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Commentary: Evidence will help achieve consensus

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Iversen and colleagues identify the problems that UK researchers have in gaining access to confidential patient information without consent.¹ The issues that arise are both legal and ethical. These are summarised in *Confidentiality: NHS Code of Practice*.² This document identifies four main areas of law that constrain or regulate the use and disclosure of personal health information: common law of confidentiality, the Data Protection Act 1998, the Human Rights Act 1998, and administrative law. At present, disclosure of identifiable information without consent is permitted for medical purposes other than direct healthcare (research and epidemiology) if the use is supported by section 60 of the Health and Social Care Act 2001. This provision is a temporary measure until anonymisation or consent can be put in place. Support is provided only on the advice of the statutory Patient Information Advisory Group.

The impression given by Iversen and colleagues that few epidemiological studies have been given section 60 support is potentially misleading. The Patient Information Advisory Group has approved more than 100 applications for support, including class support for the activities of all cancer and congenital anomaly registers and the use of the NHS Central Register for medical research studies. Under the class action covering the NHS Central Register, over 250 studies have support. The real issue, then, lies in the stringency of the criteria for support. Specifically, the requirements to show conclusively that it is impractical to obtain consent and that a high non-response rate will reduce the scientific validity of a study.

What is disproportionate effort?

Little consensus exists on these issues. On the one hand, the decisions of those responsible for controlling access to sensitive information and protecting privacy seem to suggest that the effort required to obtain consent has to be overwhelming before they are inclined to accept that a researcher need not seek consent on the grounds of "disproportionate effort." When there is

evidence of non-response, researchers also have a strong requirement to show that this does not reflect tacit withdrawal of consent.

On the other hand, many researchers argue that if levels of non-response are high, studies based only on those who consent will suffer from serious response bias among those population subgroups known to be difficult to contact. Furthermore, the need to obtain sufficient respondents to achieve adequate statistical power substantially increases the funding required for record based research to levels for which there is currently no provision.

It is therefore important to have evidence on what constitutes "disproportionate effort" in such studies and the extent to which non-response might or might not mask refusal to consent. Iversen and colleagues provide valuable information on these factors from an important study population. Further evidence from other studies would undoubtedly help to take the debate forward, establishing those circumstances in which the effort and impact of seeking consent undermines the public interest in quantifying suspected health risks to some, or all, of the population.

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Endpiece

Not lucrative

Medicine is not a lucrative profession. It is a divine one.

John Coatsworth Lettsom (1744-1815). *Oxford Dictionary of Medical Quotations*. Oxford: Oxford University Press, 2004

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