11. MEDICAL RESEARCH IN SOUTH AFRICA

Education and Ethics

BACKGROUND

South Africa “boasts” the highest number of HIV-infected persons living in one country, with approximately 1 in 10 individuals infected. In 2010, estimates put the number of infected at 5.8 million. It is not within the purview of this article to describe the drivers of the epidemic. In South Africa, HIV (the human immunodeficiency virus) is a generalized epidemic with no identifiable risk groups, and the virus is spread mainly through heterosexual intercourse. The incidence of intravenous drug abuse is low. Those who are infected are not marginalized.

HIV infection causes an insidious decline in immune function. When the damage to the immune system is advanced, infected persons develop AIDS (acquired immune deficiency syndrome.) The infected person is susceptible to a broad range of infections, as well as cancers. Tuberculosis is the most common co-infection with HIV (King & Ahuja, 2006). A number of organisms—viruses, bacteria, and even fungi—that normally do not cause disease can afflict those infected with HIV. These infections are termed opportunistic.

The time from which a person living in South Africa is infected with HIV to the time he or she becomes severely ill or dies is, on average, about 8 to 10 years. In South Africa, about 750 people die every day from AIDS. The brunt of the epidemic is borne by young women between the ages of 15 and 24 (Harrison, Richter, & Desmond, 2007). This is a very grim state of affairs. However, since the advent of antiretroviral therapy, the disease can be halted and the damage done to the immune system reversed almost completely. While there is no cure for HIV infection and, in my opinion, never will be, it has become a chronic and thus manageable disease.

Medication for HIV consists of between two to five or more tablets per day, and a person taking this medicine must do so for the rest of his or her life. South Africa has a national antiretroviral program that supplies over one million patients with these life-saving medications. While the program still falls short of meeting the need, it is nonetheless impressive and is a testament to many hard-working, dedicated, and brave health-care workers.

The first medication that received registration for the treatment of AIDS in 1987 was zidovudine (AZT). Originally a drug developed as a cancer chemotherapeutic agent, it was found to slow down the progress of HIV infection. In time, a number of newer agents were discovered and put through the rigorous clinical trial
procedure. In 1995, the use of a combination therapy of at least three antiretroviral medications changed the face of HIV infection forever. These combinations are also termed “highly active antiretroviral therapy” (HAART) (Rabkin & Chesney, 2002). What originally was a death sentence is now a long-term treatable illness not unlike diabetes or hypertension. According to the best available information, a person, once on HAART, can expect to live for 20 to 25 years, provided that he or she continues to take the drugs (Rabkin & Chesney, 2002).

A key part of the development of these medications is research in the form of clinical trials. The trials are scientifically controlled studies of the safety and effectiveness of a therapeutic agent (such as a drug or vaccine), and they are carried out on consenting human subjects.

ETHICS OF CLINICAL TRIALS

Established ethics governing clinical trials are guided by the principles of autonomy, beneficence, and justice. In order to make an autonomous decision about whether or not to participate in these trials, potential participants need to be presented with all available information about the trial and its purpose. This information includes the potential risks and benefits of the new medication, what current treatment is available, what additional procedures are involved (e.g., electrocardiograms, CAT scans, and extra blood-draws), and how many times participants will have to visit the clinic. Participants are also made well aware that their participation is voluntary. This process is called informed consent; there should be no hint of coercion. All of these details must be explained in the language of choice of the potential participants and must be communicated in a manner appropriate to their level of education and understanding.

For a drug to reach the level of a clinical trial, there must be good evidence, based on animal studies and pre-clinical trials, that the medicine will have the desired benefit and will not harm participants. The adage here is, first, do no harm (non-maleficence), and then do good (beneficence). Finally, if the drug is registered, then the community where the research is conducted should be able to access the medication should it prove to be beneficial. It would not be ethical to conduct a trial in an underprivileged community and then market the trial drug at an excessive price. An appropriate term for research done only to benefit the sponsor is “mosquito research,” where what is needed is taken and nothing is given back.

When practicing what is called evidence-based medicine, the health care provider aims to apply the best available evidence, gained from scientific method, during medical decisionmaking. Health care providers may be individual practitioners, health management organizations, regional and national departments of health, and the World Health Organization.

The level of the evidence obtained from the trial process is ranked. Level IV evidence, which is obtained from case studies, is also termed “expert opinion.” In contrast, Level I evidence is obtained from a systematic review of all trials employing random sampling of participants and employing control measures (e.g.,