Ethical considerations in recruiting primary care patients to research studies

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Background

How patients are selected and subsequently invited to take part in research has important implications for gaining informed, voluntary consent.

Objective(s)

This article identifies and discusses common ethical issues that are faced by researchers when recruiting patients from primary care settings.

Discussion

Recruiting primary care patients for research studies should be guided by the core ethical values of merit and integrity, respect, justice and beneficence. Issues of patient privacy and risk of coercion are major concerns when selecting and recruiting primary care patients, but the ethical issues will depend on the type of research and the potential risks to participants. The National Statement on Ethical Conduct in Human Research, and Australian privacy laws and principles, should be reviewed to ensure recruitment meets contemporary ethical standards prior to submitting a study protocol for ethical review.

Case

You have been approached by university researchers seeking your help to recruit patients to a research study. The study would involve your elderly, frail patients answering a survey about their chronic disease management. The study protocol requires that you write to your patients, inviting them to complete the survey. You are concerned that this may seem coercive and ask the researchers to write directly to the patients. The university collaborators question whether this approach will impinge on patient privacy and be approved by the local ethics committee.

The participation rates of general practitioners (GPs) and their patients in research are notoriously low,[1] and engaging these groups in research can be challenging.[2] There has been an increasing focus on the recruitment of patients to research studies from primary care settings,[3,4] given recognition of the need to increase applicability and translation of research findings to primary care.[5]

Techniques and strategies that seem to improve response rates have recently been described.[6–10] How patients are selected and subsequently invited to take part in research can have important implications for gaining informed, voluntary consent from participants. However, this aspect of recruitment has received minimal attention in the literature.

Like most research involving human participants, research that involves the selection and recruitment of participants from primary care, or the use of their health information, will require ethical review.[11] The procedures used to recruit participants should be consistent with ethical principles.[12] However, the ethical issues that are raised are likely to be context-dependent and will be influenced by the type of research and the resultant risks. In primary care research, these issues often concern patient privacy and gaining informed, voluntary consent (in the context of power relationships).

In this paper, we identify and discuss common ethical issues faced when recruiting patients in primary care. Common recruiting scenarios and ethical issues that arise from them, like that presented in the case scenario at the beginning of the article, are considered, as are how these ethical issues can be addressed. Strategies that GPs can use to be responsive to ethical issues in the recruitment of primary care patients to research studies are summarised in Box 1.

Ethical principles

In Australia, the National Health and Medical Research Council's (NHMRC's) National Statement on Ethical Conduct in Human Research (the Statement) must be used to inform the design, ethical review and conduct of human research that is funded by or takes place under the auspices of any of the bodies that have developed the Statement,

including universities and major research funding bodies.[12] The Statement provides researchers and ethics committees with guidelines on what is acceptable conduct for the recruitment of patients from clinical settings.

The Statement is underpinned by four core values – research merit and integrity, respect, justice and beneficence. These values provide the framework to guide the design, review and conduct of research, including recruitment strategy. However, the Statement goes beyond a simple set of rules to guide research processes. Researchers and ethics committees are encouraged to follow the values and principles on which the guidelines are based, to exercise judgement and appreciate the contexts within which research occurs.[12]

In the scenario presented at the beginning of this article, a research ethics committee would consider:

- the merit and integrity of the recruitment approach (eg will this strategy enable researchers to meet their minimum sample size requirement?)
- whether the concept of respect is ensured (eg are the privacy, confidentiality and cultural sensitivities of the participants upheld?)
- whether the recruitment strategy is just (eg is there unfair burden of participation on particular groups?)
- whether the benefits of the research (beneficence) outweigh the risks for the participants involved.

Ethical considerations in research conducted in a general practice setting

Research studies that recruit patients will nearly always require review by an ethics committee. Other designs (eg an audit of medical records for quality assurance) might not require any formal ethical review at all (Table 1). The ethical issues arising will depend on the context and become more complex with the involvement of clinical staff. For example, there are few ethical issues arising from researchers placing a flyer in a clinic waiting room inviting patients to contact researchers to register their interest in a study.

The involvement of clinical staff in the selection of participants can raise ethical issues relating to patient privacy. Further, if the person recruiting the patients is also the treating GP (face to face or by letter), issues arise about gaining informed consent and voluntary participation when there is a power difference between the patient and doctor.

Patient privacy

Prior to recruiting participants to a research study, there is a need to identify patients who meet the study selection criteria and inform them about the study. How researchers go about identifying patients for inclusion and how they gain access to the detail needed to contact potential participants will be scrutinised closely by ethics committees.

The Statement provides non-prescriptive advice in relation to privacy, saying only that:

> *researchers and their institutions should respect the privacy, confidentiality and cultural sensitivities of the participants and, where relevant, of their communities* – Section 1.11 of the Statement, 2007 (updated March 2014).[12]

In Australia, patient information is protected by national and state/territory privacy principles and/or laws (see Box 2). The key privacy principle is that personal information about an individual that was collected for a particular purpose (the primary purpose) must not be used or disclosed for another purpose (the secondary purpose) unless the individual has consented to it.

Box 1. Strategies GPs might use to be responsive to ethical issues in the recruitment of primary care patients to research studies from their clinic

- Ask the researchers to provide a copy of the ethics committee approval notice for the practice to retain as part of its record of participation in the research.
- Ensure key staff members are aware of the research and have been provided a copy of the participant information sheet. This might include the practice manager, nursing staff, practice principal(s) or management board.
- GPs should make themselves available to answer questions that patients may have about the research. This could include organising a meeting with the patient, accompanied by a trusted person who may assist them in considering their participation in the research.
- For large or significant studies, consider appointing an external, independent person to oversee the implementation of the research protocol within the practice and for patients to approach confidentially if needed.
- Invite researchers to discuss the study with other members of the primary care team and/or provide feedback to the practice about the study outcomes.

Box 2. Privacy legislation in Australia

- Private sector providers and organisations with responsibilities under the Commonwealth Privacy Act include:
  - private hospitals, day surgeries, medical practitioners, pharmacists and allied health professionals.
  - complementary medicine therapists, such as naturopaths and chiropractors
  - gyms and weight loss clinics
  - childcare centres, private schools and private tertiary educational institutions.
- Information on the Commonwealth Privacy Act can be found at www.oaic.gov.au/privacy/privacy-act/the-privacy-act
- Information on state and territory privacy laws can be found at www.oaic.gov.au/privacy/other-privacy-jurisdictions/state-and-territory-privacy-law
- The Privacy Act permits the handling of health information for health and medical research purposes in certain circumstances where researchers are unable to seek individuals' consent. Further information is available at www.oaic.gov.au/privacy/privacy-act/health-and-medical-research

Table 1. Recruitment strategies associated with common study designs in primary care research and ethical issues associated with these strategies

Type of study/ study design	Possible recruiting strategy	Examples of ethical implications
Audit of medical records for quality assurance (eg searching own/clinic electronic database[15])*	Not applicable	Minimal. This type of study is unlikely to require review by an ethics committee, so long as patients are not identifiable in any subsequent outputs. However, because of variable editorial policy, it is advisable to get ethics approval if publication in a journal is planned
Audit of medical records for research (eg the Bettering the Evaluation and Care of Health [BEACH] program[16])*	Searching clinic databases, possibly from multiple clinics	Moderate. This study would require review by an ethics committee. Major issues: • Consent needed from participating clinics/GPs • Patient consent unlikely to be needed provided data accessed is de-identified • Who has access to record data • Using records for a purpose they were not originally collected for • Safe storage of data • Privacy protection with publication (especially small sample and towns)
Qualitative study (eg interviews with patients or their carers or older patients attitudes towards GP registrars)[17]	• Notice, flyer or information pack in clinic, with information to contact external researcher or let GP or clinic staff know of interest • Searching clinic databases by GP, nurse or clinic staff, followed by invitation to participate face to face or by mail	Minimal–moderate. This study would require review by an ethics committee. Major issues: • Identifying participants – Are patients' clinical records needed to identify likely participants? – Who has access to this clinical information? – Will the GP, nurse or clinic staff know if participants have taken part in the research? • Contacting participants – How will information about the study be given? Who will give this and is there risk of coercion? • Management of data – Consent to record interviews – Access to data (eg for transcription and analysis) and safe storage of data • Dissemination of results – Privacy protection with presentations and publication. Is there a possibility the participants could be identified by the characteristics or location of your sample?
Survey of patients (eg a quality-of-life survey of primary care patients with chronic illness)[18]	• Notice in clinic • Searching clinic databases by GP, nurse or clinic staff, followed by invitation to patients to participate face to face or by mail	Moderate. This study would require review by an ethics committee. Major issues: • Identifying eligible patients • Role of GP or clinic staff in informing patients about the study, or recruiting patients to the study – Will clinic staff know which patient participates and who does not? – Will participation or non-participation impact on clinical care? • Completion of survey may constitute consent. However, if survey addresses issues or topics that may lead to distress, separate written consent may be required • Access to data (eg for data entry and statistical analysis); safe storage of data • Privacy protection with publication (especially small sample
Experimental study – lifestyle or other non-invasive intervention (eg a trial of chronic disease self-management support)[10]	• Notice in clinic • Searching clinic databases by GP, nurse or clinic staff, followed by invitation to patients to participate face to face or by mail	Moderate–high. This study would require review by an ethics committee. Major issues: • Identifying eligible patients • Role of GP or clinic staff in informing patients about the study • Randomisation to control and intervention groups† • Patient aware of risks, likely benefits or potential harms • Access to data (eg for data entry and analysis); safe storage of data • Privacy protection with publication (especially small sample and towns).
Experimental study – drug trial, medical device or other invasive procedure (eg a trial of efficacy and safety of inhaled zanamivir)[19]	• Notice in clinic • Searching clinic databases by GP, nurse or clinic staff, followed by invitation to patients to participate face to face or by mail	High. This study would require review by an ethics committee. Major issues: • Identifying eligible patients • Randomisation to control and intervention groups† • Role of GP or clinic staff in informing patients about the study • Patient awareness of risks, likely benefits or potential harms • Access to data (eg for data entry and analysis); safe storage of data • Privacy protection with publication (especially small sample and towns)

**Quality assurance (QA) activities can be defined as activities for with the primary purpose is to monitor or improve the quality of service delivered by an individual or organisation.[20] QA, evaluation, and research exist on a continuum of activity, and work that begins as one can evolve into another. Irrespective of whether an activity is called research or QA (or evaluation), the activity must be conducted in a way that is ethical. In many situations, oversight of the activity is required, but ethical review may not be necessary.[11,20]*
†In relation to beneficence in research, there may be benefits to patients taking part in research, particularly clinical trials, even when they are in a 'usual care' or control arm. Being part of research may help patients take a more active role in their healthcare and learn more about treating and managing their condition.

However, the *Privacy Act 1988* (Cwlth) does allow for use and disclosure for a secondary purpose that is 'directly related' to the primary purpose (ss 6.1–6.2).

A common, acceptable practice among primary care researchers is, following agreement from the participating practice or GP, to provide the selection criteria to practice staff (typically either the participating GP, nurse or practice manager) who will then identify patients at their clinic from information held in each patient's medical record. The participating GP will then make these patients aware of the research and invite them to take part, as was described in the scenario at the beginning of this article. These patients will then need to contact the researchers to register their interest or otherwise enrol in the study directly, perhaps by completing a survey.

Consideration of privacy and confidentiality should also be made in the reporting of results from studies of small samples, or samples drawn from small towns, such that individual confidentiality can be protected. It is important to note that ethics do not apply just to the individual, but also to the community or population.

Informed consent and power relationships

Once potential participants have been identified, they need to be informed about the study and given the necessary information to make an informed decision about participation. Good, informed consent is guided by the principle 'that a person's decision to take part in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and implications of participation in it'.[12]

The power imbalance between patients and their treating doctor is a reflection of the potentially dependent nature of their relationship. As was raised in the case scenario at the beginning of this article, ethics committees will carefully review the study protocol and wording of the material provided to patients in order to determine whether the patient is likely to experience coercion or pressure to agree to take part in the study, or receive (or alter) treatment that they would not otherwise consent to.

A further issue often considered by researchers is the use of incentives as part of the recruitment strategy. There is good evidence that incentives (both financial and non-financial) increase response rates to surveys.[13] While there is a strong ethical reason to use strategies that will increase response/participation rates (such that studies meet sample size requirements), there is also an overriding need to protect vulnerable individuals. Thus, the use of incentives remains contentious in research.

While incentives that promote risk-taking behaviour in participants would be unambiguously considered unethical, some consider that any inducement that influences decision-making is a form of coercion – that participation in research should be voluntary and/or for altruistic reasons, and that incentives compromise voluntariness.[14] Others consider that 'payment is never coercive', as it is an offer rather than threat.[14] Pragmatically, reimbursement of costs for out-of-pocket expenses related to research (eg travel, accommodation and parking) is not usually considered unethical in the Australian research context.

Limitations

Many of the ethical issues that arise in the recruitment of primary care patients for research studies are context-dependent, and this paper has only considered a small number of strategies and the ethical issues that might arise. In particular, the paper does not deal with situations where consent from a third party is required (eg in the case of children, or participants with impaired capacity to make decisions, such as those with cognitive impairment, intellectual disability or a mental illness), data banks, people highly dependent on medical care who are unable to give consent, people who do not speak English at adequate level for consent, and consideration relative to specific cultural groups (eg Aboriginal or Torres Strait Islander peoples).

Conclusion

There is a strong need for research involving primary care patients and healthcare providers. Increasingly, successful strategies and techniques used by others are available in the literature for researchers to draw upon as they develop their research plan. When this is submitted for ethical review, ethics committees will consider whether the proposed recruiting strategy is consistent with contemporary ethical principles, the type of research and its context, issues of informed consent and risks of coercion.

In Australia, both the Statement and federal and state/territory privacy laws and principles are used to guide decisions on the ethical recruitment of primary care patients to research studies. Researchers are advised to familiarise themselves with these and ensure their recruitment plan meets contemporary ethical standards prior to submitting their study for ethical review.

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