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A TRACK AND CHECK OF HUMAN RIGHTS ON THE DEVELOPMENT AND CLINICAL TRIALS OF THE RTS, S/AS01 (RTS, S) MALARIA VACCINE

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LLM (Human Rights) Amity University Uttar Pradesh (2022-2023)

Abstract

The increase in numerous types of diseases has led man to think and find ways how to curb this challenge. Malaria is a disease which has created a global alarm for a long time. The Continent of Africa has been the main victim of this disease in which its fatalities ranges to about 0.8 million each year. Recently the RTS,S/AS01 (RTS,S) Malaria Vaccine that was developed has received a good response from the participant in its clinical trial conducted over the years and this has led to the decrease in the fatality rate to 0.4 million each year, moreover this vaccine has received a nod from the World Health Organisation. However with the recent achievement and development in the medical field, this paper/ article seeks to examine and observe the process initiated in the research, development and clinical trials of the vaccine whether it is in accordance with the human rights or is it guilty of violation of human rights. Technology along with globalisation has shaped and impacted greatly in our world even within the health sector. This article is based on the various reports of the CDC, WHO and social/personal understanding approach.

Key Words: Africa, health, human rights, infringement, Malaria, vaccine, violation

Introduction

The uncertainty of life that it brings with it the unannounced arrival of death and the increase in numerous diseases and health deteriorating factors has made us conscious of our own health, after all the life given to each one of us is precious and there is beauty in each of it. August Comte also known as the Father of Sociology, in his theory of the Law of Three Stages has explained that human life evolved in three stages and the first being the Theological stage, the second being the Positive stage and the third being the Scientific stage. In all of the development leading from the first to the third stage we see that logic, discovery and inventions were the main catalysts that led to the advancement and progression in all aspects. Our world had gone through numerous

epidemics and pandemics and these have taken with it the lives of so many precious souls. The birth of new and complicated diseases and illnesses has made researchers, scientists and medical experts to find ways and methods how to control and to eradicate these hindrances which were the main culprits for the deaths of so many lives. Thus, for centuries medical research began, firstly in Europe and slowly it spread to all the different continents. These research involved and still involves clinical trials of the techniques, drugs, medicines and vaccines discovered by the researchers and scientist which act as salvation grace and to put an end or to control the diseases.

Law who existed initially as the law of nature as explained by thinkers such as Jean Jaques Rousseau, John Locke and Thomas Hobbes later developed and grew and were codified and became legislations and Acts in which in it contains the rights, duties, remedies and punishments prescribed for the individuals and citizens. Law touches every aspect and area of our world be it health, agriculture, society, economy, politics, etc. Every human is entitled to the human rights and human rights over the years have acted as a tool to track all the conducts taking place in different fields, to check if these conducts have been found guilty of violating or depriving humans from these human rights. Similarly the medical and health sector in its involvement with their medical research and their clinical trials despite of being a blessing for our health but without a doubt and as per the facts and records some of these researches were found guilty for infringement of human rights. Thus Human rights act as a tool to administer and uphold justice in all sectors amidst the world's advancement and progression that is witnessed but human rights seeks that all these are taking place within the ambit to ensure a safe, a fair and a peaceful world.

The Development phase of the RTS,S/AS01 (RTS,S)

Malaria Vaccine:

The World Health Organisation (WHO) in 2019 has estimated that there were 229 million cases of malaria infections and of these approximately 0.4 million of the infected individuals succumbed from this disease. Malaria is a serious concern and fatal disease and over the years it has alarmed the world particularly the African continent. This disease is often associated and accompanied by fever, chills, etc, and it is caused by the female mosquito *Anopheles* carrying and transmitting a parasite called *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium ovale* and *Plasmodium malariae*, thus, a female *Anopheles* mosquito when infected by either of the mentioned parasite may cause it to transmit the parasite to humans through mosquito bites and leading to malaria. Malaria can also be transmitted through blood transfusion from a person

carrying the malaria parasite to another person or even from a mother to her unborn child in her womb. Of all the mentioned parasites, the most dangerous and fatal of all the malaria parasites is the *Plasmodium falciparum* and this has been the leading cause of so many deaths if the infected individual does not receive treatment at the earliest. Drugs such as quinine and its derivative chloroquine were used in the treatment for malaria but were not completely successful up to a higher mark or degree.

“Malaria vaccine development entered a new era in 2015 when the pre-erythrocytic *Plasmodium falciparum* candidate RTS,S was favourably reviewed by the European Medicines Agency and subsequently introduced into national pilot implementation programs, marking the first human anti-parasite vaccine to pass regulatory scrutiny. Since the first trials published in 1997, RTS,S has been evaluated in a series of clinical trials culminating in Phase 3 testing, while testing of other pre-erythrocytic candidates (that target sporozoite- or liver-stage parasites), particularly whole sporozoite vaccines, has also increased.”¹ The RTS,S vaccine was the biggest achievement in the history of the development of a malaria vaccine because in 2015 it received its favoured opinion from the European Medicine Agency (EMA) and for the first time it also passed through the WHO’s highest regulatory scrutiny.

“RTS,S, the most advanced PEV, incorporates a *P. falciparum* CSP fragment comprising central repeat (hence “R”) and C-terminal regions (containing T cell epitopes, hence “T”) fused to hepatitis B surface antigen (“S”), or altogether “RTS”. RTS is expressed in yeast that also carry hepatitis B “S” expression cassettes, and thus synthesize S and RTS polypeptides that spontaneously co-assemble into mixed lipoprotein particles (or “RTS,S”) with the CSP fragment on their surface.”²

The clinical trial of the malaria vaccine was conducted in Africa, a region with highest concentration of malaria. The trial was conducted on infants, young children, adults and also on pregnant mothers largely in the Sub-Saharan region of Africa and the statistics showed a promising effect and high efficacy rate largely in young children compared to the infants. Thus this vaccine was further improved. On the 6th of October 2021, after many years of observation and further research the World Health Organisation has recommended for the widespread use of

¹ Patrick E Duffy & J. Patrick Gorres, Malaria Vaccines since 2000: Progress, priorities, products, NPJ Vaccines, 5, 48 (2020), (June 29, 2020) [http:// https://www.nature.com/articles/s41541-020-0196-3](http://https://www.nature.com/articles/s41541-020-0196-3).

² Patrick E Duffy & J. Patrick Gorres, Malaria Vaccines since 2000: Progress, priorities, products, NPJ Vaccines, 5, 48 (2020), (June 29, 2020) [http:// https://www.nature.com/articles/s41541-020-0196-3](http://https://www.nature.com/articles/s41541-020-0196-3).

the RTS,S vaccine after its successful and positive impactful results of the malaria vaccines inoculated in Ghana, Kenya and Malawi. This became one of the historic record and achievement of mankind for their fight against a dreadful disease such as malaria which has caused so much of bitterness, despair and deaths in the lives of many.

Did the Development and clinical trials of the Malaria vaccine Passed the Human Rights test?

The Second World War period witnessed the highest atrocities and health crimes especially in Germany in the concentration camps. We now live in the age of globalisation and since the end of the cold war in the 90s, our world wanted and opted for the integration of all nations together to achieve the global agendas or goals and thus the United Nations through its various bodies were given utmost importance. Globalisation has not only brought about the integration of economies, but over the years it has also brought about an increase in the international clinical trials of vaccines and medicines and most of the countries in which these trials were conducted were and are the weaker nations found in Asia, Africa and South America, thus the real question arises is that if such can be accepted or is it a violation of the human rights?

In an era where the Sustainable Development Goals are the global agendas and objectives for the world to achieve, thus in order to reach such an aspiration, it is essential and it also involves the improvement of the health sector and related aspects, thus clinical trials are important too but should be done and carried upon within the ambit of human rights. Article 3 of the Universal Declaration of Human Rights has stated that everyone has got the right to life, liberty and security of person. Vaccines, medicines, etc, are ways and measures to sustain life and to improve our health condition in this world, no doubt that over the years with the inset of various vaccines and medicines we have been able to decrease death rates from diseases which were once upon a time fatal, eg tuberculosis, chickenpox, polio, etc. For research and development purposes of such vaccines and medicines clinical trials is mandatory in order to observe and analyse the efficacy rate of medicines or vaccines.

It is learnt that the Malaria Vaccine Implementation Programme (MVIP) is being rolled out only in the continent Africa and the reason is that African continent accounts for the majorities of the malaria fatalities and infections in the world and especially the young children are the most vulnerable section of the society to contract the disease, this has suffered a lot of criticisms that

Africa being a vulnerable continent with respect to the economy, military, polity, etc, and thus was chosen as a hotspot to conduct various medical research and trials, but in relation and on the basis of Article 3 of the Universal Declaration of Human Rights that all humans are entitled to the right to health, the World Health Organisation has made a clear statement that they have opted for countries such as Kenya, Ghana and Malawi which have witnessed high and increasing number of malaria cases and also in those countries where there is a good response with the past and recent vaccination programmes, in which thousands of people could be saved through this vaccine. However, there are some medical researches and clinical trials that have always been guilty of violation of human rights in which trials and research were conducted without prior consent of the victim or the patient. Conducting of clinical trials without the consent would amount to infringement of Article 3 and in the case of “*Herczegfalvy v. Austria*”³ *a man by the name Herczegfalvy was given a sedative without his consent in a psychiatric hospital and the Court did agree that this could breach Article 3 in theory. However, the court held that in order to show that article 3 has been breached because of the absence of consent, a minimum level of harm or severity met must be shown and that such medical treatment was not essential or needed. In the case of the Malaria (RTS,S) vaccine awareness programs and information on the vaccines were given from time to time including the risk, the benefits that this vaccine could offer and the eligibility criteria of who can receive the vaccine were given. Further-more they encouraged people to continue using and adopting malaria control measures such as mosquito nets, insecticides even after receiving the vaccine.*

“Information is provided one on one by health workers, through health talks led by health officials and health providers – using flip charts, informational leaflets and posters – as well as meetings with community leaders, community health volunteers, public service announcements, and through the local health media, among other methods. Parents who bring their children to clinics for vaccination do so with the option to vaccinate their children or not, as with other vaccines. The vaccine is being delivered through EPI programmes as part of routine delivery, and similar to how other childhood vaccines are offered to families. Because it is not an experimental vaccine, but approved by the regulatory authorities, written consent is not sought for individuals who are vaccinated.”⁴

³ Herczegfalvy v. Austria(1992) ECHR 83.

⁴ World Health Organisation, Malaria: The Malaria Vaccine Implementation Programme (MVIP) (Mar 2, 2020) [http:// www.who.int/news-room/q-a-detail/malaria-vaccine-implementation-programme](http://www.who.int/news-room/q-a-detail/malaria-vaccine-implementation-programme).

The states have an obligation to take steps nationally and also through international assistance and cooperation towards the full realization and administration of various rights, including the right to health. Thus, developed countries have a human rights responsibility to help the developing and weaker nations to deliver the right to health. In India in "*Rahul Dutta v. Union of India*"⁵ and "*Swasthya Adhikar Manch v. Union of India*"⁶ Courts in both these cases have criticised the government for its failure to deal and curb the illegal trials and stated that the untimely death of trial participants in such trials is a gross violation of the fundamental right to life guaranteed under Article 21 of the Indian Constitution. The Apex Court went on to observe that the unrestrained clinical trials are causing disaster to human life. The Court by way of the writ of mandamus would direct the government to amend the laws as per international accepted standards. Article 5 of the Universal Declaration of Human Rights says that no human shall be subjected or inflicted by any means of torture, or cruelty, or inhuman or degrading treatment or punishment. It is a fact that clinical trials is a risky process and in such a process no humans should fall victim or face any fatalities else only if prior consent is given with proper explanation such as risks, benefits and side effects involving in the process is given and explained by the experts. "From the human rights perspective, all malaria initiatives must be subject to effective, accessible and transparent monitoring and accountability, to ensure not just financial propriety but also that the initiatives are conforming to human rights standards and delivering to all without discrimination."⁷

The Success Story of the Malaria Vaccine - An achievement of Human Rights:

Article 25 of the Universal Declaration of Human Rights speaks about the right of every human to an adequate standard of living for health and well-being which includes food, clothing, housing and medical care etc. The RTS,S Malaria vaccine received a good response and efficacy rate in which in 2015 the European Medicines Agency concluded that the benefits of the vaccine are more compared to the risks. However during the phase 3 of the trial cases of meningitis were found in those children who have received the malaria vaccine already, but studies show that it is not the effect of the vaccine. A positive impact was witnessed in the decrease in malaria cases in children who received the vaccine by 29%. "Among children aged 5–17 months who received 4 doses of RTS,S, the vaccine prevented approximately 4 in 10 (39%) cases of malaria over 4 years of follow-up and about 3

⁵ Rahul Dutta v. Union of India, Misc. Bench No 12280 of 2010 Allahabad High Court.

⁶ Swasthya Adhikar Manch v. Union of India, Writ Petition (Civil) No 33 of 2012.

⁷ United Nations | UN Chronicle, Poverty, Malaria and the Right to Health: Exploring the Connections, <http://https://www.un.org/en/chronicle/article/poverty-malaria-and-right-health-exploring-connections>.

in 10 (29%) cases of severe malaria, ** with significant reductions also seen in overall hospital admissions as well as in admissions due to malaria or severe anaemia. The vaccine also reduced the need for blood transfusions, which are required to treat life-threatening malaria anaemia by 29%.⁸ The University of Oxford has also made a comment that the Malaria vaccine could be a major breakthrough against the disease that has taken away too many precious lives and that its efficacy rate stands at 77%. The fatality figures have dropped by half from approximately 0.8 million in 2015 to about 0.4 million in 2019, but this disease is still a concern in many regions of Africa and the world because of the large number of population.

Conclusion:

The dawn of technology in our world has helped and assisted us to achieve many of our pending goals and objectives especially those related to the health sector. The concept of global citizenship has made us realise and transcend our thoughts beyond our nationalist or regionalist spirit and for this reason, a collective global responsibility has emerged in our fight against the challenges. The research, development and clinical trials involved with the RTS,S Malaria vaccine was not a one country's achievement but a global achievement. Since health is our first and foremost priority, it is important that the health sector must go hand in hand with Human Rights. When an achievement has been attained in the clean way without any manipulation or coercion this truly reflects that our world has firmly set its track towards reaching its global objectives.

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