

Empowering Populations to Understand Clinical Trials

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Problem/Issue Statement

The value of clinical trials as the optimum methodology for the testing and evaluating new treatments and medicines is well recognized. Progress in science has resulted in the development of innovative medical treatments, many of which could be beneficial to people living in low-income countries. In recent years, South Africa has become a sought-after venue for conducting health research that could lead to the development of some of these innovative new medical treatments. South Africa provides a particularly unique research environment encompassing high technological medical expertise and infrastructure and a significant burden of disease. The racial - cultural diversity provides an opportunity to investigate racially specific disease traits, whilst the migration of people (internally and cross-border) provides a wealth of patients with whom to investigate emerging and re-emerging diseases.

The scientists who conduct clinical trials are bound by the requirements of evidence-based medicine and the ethical conduct of research. Various codes and guidelines for research ethics dictate that all research involving human subjects should be conducted in accordance with four basic ethical principles, namely: respect for persons; beneficence, non-maleficence; and justice. Nevertheless, increasing research activity, competition in research and the attractive research environment may sometimes result in dishonest and fraudulent practice. Large portions of the South African population are illiterate, unemployed and live in poverty. Their typically dire socio-economic circumstances make them vulnerable to abuse and exploitation. Persons with limited education or illiterate people may find it difficult to understand informed consent information. Moreover, people with fewer economic resources who may have limited access to health services may see their participation in a clinical trial as the only opportunity to obtain needed health care. More often than not, it is the poorer people who are more prone to ill health (than their wealthier educated counterparts) who are invited to participate in clinical trials.

Because of the possibility that research could be misunderstood or abused, prospective participants need to be protected and must understand what may be expected of them and what will happen to them if they elect to participate in a clinical trial. The informed consent process is one example of how participants are protected. It is a universal requirement that prospective participants receive and understand all important information through the informed consent process before deciding to participate in a clinical trial.

Description of Program

Recognizing the high value that is placed on the notions of voluntary participation and the likelihood of potential rights violations in the context of clinical trials (due to researchers being more knowledgeable and acting as primary sources of information and education for prospective participants); the Steve Biko Centre for Bioethics of the University of Witwatersrand, in collaboration with the South African Medical Association and the World Medical Association, with sponsorship from Pfizer (External Medical Affairs, International) developed the "What it means to be part of a clinical trial" Talking Book. The format of the talking book is one which can have a high impact in populations where literacy levels are low. The book has vivid illustrations and push buttons by means of which the text on each page can be heard. Thus there are three sources of information in the book: read, heard and seen.



The talking book is an innovative way to share information given the language and literacy concerns that could compromise people's understanding of clinical trials. Its primary aim is to prepare and inform individuals and communities in South Africa about clinical trials and about the roles and responsibilities of participants. This will empower them to make informed decisions about participation in clinical trials and have a stronger voice, before, during, and after, the research process. Following initial research into the effectiveness and ease of use of the talking book, it is hoped that the book will be translated into other languages and distributed widely at international level. The book is specifically aimed to empower those in developing countries where literacy levels are low. Distribution would thus target these countries where the book will have maximum impact.

The Talking Book is being evaluated by means of a pilot project in South Africa in May and June 2009. The impact of the book, including its contribution to the understanding of research participants, will be assessed in this study. The ease of use of the book will also be evaluated. Further evaluations may be undertaken subsequent to the pilot study should these be necessary. It is hoped that the book will be widely distributed at – amongst others - primary health care centres and waiting rooms. As the book is a step prior to any clinical trial enrollment, it is important that those who might participate in a clinical trial have pre-trial access to the book. This will ensure that participants, when enrolled, would already be aware of their rights. Ideally, the book should be endorsed by policy makers in the country and become part of a national example of best practice.