Gender Inclusion Policy in Research

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Abstract

This paper analyzes the current National Institutes of Health (NIH) policies around gender inclusion in research. While there have been some improvements over the 30 years since the policy was put in place, the policy needs to be adjusted to further increase the rate of change. Before the passing of the NIH policy, women were rejected from research pools all together. Now, despite changes, women are vastly underrepresented in research on neurodevelopmental disorders, which leads to social ignorance and further underrepresentation. The policy permits this underrepresentation through non-specific language and limited scope of control. This paper analyzes the events and movements that lead to the creation of past and current policies. It compares other organization's policies and the function of the current NIH policy, elaborating on the wording and policy's effect. The paper also suggests some changes to further equalize the presence of women in neurodevelopmental research.

Keywords: policy, gender inclusion, representation, neurodevelopmental disorders

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Introduction

Psychological screenings, diagnoses, and treatments are all the result of research. However, there are many flaws to the research we have about women with neurodevelopmental disabilities, which are mental health disorders characterized by difficulty in common developmental stages, such as ADHD and Autism (American Psychiatric Association, 2022). Currently, in America, “all NIH-funded clinical research must include women and members of racial and ethnic minority groups” (National Institutes of Health, n.d.b). Unfortunately, this still allows gaps in research. There are ways for researchers to get around the wording of the guidelines, and people who obtain funding elsewhere are not required to follow the NIH policy. Protesters fought and increased rights and representation of women as research subjects. Yet, the policy of the United States government remains vague to avoid possible oversteps. Since these factors allow unreliable studies, people assume girls do not experience neurodevelopmental disorders at the same rates, previous studies can be presented as definitive facts, and definitions for neurodevelopmental disorders are set in stone. As a result, many blindly accept the falsehoods and disregard those who are underrepresented and are often left behind.

Populations Impacted

The NIH’s guidelines benefit certain researchers while harming women who are often left out of studies. Without guidelines, researchers can do whatever it takes to get their results, which causes women to be underrepresented in studies. The policies regarding research guidelines benefit researchers who want to get results fast and easily. By not clarifying a certain population amount, the NIH allows researchers to disproportionately exclude women. In a review of the Michigan Institute of Technology’s database of autistic research participants, girls were removed from autism studies 50% of the time, more than males, who were removed 19% of the time

(D’Mello et al., 2022). As women can show slightly different symptoms, removing them from studies can allow researchers to claim more generalizability and validity in their studies without putting in the effort to make it true. In reality, using different screening methods has led to more equal rates of diagnosis in both men and women (D’Mello et al., 2022). This means researchers are allowed to create gaps in information.

This can cause issues for people not in the categories commonly represented in those studies, especially women, who are often left out of studies related to neurodevelopmental disorders. Because of this lack of representation, women often do not know what symptoms to look for, are underdiagnosed, and therefore, more likely to develop anxiety and depression due to their symptoms (French et al., 2023). French concludes women with neurodevelopmental disorders are more at risk for falling behind in many categories due to the lack of representation in research. During these studies, while women can share their experiences, researchers are able to disregard anything they deem invalid from their studies, as mentioned above in the D’Mello (2022) study. This can create barriers toward academic proof of conditions, which will continue to create obstacles toward further screening, assistance, and academic eligibility.

Historical Context

Neurodevelopmental disorders were first conceptualized in 1820 (Morris-Rosendahl & Crocq 2020), although attention deficit hyperactivity disorder (ADHD) was not identified until the 1940s (Romeo, 2021) and autism as we know it only became recognized in the 1970s (Evans, 2013). Even so, these studies all preceded the ethical standards that define research as we know it today, including the protections for human subjects established in the 1970s and 1993’s requirement for women and minorities to be represented.

In the 1960s and 70s, America was in an upheaval over unethical experiments. From

1932 to 1972, researchers at the Tuskegee Institute tested what happened when syphilis went untreated by infecting Black men with the virus without their knowledge and refusing to give them treatment, even when it became widely available (Center for Disease Control, 2023). In addition, in 1971, the Stanford prison experiment was conducted. During this experiment, many participants became physically injured and traumatized due to the dehumanization and violence other test subjects performed, and a lack of intervention and control from the researchers (Stanford Library, n.d.). These two, and many other studies, caused a push for oversight and guidelines from the United States government.

Nationwide protests about unethical experimentation, particularly the Tuskegee experiment, resulted in the 1974 National Research Act being published. It included the creation of the Institutional Review Boards (IRB), as well as certain guidelines for research, in terms of the protection of human subjects (H.R. 7724, 1974). Even so, the act had its limits. For one, it assumed the identities of subjects to be White males. It also did not mention specific consequences for violating those protections. The results of the Stanford Prison Experiment are still frequently considered valid, despite its violation of the guidelines above, and later ones passed.

In the 20 years after the creation of the IRB, studies were being done with more ethical standards, but they commonly left out certain populations. In 1977, the boards specifically recommended barring “women of childbearing potential” from drug studies. Following this, through the 1980s, women and feminists advocated for the representation needed in studies. In 1986, the NIH made a policy that encouraged using female participants (National Institutes of Health, n.d.c), but even then, it was only encouraged, not required, and it only applied to those who obtained funding through the NIH.

Because of this Congress passed the NIH Revitalization Act of 1993, PL 103-43. This is where the policy language of “all NIH-funded clinical research must include women and members of racial and ethnic minority groups” (National Institutes of Health, n.d.b) derives from. The act required representation in studies, but only when applicable. For example, someone who is studying the societal impacts of growing up as a boy in Chicago would not need to include girls in their study. However, application can be subjective, especially with the increasing amount of publicly acceptable gender diversity. The act was revised in 2016, but only to add a header and make one minor wording change.

While some people may regard studies as definitive proof of what we know about many subjects, including neurodevelopmental disorders, even current ethical guidelines for research with human subjects are lacking. Historical guidelines were only created due to the violation of specific protections in studies, and it is important to change the current ones before that happens again.

Current Policies

The current guidelines require all research funded by the NIH must “include women and members of racial and ethnic minority groups” (National Institutes of Health, n.d.d). This is more inclusive and specific than the guidelines set forth by the American Psychological Association (APA), which gives more than 600 scholarships and grants for research (American Psychological Association, n.d.). Both organizations deal with mental health research and have policies relating to the inclusion of women. However, while the NIH requires inclusion in any applicable situation and outlines how to include women and minorities in drug trials, the APA guidelines, titled “Guidelines for Avoiding Sexism in Psychological Research,” are not requirements, but recommendations that include suggestions about using inclusive language and not generalizing studies to include women when there were not any studied (Denmark et al., 1988). In addition, where NIH reviews their policies every few years, most recently in 2017, the APA guidelines were published in 1988 and have not been updated since (National Institutes of Health, n.d.d, Denmark et al., 1988). The NIH policy is better for inclusion, but still has much to improve on.

NIH Policy Design

The NIH is the U.S. government's research programs, funded through the Department of Health and Human Services (National Institutes of Health, n.d.e). It operates on a macro level, as it is "the largest public funder of biomedical and behavioral research in the world" (National Institutes of Health, n.d.a), which means their policies for funding have a wider influence than other organizations. According to the policy, any researcher who receives the funding for clinical research must include women and minorities when applicable (National Institutes of Health, n.d.d). The policy aims to increase inclusion and generalizability of studies.

Definitions

Defining terms within the policy is important to fully understanding the policy. Clinical research includes any research with human subjects or with the focus of human application (National Institutes of Health, n.d.d). This includes studies on therapeutic intervention and behavioral studies. The definition of what is "applicable" clinical research, however, can vary. The policy includes a clause that investigators, with adequate reasoning, may present a case as to why they should not be required to include the populations (National Institutes of Health, n.d.d). This could be necessary in a study that investigates a specific population, for example, a study on the socialization of teenage boys. The definition of "minority" is up to the director of NIH to interpret, according to the NIH Revitalization Act (1993). The current definition only includes the ethnic and racial categories required by the United States Census (National Institutes of

Health, n.d.d), but future NIH directors may change the definition. These definitions outline who the policy applies to and how it applies, so that researchers must follow the guidelines.

Social Impact of Policy

Pre-Policy

Comparing the progress of the policy is difficult due to the lack of information on how women were included before 1993. This is likely because women of "childbearing potential" were excluded altogether from studies due to the U.S. Department of Health and Human Services' 1977 recommendations (Phelan et al., 2016). Other texts from around the time suggest there was very little to no inclusion, such as the 1985 Report of the Public Health Service Task Force on Women's Health Issues. Most likely, the current levels of inclusion have risen significantly from the levels pre-policy, however, with no definitive baseline, the policy's effectiveness is better determined through current representation rather than past statistics.

Post-Policy

Across all institutes of health, the NIH seems to be promoting higher rates of gender inclusion. In cancer research, "NIH-funded trials enrolled a higher proportion of women (48%) compared with industry trials (41%)" (Jenei et al., 2021). Forty-eight percent is almost representative of the general population, where 50.4% of people on the U.S. Census were female, therefore, the NIH policy would have achieved its goal. However, individual studies, especially those in neurodevelopmental studies, reflect differently. Studies about autism and ADHD frequently see discrepancies in the representation of women. One study comparing gender manifestations of executive functioning and autism had only around 28.7% female participants (Kiep and Spek, 2017), which is an underrepresentation of the general population. This is due to screening techniques. D'Mello et al. (2022) found the screening technique used by

Massachusetts Institute of Technology disproportionately removed women. This trend of underrepresentation is also visible in ADHD studies. Girls display more inattentive symptoms, which are less likely to be reported (Mowlem et al., 2019). In one survey, four out of every 10 teachers felt less sure about recognizing ADHD in girls (Quinn & Wigal, 2004). When studies are dependent on a diagnosed population, underreporting leads to further underrepresentation.

Limits of Policy

There are a few reasons the policy failed to create adequate representation and inclusion. As mentioned above, definitions provide loopholes in the policy. In addition, researchers can apply to many different places to get funding. The University of Michigan (n.d.) lists four categories, including public charities, government agencies, crowdsourcing, and commercial investments. Within the category of government agencies, the NIH is only one of seven options listed. When researchers use any other method of funding, they are not required to follow the NIH policy. Even when researchers choose NIH funding, and therefore follow the policy, the levels of inclusion are not specified. Studies on neurodevelopmental disorders can include ratios such as 99 men to 40 women (Keip & Spek, 2017) or 153 men to 48 women (Gallant & Good, 2023). This exclusion of women, which Gallant & Good (2023) describe as “consistent with previous research,” creates exclusion for diagnostic criteria, which can further decrease the sampling pool. Since the policy is non-specific, a study could contain hundreds of men and only one woman.

Recommendations

Specify the Rates

On a mezzo level, the NIH policy needs to specify how many of each population to include, with acceptable ranges for each marginalized population. Currently, the policy only necessitates some form of representation, which is what allows cases like Keip & Spek (2017) and Gallant & Good (2023) to have such dramatic differences of gender in studies. In the United States, women are 50.4% of the population (U.S. Census Bureau, 2024). For studies to be representative, they should aim to be within a certain range of the population. At the very least, representation should be within 10% of the population. The margin of error could be modified over time as the subject pool evens out, but current populations may make accurate representation more difficult for researchers. Studies about certain topics could still petition to not include genders in non-applicable research. For required inclusion, however, ratios of inclusion should be specified to represent the general population.

Broaden the Policy

At a macro level, the United States government needs to regulate all research to require applicable inclusion. The 1993 NIH Revitalization Act has led to almost representative levels of inclusion for women in some NIH studies, but the same cannot be said for other forms of funding (Jenei et al., 2021). Even after 31 years of the act, not all organizations have followed suit. This is why a government requirement is likely necessary. A requirement without enforcement, however, can lead to no action. Without the ability to enforce the policies, state laws could no longer serve any function, such as what happened with *Lawrence v. Texas (2003)* (Hagood, 2010). Like the NIH policy, arguments could be made for the applicability in certain studies, but the IRBs should have inclusion policies in their necessary ethics review of all human subject studies. This will increase the levels of inclusion in not just NIH-funded research, but all research done in the United States.

Diverse Populations

In order to achieve more equal gender ratios, women, especially women of color, must be brought into research spaces. As subjects, women can provide information on their experiences that men might not have. For example, women are more likely to mask their autism than men (Russo, 2018). While masking can make it seem like someone is not experiencing dysfunction from a disorder, frequent masking of symptoms can lead to even greater psychological harm (Russo, 2018). As researchers, women can create tests and evaluations that reflect more of their own lived experiences. They can advocate for their client's needs and comforts, since they are on a more even playing field with other researchers than their clients may be. Increasing the representation of women in research positions can further increase their presence in both academic pursuits and testing samples.

Opportunities

If the government regulates inclusion, they can create grants that aim to fund research and offset any costs occurring as a result of incentivizing women to participate in studies. This can include incentives like gift cards or useful items, or it may include advertising. Over time, as more women become integrated into research, the additional funds will be less needed to balance gender inclusion in research. When this happens, the foundation could either continue to fund all research or it could transition to funding research about issues that are more common in women.

In addition to funding research, educational scholarships should be made for women interested in performing research. Reducing cost inequities in education could increase the rates of women in research. Currently, only 33% of researchers are women (United Nations, n.d.). Creating scholarships could help shift the ratio closer to the general population. Some women, however, may change their mind during their education. In cases where someone decides to pursue research later in their education, they should still be allowed to apply. In cases where someone previously interested in research decides to shift their focus, they should not be penalized by losing their scholarship. There are benefits to an increase of women in almost every STEM field, and even if they do not pursue research, they can still contribute to the knowledge base and reduce stigma.

Challenges/Limitations

There are challenges that a change in policy could create. For example, requiring inclusion may result in tokenization. This is defined by Cambridge University Press (n.d.) as creating inclusion without putting significant effort toward creating change. In research, this means researchers may include the women required but may still norm the results on male results. Some studies, like outlined in D’Mello et al. (2022), may categorize the female results as outliers and remove them from the study. This can lead to women feeling further ignored and misrepresented in research. If women are only being included to meet the criteria but not to create change, women would be less interested in joining research, even with financial incentives. The culture around women in research needs to shift to prevent this.

Conclusion

Women are underrepresented in research, especially research relating to neurodevelopmental disorders. Current policies are the results of people pushing for protection and representation when those ideals were violated, yet the policies fail to fulfill these ideals for women with neurodevelopmental disorders. To fix the inequality, the NIH should include specific rates of inclusion in their policy, and the U.S. government should normalize that policy across all research. This can create opportunities for women in research but can also create challenges in the process that the government should be prepared to counter. With these suggestions, hopefully women will become more represented in all research.

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