randomised controlled trial on the clinical efficacy of a system for delivery of continuous local anaesthetic for management of post-operative wound pain.

### 4. Preparation of the pilot study

The investigating team planned to conduct a pilot study to establish the parameters and operational standards for the main study. The institution's Human Research Ethics Committee approved both the pilot and main studies. In addition, the project team was successful in obtaining funding for both the pilot and the main studies from two separate funding sources.

This pilot study was undertaken over a 3 month period using the methodology of the main study. This time period included initial preparation of printed materials and staff education. Participant recruitment and data collection was anticipated to take 4 weeks. A sample size of 10% of the main study sample was to be used. Whilst the aim of the main study was to test the clinical efficacy of a specific pain control delivery system, the intended objectives for the pilot project were to achieve:

1. validation of recruitment, consent and randomisation procedures;
  2. confirmation of sample size for the main study;
  3. confirmation of the inclusion/exclusion process;
  4. testing the appropriateness of instruments used during the study;
  5. testing the appropriateness of timing of data collection points;
  6. development of data collection material;
  7. monitoring of the operational process;
  8. formalising the protocols for analgesic and anaesthetic regimes; and
5. Procedure for the pilot study

The pilot study was conducted over a period of 3 months. The research population was all patients in a Level 1 tertiary trauma referral hospital having elective surgery for inguinal or femoral hernia repair or for an abdominal hysterectomy with or without a salpingo-oophorectomy. Sample size for this pilot project was 12 patients, which represented 10% of the sample size calculated for the main study. All suitable consenting patients were recruited into the project and randomly assigned to one sub-group or the other within their required surgical procedure grouping.

This was to be a prospective comparative study with participants undergoing one of two surgical procedures: A (hernia repair) or B (abdominal hysterectomy). The purpose of the study was to examine a new technique in the delivery of pain management implemented alongside standard practice protocols of pain management. A standard protocol for anaesthetic and analgesia was written by one of the anaesthetists. Therefore, all participants in the pilot study were treated with prescribed analgesic and anaesthetic medications according to this protocol, based on current practice. Within each category (A and B) participants were randomised into two groups. Groups AI and BI received additional local analgesic medication delivered via the elastometric device; Groups AII and BII received the standardised protocol alone.

#### 5.1. Implementation of the pilot study

A research assistant undertook recruitment in the pre-admission clinic. A general information letter describing the project was included in the information posted to patients as part of the pre-admission process. At the clinic, potential participants were identified, given more comprehensive written and verbal explanations about the pilot project, and asked whether they agreed to participate. This multifaceted approach to recruitment helped to facilitate better understanding about the project ([Harris and Dyson (2001)]). The process of randomisation was undertaken in the pre-admission clinic so that patient education could be undertaken (it is standard practice to include

information about post-operative pain control at this time). Once informed consent had been obtained the process of randomisation was conducted by use of an envelope system.

## 5.2. Instruments

Five data collection instruments were selected for the study. Three of these scales were currently in use throughout the recovery unit and hospital wards. These included the visual analogue scale ([Holroyd et al (1996)]), an internationally accepted, well validated and reliable scale; a nausea scale; and a sedation scale. The remaining instruments included an adapted six-grade mobilisation scale ([Rawal et al (1984)]) to measure post-operative mobility and a five-question survey to collect information (via phone) about the participant's perception of having the elastometric system. The first four instruments took less than 1 min each to complete and the telephone survey required approximately 5 min.

Data were collected at three time points: (i) at the point of leaving the recovery room, (ii) after 6 h post-operatively, (iii) and after 24 h post-operatively. It was anticipated that data collection at the 24 h time point would most frequently be conducted in the participants' homes for those participants having hernia repair. Data completion rate for the pilot study was 100%.

## 6. Outcome of the pilot study

The research methodology for the pilot project was structured on the framework established for the main study. Drawing on a smaller scale and focused objectives this pilot study provided important information for the main study. This case report demonstrates the importance of establishing specific objectives to be achieved in the trial. As demonstrated, these objectives relate to the research process rather than research outcome. Based on the findings (see Table 1) recommendations were made to modify the main study to strengthen the research process and avoid problems that were identified in the pilot. Hence the findings of the pilot were directed towards providing information to improve the operational aspects of the main study.

### Table 1. Pilot study findings

However, despite these focused objectives, findings that relate to modification of the research process, and a successful launch of the main study, the project had to be abandoned. This was due to a complex range of factors that were largely outside the control of the research team and unrelated to adequate planning. None-the-less, as we reflected on the process and outcome of the pilot study we recognised early indications of these operational factors and their potential to compromise the success of the main study.

## 7. Unanticipated influences

There were several clues in the overt findings, which in retrospect indicated potential problems. If recognised by the research team these clues may have provided

important information about the likelihood of success for the main study. The difficulty in sustaining the project related to two main issues that impacted upon participant recruitment and retention: staff education and hospital processes.

#### 7.1. Staff education—participant recruitment and retention

Staff education about the purpose of the trial, participant recruitment and staff involvement was identified in the pilot study as important to improve the operational processes of the main study. There were many areas in the hospital that were identified as needing project education. These included surgical bookings, pre-admission clinic, day surgery unit, recovery room, theatre staff, surgeons and anaesthetists and ward staff in the post-operative areas for patients having hernia repair and abdominal hysterectomies. In response to this identified need, posters were placed in all of these areas, education sessions were conducted by the researchers, and project newsletters were sent to surgeons and anaesthetists in addition to information sessions for these medical officers at staff meetings. The volume of education, however, whilst adequate, could not address the complexity inherent in conducting a trial that crossed both service and discipline boundaries. Participants were not always returned to surgical areas of the hospital post-operatively and clinical staff in those outlying areas had only occasional and insufficient exposure to the trial. Additionally there was an unanticipated reluctance by some anaesthetic staff to conform to the protocol of a nurse-led research project. These attitudes were related to discipline boundary issues that could not be overcome through education. Consequently many consenting participants were lost to the trial.

#### 7.2. Hospital processes—participant recruitment and retention

During the pilot study an audit was conducted to confirm sample size calculations and availability. The audit confirmed the availability of monthly figures necessary to obtain the requisite sample size in the time frame of the study. However, despite the audit figures there was difficulty during the pilot study in recruiting participants for hysterectomy to the trial in contrast to hernia participants. There was an early indication of a change in clinical practice away from abdominal hysterectomies towards vaginal procedures. However, the numbers in the pilot study were sufficient to complete the objective and thus this 'clue' was not followed up. In effect this trend continued resulting in difficulties in recruitment of participants to the hysterectomy group.

In addition to this a seasonal increase in medical illnesses, trauma admissions and emergency surgery resulted in frequent cancellations of the elective surgery list due to lack of availability of operating rooms and/or available beds. This had serious consequences for the recruitment of participants to meet sample size requirements and thus the viability of the trial.

Due to the combination of these two factors and their influence on participant recruitment, and therefore on the sample size, it was determined by the research team to abort the study. This decision was taken rather than continue according to the projected timeline and have insufficient data to produce meaningful study results according to the requirements of the proposed methodology.

Specific lessons from this case study report may not apply to other clinical research settings. However the principles relating to process questions in pilot studies and

careful analysis of pilot study findings should be in the preparatory agenda for all research teams in the current dynamic health care environment.

## 8. Conclusion

In conducting a pilot study, nurse researchers must be focused towards process outcomes to ensure successful operational conditions for the main study. A review of the literature reveals that many reports on pilot studies are related to research, rather than process, outcomes. This presents an unrealistic expectation for novice researchers that pilot studies are a small-scale mimic of the research projects and will in themselves produce meaningful statistical results.

Further to this there is a need for researchers to remain open to the unanticipated findings of a pilot study. There are several imperatives that can influence a research team in their decision to proceed with a study in light of the planned and unanticipated findings from a pilot. A strong driver to proceed with a planned research project is the availability of research funding. In a climate where funding for research is uncertain, and reputations need to be built or sustained, to return funds and not proceed with a trial can seem untenable and may influence a team's assessment of a pilot study's findings. This may also influence a team's decision to proceed with a specific methodology. Funding bodies are more likely to fund projects that use experimental methods rather than non-experimental designs. In the study reported here the principal reason to abandon the research was the inability to recruit a sufficient sample size for the research design. A research methodology based upon qualitative interviews may well have produced important knowledge to inform clinical practice in postoperative pain management. However this research approach was less likely to attract or retain funding support.

An additional imperative to influence a research team's decision to proceed with a study is the contemporary health service environment. This is an environment that is subject to ongoing development, innovation and funding pressures. Health service researchers therefore often need to stay ahead of practice change to maintain control of the research environment. These factors bring pressure to the research timeline. In this case report there was incentive to proceed with the trial and contribute to the body of evidence before surgical teams started using the local anaesthetic delivery device. This is also related to the measure of control that nurses may or may not have over implementation of practice changes and patient 'ownership'.

As more nurses are embarking on research in response to the cultural and clinical imperatives of evidence based practice, there is a greater need for experienced researchers to serve as role models. Publication of pilot study results from abandoned projects can be of benefit in highlighting the continuing and emerging factors that may influence the success of research projects in the contemporary and dynamic health service environment. Ultimately this contributes to development of the discipline and furthering the nursing research agenda.

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