



Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.



## Short Communication

## Efficacy of COVID-19 vaccines by race and ethnicity

N. Salari <sup>a</sup>, A. Vepa <sup>b</sup>, A. Daneshkhah <sup>c</sup>, N. Darvishi <sup>d</sup>, H. Ghasemi <sup>d</sup>, K. Khunti <sup>e</sup>,  
M. Mohammadi <sup>f,\*</sup>

<sup>a</sup> Department of Biostatistics, School of Health, Kermanshah University of Medical Sciences, Kermanshah, Iran

<sup>b</sup> Northwick Park Hospital, London North West University Healthcare NHS Trust, London UK

<sup>c</sup> Research Centre for Computational Science and Mathematical Modelling, Coventry University, Coventry CV1 5FB, UK

<sup>d</sup> Student Research Committee, Kermanshah University of Medical Sciences, Kermanshah, Iran

<sup>e</sup> Leicester Diabetes Centre, University of Leicester, UK

<sup>f</sup> Cellular and Molecular Research Center, Gerash University of Medical Sciences, Gerash, Iran



## ARTICLE INFO

## Article history:

Received 5 March 2022

Received in revised form

21 April 2022

Accepted 27 April 2022

Available online 5 May 2022

## Keywords:

Efficacy

COVID-19

Vaccine

Race

Ethnicity

Review

## ABSTRACT

**Objectives:** Vaccine uptake amongst ethnic minority populations has been persistently lower, which may be because of socio-economic factors such as health literacy and health insurance status. This review aimed to assess to what extent COVID-19 clinical trials have considered the impact of race and ethnicity on COVID-19 vaccine safety and efficacy.

**Study design:** This was a systematic review.

**Methods:** Data regarding ethnicity in COVID-19 vaccine clinical trials were systematically reviewed according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines in this systematic review, which ran from inception until June 2021. Three international databases, PubMed, Scopus and Web of Science, were used to conduct systematic article searches. Only two studies reported vaccine efficacy among ethnic minority groups.

**Results:** The efficacy of the mRNA-1273 vaccine was confirmed to be 95% in Caucasians and 97.5% in 'people of colour' in a study by Baden et al. In another study by Polack et al., BNT162b2 mRNA vaccine efficacy was reported to be 95.2% in Caucasians, 100% in Afro-Caribbean or African Americans, 94.2% in Hispanic or Latinx and 95.4% in non-Hispanic, non-Latinx people.

**Conclusions:** Given the highly differing effect of COVID-19 on the Afro-Caribbean, Hispanic and South Asian populations, it is imperative for COVID-19 vaccine clinical trials to thoroughly assess the safety and efficacy of vaccines in different ethnicities and, if necessary, develop ethnicity-specific protocols, which can minimise the disproportionate effect of COVID-19 on ethnic minority populations.

© 2022 The Royal Society for Public Health. Published by Elsevier Ltd. All rights reserved.

## Introduction

Globally, it is well established that ethnic minority populations, such as Afro-Caribbeans, South Asians and Hispanics, have been identified as carrying a higher risk of mortality from COVID-19.<sup>1</sup> However, despite this, vaccine uptake amongst ethnic minority populations has been persistently lower, which may be because of socio-economic factors, such as health literacy and health insurance status, mobility and social marginalisation.<sup>2,3</sup>

Addressing injustice and inequality in the impact of the vaccine on different ethnic groups requires a multifaceted approach that focuses on the needs of marginalised groups and ethnic groups.<sup>4</sup>

Distrust of science and treatment, as well as vaccination, is rooted in a history of mistrust resulting from immoral research, especially on African American, Latino, and Asian American populations.<sup>4,5</sup> Racism is an important factor in creating inequality in the face of disease, morbidity and mortality, especially vaccination against various diseases, and the same is true for COVID-19.<sup>4–6</sup> Policies that are designed to benefit many and to the detriment of others so that some races and ethnicities have unequal access to care and health care and even educational and employment opportunities.<sup>4–6</sup>

Given the complex interplay between ethnicity and COVID-19 disease and considering that the effect of race and ethnicity on the safety and efficacy of COVID-19 vaccine has not been studied in

\* Corresponding author.

E-mail addresses: [n\\_s\\_514@yahoo.com](mailto:n_s_514@yahoo.com) (N. Salari), [Vepa.Abhinav@nhs.net](mailto:Vepa.Abhinav@nhs.net) (A. Vepa), [ac916@coventry.ac.uk](mailto:ac916@coventry.ac.uk) (A. Daneshkhah), [darvishiniloofar@gmail.com](mailto:darvishiniloofar@gmail.com) (N. Darvishi), [Hoomanghasemi1997@gmail.com](mailto:Hoomanghasemi1997@gmail.com) (H. Ghasemi), [kk22@le.ac.uk](mailto:kk22@le.ac.uk) (K. Khunti), [Masoud.mohammadi1989@yahoo.com](mailto:Masoud.mohammadi1989@yahoo.com) (M. Mohammadi).

general, and its aspects are still unknown. This systematic review study was conducted to investigate the effect of different races, the effect of racial issues and racism on clinical trials of the effect of the COVID-19 vaccine to reveal all aspects of this effect.

**Methods**

The research protocol was registered in the PROSPERO (CRD42021261961). Data regarding ethnicity in COVID-19 vaccine clinical trials were systematically reviewed according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines in this systematic review, which ran from January 2020 until June 2021. Three international databases, PubMed, Scopus and Web of Science, were used to conduct systematic article searches. In addition, the Google Scholar search engine was examined. A survey was then performed to collect grey literature from libraries. In accordance with PECO (Population, Exposure, Comparator, and Outcomes) guidelines, the keywords used for the search in this study were chosen based on published preliminary studies and Medical Subject Headings (MeSH terms; in the reviewed database), as well as a thorough analysis of the study questions. Keywords used in this report included combinations of COVID-19, SARS-CoV-2 infection,

2019-nCoV infection, mRNA COVID-19 vaccine, vaccine, COVID-19 vaccine, nCoV-19 vaccine, RNA vaccine and RNA-based COVID-19 vaccine. Of a total of 356 identified studies, 11 were included after considering both inclusion and exclusion criteria. The inclusion criteria were (1) randomised clinical trials experiments, (2) studies evaluating the effectiveness of COVID-19 vaccines, (3) studies with full text available, (4) studies of high and medium quality (score 16 and above), and (5) studies that have been released until the implementation of the systematic review process in this report (January 2020 until June 2021). The exclusion criteria were (1) cohort and control case studies, (2) case series, (3) case reports, (4) review studies, (5) studies without full text, (6) letter to the editor and (7) and (8) low-quality studies with a quality score of less than 16.

The quality of confirmatory studies was assessed with the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) checklist. The checks in this checklist were performed using 32 different items (scores between 0 and 32). In this study, studies that received a score of 16 or higher from the authors were selected and selected as mediocre and good-quality articles. Studies that received a score below 16 were considered poor quality and were excluded from the study. In these studies, none of the articles were deleted due to poor quality.

**Table 1**  
Information on studies entered in the systematic review.

First author	Vaccine	Type of study	Total enrolled (detail) (n)	Caucasian/ethnic minorities (%)
Baden, L. R. <sup>3</sup>	mRNA-1273	Phase 3 randomised, stratified, observer-blinded, placebo-controlled trial	30,351 (Caucasian: 24,024, Asian: 1382, Afro-Caribbean or African American: 3090, American, Indian or Alaska Native: 233, Native Hawaiian or Other Pacific Islander: 67, multiracial: 634, other: 637, not reported and unknown: 282)	79.2/20.9%
Anderson, E. J. <sup>7</sup>	mRNA-1273	Phase 1, dose-escalation, open-label clinical trial	40 (Asian: 1, Caucasian: 39, Hispanic or Latino: 1)	98/2%
Folegatti, P. M. <sup>8</sup>	ChAdOx1 nCoV-19 vaccine (intervention) – MenACWY vaccine (control)	Phase 1/2, participant-blinded, multicentre, randomised controlled trial	1077 (not mentioned)	79.2/20.9%
Jackson, L. A. <sup>9</sup>	mRNA-1273 vaccine candidate, encodes the S-2P antigen	Phase 1, dose-escalation, open-label trial	45 (American, Indian or Alaska Native: 1, Asia: 1, Afro-Caribbean: 2, Caucasian: 40, Unknown: 1, Hispanic or Latino: 6)	89/11%
Keech, C. <sup>10</sup>	NVX-CoV2373 rSARS-CoV-2	Phase 1–2 Trial open-label	131 (American Indian or Alaska Native: 7, Asian: 17, Afro-Caribbean or African American: 2, multiracial: 1, Native Hawaiian or Other Pacific Islander: 1, not reported: 0, Caucasian: 103, Hispanic or Latino: 19)	78.6/21.4%
Logunov, D. Y. <sup>11</sup>	Gam-COVID-Vac combined vector	Phase 3 randomised controlled trial	19,866 (Caucasian: 19,571, Asian: 286, Other: 9)	98.5/1.48%
Mulligan, M. J. <sup>12</sup>	RNA vaccine BNT162b1	Phase 1/2 placebo-controlled, observer-blinded dose-escalation study	45 (Caucasian: 37, Afro-Caribbean or African American: 1, Asian: 7)	82.2/17.8%
Polack, F. P. <sup>13</sup>	BNT162b2 mRNA	Phase 2/3 placebo-controlled, observer-blinded, pivotal efficacy trial	37,706 (Caucasian: 31,266, Afro-Caribbean or African American: 3492, Asian: 1608, Native American or Alaska Native: 201, Native Hawaiian or Other Pacific Islander: 76, multiracial: 855, not reported: 208, Hispanic or Latino: 10,543)	82.9/17.1%
Ramasamy, M. N. <sup>14</sup>	ChAdOx1 nCoV-19 vaccine	Phase 2/3 single-blind, randomised, controlled	552 (Caucasian: 524, Afro-Caribbean or Afro-Caribbean British: 1, Asian or Asian British: 19, mixed race or ethnicity: 4, other race or ethnicity: 4)	95/5%
Richmond, P. <sup>15</sup>	SCB-2019 vaccine	Phase 1, randomised, double-blind, placebo-controlled trial	151 (race: Asian: 16, Afro-Caribbean: 1, Caucasian: 132, Other: 2/ethnicity: Hispanic or Latino: 10, not Hispanic or Latino: 141)	87.4/12.6%
Stone, J. H. <sup>16</sup>	NVX-CoV2373	Phase 1/2 randomised, placebo-controlled trial	131 (American Indian or Alaska native: 7, Asian: 17, Afro-Caribbean or African American: 2, multiracial: 1, native Hawaiian or other pacific: 1, Caucasian: 103, Hispanic or Latino: 19)	78.6/21.4%

## Results

The studies, as shown in Table 1, included phase 1, 2 and 3 trials, as well as different vaccines. The total population included in the 11 studies was 90,095, of which 85% were of Caucasian ethnicity. Only two studies reported vaccine efficacy among ethnic minority groups. The efficacy of the mRNA-1273 vaccine was confirmed to be 95% in Caucasians and 97.5% in ‘people of colour’ in a study by Baden et al.<sup>13</sup> In another study by Polack et al., BNT162b2 mRNA vaccine efficacy was reported to be 95.2% in Caucasians, 100% in Afro-Caribbean or African Americans, 94.2% in Hispanic or Latinx and 95.4% in non-Hispanic, non-Latinx people.<sup>17</sup> The remaining studies did not look at the efficacy or effects of vaccines based on ethnicity or race.

## Discussion

Overall, our results indicate that ethnic minority populations are often excluded or under-represented in clinical trials. Various reasons have been postulated to account for this phenomenon, such as language barriers, health illiteracy, mistrust of research, stigma, cultural factors and loss of earnings in deprived populations.<sup>2,18</sup> In addition to reduced clinical research participation by ethnic minority groups, many clinical trials also often do not report ethnicity despite its clinical relevance.<sup>19</sup>

In conclusion, it is evident that several COVID-19 vaccine clinical trials have not considered the impact of ethnicity on the safety and efficacy of COVID-19 vaccines in concordance with the surrounding literature.<sup>19</sup>

Various studies have raised various debates about racism as a key factor, which may cast doubt on the effectiveness of the vaccine among different ethnic groups. Bagasra et al. reported in their study that a significant difference in the level of trust in the government’s response to the COVID-19 pandemic, with Indian/Alaskan Natives reporting lower trust compared with Whites, Blacks and Asians.<sup>6</sup>

The study by Hussain-Gambles et al. also reports that ethics committees can address racial and ethnic inequalities by providing guidance to researchers and more rigorously reviewing clinical trial protocols.<sup>20</sup>

The study by Kahn et al. also reports that the scientific community must systematically collect accurate data on race and ethnicity to eliminate ethnic inequalities in clinical settings and provide appropriate feedback at the individual and create social.<sup>21</sup>

Given the highly differing effect of COVID-19 upon the Afro-Caribbean, Hispanic and South Asian populations, it is imperative for COVID-19 vaccine clinical trials to thoroughly assess the safety and efficacy of vaccines in different ethnicities and, if necessary, develop ethnicity-specific protocols, which can minimise the disproportionate effect of COVID-19 on ethnic minority populations.

## Author statements

### Acknowledgements

By Student Research Committee of Kermanshah University of Medical Sciences.

### Ethics approval

Ethics approval was received from the ethics committee of deputy of research and technology, Kermanshah University of Medical Sciences (3011574).

## Funding

This study was funded by Deputy for Research and Technology, Kermanshah University of Medical Sciences (IR) (3011574). This deputy has no role in the study process.

## Competing interests

The authors declare that they have no conflict of interest.

## Authors’ contributions

N.S., M.M. and A.V. contributed to the design. M.M., N.D. and H.G.H. participated in most of the study steps. A.D., M.M., N.D., H.G.H. and K.K. prepared the article. All authors have read and approved the content of the article.

## References

- Mackey K, Ayers CK, Kondo KK, Saha S, Advani SM, Young S, et al. Racial and ethnic disparities in COVID-19-related infections, hospitalizations, and deaths: a systematic review. *Ann Intern Med* 2021;**174**(3):362–73.
- Razai MS, Osama T, McKechnie DGJ, Majeed A. Covid-19 vaccine hesitancy among ethnic minority groups. *BMJ (Clin Res Ed)* 2021;**372**:n513.
- Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, et al. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. *N Engl J Med* 2021;**384**(5):403–16.
- Corbie-Smith G. Vaccine hesitancy is a scapegoat for structural racism. *JAMA Health Forum* 2021;**2**(3):e210434.
- Washington HA. *Medical apartheid: the dark history of medical experimentation on black Americans from colonial times to the present*. 10th ed. Doubleday; 2016.
- Bagasra AB, Doan S, Allen CT. Racial differences in institutional trust and COVID-19 vaccine hesitancy and refusal. *BMC Public Health* 2021;**21**:2104. <https://doi.org/10.1186/s12889-021-12195-5>.
- Anderson EJ, Roupael NG, Widge AT, Jackson LA, Roberts PC, Makhene M, et al. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. *N Engl J Med* 2020;**383**(25):2427–38.
- Folegatti PM, Ewer KJ, Aley PK, Angus B, Becker S, Belij-Rammerstorfer S, et al. Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial. *Lancet (London, England)* 2020;**396**(10249):467–78.
- Jackson LA, Anderson EJ, Roupael NG, Roberts PC, Makhene M, Coler RN, et al. An mRNA vaccine against SARS-CoV-2 — preliminary report. *N Engl J Med* 2020;**383**(20):1920–31.
- Keech C, Albert G, Cho I, Robertson A, Reed P, Neal S, et al. Phase 1-2 trial of a SARS-CoV-2 recombinant spike protein nanoparticle vaccine. *N Engl J Med* 2020;**383**(24):2320–32.
- Logunov DY, Dolzhikova IV, Shcheblyakov DV, Tukhvatulin AI, Zubkova OV, Dzharullaeva AS, et al. Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine: an interim analysis of a randomised controlled phase 3 trial in Russia. *Lancet (London, England)* 2021;**397**(10275):671–81.
- Mulligan MJ, Lyke KE, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults. *Nature* 2020;**586**(7830):589.
- Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *N Engl J Med* 2020;**383**(27):2603–15.
- Ramasamy MN, Minassian AM, Ewer KJ, Flaxman AL, Folegatti PM, Owens DR, et al. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. *Lancet (London, England)* 2020;**396**(10267):1979–93.
- Richmond P, Hatchuel L, Dong M, Ma B, Hu B, Smolenov I, et al. Safety and immunogenicity of S-Trimer (SCB-2019), a protein subunit vaccine candidate for COVID-19 in healthy adults: a phase 1, randomised, double-blind, placebo-controlled trial. *Lancet (London, England)* 2021;**397**(10275):682–94.
- Stone JH, Frigault MJ, Serling-Boyd NJ, Fernandes AD, Harvey L, Foulkes AS, et al. Phase 1-2 trial of a SARS-CoV-2 recombinant spike protein nanoparticle vaccine. *N Engl J Med* 2020;**383**(24):2333–44.
- Treweek S, Forouhi NG, Narayan KMV, Khunti K. COVID-19 and ethnicity: who will research results apply to? *Lancet* 2020;**395**(10242):1955–7.
- Pan D, Sze S, Minhas JS, Bangash MN, Pareek N, Divall P, et al. The impact of ethnicity on clinical outcomes in COVID-19: a systematic review. *EClinicalMedicine* 2020;**23**:100404.
- Flores LE, Frontera WR, Andrasik MP, del Rio C, Mondríguez-González A, Price SA, et al. Assessment of the inclusion of racial/ethnic minority, female, and older individuals in vaccine clinical trials. *JAMA Netw Open* 2021;**4**(2):e2037640–e2037640.

20. Hussain-Gambles M. Ethnic minority under-representation in clinical trials. Whose responsibility is it anyway? *J Health Organ Manag* 2003;**17**(2): 138–43.
21. Kahn JM, Gray DM, Oliveri JM, Washington CM, DeGraffinreid CR, Paskett ED. Strategies to improve diversity, equity, and inclusion in clinical trials. *Cancer* 2022;**128**(2):216–21.