Ethical issues regarding recruitment to research studies within the primary care consultation

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Recruitment to primary care-based studies may occur within the consultation or in dedicated research clinics. For practical and logistic reasons, some patients are recruited to research studies by their family doctor during the consultation. However, this may preclude patients from discussing participation with others and some patients may not feel empowered to refuse participation. This may be a particular problem when patients have their own family doctor, whom they generally see, and the patient feels dependent on their practitioner’s goodwill for ongoing care. Recruitment within the practice, therefore, raises ethical issues that warrant further exploration.

This discussion article argues that there are reasons to suppose there may be problems associated with family doctors recruiting their own patients into research. Nevertheless, assumptions that patients feel undue pressure or obligation to participate in primary care research may not be justified. It is important that potential research participants have time to consider the implications of participation. However, the risks to patients of consenting to participate in research are, in many instances, less than the risks inherent in their routine treatment. We conclude that it is important that those responsible for the implementation of research ethics approvals and governance procedures are careful to avoid imposing inflexible rules that prevent patients from acting according to their own wishes.

Keywords. Coercion, consent, ethics, inducement, recruitment.

Introduction

People consult their family doctor for a number of services including vaccinations and general health advice, as well as diagnosis and the dispensing of prescriptions. In the UK, 78% of registered patients consult their family doctor at least once a year and the average patient has three practice-based consultations each year with their doctor. These consultations can provide an opportunity for patients to be recruited to primary care research studies.

During a consultation, doctors must determine the reason for the consultation and, where relevant, make a diagnosis and prescribe a treatment. In addition, they should respond flexibly to the needs and expectations of different individuals. This involves understanding the reasons why different patients decide to consult and considering how this may affect the outcome of the consultation. A shared understanding of the problem and its management needs to be negotiated with the patient. Furthermore, a commitment to health promotion needs to be demonstrated, as well as recognizing the potential tension between this role and the patient’s own agenda; and any conflicts between personal health needs, evidence-based practice and public health responsibilities need to be managed. If patients are eligible to be recruited into relevant research studies, the doctor also needs to consider how he or she can explain the purpose of the research, the requirements of participants and the potential risks and benefits. Although the family doctor does have some flexibility in determining the length of a consultation, there is much to be achieved in a relatively short space of time (the average consultation lasting 12 minutes).

Recruitment within the consultation

Not all patients who participate in primary care research are recruited directly by their family doctor. Historically, much of the research undertaken in
primary care has taken the form of observational studies (analyses of retrospectively collected data or surveys) or been qualitative in nature; and recruitment for such studies is often by means of a letter of invitation from the family doctor or a researcher. Some research projects have funding to enable the employment of a dedicated research assistant/nurse to whom eligible patients can be referred to discuss their potential participation further. However, even referral to a researcher requires some explanation, and hence time, during the consultation. There are also some occasions when there is little option other than for family doctors to consider research recruitment during the consultation—for instance, where the patient cannot readily return for another consultation that focuses on research participation (either with the same doctor or with a research nurse) or where the condition is acute and immediate treatment is required.

Ethical problems with recruitment in the consultation

Given the intensive agenda within each consultation, the recruitment of patients into research studies may, therefore, seem overly onerous for both the doctor and patient. Time pressures are only one of a range of factors that discourage family doctors from participating in research. Ethical difficulties may include the following: patients not feeling empowered to refuse to participate (especially when they are dependent on the doctor for their ongoing care); patients being unable to go away and discuss their participation with others and take some time to consider whether or not they want to participate and the focus of the consultation being shifted away from the patient to the research. Given these potential problems, it is not unreasonable to consider whether it is ethical to include the topic of potential research participation during a standard clinical consultation.

Overview of recruitment and consent

The National Research Ethics Service provides guidance to UK researchers on the seeking of consent; these guidelines include a summary of the General Medical Council Guidance. The emphasis is on taking particular care to be sure that anyone asked to consider taking part in research is given the information necessary to make an informed choice, presented in ways that they can understand. This information is usually provided in the form of a written patient information sheet and must include the following:

- information about possible benefits and risks;
- evidence that a research ethics committee has given approval and
- advice that they can withdraw at any time.

Researchers are reminded

- to ensure that participants must have the opportunity to read and consider the research information leaflet;
- that participants must be allowed sufficient time to reflect on the implications of participating in the study;
- they must not put pressure on anyone to take part in research and
- they must obtain the person’s consent in writing.

The italics are ours and highlight the areas that we focus on in this paper: i.e. having time to consider participation and the possibility of pressurizing potential participants.

The difference between consent for participation in research and consent for treatment

Consent for participation in research is generally thought to be significantly different from consent to treatment. Simplistically expressed, in the case of treatment the patient must decide whether or not to follow the advice of the doctor (given in the context of a duty of care to that patient) which reflects the doctor’s opinion of what serves the patient’s interests. When consent is sought for treatment, refusal of consent is considered a serious matter as it goes against expert advice, and from this perspective, it is likely to be to the detriment of the patient not to follow this advice. It is, therefore, usually thought that a patient needs to have a greater degree of understanding about their condition and the implications of refusing the advised treatment to refuse expert advice than they need to follow it. Conversely, in the case of research, while an invitation to participate should not be contrary to the patient’s interests, the benefits to the individual patient may be uncertain (indeed the research would be unethical if the family doctors recruiting their own patients were not in equipoise). It may even be that the likely beneficiary will be a different patient altogether.

The potential risks and burdens and consent for research

For many research studies, the effects of participation may be relatively trivial (e.g. giving additional blood, having medical records examined confidentially) compared to a therapeutic procedure (e.g. where the patient may have to weigh potentially significant harms against likely benefits). Nevertheless, the level of detail contained in guidelines for seeking consent for research implies that the decision to participate in research is a generally more serious decision than consent for treatment.

Most research studies have some, even if in some instances they may be considered relatively trivial, risk attached to them. Even the completion of a postal
survey are already circumstances where it is clearly
of minutes, whereas others may need more than a day.
able to properly consider the information in a matter
some potential participants for some studies may be
cate sufficient time both to communicate a thorough
or undue influence, recruitment processes should allo-
It is widely recognized that, in order to avoid coercion
supererogation (more than duty or necessity requires)
having such skills to present robust arguments to justify the
inappropriate, for instance when recruiting research
participants in emergency situations (e.g. road traffic
accidents, cardiac arrest). On these occasions, the
need to enter a patient into a trial quickly, the impor-
tance of the trial and the additional safeguards that
are in place are deemed sufficient justification for by-
passing normal procedures, even though the risk of
the intervention, because of the patient’s clinical cir-
cumstances, may be significant. This suggests there is
some recognition that allowing 24 hours for consider-
ation is not an absolute requirement, but rather an
ideal that admits exceptions. It is, however, unclear
why these exceptions should only be those of high
emergency where time is of the essence. What about
the other extreme where participation requires but
a trivial decision? Norms, almost by definition, lie be-
tween extremes and these extremes can be ethical as
well as literal exceptions to the norm. These norms
also assume that patients are similar, which of course
they are not.

Challenging normal safeguards

Understanding the origins of the ethical safeguards sur-
rrounding research using human subjects may, however,
allow primary care researchers to challenge the appro-
priateness of these safeguards in certain clearly defined
circumstances. For example, when the effects of partici-
pators are likely to be more trivial than other interven-
tions that are routinely decided upon during a health-
care consultation (e.g. giving an additional blood sample
during routine blood testing or completing a short non-
intimate survey) and where consent can be withdrawn
readily and effectively (though there is some evidence to
suggest that it must be impressed upon participants
that the option to withdraw is a genuine possibility). The
one of the most important lessons that a doctor learns
about patients is that they are not all the same: their
needs, levels of understanding, competencies and per-
sonalities are very different and this is most evident in
the consent process. Yet, safeguards for research par-
ticipants seem to assume a standard, somewhat cautious
person for whom participation in research is an act of
supererogation (more than duty or necessity requires)
that always carries with it weighty risks.

Having time to consider participation

The 24-hour norm
It is widely recognized that, in order to avoid coercion
or undue influence, recruitment processes should allo-
cate sufficient time both to communicate a thorough
explanation of the study and to give the prospective
participant adequate time to consider the information
before making a decision on participation. What is
less clear is how ‘adequate time’ can and should be
defined. Though the recommended norm is 24 hours, some potential participants for some studies may be
able to properly consider the information in a matter
of minutes, whereas others may need more than a day.
The 24-hour norm is a guide rather than a rule and
there are already circumstances where it is clearly

Is 24 hours always necessary?
Some people are cautious by nature, whereas others
prefer not to agonize over decisions; some are risk tak-
ers and others advice seekers and some like to make
their own decisions, while others prefer to share deci-
sion making. Take HIV home testing: it has been ar-
gued that while counselling should be available, it is
paternalistic to make it a compulsory prerequirement of
testing. It is arguable, therefore, that while some
patients will welcome having 24 hours to make a deci-
sion on whether or not to participate in research, for
others this may be an unwelcome inconvenience and
a deterrent to participation. Any unnecessary barriers
to participation may result in some patients being de-
 nied the potential benefits of protocol-delivered care
provided by participation in research (as well as the
moral satisfaction of participation). It could also
lead to the recruitment of a selected group of partici-
pants and result in a study either failing to meet its
recruitment target or in research findings that are not
generalizable.

It is plausible, then, to suppose that some patients
might prefer to waive the 24-hour consideration
period; that some decisions might not require 24 hours
consideration (those that relate to relatively trivial
matters) and certainly that necessity may prove a justi-
iable exception. These suppositions are, of course,
based on the assumption that researchers are both
scrupulous and willing and able to assess potential par-
ticipants’ needs and characters.

Skill and knowledge of ethics is necessary when normal
safeguards are challenged
Researchers wishing to deviate from standard ethical
guidance, such as the 24-hour norm, must acquire
the skills to present robust arguments to justify the

ad hoc, clinical care.
departure. However, they are also dependent on the assessing research ethics committee having the confidence and skills to see beyond the letter of the guidance to its purpose, and, perhaps crucially, having the will and fortitude to negotiate with researchers over how best to implement departures without compromising participants.

Ethics committees exist not just to safeguard participants but also to ensure the quality of the research (poor-quality research is unethical in itself) and give the public confidence in the ethical process of research. Guidelines may offer some protection to participants from insufficiently supervised novice researchers or researchers who are so focussed on the potential benefits of the research that they have lost sight of the interests of participants. At the same time, ethics committees should facilitate and not hinder research. The skill and judgement of individual research ethics committees may be key when researchers propose any deviation from national guidance.

Avoiding pressurizing potential participants

Recruitment during the consultation as especially potentially coercive?

Family doctors may have a pre-existing and ongoing relationship with their patients, and patients may be dependent upon them for a range of medical services. It may be thought that this relationship has a potentially coercive effect if family doctors use the consultation as an opportunity to invite their patients to participate in research. Although it is never (we assume) the intention of doctors to trade participation in research for medical care, patients may nonetheless feel obliged to participate in research suggested by their doctor either through a belief that refusal may compromise future care or through a perceived obligation to reciprocate for the care and attention they have received over the years. The need for reassurance that future management will not be compromised by non-participation may be greater in primary care, where patients may have been visiting the same doctor for a number of years and wish to continue doing so.

The appropriateness of family doctors recruiting their own patients is further complicated if they receive financial reimbursement or reward. One potential concern is that if family doctors are paid to recruit people into research studies, they may be motivated by financial gain. While this may be a reason for caution, actual evidence of coercion to participate in research is absent from the literature.

It is fair to say that family doctors are often trusted with our lives and well-being and rarely do they let us down in pursuit of financial profit. Family doctors have other opportunities to make a profit by taking advantage of patients (e.g. by pressurizing them to undergo cervical screening or have their children vaccinated) but there is no evidence that this is the case. Given the trust that is already placed in family doctors, it is inconsistent to question their motivations only when research enters into the equation.

A sense of obligation to participate in research

Perhaps the anxiety about the potential for coercion if patients are recruited to research during the family practice consultation depends more on the patient’s perceptions of their obligation to their family doctor—their openness to feel coerced, even—than on any evidence that family doctors display Jekyll and Hyde tendencies when they are engaged in research recruitment. Beauchamp and Childress draw an important distinction between ‘... a subjective response in which people comply because they feel threatened ... (and) ... coercion ... because coercion requires that a real, credible and intended threat is brought on a person so that his or her self-directiveness is displaced’. Bearing this distinction in mind, it could be argued that recruitment from within the consultation should be avoided not because family doctors cannot be trusted not to misuse their power but because patients cannot be trusted not to feel obliged to their family doctors.

It is, however, not necessarily wrong for a patient to act upon a sense of obligation to their family doctor if that obligation is well placed and is not being exploited. A sense of just reciprocity may indicate a well-adjusted moral person and if a person feels the obligation to reciprocate, participating in research may be an appropriate way of doing so providing it is proportionate.

The idea of a patient having reciprocal obligations to their family doctor may seem alien in societies where doctors are paid (either directly or indirectly by the patient) for their services, but some patients may feel their doctor does more for them than they ‘get paid to do’ and therefore might feel they owe something over and above simply paying their taxes or settling the bill. It is unclear what reason we might have for being critical of this attitude or motivation and what justification there might be for wanting to prevent it from being acted upon. Furthermore, if we are concerned about the coercive role that a sense of reciprocity might play, we should possibly also be concerned for the family doctor. A patient may trade on a doctor’s moral sensibilities and participate in research with the unspoken expectation of receiving better care in return, which may leave the doctor open to unreasonable future demands.

Is familiarity a bad thing?

We have discussed the potential problem of familiarity and the pressure this may place upon patients, but it is
for the nature of their relationship with their patients and how this may be altered by including recruitment in the consultation process.

- Patients should always be given information that describes the proposed research and emphasizes that withdrawal of consent, or refusal to participate, will not affect their clinical care. Written information is commonly used but other means of providing information may be necessary depending upon the need of the individual patient.

- Where it is reasonable to do so, potential participants should be invited back to a dedicated research clinic, after a period of reflection, where the study is more fully described, questions answered and consent obtained. Where that is not possible, or where the patient clearly feels that this would not benefit him or her, consent can be sought within the consultation.

- The consent process should include a disclosure of gains and an explicit discussion about different senses of obligations that may be felt by both parties.

- Additional time should be available in the consultation, if eligibility for research is to be considered, to ensure that the patient’s therapeutic needs are met before research participation is discussed.

Conclusions

In summary, while we suggest that there is good reason to suppose there may be particular problems associated with family doctors recruiting patients into research, we propose that we must be careful to avoid making regulations so strict that they prevent patients from acting according to their own reasons. It is important to acknowledge that there is no such thing as the ‘standard patient’ and that individuals will require different amounts of time to consider information. They will also have different views about where their obligations lie and why and what counts as a significant factor in their decision making. It should be assumed that family doctors are generally trustworthy and that their participation in recruitment for research offers no exception to this assumption. It is more appropriate to enforce serious penalties for abuses of this trust than it is to have guidelines that unjustly assume practitioners to be untrustworthy.

No research should be allowed to proceed where the harms to the participants outweigh any potential future benefits, either to themselves or to others. Some research does entail serious potential risks and therefore requires close scrutiny. But this is not true of all research, and the benefit of such research is not necessarily lessened as a result. Where recruitment takes place in the context of the consultation, it is important that the main focus of the consultation remains firmly fixed on the therapeutic outcomes for the patient. There is a danger that the guidelines governing research result in practices and procedures that suggest that the research is more significant than the therapeutic options (e.g. by making special arrangements for consent, time to consider, emphasizing the right to withdraw—all of which are aspects of consent for therapeutic options, too). This danger should be given as much weight as the other potential risks of research participation.

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