Forum: World Health Assembly (WHA)

Issue: Measures to ensure that medical research is representative

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Introduction

The first topic that will be discussed this year is the "Measures to Ensure that Medical Research is Representative". This topic will allow for all delegates to explore the disparities within medical research that lead to false and inaccurate findings, and the importance of representation within medical research, as it could ultimately lead to life or death situations. These disparities can come from any factors that are within our intersectional identities, and so could include race, age, gender, sex, ethnicity and etcetera. All these factors come into play and affect how we react to different situations, such as new medicinal treatments or behavioural therapy. The main countries surrounding this topic are those with the largest populations and those where it is greatly diverse as there will be more people affected by the exclusion of the different intersectional factors of their identity from medical research that should presumably be beneficial for them. Therefore the most prevalent countries affected will include the following but is not limited to the Permanent 5.

Definition of Key Terms

Population demographics

Population demographics are statistics about the said population that can describe and characterise it; these could include age, sex, nationality, religion and etcetera.

Intersectionality

Intersectionality is the interlinked nature of social constructs that can categorise the human race. These factors of intersectionality are often seen as overlapping and also acknowledge the fact that they can have a way of effecting different forms of discrimination and oppression.

Minority/ minorities

Minorities are the smaller numbers or categories of people that represent less than half of the entire population.

Population

The number that represents the number of inhabitants in a specific area.

Target Population

In studies, this population is the group of people the researchers want to be investigating, whilst in clinical trials, it means the group of people the researchers believe the experimental drug may be beneficial to.

Medical Research/ Clinical Trials

These are research studies conducted on both humans and animals to evaluate the safety and effectiveness of new medical, behavioural, and surgical mediation and intervention.

Background

Representation in medical research has always been paramount, but possibly now more than ever with the world becoming more diverse and interconnected. The lack of representation in research could lead to the lack of access to life-saving medical treatment due to issues with approval processes that only allow the therapy to be prescribed to those who fit in the same categories as the patients who it was tested on.

History about medical research

Women

The history of this topic dates back to when clinical trials were found to have first started, when scurvy treatments for sailors were studied by James Lind. Ever since then, the lack of representation has always persisted. Even after the Congress passed the National Institutes of Health Revitalisation Act in 1993, whereby researchers were required to include women and minorities in all NIH-funded research, women were still rarely asked to partake in these trials, as the researchers did not see women's general health as an important area of study. Moreover, only women's reproductive health was seen as an important area of study, as it was the only way families could bear children. In the United States, women make up about 50 to 51% of the population, but are only represented as about 41% of medical trial participants overall. In particular, 49% of people with cardiovascular diseases are female, but only 42% of participants in cardiovascular health research are female. Furthermore, 50% of cancer patients in the US are female, but only 41% of cancer treatment trial participants are female. In mental health studies, only 42% of trial participants are female, even though 60% of people with mental health disorders are female. All these statistics lend themselves to showing the major differences in representation, in terms of gender and sex.

People of colour and other minority groups

Another reason for the lack of representation in clinical research is due to the longstanding history of unethical treatment of minorities that have generated a giant cluster of mistrust and fear in marginalised communities. An example of the said unethical treatment is the Tuskegee Syphilis Study. Hundreds of Black men in the United States were studied without informed consent and were deceived about the real aims of the study whilst being enticed by several offerings such as free food and healthcare. Instead of receiving real medical care for various illnesses including syphilis, they were given it so that the researchers could study the disease's progression, leading to the unnecessary death of dozens who passed the disease onto their family. All things considered, the history of medical research and the representation in it will allow for and inspire further improvements in today's society, with ideas being able to be brought out starting but not ending in this very council at this conference.

Major points to consider

Lack of awareness

The lack of awareness surrounding clinical trials and medical research could also be a factor in calculating why there is a lack of representation of different identities within the research. Whilst the lack of awareness could stem from the lack of transparency and information dispersed out into the public, it could also be due to language, location and such barriers that restrict people from participating in these trials. Even back in 2001, studies showed that awareness can change attitudes towards the participation and enrollment of clinical trials. The Harris Interactive Survey found that 85% of medical patients were unaware and unsure that participation was a viable option for them to partake in, and 75% of those same patients said they would have enrolled if they knew of the choice. In 2005, a survey was conducted by the NIH with nearly 2000 cancer patients, with 73% of those patients stating that they participated in the research solely due to the awareness of the fact it was happening by their health care providers.

Lack of trust and transparency

Major points to consider surrounding this topic are the ways trust can be built back up between minority communities and the medical system, and how detailed information can be disseminated by the medical system to allow every person to understand the treatments and procedure of the trials. Much research has been conducted on the trust surrounding medical research. Meta-analyses from Schmotzer, Geogge et al, Limkakeng et al and Brown et al all affirm the role of trust and mistrust as a primary determinant of participation in medical research. They identified that there were a few common themes related to the role of trust, one of them being that participants worry about mistreatment and being taken advantage of.

Cultural differences

Cultural differences could also come into play, so delegates must acknowledge the differences between culture and how they may react to the different factors that can encourage people to participate in medical research and trials. For example, the mass guerilla marketing that may attract hundreds to thousands of people in one part of

the world, may not be the same strategy used to try to attract the sign ups of people from another part of the world. Altogether even though the people may not be living in different parts of the world, there are still cultural differences within a country or area itself, so the medical providers and systems need to be aware of it in order to increase the involvement and engagement of a more diverse range of people within the trials' target populations. As of now, countries are not actively sharing medical knowledge with each other due to the competition between countries to create the best means of intervention and medicine, and the desire to monopolise the trade of health care, which may lead to the lack of global awareness and research that has been done by other countries.

Discrimination as a reason why medical research may not be representative

Discrimination held by researchers such as forms of racism and sexism are also determining factors in the participation of different people in research. Additionally, researchers may ignore the lack of representation in their research due to the need for their research to succeed. These researchers may already know that the drug administered within the research may only work for men in their 40s, and so will actively try to create a sample that consists mostly of people who fit into that category.

Major Parties Involved

The United States of America

The FDA oversees clinical trials in the United States of America, whilst ensuring that research is designed and conducted in accordance with federal law, and adheres to "good clinical practice (GCP)" statutes. These practices allegedly ensure that the entire population is represented, whilst allowing for good ethical etiquette. However in 2018 it was reported by 'PharmaVoice" that there is a "disconnect between the makeup of the population and diversity representation in clinical trials." Whilst African Americans comprise 13% within the whole population , only 5% was represented in clinical trials. Hispanic people represent around 16% of the population, but only make up 1% of the participants. On the other hand, Caucasians represent around 67% of the population, but make up 83% of medical research participants. These statistics were gathered after the FDA Safety and Innovation Act (FDASIA 907) was passed, where the FDA were required to report to Congress the diversity of participants participating in all clinical trials they oversaw. It was also compulsory for the FDA to state the extent to which the data collected was based on demographic factors, but this has not improved the representation within trials. As the FDA preaches the importance of diverse participation in clinical trials on the Internet, they have slowly increased policy-making (such as producing a draft guidance to improve enrollment of participants from underrepresented groups in clinical trials) to ensure diversity within clinical trials is reached.

The European Union (EU) - European Medicines Agency (EMA)

The European Union currently consists of 27 members, all who have adopted the use of the European Medicines Agency. This agency has created many regulations, all of which are "binding legislative acts' according to the EU. The EMA's 2001/20/EC directive was rescinded due to the production of Regulation No 536/2014, and

enforcement of it from January 2022, also known as the Clinical Trials Regulation or CTR. Clause number 14 of the EAM Regulation No 536/2014 of the European Parliament and the Council of 16 April 2014 states that "(14) Unless otherwise justified in the protocol, the subjects participating in a clinical trial should represent the population groups, for example gender and age groups, that are likely to use the medicinal product investigated in the clinical trial." This means that all 27 members within the EU (such as France, Sweden and Slovakia) must adhere to these laws when conducting medical research, thereby adequate representation must be enforced.

Previous Attempts to Resolve the Issue

- As the history of the topic and above points are considered, delegates must also be aware of the previous efforts and attempts that have been made to resolve the issue.
- In 1986/7, the National Institutes of Health (NIH) produced their first piece of significant improvement towards creating more inclusive clinical trial policies. In response to a US Public Health Service Task Force on Women's Health Issues, the NIH started to endorse and enforce the Women and Minorities in Clinical Research Policy, to ensure that clinical trials were able to provide a more widespread understanding of how sex, race, ethnicity and etcetera were able to generate different outcomes with the same procedure within a trial.
- However, this policy proved to be faulty with inconsistent application. Therefore the Congressional Women's Caucus took legal action by passing what is now known as the "Women's Health Equity Act of 1990".
- The "Inclusion Across the Lifespan (IAL)" policy was also created by the NIH in 2016, whereby all ages were to be included in clinical trials unless otherwise justified. There was also an IAL workshop held in 2017 whereby it was concluded that most clinical trials did not include or mention individuals with disabilities (either physically or mentally) in either the inclusion or exclusion criterias, leaving them out of clinical trials that may very well be beneficial to them. In addition, Nours (2021) stated that the Inclusion Governance Committee was responsible for monitoring NIH diversity reporting, to ensure the enforcement and accountability of their efforts to increase representation.
- Furthermore, as the aforementioned sections have stated, the 2012 FDA Safety and Innovation Act (FDASIA 907) was indeed unsuccessful, proving that other means to resolve this issue is necessary. However the FDA Center for Drug Evaluation and Research (CDER) has effectively increased representation in their drug research. Through their "Drug Trials Snapshots" which provide ample information about the demographic compositions of the collected data on numerous medications, they effectively improved their representation. For example, trial demographics only included a 40% inclusion of females in 2015, but increased to 56% in 2018, after the transparency initiative started operating and summary reports were made annually. Black and African American participation rose from 5% in 2015 to 10% in 2018, whilst Latino or Hispanic patients were not

recorded in the first two summary reports, but made up 14% of trial participants in 2018. With that being said, different ways of incentivising participants to enrol and different target populations may have contributed to how these two ways of trying to resolve the lack of diversity and inclusion resulted in differing outcomes.

Possible Solutions

- The African continent consists of 17% of the global population and carries 25% of the world's disease burden, yet it accounts for less than 3% of the participants in clinical and medical trials, possibly due to the fact clinical research remains concentrated in high-income countries. So, how would the World Health Assembly be able to disperse clinical research to de-monopolise it? Perhaps countries can work together to allocate some funds to fund further research on the diseases and viruses in Africa, or can help Africa in creating a more effective and accessible healthcare system. However, delegates must take note of the fact this may infringe on the sovereignty of the African governments.
- The effects of Covid-19 have been severe in all aspects, and with the underrepresentation in Covid-19 clinical trials, it may affect how different medicines and vaccinations may affect different sub-groups according to age, sex, race, ethnicity, and etcetera since all these factors are able to influence the way medicine and drugs work within the body. Therefore, delegates may want to implement legislative measures that ensure there are more categories of people that can represent the target population when conducting medical research.
- Additionally, a way to target the fear within racial and ethnic minorities needs to be addressed as mistrust between the minority groups and the medical system is prevalent. Ways mistrust could be prevented would be to increase the representation in the medical field in terms of doctors, advocates, organisations and etcetera, and to increase the education and knowledge of vaccinations and other medical procedures so that patients are fully aware of the procedures to gain more understanding of the ways it is necessary. In order to increase the education and representation within medical research, delegates may want to implement compulsory diversity, equity and inclusion activities and classes in state-funded schools. Delegates may also want to increase the awareness surrounding the topic by creating compulsory news sections in newspapers or magazines dedicated to spreading awareness about medical trials and the importance of representation within it.
- To increase representation in clinical research, it may be important to increase cooperation between different countries to combine populations and to find target populations. This could help aid in the lack of representation from different countries and how different environments may also affect the effectiveness of the drug or medicine being ingested.
- The cost (both literally and physically, such as incentives, travel-costs, bonuses, travel-time, possible risks and side effects) of including participants from different backgrounds and sub-groups may also be a possible factor affecting the total representation of the target population in clinical trials. Sometimes

clinical trials may require the participants to pay for the medical treatment and such out of their own pockets or through insurance, discouraging participants' engagement.

- Sometimes clinical trials may use experimental designs such as a single-blind or double-blind experiments, where the participants are not allowed to know the true aims of the study beforehand, possibly causing hesitancy to join the trial within the participants. Researchers may also need to enforce steps to guarantee privacy and confidentiality to ensure that the trials are ethical and stick to ethical guidelines.
- Moreover, there is no guarantee as to whether the clinical trials will work or not, leading to a low level of participation in these trials. Therefore, delegates need to consider how to resolve these issues before generating ideas on how to incentivise participants from underrepresented populations to participate in different clinical trials, as increasing the compensation

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