Primary care research ethics

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SUMMARY. Research activity in primary care is increasing rapidly, and raises a range of specific ethical issues. Many of these relate to the involvement of individuals in the community who are not seeking medical care and to the impact of research participation on relationships between general practitioners and their patients. The ethical issues pertinent to a range of quantitative and qualitative research methodologies in primary care are identified and considered.

Keywords: primary health care research; research methodology; medical ethics.

Introduction

THE need to consider the ethics of biomedical research has long been recognized,[1] but traditional research ethics committee approaches may be inadequate for some of the issues raised by recent developments in primary care research. A key reason for this is the shift of research focus from patient populations to a community base. Improving our understanding of much of primary care requires us to go out into the community, to describe the natural history of common conditions, the patterns of self-care and the processes by which people become patients, alongside the many factors that influence demand for and access to health services.

All research is potentially exploitative and researchers' motives can frequently be mixed; while wishing to contribute to knowledge and improve patient care, they may also be caught up in a 'publish or perish' mentality. Published research improves job promotion prospects and researchers working in academia are under increasing pressure to contribute to their departments' research profiles. Participants in research may be ill-equipped to safeguard their own interests; researchers owe participants a duty of care, particularly when general practice registers are used to select those who have not yet entered care, and who may be perturbed by invitations to participate in medical research.

Gillon has provided a valuable framework in which to consider the ethics of medical care;[2] in this framework, respect of patients' autonomy and the pursuit of beneficence, non-maleficence and justice are regarded as cardinal ethical duties, and these apply equally forcefully to medical research.

In this discussion paper, we have drawn on our experience of involvement in primary care research in the United Kingdom over the last decade and have selected a number of topics of particular interest and potential difficulty for consideration. We aim to identify ethical problems which may arise in the recruitment and involvement of individuals who are not seeking medical care and in the relationships between patients, their general practitioners and researchers, who may themselves be general practitioners. As well as discussing problems arising from epidemiological and quantitative research studies, difficulties that may be encountered in qualitative studies, where non-medical researchers may have close interactions with their research subjects and where there may be legal implications, will be discussed.

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Access to data and recruitment of patients for research studies

General practice registers/databases

Participation of individuals in research studies always threatens, and may compromise, autonomy. In the UK and some north eastern European countries (for example, Norway and the Netherlands), general practitioners hold lists containing details of the populations registered with their practices. The increasing sophistication of such records means that details of age, sex, morbidity and prescribing can all be extracted with ease, often using computer software. This has increased the accessibility and attractiveness of general practice registers as sampling frames for researchers planning epidemiological studies, particularly for those studies concerned with subjects who have not yet sought health care.

Patients may be identified and selected from databases of this kind, and asked to take part in data collection through postal questionnaire or interview. Patients provide personal information for clinical care, not for research purposes; for general practitioners to disclose such information to researchers could be construed as breaking medical confidentiality and threatening patient autonomy and may have legal consequences. General practitioners could request permission from individual patients before granting researchers access to their names and addresses or before identifying them as members of particular diagnostic categories.[3] Such procedures are likely to add substantially to the costs of the research, particularly in large-scale studies. Moreover, the workload implications may increase general practitioners' reluctance to participate. Conversely, it might be argued that simply supplying researchers with a list of names and addresses does not compromise patient confidentiality, as long as no other information is released. This would appear to facilitate population-based prevalence studies. Further problems arise, however, in relation to sending reminders to non-respondents, which involves disclosure of patients' details to the researchers. Decisions about what is or is not appropriate will relate to the nature of the information divulged, the research methods proposed and the scale of the study itself, and need to be made by the researchers and general practitioners involved.

Whether or not patients' permission is negotiated before access to registers is granted, general practitioners should be given the opportunity to vet lists of potential participants before they are contacted. This will ensure that those who are unsuitable, for either medical or personal reasons, are not approached. It is important to recognize, however, that selection of this kind may introduce bias into sampling.

Selection of patients. Even if patients are not concerned about the disclosure of their medical details, anxiety may be caused by being invited to take part in research; they may believe that their selection indicates that they are at risk in some way. Patients fre-

quently express surprise at being included in surveys, and some may have difficulty in understanding the concept of random selection; they may fear that their selection for research on a clinical topic indicates that the researcher has sinister information about them of which they themselves are unaware. In studies employing quota or stratified sampling this may, of course, be a correct interpretation. Some of these problems may be overcome by providing subjects with a letter describing the information made available to the researchers and clarifying the reason for their selection.

Patient consent. A potential conflict exists between ensuring that patients feel free to refuse to take part in research and maximizing the response rates. One widely used strategy to optimize response rates is the use of personalized explanatory letters from general practitioners,[3,4] emphasizing the importance of the study and urging cooperation in completing questionnaires or attending for interview.[5] Under these circumstances, patients may feel reluctant to refuse, either because of personal loyalty to the general practitioner or because they feel that they might be discriminated against in their future care. Although successful, this strategy is at least potentially coercive. One solution is for patients to be assured that their general practitioner will not be informed about whether or not they have taken part in the study and that future care will not be compromised. Sending reminder letters may undermine this assurance, even if the reminder comes from the researchers.

Patients are often assured in approaches of this kind that information collected in the research will be anonymous and confidential, and the use of these words has to be considered carefully before being used with conviction; other words such as non-attributable may, in certain circumstances, be more appropriate and preferable. Researchers also have a duty to ensure secure storage of data to minimize the risk of unauthorized or accidental disclosure.

The notion of informed consent assumes that patients have adequate information upon which to base their decision about participation in a study. This is not a straightforward issue — a competence (knowledge and understanding) gap exists between biomedical and social researchers and many of their subjects. For the sake of clarity researchers may present patients with an oversimplified view of the research. Researchers have a duty not to use this process of simplification to obscure the true nature of the project.

Implications to the patient of participation. It is important to explain to patients what will be involved if they agree to take part in research, being as precise as possible about the likely time commitment, inconvenience, risks and discomfort involved. It may be helpful if patient information leaflets containing such details accompany the invitations to participate in the research. Questionnaire surveys often ask whether the subject is prepared to be contacted again by the researchers. The nature of this contact is frequently unspecified and may result in a request for an indepth interview, often conducted in the patient's home, which the patient may not have realized would occur.[6,7] Although patients can decline to participate at a later date, it may be more helpful to give the respondent information about the nature of the proposed follow up at the recruitment stage.

General practitioner consultation

Recruitment of patients for research studies may also take place at their point of contact with the health care system. The potentially coercive influence of the doctor–patient relationship in recruiting research participants may operate more strongly here than where patients are recruited via information from practice databases, particularly when a direct request by the general practitioner is made during a consultation. Perhaps patients should be offered a 'cooling off' period, analogous to that applied to some financial agreements, before agreeing to participate in a research study. Written consent from patients will generally be required when patients are recruited by this method for reasearch studies.

Patients consult their general practitioners in the belief that everything that happens in the consultation is confidential, yet the act of consultation may itself act as a trigger for involvement in a research study. An example might be a general practitioner referral letter to a hospital specialist.[8] If the aim of the study is to observe general practitioner referral behaviour the general practitioner will be unaware of the inclusion of a patient in the study and will therefore be unable to obtain the patient's consent. One consequence might be that the patient receives a questionnaire before notice of the appointment to see the specialist has been received. Other clinical events such as issuing a prescription or arranging an investigation may also act as triggers for inclusion in research. All these triggers for involvement in research again raise questions about the confidentiality of the doctor–patient encounter and threaten patient autonomy.

Data collection

Epidemiological studies

Epidemiological studies may raise particular problems about the ethical responsibilities of the researchers in relation to information that they collect. For example, in a study that sets out to document the prevalence of gastrointestinal symptoms in the community it is likely that, in a large sample of non-consulting patients, some will turn out to have a complex of symptoms which suggests the possibility of serious but unrecognized disease. Rectal bleeding, changes in bowel habit, persistent abdominal pain, weight loss and difficulty in swallowing are examples of these, all of which have been reported by patients responding to structured questionnaires designed to determine the prevalence of such symptoms.[9]

What are the ethical obligations of the research team to the patients and to their general practitioners in terms of beneficence and non-maleficence? Individual general practitioners express a range of views on this subject. Some insist that information of this kind should be reported so that appropriate action, for example an invitation to the registered patient to consult, can be taken. This itself, however, can be construed as a breach of the confidentiality promised by researchers, even when such reporting is deemed to be in the medical interests of the patient; that is, autonomy is in conflict with beneficence. Some doctors adopt the opposite ethical stance, asserting that patients have a right to make their own decisions about whether or not to consult. This position can to some extent be countered by the argument that many people do not have enough information on which to make an informed decision about seeking medical advice.

The situation is further complicated when the survey forms part of a longitudinal study to determine the natural history of a disease. Subsequent observations may be contaminated if the research process itself triggers interventions. It is essential that these issues are discussed and resolved to the satisfaction of the researchers, general practitioners and patients before the research begins.

Structured questionnaires

Structured questionnaires administered by interviewers raise problems different from those raised by epidemiological studies. Respondents are often given a limited choice in terms of the kind of answers that are acceptable, and they may be asked to reduce their complex thinking to a set of ticked boxes.[10] Patients may

find this an anonymous and unnerving experience, especially when talking about emotionally charged issues. In the search for reliability, interviewers are generally instructed to adopt a neutral manner, which again can de-personalize the encounter and leave patients feeling exploited.[11]

At the very least it is important to plan time for debriefing and for establishing a more reciprocal relationship between the interviewer and the subject after completion of the questionnaire. It may be important to offer patients scope at the end of the interview to communicate something of the richness and complexity of their experience, and consideration might be given to including space for some free-text responses in the questionnaire, even if these cannot be given priority in subsequent analysis.

Indepth interviews

Indepth interviews may raise almost opposite problems to those raised by structured questionnaires in relation to the interaction between subject and interviewer. Careful listening by a skilled interviewer can be therapeutic; for most of us it is an unusual experience to be listened to with sympathy and without interruption. As a result, subjects can become conscious of distress, such as traumatic events or continuing difficulties in life, which for the rest of the time they manage to ignore. Acknowledging such distress is not in itself damaging, but does raise the issue of what the interviewer does next. An interviewer may feel that it is impossible to walk away at the end of the interview and abandon the subject to his or her distress, and may attempt to stay in contact with the subject and try to help him or her cope with the distress revealed during interview.[12] However, it is impossible to maintain contact with everyone who is interviewed, and it is also important to realize that these subjects have agreed to be interviewed on the understanding that this is going to be a short-term relationship. One solution is to schedule a second interview for the purpose of debriefing the subject and helping the subject to deal with the distress in studies in which difficult material is likely to be elicited and emotional impact is expected.

However, candour and openness of subjects may reflect the safety generated by the very transience of the interviewer–subject relationship. Subjects can take risks in being open with the interviewer, knowing that there will be no follow up; remaining in contact after the interview would not allow such openness.

Interviewees may disclose facets of their illnesses that are unknown to their general practitioners. This poses similar dilemmas to those discussed above in relation to epidemiological studies. The situation, however, may be further complicated where the interviewer lacks medical knowledge and expertise but where the subject assumes that the interviewer is able to understand the significance of information and possesses medical expertise. It is also conceivable that a patient will assume that the interviewer will act upon information and may even expect the interviewer to relay such information to the general practitioner concerned. Clear communication with interviewees about such issues is important, so that confusion and misunderstanding can be avoided.

Participant observation

Participant observation may sometimes be employed in general practice studies, which are increasingly making use of methodological approaches derived from the social sciences. Examples include the use of simulated patients or the direct observation of patient–professional interactions.

This approach poses a further group of ethical problems related to the principle of informed consent. In some participant observation studies, those being observed may be kept in ignorance of the presence or intentions of the researcher.[13,14] Such research has methodological advantages because it minimizes reactivity, that is, the risk that the findings are an artefact of the research process is minimized. However, even where consent for access to settings, for research purposes, is apparently openly negotiated, there is a danger that the researcher will negotiate with more powerful members of a group, for example doctors, but not with the less influential members, for example nurses, receptionists, secretarial staff and patients. Further, it is not always practical to negotiate access with everybody concerned, for example when observations are being made of activities in a public place, such as a health centre waiting room.

General ethical issues

Confidentiality, anonymity and non-attribution have been discussed earlier in relation to patient consent, but it may be almost impossible, particularly in qualitative work, to obscure the identity of the setting in which research is being carried out. For example, practice team members may recognize themselves and each other in a description of a practice. When narrative material is used and direct quotations from participants are included in written reports of research, anonymity may be preserved but confidentiality is necessarily abandoned. The likely format of reports and publications emanating from research studies should be considered by the researchers and possibly communicated to subjects in advance of interviews or other contacts; recognizing one's own statements in print, either as a professional or a lay subject, can only undermine earlier assurances of confidentiality.

Sinister medical findings have also been mentioned in relation to beneficence and non-maleficence, but it is important to emphasize the need for clear ground rules for non-medical researchers about what to do when patients reveal sensitive or alarming information about themselves or ask for reassurance. In practice this is a difficult problem, because in a long interview the researcher is likely to empathize strongly with the subject. Most researchers try never to be drawn into giving an opinion but are likely to become anxious when patients describe something which sounds as if it should be clinically investigated. There may well be situations where disclosure should take precedence over confidentiality (beneficence at the expense of autonomy); some consideration needs to be given to the legal implications for the researcher of non-disclosure of information and in some situations the consent form may include a legal disclaimer. A non-consulting subject with rectal bleeding and changed bowel habit, reported at interview to a non-medical researcher, might feel aggrieved when, at a later date, hepatic metastases from colorectal cancer are diagnosed.

Other information elicited at interview may be particularly sensitive. Research in the area of child abuse may create difficult ethical dilemmas for researchers who discover previously undisclosed activities, with inevitable conflict between assurances of confidentiality and moral, and possibly legal, responsibilities. Another area of difficulty is that in which distress itself is the subject of research, such as in bereavement or terminal illness. It is possible for the researcher to feel almost voyeuristic in the research and analysis of the distress of others.

Dissemination of research results

Protection of the sources of research data is important, and part of the undertaking of confidentiality and anonymity. However, going to excessive lengths to obscure the sources of data may be difficult and may make it impossible for readers of the research report to appreciate the setting in which the research was conducted and to determine whether the results can be generalized to their own circumstances. While outsiders may not recognize individuals or places, insiders (that is, the subjects, who may be medical professionals as well as patients) almost certainly will, and it may be important for them to see the research report before publication.

Feedback to subjects may be important in epidemiological studies. For example, in one study on general practitioner referrals of patients with rectal bleeding, 83% of patients indicated that they would like to see a copy of the report.[15] In a qualitative study on patients' consultation behaviour, 61% of participants requested information about the results.[16] This may indicate a wish for greater involvement and for more information by subjects, in some areas of research at least, although there are logistic difficulties in providing this information and also problems of interpretation when the information is presented as part of a formal research report, although an abbreviated or summary version of the research study report could be produced.

Consequences for participants also need to be considered. Collecting information about smoking or drinking habits, for example, may simply serve to stigmatize certain social groups and to reinforce inappropriate stereotypes. Re-interpretation of research data through the lay media may caricature not only the research findings but also the research subjects. Research that has implications for increasing the provision of services, requiring allocation of resources over which the researchers themselves have no control, may create inappropriate expectations and subsequent disappointments if suggestions for increased resources are not implemented. Researchers have to pay particular attention to the presentation and discussion of information in which criticism of the subjects of research, who may be colleagues or other medical professionals, is explicit or implicit, as well as considering the likely effect of such criticism on future research collaboration.

Conclusion

This paper has discussed some of the ethical problems facing primary care researchers, some of which are specific to research undertaken in the community and in general practice and often reflect dilemmas which apply generally to medical research. These issues have, we believe, implications not only for the assessment of the ethics of research proposals, and for ensuring that research ethics committees are appropriately constituted, but also for the designs of the research studies themselves. None of the ethical dilemmas presented here should be regarded as a barrier to research that sets out to answer questions likely to inform better clinical practice, but they should be considered by researchers when framing research questions, choosing study methods and presenting results. In grasping the rich research opportunities available to them, primary care researchers need to ensure that their concerns for the rights and well-being of the individual as a research subject are articulated at least as strongly as general practitioners' advocacy for the individual as a patient.

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Obstetric care by family physicians in Canada

THIS Canadian article describes intrapartum care given by family physicians in a hospital staffed by four obstetricians and 39 family physicians with 'hospital privileges'.

Of 925 women giving birth between January and June 1990, 74% were booked for local family physician care. Of these 683 women, 82 were transferred to obstetrician care before giving birth. The study focuses on the remaining 601 women, 44% of whom were primiparous. Eleven per cent of the primiparous women and 8% of the multiparous women had caesarian sections. These are considered examples of low intervention rates which might surprise readers in the United Kingdom but this is a north American study, and just over a third of women booked for care by the family physicians were described as 'high risk'. Unfortunately the risk factors are not described.

The proportion of low risk women having epidural anaesthesia was 7%, lower than other Canadian studies quoted. Induced births (14% of all women) and episiotomy (43% of all women) are described as low rates which again comes as a surprise.

Family practice plays a much more prominent role in intrapartum care in Canada than in the UK. The author talks about the lack of an effective voice for family practice in maternity care. I was envious of family physicians' level of commitment and wondered what lay behind the disparity between Canada and the UK. Canada has only just recognized midwives and, although I welcome the role of midwives, it will alter the role of family physicians at births. Canadian general practitioners can hardly learn from general practitioners in the UK as we have been unable to clarify effectively our role, let alone justify it.

Overall, this was an encouraging paper for those (like myself) who believe that general practitioners have a role at births. However, it was surprising (and wounding) to see how little the UK literature was quoted.

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Source: Radomsky NA. Family practice obstetrics in a community hospital. *Can Fam Physician* 1995; **41:** 617-624.

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