Recruitment to Cancer Clinical Trials: Challenges and Strategies

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Disclosure

- I have nothing to disclose
Objectives

- Describe three challenges in recruiting participants to cancer clinical trials.
- Identify three strategies to improve recruitment of participants to cancer clinical trials.
- Discuss two strategies to improve recruitment of underserved or underrepresented populations to cancer clinical trials.
Introduction

- Validity of clinical research studies are dependent on:
  - Recruitment of adequate numbers of a required participant population
  - Retaining participants
  - Ensuring the protocol is followed
- Inefficient recruitment may have scientific, economic, and ethical consequences
The Issue: Recruitment in Clinical Trials

- 86% of all clinical trials fail to finish on time
  - 60% of clinical trials are delayed or terminated due to lack of enrollment
  - 19% of clinical trials terminate early
  - 20% delayed 6 months or longer
- Delays slow the progress of research and can lead to early closure which exposes participants to risk for potentially no benefit
- Hard to reach populations
- Traditional methods of recruitment are costly with low participation rates

Huang et al, 2018
Recruitment in Cancer Clinical Trials

- Approximately 20% of adult cancer patients are eligible for a clinical trial and 15-25% of eligible patients participate in a clinical trial
- Only 2-8% of cancer patients in U.S. participate in a cancer clinical trial
- Participation decreases with age
- Ethnic and minority groups are underrepresented
Barriers to Participation

- CLINICIAN
- SYSTEM
- PATIENT
  - General population
  - Underserved/Underrepresented populations
Clinician Centered Barriers...

- Time Constraints
  - Extra paperwork
  - Patient education
  - Extended follow-up or clinic visits
- Lack of support staff
- Impact on doctor-patient relationship
- Concern for patients
- Clinician bias
Clinician Centered Barriers

- Obtaining consent
- Poor financial reimbursement
- Lack of interest in the specific research question
- Fear of not being kept informed about patient’s care
System Barriers

- Institutional
- Protocol Issues
  - Eligibility
  - Procedures
- Expense
- Competition
- Sponsor-centered
  - Adequate funding
  - Site selection
  - Investigator selection
General Population Barriers

- Lack of Awareness
- Mistrust
- Demands of the study
- Preference for a particular treatment
- Concerns about side effects
- Comfort level with physician

- Language and literacy
- Loss of privacy
- Portrayal as guinea pig
- Misperceptions
- Geographical limitations
- Financial Considerations
Barriers to Recruiting Underserved/Underrepresented…

- Lack of awareness of clinical trials
- Lack of awareness of benefits to participation
- Distrust of doctors
  - Different values or beliefs
  - Lack of cultural sensitivity
  - Language or literacy barriers

Underserved/underrepresented: older adults, racial/ethnic minorities, and sexual/gender minorities, patients with well-managed comorbidities
… Barriers to Recruiting Underserved/Underrepresented

- Employment obligations
- Comorbid conditions
- Presentation at late stage of disease
- Limited transportation
- Sense that participants don’t get anything from participation
- Lack of minority Principal Investigators
Community-Based Barriers

- Organizational, financial, and administrative challenges to implement a clinical trial program at a community site
- Lack of understanding and appreciation of the value and conduct of clinical trial participation
- Managing clinical and research workflow
- Leadership support
- Physician commitment

Minasian & Unger, 2020
Good News!

- 94-96% participants said that they would participate in a clinical trial again

STRATEGIES

If you always do what you always did, you’ll always get what you always got.

 amor
Stating the Obvious

- Identify and remove barriers
  - Assess barriers to clinical trial participation
  - Identify actions to remove barriers
  - Prioritize actions
- Introduce clinical research/clinical trials earlier within the patient experience
Recruitment Plan…

- How and by whom potential participants will be approached about participation
  - Active: Potential participants are identified by investigators and contacted about participating in a study
  - Passive: Potential participants contact investigators about participating in research
- From where potential participants will be recruited (e.g., in subject unit, walk in clinic, emergency room, ICU, or private practice)
Recruitment Plan

- Recruitment methods
  - Advertisements
  - Study specific websites
  - Email
  - Banner Advertising
  - Chat rooms & forums
  - Podcasts
  - Search engine advertising
- Use of third parties (calling centers/centralized screening centers)
Leveraging Technology

- Use of EMR/EHR to trigger an alert if a patient is likely eligible for an ongoing clinical trial
Protocol

- What makes this protocol exciting/important?
- What type of competition is out there?
- Why would a patient enroll in this study?
- Why would a patient not want to enroll in this study?
- Why would a physician be reluctant to refer a patient to this study?
Study Population

- Know your catchment area
- Study population should be appropriate for the research question being asked
- Involve members of the study population in planning efforts when possible
Broadening Eligibility Criteria…

- 2016: American Society of Clinical Oncology (ASCO) and Friends of Cancer Research began a joint project to evaluate current eligibility criteria and determine how to broaden the criteria
- FDA published guidances:
  - Brain Metastases
  - HIV/AIDS
  - Organ Dysfunction and Prior and Concurrent Malignancies
  - Minimum Age for Enrollment
February 2021 additional recommendations published to broaden criteria related to:
- Washout periods and concomitant meds
- Performance status
- Laboratory test intervals and reference ranges
- Prior therapies
Increase Awareness in the Community

- Take message to the study population
- Invest in community education and outreach programs
- Community-based organizations
- Enhance credibility of study by using a community spokesperson/lay outreach workers
- Places of Worship
- Give something back to the community
- Resource: Center for Information and Study on Clinical Research Participation (CISCRP)
Underserved/Underrepresented…

- Getting the word out (e.g., Community events; Health Fairs; Workshops
- Speak the language of the community.
- Provide culture and language-appropriate informational materials
- Involve minority researchers/physicians
- Clarify the agenda behind the research
…Underserved/Underrepresented

- Reach out to key decision makers in targeted groups
- Leverage satellite sites to conduct clinical trials
- Staff/researcher education
  - Cultural sensitivity
  - Bias
Navigator…

- Member of the healthcare team who helps patients “navigate” the healthcare systems
  - Coordinate patient care
  - Connect patients with resources
  - Help patients understand the healthcare system

- Patient navigators
  - Nurse navigators
  - Community navigators
…Navigator

- A navigator can increase patient clinical trial access, awareness, and knowledge as well as appropriately match trials for patients
- Engage navigators for input on study design and recruitment for underserved/underrepresented populations
- Include a culturally competent navigator as a member of the clinical trial team to promote patient participation
Social Media

Advantages

▪ Wider audience
▪ Low cost (?)
▪ Instantaneous communication
▪ Easy updating
▪ Interactive
▪ Self-education

Disadvantages

▪ Information chaos!
▪ Misinformation abounds
▪ Communication “too easy”–just a click
▪ Lack of patient/physician boundaries
▪ “Private” information becomes “public”
▪ Self-selection bias

Topolovec-Vranic et al, 2016
Promising Research With Social Media as a Recruitment Tool

- HIV vaccine clinical trials (2009 – YouTube, Wikipedia, Facebook, Craigslist)
- Occipital nerve studies (2013)
- Pediatric cancer (2015 - Facebook)
- Depression prevention (2013)
- Smoking cessation (2013 – Google AdWords, WebMD.com, Facebook, Twitter; 2014 - Facebook)

- Hard to reach populations:
  - Young cancer survivors (2014 – online newspapers, Craigslist, university website, email to advocacy groups, Facebook, Twitter)
  - Gay Latino males (2014 – Facebook, Craigslist, smartphone apps [Grindr, SCRUFF, Jack’d])
  - Deaf community (2013 – project website)

Gelinas, 2018
But......

- Lack of regulatory guidance
  - Informed consent process begins with recruitment
  - IEC/IRB review of recruitment materials
  - PI should be able to recruit the required number of participants in a specified timeframe

- Few resources

Ethical Principles Applied to Social Media Recruitment

- Respect for privacy and confidentiality
- Information security, as related to identity
- Transparency
  - Accuracy of study benefits/risks
  - Disclosing presence on social media
Things to Consider When Using Social Media…

- Online recruitment materials should follow the same guidelines applicable to traditional recruitment methods
- Recruitment materials must be reviewed and approved by the IEC/IRB
  - Investigator contact information, information about the purpose of the study, any eligibility criteria, benefits to the subject, and time commitment required for participation in the study
  - No promise free medical treatment, imply unanticipated benefits, or emphasize payment
Things to Consider When Using Social Media…

- Potential participants interested in the study should be directed to contact the study team via non-public means.
- Research teams need to:
  - be familiar with the terms and conditions of any sites used for recruitment to ensure potential participants are not asked to violate a service agreement.
  - consider informing participants that they should be aware of the terms and conditions of the website to understand what, if any, data may be used/maintained by the website itself.
  - consider how the target population uses social media.
...Things to Consider When Using Social Media

- Inform participants of third-party risk of interception when transmitting data and data back-up processes
  - “Your confidentiality will be kept to the degree permitted by the technology being used. No guarantees can be made regarding the interception of data sent via the Internet by any third parties.”
  - “Data may exist on backups or server logs beyond the time frame of this research project.”
Social Media Resource

  - Investigator checklist
  - IRB checklist
Conclusion

- Advances in cancer treatment require efficient clinical trial processes especially focused on recruitment
- Recruitment can impact the ability to answer research questions
- Assess local/regional barriers to recruitment and identify strategies to overcome these barriers
- Plan up front for recruitment!!
Selected References…

…Selected References…


…Selected References…


Selected References


QUESTIONS
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