

Cancer trials lacking in diversity, study shows

From 2008 to 2013, just 13 of 112,000 US trial participants were Native American

Researchers from Canada and the United States have found that black and Hispanic people were underrepresented in trials that led to FDA approvals of oncology drugs, compared to their proportion among the US cancer population.

In total, just 7.8% of trials of cancer drugs involved at least one participant from each of the major ethnic groups (black, white, Asian and Hispanic) in the US.

In trials of cancer drugs from July 2008 to June 2013, 76.3% of participants were white, 18.3% were Asian, 6.1% were Hispanic, and 3.1% were black. There was little improvement in representation in trials from between July 2013 and June 2018.

This meant that black and Hispanic people were heavily underrepresented, compared to their share of the US cancer population. While white people were highly the most part well represented in clinical trials as compared to their share of the cancer population, Asian people were way overrepresented in trials of cancer drugs.

The researchers also found that only 56.6% of trials reported on the race and ethnicity of their participants between



2008 and 2013. However, the situation had improved in studies from the years between July 2013 and June 2018.

The findings raise the concern that clinical trial data may not apply to those in groups that are underrepresented in clinical trials, as drugs may not be as effective in one population as they are in another.

The study's lead author, Dr Jonathan Loree, Assistant Professor at the University of British Columbia, noted that one lung cancer drug proved highly effective in Asian woman who had never smoked (due to a rare genetic mutation common in that population) but that the same drug showed mediocre trial results in the rest of the world's population.

Dr Loree commented: "Our findings

show that the science might not be applicable to the population that's going to receive the medications. If patients are going to be receiving the drug, we need to know that it's going to work for them with the same effectiveness that's seen in the trial."

The researchers also raised concern about the representation of Native Americans in clinical trials. Dr Loree noted: "One thing particularly relevant to the Canadian context is that we weren't able to analyse the participation of Native Americans in trials because there were only 13 patients reported out of a total of 112,000 participants. That's shocking and definitely shows an area where improvement is needed."

Researchers are misrepresenting published trial results, review warns

The abstracts of more than half of all clinical trials published in top psychology and psychiatry journals contain 'spin' – exaggerated claims as to the significance of the treatment in question, without statistics to back up the claim – according to a review published in *BMJ Evidence Based Medicine*.

The review, which looked at 116 trials from six top psychology and psychiatry journals (including *JAMA Psychiatry*, *American Journal of Psychiatry*, *Journal of Child Psychology and Psychiatry*, *Psychological Medicine*, *British Journal of Psychiatry*, and *Journal of the American Academy of Child and Adolescent Psychiatry*) found that more than half

contained some level of 'spin'.

The review looked at trials published on PubMed from 2012-2017, in which the findings had not been statistically significant, in order to see how often researchers had misrepresented or 'spun' their findings by scrutinising them against a previously published definition of 'spin'.

Spin was defined as the "use of specific reporting strategies, from whatever motive, to highlight that the experimental treatment is beneficial, despite a statistically nonsignificant difference for the primary outcome or to distract the reader from statistically nonsignificant results."

The researchers found 'spin' in more than half (56%) of the abstracts of the 116 clinical

trials. This included spin in 2% of titles, 21% of results sections, and 49% of conclusions. Spin was most common in studies that compared a drug or behavioural approach with a placebo or usual care.

Prior studies have also found higher prevalence of spin in industry-funded studies. However, the study found that spin was not associated with industry funding and industry-funded studies were not more likely to contain spin. In total, ten of the 65 trials containing spin were industry-funded.

The findings are of particular concern due to the fact that current evidence suggests that abstracts alone are capable of changing care decisions made by the majority of clinicians.

The study authors commented: "Researchers have an ethical obligation to honestly and clearly report the results of their research. Adding spin to the abstract of an article may mislead physicians who are attempting to draw conclusions about a treatment for patients. Most physicians read only the article abstract the majority of the time.

"Those who write clinical trial manuscripts know that they have a limited amount of time and space in which to capture the attention of the reader. Positive results are more likely to be published, and many manuscript authors have turned to questionable reporting practices in order to beautify their results."

What got the world talking about microplastics?

Last autumn, the European Parliament voted to ban single-use plastics in the EU by 2021. The vote came one day after global media highlighted that new research revealed the presence of microplastics in human stools. Not a coincidence, but the result of a carefully crafted, influential and timely communications campaign.

Spink, a UK-based healthcare communications agency, developed the campaign for long-standing client United European Gastroenterology (UEG), a non-profit organisation representing the leading European societies concerned with digestive health. Challenged with the ongoing task of raising awareness of the burden of digestive diseases, influencing the political agenda and raising the profile of UEG, Spink constantly scans the scientific horizon for ground-breaking and newsworthy research.

Spink uncovered a small study, due to be presented as a poster at UEG's global congress UEG Week, which demonstrated novel evidence of microplastics in human stools from people across the globe. Aware that a key vote to ban the use of single-use plastics was due to take place in EU Parliament, the research was deemed by Spink to be highly topical.

A carefully crafted, 360-degree media campaign was developed alongside direct political engagement to share the research. The campaign broke the day before the EU vote with over 800 pieces of coverage including front page headlines, broadcast interviews and a social media frenzy spanning environmental, non-government, political and scientific organisations, ranging from DEFRA to National Geographic.

With an OTS of over five billion, the campaign successfully raised awareness of UEG Week and the potential impact of single-use plastics on digestive health. As media coverage and political commentary continued to flow the day after launch, news came in that MEPs in the European Parliament overwhelmingly approved the ban (571-53) on single-use plastics in Europe by 2021.

Driven by thirty years of rich insight, Spink is passionate about driving meaningful change through influencing what people think, feel and do, and has been recognised for delivering award-winning campaigns in the consumer health, pharmaceutical and public sector markets.

To find out how Spink can make a difference to your campaigns, contact them at ideas@spinkhealth.com or visit its website: www.spinkhealth.com

