Identifying Enrollment Barriers in Oncology Clinical Trials: A Systematic Review

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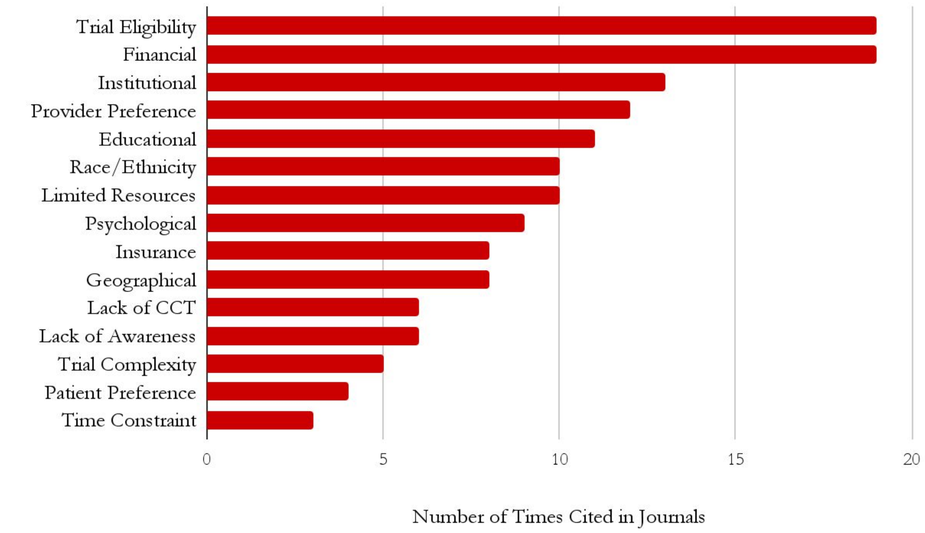
Background and Goals

- Oncology clinical trials are crucial for developing novel cancer treatments and improving current treatment guidelines.
- Only 2-4% of eligible cancer patients currently participate in clinical trials.
- Thirty percent of Phase 3 trials fail to complete due to enrollment issues and 80% of trials miss recruitment targets and timelines.
- Overall trial participation rate averages 14.8% at academic medical centers and 6.3% at community health centers.
- Our goal: Identify the barriers to clinical trial enrollments through review of current literature.

Methods

1. Initial qualitative literature review was conducted using Medline, PubMed, and WorldCat to identify barriers using the PRISMA method, and carefully selected MeSH terms.
2. Exclusion criteria included: papers not written in the United States; not oncology focused; not from 2021-2023; and not clinical trial barrier-focused.
3. Barriers were classified through a double-blind categorizing process.
4. *Current research extension:* systematic review using PubMed, World of Science, Embase, and Cochrane Library focusing on provider-focused barriers including papers published in the years 2018-2024.
5. Screening was conducted using a double-blind method process via Rayyan. First screening utilized only article titles while second screening incorporated paper abstracts with the titles. Final in-depth analyses were conducted for relevancy and for inclusion in the final cohort.

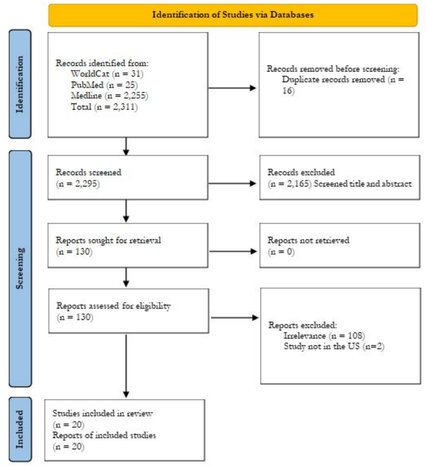
Results Table



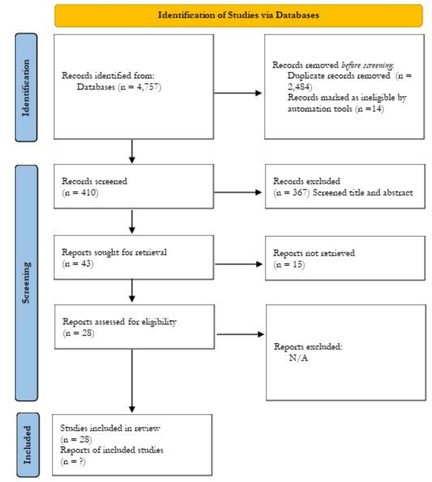
Results

- The review strictly examines the barriers as documented in the results sections of applicable journal articles.
- There were 143 unique barriers identified, which were then regrouped into the broader categories and then listed in the results graphic above.
- Barriers were counted based on the number of times they were cited in a journal.

Previous PRISMA Flow Diagram



Current PRISMA Flow Diagram



Past Findings and Limitations

- Past systematic review encompasses 20 studies from 2021-2023.
- Four broad categories of barriers identified: patient-specific, provider-specific, institutional, and regulatory.
  - *Patient:* financial, geographical, educational, psychological factors, race and ethnicity, and patient preference.
  - *Provider:* lack of clinical trial awareness, provider preference, and race and ethnicity.
  - *Institutional*: financial, geographical, limited resources, race and ethnicity, time constraints, and trial eligibility.
  - *Regulatory:* trial complexity, strict eligibility criteria, financial and institutional barriers, lack of available clinical trials, and insurance.
- The most prevalent barriers were related to **financial and trial eligibility**.
  - Financial eligibility includes insurance coverage, income restrictions, institutional resources, and lack of reimbursement.
  - Trial eligibility includes stringent trial criteria, trials targeting specific populations, and age limitations.
- Each barrier may influence others and the issues are multifaceted.

Conclusions

This study has underscored the critical role of oncology clinical trials in advancing cancer research and patient care. However, it has also illuminated significant barriers to enrollment, such as stringent eligibility criteria, limited patient and provider awareness, and systemic challenges including financial constraints and insurance issues. These factors diminish the pool of potential participants and may hinder progress in cancer treatment. Addressing these challenges requires a comprehensive approach that involves streamlining administrative processes, enhancing education for patients and providers, and tackling logistical and financial obstacles. There is a pressing need for collaborative efforts between and among healthcare professionals, researchers, industry sponsors, and policymakers to expand access to clinical trials. Such efforts are paramount to catalyzing advancements in cancer treatment and care. Further systematic research and institutional actions are essential, mainly focusing on mitigating financial barriers and creating viable solutions. Such future research will provide valuable insights for policymakers and sponsors, guiding efforts to improve trial enrollment and ultimately fostering significant progress in the battle against cancer.

Next steps

- Conduct provider interviews and surveys at the Massachusetts General Hospital Cancer Center relative to real and perceived barriers.
- Initiate additional systematic research on patient-centered barrier solutions; This has been identified as an unmet need.

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References