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# Practice based research

## Lessons from the field

**Background**
The authors sought to describe the process of conducting a successful randomised controlled trial in a primary care setting and identify enabling factors and barriers.

**Methods**
Descriptive report of methods used to conduct a randomised controlled trial investigating the effect of allowing sutures to be wet and uncovered in the first 48 hours following minor excisions.

**Results**
The trial identified several enabling factors and barriers to conducting research in a primary care setting. The project described in this article was successful because a group of general practitioners sought to answer an interesting question which was relevant to their clinical practice and which had not been answered by current evidence.

**Discussion**
The findings are likely to assist groups seeking to conduct practice based research in the primary care setting.

**Primary care research has been described as 'a lost cause',[1] and Australian general practice has been advised there is some 'catching up' to do in the area of research performance.[2,3] Australian general practitioners publish less research than their public health physician colleagues, both nationally and internationally.[4]**

Primary care and general practice research in Australia has been criticised for conducting mainly small descriptive and survey based studies.[5] Only 13% of all 248 General Practice Evaluation Program (GPEP) projects funded from 1990–1999 were intervention studies.[5] This is partly because many of these studies were conducted in single practices, with numbers insufficient to produce results of high statistical power. General Practice Evaluation Program grants were generally limited to 1 year, with insufficient time to conduct large scale randomised controlled trials (RCTs).

Very few large RCTs have been conducted in a primary care setting. A search of family practice related Pubmed citations from 1960–2003 revealed that of 50 288 citations from 80 countries, only 1585 were RCTs conducted in a family practice setting.[6] Only 5% of research projects conducted in Australian general practice in the 1990s were RCTs.[7]

Difficulties have been reported in recruiting both patients and clinicians[8–10] and RCTs have been reported as being methodologically and practically difficult to conduct in general practice.[7,11]

## Methods

A group of GPs in Mackay (North Queensland), including the principal author of this article, recently conducted a prospective, randomised controlled, multicentre trial investigating the effect of allowing sutures to be wet and uncovered in the first 48 hours following minor excisions.[12]

Eight hundred and fifty-seven patients were randomised to either keep their wound dry and covered, or to remove the dressing and wet the wound. The incidence of infection in the intervention group was not inferior to the incidence in the control group. The results indicated that

wounds can be uncovered and allowed to get wet in the first 48 hours after minor skin excision without increasing the incidence of infection.

This article reflects on the process by which the RCT was conducted and identifies both enabling factors and barriers. The lessons learned from this experience can inform research conducted in practice based settings and may be applicable to a range of projects including – but not confined to – intervention studies.

## Establishment of the research group

Mackay is a provincial town with a population of 75 000. A total of 104 GPs practise in the Mackay region. A GP evidence based medicine (EBM) group has existed in the region since the 1980s and currently meets on a monthly basis. Meetings are usually attended by 10–15 GPs. Meetings involve the delivery of conference reports, discussion of interesting cases and presentation of EBM literature reviews. The results of these literature reviews can reveal gaps in evidence, which can then be used as topics for research projects.

## Identifying a question

The research question was established by two senior members of the group, who were reported to have had a heated discussion as to whether wetting and uncovering sutures in the first 48 hours following minor excisions could increase infection rate.

The group had previously discussed potential research topics without reaching consensus. In this case, the topic emerged from an every day practical issue. The clinicians in question had advanced the topic as far as conducting a pilot project within their own practice. They were emphatic that they wanted to publish their findings, as

Table 1. Recommendations relating to enabling factors

| Enabling factor | | Recommendation |
|---|---|---|
| Background | Members of the group previously involved in a research project | Build on pre-existing infrastructure and common commitment to improving practice through evidence |
| | Research group self selected from established evidence based medicine group | Build on experience. A small 'toe dipping' short term project is a good start for a new group |
| Question | Research topic devised and decided by a group of clinicians | Research topics which evolve from practice based debate are likely to be clinically relevant and engender group commitment<br>Research topics imposed by 'outsiders' are less likely to facilitate group 'ownership' and commitment |
| | GPs 'owned' project, and were co-investigators and co-authors rather than participants and data collectors | Facilitate ownership by local stakeholders. Accept that some will take leadership roles, while others take more passive participant roles<br>Reward the former with co-authorship and CPD points where appropriate |
| Method | PHCRED novice research grant was quickly available to group before they lost enthusiasm | Expedite access to funding, especially for first project. Be aware that competitive grant schemes generally have a 12 month turnaround, so enthusiasm can be lost[14] and grants may be difficult for novices to obtain |
| | Engagement of practice owners as co-researchers enabled easy access to practices and enthusiasm of participating staff | Try to engage practice principals/owners in research process |
| | Engage practice nurses as co-researchers | Engaging practice nurses can lead to greater commitment to project and data collection rigour, particularly for long term projects[14] |
| | Project design and method developed by group of co-researchers | Engaging co-researchers enhances 'ownership' and commitment to project and ensures that all elements of project remain practice based and practice relevant |
| Data collection | Participating GPs had minimal extra work | Minimising GP participant workload is particularly important in multiphase and long term projects[14] |
| | Practice nurses were excellent data collectors | Utilise and fund practice nurses to collect data |
| Analysis | Principal researcher was given academic and statistical support by two experienced supervisors | Ensure principal researcher is given adequate academic support |
| | Although principal researcher had university appointment, she was also an established local clinician | Using a primary researcher who is an established clinician in local area ensures commitment to project and clinical relevance of question, methods and results |

Table 2. Recommendations relating to barriers

| Barrier | | Recommendation |
|---|---|---|
| Background | Workforce issues may deplete research group capacity | There needs to be a foundation of adequate GP workforce in order to build practice based research |
| Method | Administration is onerous | Ensure administrative support. Most research funding agencies allow this to be built into budget |
| | It is difficult to 'sell' clinical rigour to GPs | Use pragmatic RCTs.[15] 'Classic' RCTs have been criticised as tools for primary care research,[7,11] therefore need to use key RCT principles but tailored to meet the reality of general practice setting |
| | Ethics approval process can take time, depending on the frequency of ethics committee meetings, the complexity of the project, and the quality of the application. Long delays can sap enthusiasm | Know what is required by the ethics committee to which application is sent<br>Ensure that requested information is provided in sufficient detail for committee to assess<br>Be prepared for at least 6–8 weeks turnaround |
| Analysis | Some co-authors did not have regular internet access | Encourage internet use. Be prepared to use other methods of communication |
| | There may be lengthy waits for journal decisions, and rejection is common | Be aware of time involved and have realistic expectations regarding publication |
| | Most work done by one person | Support principal researcher. PHCRED units might be able to assist. Most research funding agencies allow this to be built into budget |

they felt the results would be useful to other practitioners, and were happy for the project to be developed to establish sufficient rigour for publication.

The core research group of six GPs was self selected from among those members of the EBM group interested in becoming co-investigators, and included the two GPs who had established the original research question. These two GPs volunteered their involvement rather than being actively recruited.

### Project funding, approval and planning

The project was funded by a Primary Health Care Research Development Evaluation Program – James Cook University Research Fellowship. Ethics approval was obtained through the James Cook University Human Research Ethics Committee.

The research design and methods were developed by the group of co-investigators, with each member assigned a specific task. The research protocol was developed and approved by all members over the course of two 1 hour workshops conducted over 2 months.

## Results

Key enabling factors, barriers and resulting recommendations are summarised in *Table 1* and *2*.

Data was collected between October 2004 and May 2005. In three of the four research practices, the practice owner was a co-investigator and member of the core research group, which facilitated the involvement of additional GPs and practice nurses. All practice nurses and GPs at participating practices were approached by the principal researcher and practice owner to seek their participation in the project, and all were recruited.

Practice nurses were responsible for data collection, and though they were not included in the core research group, practice nurses contributed important ideas (eg. introducing a numerical system to indicate body site) which improved project methods and data collection.

In addition to the core research group of six GPs, another 10 GPs had a passive participatory role, allowing their patients to be recruited in the project. These doctors collected continuing professional development points for their participation in the study. The study involved very little extra work for the participating GPs; they were not responsible for any data collection.

The data analysis was performed, in most part, by the principal author, with support from her supervisors. The core research group contributed to the final article and were given appropriate recognition as co-authors.

## Discussion

'Bag carrying' GPs, working in clinical rather than academic practice, generally support the need for relevant research in clinical topics.[13] Historically however, many GPEP funded projects focus on service organisation and supply, education, training and research methods[4] – a necessary step in establishing a strong research culture and expertise base in Australian general practice.

The success of the project was due to the fact that the research question was established by a group of GPs who had an interesting

question which was relevant to their clinical practice and which had not been answered by current evidence.

The authors feel it is no longer appropriate to request GPs to merely collect data for large research projects designed by university academic departments. Chew[5] states: 'The gap between evidence and clinical practice is more likely to be bridged if the gap between researcher and clinician is bridged with greater ownership of the research agenda by clinicians rather than government committees'. Often, university based academics have particular skills, expertise and access to resources to assist practice based researchers, and this is facilitated by the PHCRED program, which provided essential support for our project. However, our overall approach was 'bottom up' rather than 'top down'.

In Mackay, the GPs 'owned' the research project, and therefore were more prepared to participate. However, practice based research needs to be supported with adequate and consistent funding that is readily and quickly available.

Conflict of interest: none declared.

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