

can severely hinder research, as critical information is lost.² While there will always be some patients who do not complete the *treatment* protocol, their data may and should still be used to complete the *study* protocol, wherever it is practical and where consent can be obtained.^{3,4} If the reason for stopping treatment is due to patient denial of the previously agreed consent, a conflict arises between the rights of the individual and those of the population since the latter might benefit from this lost patient information.

As Eriksson & Helgesson⁵ explain, there are various reasons why patients may choose to ask for their data to be removed from studies. These are legitimate concerns and should never be taken lightly. However, every patient who has received medical treatment has reaped the benefits of previous studies, that is to say, from individuals who have voluntarily allowed their data to be used for the benefit of humanity. It could be argued that it is the duty of every patient to repay this debt. We think that, once informed consent has been given, data belong to the protocol and may be used within the context that was previously agreed: report, publication and oral presentation. Some have argued that “once consent has been given, participants should not necessarily have unconditional or absolute rights to withdraw”.⁶

This discrepancy hindered our own research recently when one of us tried to distinguish between withdrawing from treatment and withdrawing from the study. The Independent Review Board referred him to item 22 of the Declaration of Helsinki,⁷ which states that: “The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal.” But the World Medical Association’s International Code of Medical Ethics⁸ divides these patient’s rights into two parts. Under this code, item 2 of “Duties of physicians in general” states that: “A physician shall respect a competent patient’s right to accept or refuse treatment” and item 4 of “Duties of physicians to patients” states that:

“A physician shall respect a patient’s right to confidentiality. It is ethical to disclose confidential information when the patient consents to it or when there is a real and imminent threat of harm to the patient or to others and this threat can be only removed by a breach of confidentiality.” Therefore, when volunteering to participate in a randomized clinical trial, a patient effectively agrees to two different requirements: on the one hand, to random allocation to treatment, and on the other, to measurement and use of aggregated data that is made suitably anonymous. The current wording of the Declaration of Helsinki fails to distinguish between consent to treatment and consent to data. Therefore, when the World Medical Association meets in Seoul, Republic of Korea, in October 2008, we feel that it should deliberate on how to avoid such confusion. ■

Erik Cobo,^a Stephen Senn^b
& Matthew Elmore^a

References

1. Williams JR. The Declaration of Helsinki and public health. *Bull World Health Organ* 2008;86:650-1. doi:10.2471/BLT.08.050955
2. Porta N, Bonet C, Cobo E. Discordance between reported intention-to-treat and per protocol analyses. *J Clin Epidemiol* 2007;60:663-9. PMID:17573981 doi:10.1016/j.jclinepi.2006.09.013
3. Lachin JM. Statistical considerations in the intent-to-treat principle. *Control Clin Trials* 2000;21:167-89. PMID:10822117 doi:10.1016/S0197-2456(00)00046-5
4. Cobo E. Diseño y análisis de un ensayo clínico: el aspecto más crítico. *Med Clin (Barc)* 2004;122:184-9. PMID:14998455 doi:10.1157/13057825
5. Eriksson S, Helgesson G. Potential harms, anonymization, and the right to withdraw consent to biobank research. *Eur J Hum Genet* 2005;13:1071-6. PMID:15986039 doi:10.1038/sj.ejhg.5201458
6. Edwards SJL. Research participation and the right to withdraw. *Bioethics* 2005;19:112-30. PMID:15943021 doi:10.1111/j.1467-8519.2005.00429.x
7. Declaration of Helsinki 2004. Available from: <http://www.wma.net/e/policy/b3.htm> [accessed on 1 September 2008].
8. World Medical Association International Code of Medical Ethics. Available from: <http://www.wma.net/e/policy/c8.htm> [accessed on 1 September 2008].

Withdrawing from the treatment does not mean from the study

Having read the recently published paper by Williams on the ethical conflict between individual rights and public health rights when conducting research on humans,¹ we would like to call attention to a common misconception that occurs in clinical trials: withdrawal from treatment under study necessarily implies withdrawal from the study. Failure to continue to study patients who have withdrawn from treatment

^a Department of Statistics and Operations Research, Technical University of Catalonia, Barcelona, Spain.

^b Department of Statistics, University of Glasgow, Glasgow, Scotland.

Correspondence to Erik Cobo (e-mail: erik.cobo@upc.edu).