Commentary: Methodological reasons for not gaining prior informed consent are sometimes justified

Angus J Dawson

Informed consent is generally required before medical research interventions.[1–3] Despite this, good reasons not to seek such consent often exist. Examples might include research with incompetent patients, research using anonymised tissue samples, and certain types of epidemiological research.[4] Another reason, often forgotten, is where there are methodological reasons not to seek consent in advance of the intervention. Boter et al's study represents such an occasion.[1] Informed consent could not be given before the research as the methodology involved the patients assessing their own quality of life. Requiring prior consent would have led to potentially biased results.[5]

Is this study unethical because informed consent was not gained in advance? Leaving aside the fact that the research could not have been accomplished if such consent were required, such a claim raises an important ethical issue. Arguably, no ethical principle should be absolute in this way. Situations are complex, and minor changes can make a significant difference to the way that we assess them. Different ethical and methodological issues need to be weighed against each other and a defensible judgment made on the basis of all of the relevant factors.

In this case, the procedure for consenting was ethically justified because the study considers an important issue; the results could be achieved with blinding to the issue to be investigated; and any possible harm to the participants was negligible.

Even if we agree that the alternative of not doing the study would have treated the patients with more respect,[6] it is not clear it would have been more ethical, as the results of the study will improve the quality of life of stroke victims.[5] Blindly applying absolute principles such as "always gain prior informed consent" does not guarantee ethical outcomes. Such an approach might well be harmful, as potentially beneficial studies will not be done.

One concern about the study's approach might be that it still places too much emphasis upon consent.[7] Informing the participants in advance that some information about the research was withheld could have caused anxiety. As a result, participants might have imagined themselves in all sorts of distressing scenarios. An alternative would have been to say nothing about the consent issue until after the study was completed. It is not clear that the "modified" informed consent procedure is preferable. However, it is important that this research found that most participants could, retrospectively, appreciate the methodological reasons for not seeking prior consent, and they generally seemed happy to be involved in such research.

Researchers, journals, and the members of research ethics committees should all take note of these findings and should be more willing to weigh up the appropriateness of seeking prior informed consent given the methodology employed in a study. An absolute requirement to gain always an informed consent may do more harm than good.

Competing interests: None declared.

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Centre for Professional Ethics, Keele University, Staffordshire ST5 5BG
Angus J Dawson *director*
a.j.dawson@keele.ac.uk

Comparison of reporting of ethnicity in US and European randomised controlled trials

Aziz Sheikh, Gopalakrishnan Netuveli, Joe Kai, Sukhmeet Singh Panesar

Increasing evidence shows that different ethnic groups respond differently to educational, psychosocial, and pharmacological interventions. If diverse communities are to benefit from the implementation of appropriately derived evidence then it is imperative that the ethnic diversity of populations under study are reflected in clinical trials. In the United States, since 1993, the National Institutes of Health have instituted policy insisting that minority groups are represented in study samples unless there is a compelling reason not to do so.[1] However, no comparable legislation exists in Europe. We sought to compare reporting of ethnicity in published reports of US and European randomised controlled studies.

Methods and results

We searched Medline for reports of trials published in 2002 using the Cochrane optimal search strategy.[2] We

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GP Section, Division of Community Health Sciences, University of Edinburgh, Edinburgh EH8 9DX
Aziz Sheikh *professor of primary care research and development*

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