How informed are our subjects?

Informed consent is the foundation, on which the edifice of ethics stands. While it is true that a good consent procedure does not necessarily lead to an ethical study, with a bad consent, an unethical study is inevitable.[1] The quality of consent is, therefore, a key, though not the sole parameter of ethical compliance, and remains a concern worldwide.[2]

Newer geographies such as the Gulf are seeing a surge of research. For a variety of reasons, sponsors are exploring newer site to conduct their studies. As clinical research activities have migrated to developing countries, ethical concerns have been raised about their conduct. While cultural differences may be a cause of this perception, there could also be a lower standard of ethical compliance. Research misconduct has become real possibility, with the "publish or perish" paradigm being followed to catch up with the developed world.[3]

The role of the informed consent form (ICF) in ensuring subject autonomy has been widely accepted. The quality of consent documents has been a topic of discussion for long, those that are used for both procedures and research.[4] Subjects are more particular and choosy while consenting for interventional rather than observational trials.[5] The importance of subjects understanding the consent document cannot be overestimated, and it is the most common cause of accepting or refusing to participate.[6]

A group of workers from the Gulf has done a detailed study of these factors. In the past, Nair and Ibrahim, studied the difference between industry-sponsored and nonsponsored trials on the basis of GCP compliance and readability of consent documents.[7] Nair *et al.*, in this issue have extended the study to observational and interventional studies. They analyzed ICFs of studies conducted in the member countries of the Gulf Cooperation Council and rated their compliance to regulatory requirements and readability. The compliance was calculated on the basis of presence or absence of the essential elements as per the local regulations, and readability using Flesch-Kincaid scale that reflects the ease of understanding.

That the authors have quantified compliance and readability of informed consent documents is of greater importance than the observations that they have made. Although the Flesch-Kincaid scale existed for long, its use in informed consent documents, at least in our part of the world is rare. Even in the western world, its use is not very common. A similar study conducted in 2010 demonstrated the shortcomings of consent used in dentistry.[8]

The shortcomings of consent documents are not a new thing. If subjects fail to understand the details of the study, the "informed consent" becomes a mere "consent." Yet there seems little interest in applying these scales for consents documents routinely. A picture is worth a thousand words and probably the use of illustrations would increase the comprehensions of subjects. This was first suggested way back in 1998,[9] and there are repeated calls to use multimedia in these documents.[10]

Attractive visual aid presentations have been prepared and tested as alternatives to the regular consent process; they have been found to increase the recruitment rate from 22% to 45%.[11] Web-based tools have been demonstrated to improve comprehension in schizophrenic patients,[12] though these may not be suitable for use in Indian settings. Multimedia-based informed consents or even PowerPoint-based informed consent could be used for improved comprehension, though the printed forms will be required to document the consent.

Informed consent documents are mostly prepared by the pharmaceutical industry, which sponsors most new drug studies. This industry is very well versed in the use of multimedia since most of their promotional material is in this form. When the industry can make and break

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opinions of medical professionals, it should be a minor thing to improve subject comprehension. Using these skills in preparing consent forms will benefit research subjects, and the subsequent increase in recruitment rates will benefit the sponsors themselves.

Although the informed consent form became mandatory after the Nuremberg code, it was first used by Walter Reed in 1900.[13] The form is thus 116 years old. Over time the consent forms have become longer and more complex; subjects, often very ill ones are expected to read and comprehend their meaning. It is the time, we put them through a thorough check for quality and readability or introduce a multimedia-based document.

Ravindra B. Ghooi

Director, Scientia Clinical Services, Pune, Maharashtra, India

Address for correspondence:
Dr. Ravindra B. Ghooi,
Director, Scientia Clinical Services, G 801 Rohan Nilay, Aundh,
Pune - 411 007, Maharashtra, India.
E-mail: ravindra.ghooi@gmail.com

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