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Race and ethnicity of people taking part in early-phase clinical trials for new cancer medicines

Date of summary: February 2021

The full title of this article is: Race and ethnicity representation in clinical trials: findings from a literature review of Phase I oncology trials¹

What is a literature review and why do we do them?

- The purpose of a literature review is to gain an understanding of existing research on a topic of interest. It involves collecting information from published papers.
- Researchers conduct literature reviews to find areas that may not have been researched in detail. This allows researchers to find any gaps or shortcomings that may need addressing.

What did we look at in this review of the literature?

- Researchers perform clinical trials to look at how safe and effective potential new medicines are.
- Phase I trials are the first step in looking at new medicines in humans.
 - They are usually small trials, typically recruiting 20–80 people on average. Trials of new medicines for cancers may be open to people with certain advanced cancers, usually those who have already received all other available treatments.
- Phase I trials aim to find out:
 - How much of the medicine is safe to give.
 - What the side effects are.
 - During clinical trials, patients are asked to report if they feel unwell or notice anything different about their bodies. If the trial doctor thinks these feelings or changes may be related to the treatment patients are taking, it is called a side effect.
 - How the body gets rid of the medicine.
 - If the medicine helps shrink the cancer.
- Past research has shown that certain groups of people are not well represented in clinical trials of new cancer medicines.
 - In particular, the literature shows that certain racial and ethnic groups are not well represented.
 - This means that clinical trials may not test new cancer medicines in populations that fully reflect different racial and ethnic groups.
 - Trials should ideally, as a bare minimum, recruit groups of people that represent the population at large.
 - Some cancers can occur more often in certain groups of people compared to others, so it is important that such groups are involved in tests for medicines they may eventually go on to take.
 - In addition, the US Food and Drug Administration (responsible for approving new medicines in the United States) has guidance to encourage a wider range of people to take part in clinical trials. The aim is to better represent the population most likely to use the medicine if approved.

Further information

For more information on this study, please visit:

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For more information on clinical studies in general, please visit:

<https://www.clinicaltrials.gov/ct2/about-studies/learn>

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are>

- In this study, researchers wanted to find out which groups of people took part in early (Phase I) trials of new medicines for cancer treatment. The researchers looked at clinical trials that were published in 2019.
- This summary describes how many people took part in:
 - Worldwide trials.
 - Trials that took place in the United States only.

How was the literature review performed?

- The review of the literature involved searching for and collecting information from published scientific papers/articles of Phase I cancer trials.
- One reviewer performed the initial search and choice of papers. A second reviewer then conducted a cross-check of the findings.
- We searched for scientific reports that were published in English language in 2019.

What were our findings?

Worldwide:

- Race/ethnicity was not reported in over 40% of the Phase I oncology trial publications included in our analysis.
- Overall, 9,972 people took part in 220 cancer trials where researchers reported race or ethnicity. Of these:
 - 62% were White.
 - 30% were Asian (mainly from studies conducted in Asian countries where all participants were classified as Asian).
 - 4% were Black/African Americans.
 - 1% were Hispanic/Latinx.
 - Participation of Native Hawaiian/Pacific Islanders or American Indian/Native Alaskans was extremely low (about 1 in 1,000 people).

United States only:

- 3,197 people took part in 137 cancer trials where researchers reported race or ethnicity.
- An even greater proportion of participants were White compared with worldwide trials:
 - 84% were White.
 - 7% were Black/African Americans.
 - 3% were Asian.
 - 3% were Hispanic/Latinx.
 - And participation of Native Hawaiian/Pacific Islanders or American Indian/Native Alaskans was extremely low (about 1 in 1,000 people).
- In the United States' population, around 13% of people are Black, 18% are Hispanic, and 6% are Asian. Hence, the proportion of people taking part in clinical trials for new cancer medicines is not reflective of the wider population.
- There were equal numbers of men and women taking part in the cancer trials.

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What were our main conclusions from this review?

- Some racial or ethnic groups have not been well represented in early-phase clinical cancer trials for many years.
- Our findings highlight a continued need for a wider range of people to take part in clinical trials for new cancer medicines.
- Trials should aim to not only be more inclusive of the general population, but also of populations where certain cancers are more common.
- Greater attention is needed to encourage more people from some ethnic groups to take part in clinical trials to fully reflect the wider population.
- More research is also needed to understand and overcome barriers that stop people taking part in clinical trials. This is especially important:
 - In groups that are not well represented at the moment.
 - In clinical trials of cancers that can occur more often and/or result in reduced survival rates in different racial or ethnic groups.
- Race/ethnicity was not reported in over 40% of the Phase I cancer trial publications included in our analysis. Without this information, it was not possible to assess the representation in those trials. This lack of reporting hampers efforts to increase diversity.
- More reporting of race/ethnicity data needs to be encouraged, using a standardized method of collecting these data.
- Further research and the publication of data highlighting this imbalance in representation should help increase awareness of this issue.

Who sponsored this review?

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Disclosures

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Reference

1. Jacobs I, Camidge DR, Park H, et al. Race and ethnicity representation in clinical trials: findings from a literature review of Phase I oncology trials. *Future Oncology* (2021). doi: doi.org/10.2217/fon-2020-1262.

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