

## Editorial

# The Ethical Aspects of Medical Research

Sarra Elamin\*

Consultant physician and nephrologist, Ahmed Gasim Cardiac Surgery and Kidney Transplant Center and the Sudan Peritoneal Dialysis Program

The patient-doctor relationship is often characterized by strong faith and psychological subjection, especially in under-privileged communities. It is the duty of the physician to ensure that patient's autonomy is maintained, and to provide guidance rather than dictate medical decisions. The principle of informed consent influences everyday activities of the medical profession, but its importance is even more marked in clinical trials that involve human subjects.

Although the concept is relatively straight forward, practical complexities are often noted. One example is illustrated by Wassenaar *et al* [1], who recently evaluated the ethical aspects of using students as participants in a study of eating disorder in South Africa. The analysis revealed that research that, on superficial analysis, seems to be low risk and non-interventional can result in adverse psychosocial effects and complexities for research participants and researchers alike. The study underlines the need for special ethics scrutiny of mental health-related research proposals involving students as research participants, especially when conducted by their own teachers [1].

Another complexity arises from a mechanism known as the nocebo effect. Rigorous research suggests that providing patients with detailed enumeration of every possible adverse event, especially subjective self-appraised symptoms, can actually increase side effects. A delicate balance is required to minimize nocebo responses while still maintaining patient autonomy by taking into

account possible side effects, the patient being treated, and the particular diagnosis involved [2].

Some researchers claim that the quality of informed consent of clinical research participants in developing countries is worse than in developed countries. To evaluate this assumption, Mandava *et al* [3] conducted a comprehensive literature review to identify studies published from 1966 to 2010 that used quantitative methods, surveyed participants or parents of pediatric participants in actual trials, assessed comprehension and/or voluntariness, and did not involve testing particular consent interventions. Their data suggested that: (1) comprehension of study information varies among participants in both developed and developing countries; and (2) participants in developing countries appear to be less likely than those in developed countries to say they can refuse participation in or withdraw from a trial, and are more likely to worry about the consequences of refusal or withdrawal [3].

Munung *et al* [4] assessed the extent of research ethics approval and informed consent reporting in publications emanating from Cameroon and indexed in PubMed from 2005-2009. In their review of 219 full-length articles, they found that 57.5% reported ethics approval, 70.8% informed consent, and 50.7% both ethics approval and informed consent. Reporting these procedures was more common in randomized clinical trials than in other study designs [4].

In this issue of AJNT, Izadi and colleagues endeavored to outline some of the ethical dilemmas related to informed consent in developing countries. We hope this will draw the reader's attention to this important aspect of clinical research.

---

\* Correspondence author: Ahmed Gasim Cardiac Surgery and Kidney Transplant Center and the Sudan Peritoneal Dialysis Program; E mail: sarraelamin@hotmail.com

## References

1. Wassenaar DR, Mamotte N. The use of students as participants in a study of eating disorders in a developing country: case study in the ethics of mental health research. *J Nerv Ment Dis.* 2012 Mar;200(3):265-70.
2. Wells RE, Kaptchuk TJ. To tell the truth, the whole truth, may do patients harm: the problem of the nocebo effect for informed consent. *Am J Bioeth.* 2012 Mar;12(3):22-9.
3. Mandava A, Pace C, Campbell B, Emanuel E, Grady C. The quality of informed consent: mapping the landscape. A review of empirical data from developing and developed countries. *J Med Ethics.* 2012 Feb 7.
4. Munung NS, Che CP, Ouwe-Missi-Oukem-Boyer O, Tangwa GB. How often are ethics approval and informed consent reported in publications on health research in Cameroon? A five-year review. *J Empir Res Hum Res Ethics.* 2011 Sep;6(3):93-7.