EDITORIAL

Is it ethical to conduct HIV vaccine research trials on human subjects?

Human immunodeficiency virus [HIV]/Acquired immune deficiency syndrome [AIDS] is the most captivating topic in today's research. It has gathered millions of attention since its evolution decades ago. Everybody in the world is doing their best to control this deadly organism, which has sucked up many human lives. It's spreading like fire and if it didn't get controlled, it might endanger the human species. Therefore today, world's biggest pharmaceuticals and biotech companies and many scientists have put their endless efforts to get hold of it. For that purpose, HIV vaccine research trials are being taken place since 25 years. However, ethics of such trials are questionable, even after 50 years of declaration of Helenski and human rights. As, these trials may not protect the life, health, privacy and dignity of human subjects thereby causing physical, social, economic and mental strain to the participants. This point grabbed my attention and it was boost up by my nursing research class on ethics which exposed me to the concept of non therapeutic research that gave benefit to future generations but not to the subject (Burns & grove, 2007). This concept evokes several questions in my mind for example about subject rights, risks and benefits of participation, significance of research and etc. Fortunately, this platform gave me an opportunity to explore this issue in detail. Therefore, my purpose of writing this paper is to make people sensitized about the consequences of human trials of AIDS vaccine research. Albert Sabin (1992), one of the most prominent proponents of viral vaccines of the twentieth century, commented that ''the available data provide no basis for testing any HIV vaccine in human beings either before or after infection'' (as cited in Veljkovic, V., et al. 2008). Accordingly, it is considered unethical to conduct HIV vaccine research trials on human subjects because; trial participation risks outweigh its benefits.

On one of the major risk of conducting vaccine trials on human is that, it violates human rights of autonomy and justice. Since it has been observed that mostly resources rich countries are sponsors and resource poor are participants like South Africa. Their contextual variables like lack of empowerment, poverty, illiteracy and poor health makes them more vulnerable thus increase their risk of getting the disease (Essack, Z., et al. 2009). Such low education status and lack of awareness of participants may hamper their understanding of different aspects of the research and that may impact on their decision-making ability. Also, monetary funds and access to otherwise unavailable health care provided to participants makes voluntariness doubtful (Essack, Z., et al. 2009). Thus, research in such circumstances can imperil human dignity. On contrary, it is also true that no ideal model exists that can imitate the natural history and pathogenesis of HIV in the human body. As it exclusively infects and causes disease in humans (NIAID, 2006). There is some truth to the argument that models are limited. However, in such cases, humans have right to be protected from discomfort and harm that is right to non maleficence. As, from Reynolds (1972) classification for the level of discomfort, participants in these trials have a risk of permanent damage that is of contracting the infection. Hence, it compromises ethical principle and right of beneficence of human, which is needed to be protected.

Second key evidence is based on the fact that knowledge about AIDS virus pathogenesis is still incomplete even after the decades of it discovery. Moreover, the exact type and level of immune responses necessary for protection are not known (Veljkovic, V. et al. 2008). Also it is not known whether a vaccine protecting against one subtype of HIV would also protect against the other subtypes. And, there is a lack of understanding of how HIV and immune system will interact (Veljkovic, V. et al. 2008). Therefore, there is a risk that participants can become vaccine-induced HIV seropositive or may have a greater risk of developing infection, or of progression more rapidly once infected. Additionally, it gives people false sense of security that is therapeutic misconception which encourages risky behaviors (Slack, C., 2005). Thus such trials can cause further increase in the number of infections and ultimately causing damage to human lives. On the other hand scientists have proved that even a partially effective vaccine between 30- 50% or even less could reduce the risk of transmission by decreasing the viral load (Veljkovic, V., et al. 2008). I do agree to an extent that even partially effective vaccine would be helpful. However, efficacy of such vaccine is not certain as it may not imitate natural immunity and can pose further threat to human life by escalating the risk of acquiring the virus or either by accelerating the HIV evolution towards more infectious and lethal strains. Thus, it can cause more damage to present and future generations.

One more worth mentioning risk of using human models is that it can cause stress. Since, participation in a complicated and lengthy trial involves repeated

HIV testing, travelling and exposure to culturally different scientific and medical concepts, which may cause anxiety, depression and stress (UNAIDS Guidance Document, 2004). Increased tension with partners and/or with family, complications in insurance applications or at health care facilities, decrease job performance and fear of risks of participation and of loosing the job may worsen the mental health (Essack, Z., et al. 2009). As a result, trial brings psychological, physical, emotional and economic burden on an individual which poses a great risk to their health. In contrast, researchers follow Utilitarian approach that is good for all. Since HIV vaccine is major good for future generations which would decrease morbidity and mortality. This consequently, decrease stigma and discrimination, economic burden and social disruption, which could save millions of lives. However, it is true that is a major good for generations but participation, if becomes publicly known or if participant is perceived to be HIV-infected, it not only breach confidentiality but may also lead to negative reactions from family, friends and the general community that can cause more stigma and discrimination (Essack, Z., et al. 2009).

In the lines of reasoning presented above it is apparent that it's dangerous for human to participate in HIV vaccine research trials. Because, even today nature of virus is under research and presence of safe and effective HIV vaccine is uncertain. Besides, participation not only causes stigma and discrimination but also threatens dignity. Since the prime purpose of the vaccine is to decrease the disease burden and save lives but its in turn increase infection, degrading human rights and prone them to major stress of being participant. In the light of such consequences it's erroneous to stake human lives in the name of research when it poses threat to human existence in physiological, ethical, psychosocial ways. Therefore, trials should be discontinued on humans in order to save the man kind from greater harm. And, it is now high time to ask ourselves that should the trials be continued on the cost of human life or would it be right to jeopardize humanity for sake of altruism? And if an effective HIV vaccine is not possible without human trials then our research and efforts must be headed toward exploring other alternatives for controlling the AIDS pandemics like curative treatment, awareness and etc.

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