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Consent bias in research: how to avoid it

Consent bias, also known as authorisation bias or volunteer bias, is described as a systematic error in creating patient groups, such that they differ with respect to study outcome. That is, the groups differ in measured or unmeasured baseline characteristics because of the way participants were selected or assigned. It is also used to mean that the participants are not representative of the population of all possible participants.¹ In short, it describes the impact on a study when those who consent to participate in research differ from those who do not or cannot consent. Buckley et al² in the current edition of HEART add to the small but important body of evidence showing how ethical requirements can bias medical research in the area of cardiovascular disease in a large community based cohort.^{3 4}

Why is it important?

Why is consent bias important for researchers and clinicians? In a review Hewison et al⁵ noted that consent requirements for recruiting patients to medical research could result in a failure to include participants who are most likely to benefit from interventions, such as older or socio-economically deprived patients. It could lead to under or overestimation of incidence or prevalence of a condition, it could bias assessment of an association between risk factors and health outcome, fail to detect differences in quality of care between certain patient groups and fail to capture the full range of views about a health issue. Biased research ultimately leads to poorer patient care, as evidence may be unreliable or invalid (low response rate), misleading (failure

to capture an important association due to selection bias) or lacking (failure to start or complete research projects due to prohibitive costs and administrative burden).

Whilst scientific evidence on the effects of consent requirements are growing, there has been surprisingly little research into patients' views on this issue.⁶ Ethical review boards are often enforcing the opt-in approach with the patients' interest at heart. Whilst there is a suggestion that an opt-in approach is what patients expect,⁷ there is no evidence that patients would chose improved confidentiality over improved health, if asked to make a cost benefit trade-off between poor medical research and the risk of intrusion of privacy. Non-response is more likely to be due to apathy⁸ or misconception⁹ than to principled objection. Few patients deny consent⁸ or object¹⁰ when contacted directly, and even fewer complain about being approached for research.⁸

What can researchers do about consent bias?

One way to deal with consent bias, in an environment where opt-out is no longer considered an ethical option, is to adjust for it using an anonymised sample of the full patient data.¹¹ However, this is no panacea. Whilst the proposed method may detect bias and adjust for it, it is also clear that no amount of statistical manipulation can remedy poor data. In addition, even obtaining anonymised data represents hurdles and the process is likely to add to the recognised substantial time-intensive and costly burden of ethics and governance requirements.¹²

An alternative solution for UK researchers would be an application to the Patient information advisory group (PIAG) provision under the Health & Social Care Act

(2001). This body can give permission to use data without patient consent, where the effort to obtain consent is impractical and it can be proven that a low response rate would compromise the validity of the research. Application to PIAG however is still a lengthy process and it is open to interpretation about what constitutes compromised research or a disproportionate effort to obtain consent.

Another plausible solution would be to explicitly ask the ethics review board to consider the opt- out approach as default when submitting an ethics application and draw on published research as evidence in favour of the opt-out approach.³ The patients' right to opt out of their data being used is safeguarded and patients who would not be able to opt out due to mental ill health or terminal illness are protected by their doctors from being approached for research.⁵

What can ethics review bodies do about consent bias?

It is the interpretation of the law by guardians and review bodies rather than the law (Common law of confidentiality, the Data protection act 1998 and the Human rights act 1998) itself which unnecessarily hinders important medical research, as some ethics committees find opting-out of patient recruitment acceptable.¹³ In the light of observed variability in decision making, a recent report issued by the Academy of Medical Sciences called for a clearer framework on these issues.¹⁴ In addition to considering opt-out as default an explicit assessment of risks and benefits has been proposed, which might help reach sensible, more standardised decisions for each individual study.¹⁵

What can clinicians do about consent bias?

It is important that clinicians and patients as “end users” of research are able to spot consent bias and draw appropriate conclusions. In addition to critically appraising each paper, we propose a checklist to look for effects of consent or authorisation bias (see box).

1. Are the total numbers in the study approached for consent reported? If not, it is difficult to gauge how representative this paper is of your patient population – treat with caution.
2. Is the consent method documented?
Is it Opt in or active consent (more likely to lead to bias)
or Opt out or passive consent (less likely to lead to bias)
3. Is the percentage response / consent rate reported? A response rate of at least 60% is common in community cohorts, while it is expected to be higher for hospital based cohorts. A low response rate may lead to diminished validity for your patient population.
4. If the study used an opt-in approach:
Have comparisons or adjustments been made to ensure generalisability?
Do the authors report the impact of their approach on generalisability or validity on their study?
5. Are the baseline characteristics of the patients in the study broadly similar to your patient population?

Conclusion

Consent bias has potentially serious consequences for the quality of medical research, the use of public resources and the quality of patient care. A public debate on the benefits and harms of being approached for medical research is important but has not happened to date. As Buckley et al argue in their paper, there is a public lack of knowledge about research and education about research was shown to increase patients' willingness to participate in research.¹⁶ It is possible that the public may decide that individual privacy is more important than the societal benefits of research, once an open debate has taken place. In this case, patient education may be the only way forward to ensure adequate and unbiased participation in research. Until that debate however, we need more fearless ethics committees, more critical doctors, more assertive researchers and rigorous data security.

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Declaration Of Competing Interest

All authors declare that the answer to the questions on your competing interest form [<http://bmj.com/cgi/content/full/317/7154/291/DC1>] are all No and therefore have nothing to declare

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Reference List

- (1) Selection bias. Bandolier (<http://www.jr2.ox.ac.uk/bandolier/booth/glossary/selectbi.html> accessed 19 1 2007) 2007.
- (2) Buckley B, Murphy AW, Byrne M, Glynn L. Selection bias resulting from the requirement for prior consent in observational research: a community cohort of people with ischaemic heart disease. *Heart* 2007; in press.
- (3) Junghans C, Feder G, Hemingway H, Timmis A, Jones M. Recruiting patients to medical research: double blind randomised trial of "opt-in" versus "opt-out" strategies. *BMJ* 2005; 331(7522):940.
- (4) Al-Shahi R, Vousden C, Warlow C, for the Scottish Intracranial Vascular Malformation Study (SIVMS) Steering Committee. Bias from requiring explicit consent from all participants in observational research: prospective, population based study. *BMJ* 2005; 331(7522):942.
- (5) Hewison J, Haines A. Overcoming barriers to recruitment in health research. *BMJ* 2006; 333(7562):300-302.

- (6) Robling MR, Hood K, Houston H, Pill R, Fay J, Evans HM. Public attitudes towards the use of primary care patient record data in medical research without consent: a qualitative study. *J Med Ethics* 2004; 30:104-109.
- (7) Wilkie T. Public opinion may force researchers to seek "opt in" consent for all studies (commentary). *BMJ* 2001; 322(1221).
- (8) Iversen A, Liddell K, Fear N, Hotopf M, Wessely S. Consent, confidentiality, and the Data Protection Act. *BMJ* 2006; 332(7534):165-169.
- (9) Crombie IK, McMurdo MET, Irvine L, Williams B. Overcoming barriers to recruitment in health research: Concerns of potential participants need to be dealt with. *BMJ* 2006; 333(7564):398.
- (10) Barrett G, Cassell JA, Peacock JL, Coleman MP. National survey of British public's views on use of identifiable medical data by the National Cancer Registry. *BMJ* 2006; 332(7549):1068-1072.
- (11) Boardman HF, Thomas E, Ogden H, Croft PR, Millson DS. A method to determine if consenters to population surveys are representative of the target study population. *J Public Health* 2005; 27(2):212-214.
- (12) Elwyn G, Seagrove A, Thorne K, Cheung WY. Ethics and research governance in a multicentre study: add 150 days to your study protocol. *BMJ* 2005; 330(7495):847.
- (13) Pegg MS. Overcoming barriers to recruitment in health research: Some research ethics committees believe in facilitating ethical research. *BMJ* 2006; 333(7564):398-39a.
- (14) Personal data for public good: using health information in medical research (www.acmedsci.ac.uk). A report of the Academy of Medical Sciences 2006.
- (15) Davies C, Collins R. Balancing potential risks and benefits of using confidential data. *BMJ* 2006; 333(7563):349-351.
- (16) Cousins G, McGee H, Ring L, Conroy R, Kay E, Croke D. Public perceptions of biomedical research: a survey of the general population in Ireland. Health Research Board 2005.