Recruitment in primary care research

Primary Care Alliance for Clinical Trials (PACT)

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Research life

The facts

Once you have the tools to conduct research, three major impediments stand between you and answering your research question: funding, ethics and recruitment. Here I look at recruitment pitfalls and pragmatic ways to address them based on methods developed for the Second Australian National Blood Pressure Study (ANBP2). The ANBP2 was a large trial comparing diuretic and angiotensin converting enzyme (ACE) inhibitor based therapy for hypertension conducted entirely in Australian general practice between 1995 and 2001.[1]

Early estimates of patient availability are usually unrealistically high with patients presumed eligible for a study during planning mysteriously disappearing as soon as the study starts! Recruitment will often be more difficult, cost more and take longer than planned. Patients recruited will be healthier than planned in the sample size calculations (selection bias) and endpoint rates lower (underpowered). It is therefore imperative that you pay attention to this critical time in your project.

Planning

Several steps are needed for successful recruitment. First, you need reliable data to estimate patient availability. This can be from similar studies recently conducted or piloting your project in a small number of practices. Pilot data is also useful to assure granting bodies of feasibility before funding. Second, you need a general recruitment strategy outlining steps in your recruitment process including your network for recruitment. The following approaches can be taken.

Patient contact – direct

Recruiting subjects opportunistically as they present at a surgery, via general practitioners/clinic nurses – here others can identify subjects for you using predefined inclusion/exclusion criteria or clinical conditions, and by screening 'walk in' patients.

Patient contact – indirect

Direct mailings or telephoning is now a more efficient process with the increased computerisation of general practice. Clinical software allows you to prescreen so that only those most likely to be eligible for your project can be sent a letter. Such letters can be generated by 'mail merge' (available on word processing programs such as Word for Windows).

In our experience, a typical response rate to these mailouts is 20%.[2] To avoid errors, make sure you telephone any contact number on the letter before posting, and check that details are sufficient to allow someone to get to an address and that it is correct. Release letters in batches so as not to overload receptionists with bookings if they are making appointments. Be aware of the privacy implications of this strategy and make sure that the practice has a privacy policy in situ and a poster in the waiting room advising patients that the practice participates in research (supply this if not available). Also be aware that nonclinical software is not a good database for such a strategy. Clinical software is usually updated for deaths and billing software is not. (A widow will be very upset at receiving a letter for her recently deceased husband).

Appeals via media/advertisements can generate a lot of interest but is not well targeted. Be prepared for large numbers of enquires by ineligible persons and also for misinformation perpetrated by the media. If you are relying on GP cooperation this is not suitable as you may lose most of your subjects when you can't recruit the GP.

Askew et al[3] found that although 84% of Queensland GPs surveyed by them had a positive attitude toward research, only 29% wanted more involvement. They suggested this could be addressed by reputable researchers being aware of the environment of everyday practice, conducting research relevant to the GPs and their patients, and making payments to offset costs.

Be aware that any GP payments should not be of such a magnitude as to blow your budget or be seen as an inducement that exploits the special doctor-patient relationship. Ethics committees are very wary of this

and you must justify any payments to them.

Which method you choose depends on what you are studying, its prevalence, and the study methods you employ (*Table 1*).

Avoiding common mistakes

Treat your recruitment period as a critical time in the trial. Have a realistic recruitment goal and monitor recruitment throughout this period by keeping regular and up-to-date figures on recruitment; discuss this with investigators and staff to identify and address barriers. Allow sufficient time in your planning and have sufficient resources set aside. Be aware of special groups that are difficult to recruit due to ethical or pragmatic reasons such as children, the elderly, pregnant or lactating women, and indigenous populations. The same is true for certain clinical conditions, eg. drug abuse and depression. Be aware of the difficulties associated with recruitment in those of non-English speaking backgrounds. They require translation of communications, pamphlets and subject information sheets, and require staff with language and cultural skills. At the same time, avoiding or excluding these special groups may limit the generalisability of your research. A good strategy is to recruit from practices in areas where census data indicate these groups are concentrated, or where a division database identifies a GP as speaking a particular community language.

Remember that you may be competing with other trials for the same target population or others within the same trial (competitive recruitment in multicentred trials). Keep colleagues, institutions and other stakeholders onside by keeping them informed of what you are doing. Don't forget to inform receptionist staff and the practice manager as your project is likely to impact on practice routine, and patients may ask them about the project.

Ongoing problems

Keep those in the trial enthusiastic during recruitment by feedback (eg. newsletters) and encouragement. Deal with the unforeseen adverse events with due deference and speed. Apologise and explain the circumstances to any participating GP if such a situation arises. If the project is longitudinal, remember that patients may change clinic, which means that recruitment of GPs may need to continue. Make sure you have two or three alternative contact persons for each subject should this occur and keep these updated.

Good luck!

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References

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Table 1. Research methods

Method	Example
Direct patient contact	A study on hypertension. At 6% this is the commonest management problem in general practice.[4] Hence, one can simply identify patients for the study during clinical consultations
Via GPs/clinic nurses	A study on minor adverse events postimmunisation. The practice nurse can be asked to recruit parents and infants who attend for immunisation
Screening 'walk in' patients	A study on the incidence of depression in general practice. A self administered depression questionnaire can be distributed to adults who attend a practice on a particular day to identify those with depression
Direct mailing or telephoning	A study on patients' experience of colonoscopy. The practice computer database can be searched for 'colonoscopy' and a list compiled for the mailout to those so identified
Indirect patient contact, appeals via media/advertisements	A study on knowledge and attitudes of women toward breast cancer who have a positive family history. An article in the local paper or an interview on a local radio station outlining the study and contact details is likely to bring many enquiries

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