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Poster #21

Leveling the playing field: Diversity, equity, and inclusion (DEI) in clinical research and publications

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Ensuring diverse and equitable patient representation in clinical trials and data reporting is a shared responsibility across regulatory bodies, pharmaceutical companies, journals/publishers, and medical communication agencies

Share your thoughts!

Please take a 5-question survey regarding your experience with tactics aimed at DEI in publications.

Introduction

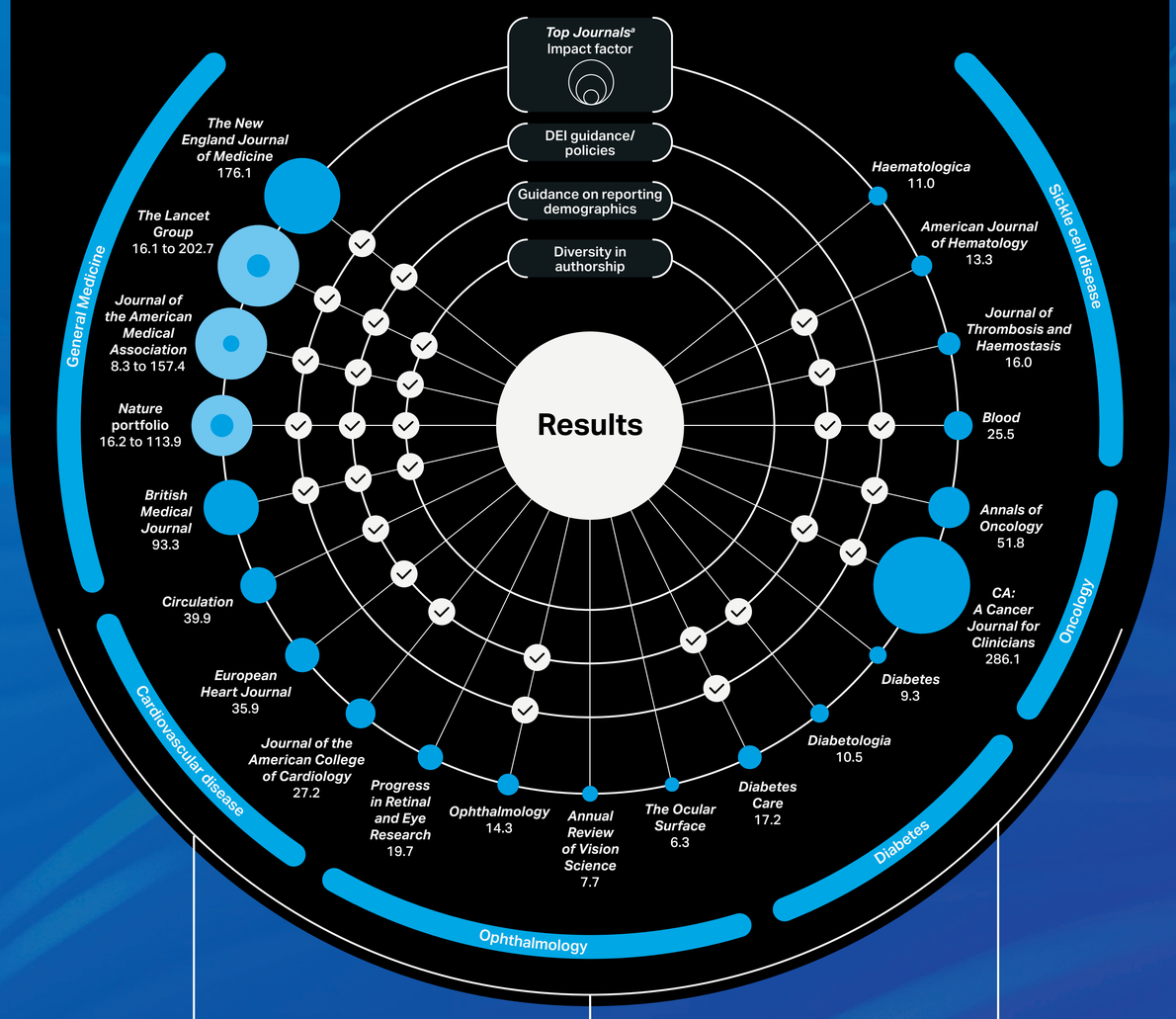
- Although racial and ethnic minorities are disproportionally impacted by several diseases (eg, diabetes and infectious and autoimmune diseases),[1,2] their underrepresentation in clinical trials and treatment biases[3-8] limit the generalizability of study findings,[9,10] and impact other social, economic, cultural, and environmental determinants
- Such a lack of diversity in clinical trials perpetuates existing health inequities and reduces the quality of individual patient care[10,11]
- Accurate reporting of data contextualizing this underrepresentation in trials is lacking, primarily due to inconsistent or inadequate enforcement of policies by regulatory bodies and medical journals

Objective

- Evaluate journal requirements for reporting participant diversity in clinical trial publications and outline best practices and recommendations for key stakeholders to ensure enforcement of diversity guidelines

Research design & methods

- DEI-related guidelines from the US Food and Drug Administration (FDA),[12] European Medicines Agency (EMA), and the top journals (by impact factor) across 5 therapeutic areas were collected (Diagram)
- Journal impact factors and rejection rates were identified using Journal Selector (Sylogent, an Anju Software Company) and information posted on journal websites



Only 4 of 21 top-tier journals/journal networks provide guidance on authorship diversity

Journals with robust DEI reporting requirements (4 of 21) have a rejection rate of ~95%; thus, the potential effects of biases from patient underrepresentation were likely not reflected in most clinical trials published in top-tier journals

Of 21 top-tier journals/ journal networks, 5 do not require any DEI reporting

[a]Includes journals with the top 5 impact factor ratings in each therapeutic area. The top journal networks for general medicine have been included separately and have not been repeated under the therapeutic areas to avoid redundancy.

Quick Wins for Medical Communications Professionals to Ensure Inclusion

Tactics

- Plain language content
- Accessible content
  - Color-blind friendly palette
  - Alt text on images
  - Hyperlinks to an accessible webpage
  - Infographics and pictorial depictions
- Hard copies of educational content/infographics
- Translation of content to cater to regional populations

Roles

- Ensure agency-wide awareness of FDA DEI guidance[12]
- Familiarize with relevant style guidelines
- Understand regulatory requirements (FDA guidelines, etc)
- Collaborate cross-functionally
- Leverage technology and tools (eg, translations of materials using AI, color-blind compliance assessment[13]

Conclusions

- Despite DEI guidance from the FDA and EMA, very few journals require authors to address the lack of diversity in clinical trial publications
  - Journals/publishers could enforce standardized guidelines that require reporting of any potential biases and disclosing the lack of generalizability across patient populations as a study limitation in clinical trial publications
- Given the updated guidance in GPP 2022, publications professionals can ensure greater transparency in reporting the impact and limitations of underrepresentation on clinical trial results
- Encouraging diversified clinical trial investigators and authorship could also be a step toward overcoming healthcare disparities

Recommendations

Moving Towards Diverse & Equitable Participant Inclusion in Clinical Trials

	Ongoing Clinical Trials	Planned Clinical Trials
Health Authorities	• Provide statistical support to allow pharmaceutical companies to conduct post hoc analyses evaluating trial data for underrepresented patient groups • Review SAPs for ongoing trials for generalizability to affected populations	• Enforce compliance to the latest FDA diversity guidance[12]
Pharmaceutical Companies	• Prepare addendums to the SAPs to ensure data analyses are inclusive and generalizable across population • Conduct post hoc analyses evaluating trial data for underrepresented patient groups	• Ensure diverse participant selection by - Trial eligibility criteria evaluation - Site planning • Ensure diversity across trial investigators and authors • Provide alternatives to clinic visits • Develop patient-friendly resources to improve recruitment diversity
Publication Agencies	• Encourage clients to conduct post hoc analyses examining potential biases in results • Ensure any potential biases are discussed as limitations to the trial results within the trial publication	• Ensure accuracy in reporting DEI information in publications • Encourage and support development of resources to improve recruitment amongst minority populations • Ensure compliance with the FDA DEI guidance when supporting regulatory or clinical trial content • Propose submitting a PLS with publications
Journals	• Require reporting of any potential biases and explanation for lack of generalizability across patient populations in clinical trial publications	• Require a brief background on how the disease affects different populations, highlighting high-risk groups • Require detailed outcomes across racial and ethnic subgroups • Encourage submission of the diversity plan as a supplemental material for clinical trial publications • Require diversity in authorship and journal editorial board

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Abbreviations: AI, artificial intelligence; DEI, diversity, equity, and inclusion; EMA, European Medicines Agency; FDA, US Food and Drug Administration; GPP, Good Publication Practice; PLS, plain-language summary; SAP, statistical analysis plan.

References: 1. Golden SH, et al. *J Clin Endocrinol Metab*. 2012;97:E1579-1639. 10.1210/jc.2012-2043. 2. National Institutes of Health. https://www.niaid.nih.gov/research/diseases- disproportionately-affecting-minorities. Accessed March 28, 2023. 3. Power-Hays A, McGann PT. *N Engl J Med*. 2020;383:1902-1903. 10.1056/NEJMp2022125. 4. Cohen MG, et al. *Circulation*. 2010;121:2294-2301. 10.1161/CIRCULATIONAHA.109.922286. 5. Anstey ED, et al. *Clin Cardiol*. 2016;39:585-595. 10.1002/clc.22570. 6. Graham G. *Clin Cardiol*. 2016;39:299-306. 10.1002/clc.22524. 7. Lee L, et al. *Public Health Rep*. 2019;134:599-607. 10.1177/0033354919881438. 8. Price JH, et al. *Biomed Res Int*. 2013;2013:787616. 10.1155/2013/787616. 9. Cook NL, Mensah GA. *Circulation*. 2015;132:1519-1521. 10.1161/CIRCULATIONAHA.115.018953. 10. Clark LT, et al. *Curr Probl Cardiol*. 2019;44:148-172. 10.1016/j.cpcardiol.2018.11.002. 11. Nelson A. *J Natl Med Assoc*. 2002;94:666-668. Food and Drug Administration. Diversity plans to improve enrollment of participants from under represented racial and ethnic populations in clinical trials–Guidance for Industry. April 2022. https://www.fda.gov/media/157635/download.

Disclosures: R Parthasarathy and D Hutta are employees of ProEd Communications, Inc., a Healthcare Consultancy Group company. A Koning is an employee of Synergy, a Healthcare Consultancy Group company. K Andersen and A Biswas are employees of Chameleon Communications International, Ltd., a Healthcare Consultancy Group company.

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