Social Determinants of Health and Impact on Care Disparities. Pharmacist Role, Patient Education about Trials

Shanada Monestime, PharmD, BCOP
Director, Community Engaged Research
GO2 for Lung Cancer
In your opinion, do you believe pharmacists could play a significant role in improving clinical trial enrollment rates?

- Yes, I strongly believe pharmacists have a significant role.
- Yes, I believe pharmacists have some role.
- No, I don't think pharmacists play a significant role.
- I am unsure.
Learning Objectives

- Investigate and discuss patient advocacy case studies as they relate to clinical trial enrollment.
- Explain the role of Social Determinants of Health (SDOH) in influencing clinical trial enrollment.
- Differentiate between clinician barriers, patient barriers, trial barriers, and institutional barriers to clinical trial enrollment.
- Explore evidence-based interventions that enhance oncology clinical trial enrollment that are relevant to pharmacists.
Case Study: Zip Code Disparities

Case 1

• Maria, a 52-year-old woman, has lived in zip code 33311 for most of her life. She is insured through her employer, which offers comprehensive health coverage. Maria has a primary care physician who emphasizes regular check-ups and preventive care. As a result, she has been proactive in managing her health and participating in early cancer screenings.

• In 2020, Maria was diagnosed with breast cancer after a routine mammogram revealed abnormalities. Her healthcare team identified her as a suitable candidate for a clinical trial testing a novel targeted therapy. Maria eagerly enrolled in the trial, benefiting from cutting-edge treatment options not widely available. Her cancer responded positively to the experimental therapy, and she experienced a higher likelihood of achieving remission and an improved quality of life.
Case Study: Zip Code Disparities

Case 2

• Robert, a 58-year-old man, also calls zip code 33311 home. However, his healthcare journey has been marked by barriers. He works **part-time in a low-wage job** and **lacks health insurance**. Financial constraints have prevented him from seeking **regular medical care** and cancer screenings.

• In 2019, Robert began experiencing persistent cough and fatigue. When he finally sought medical attention, he was diagnosed with advanced-stage lung cancer. Due to his late-stage diagnosis and uninsured status, Robert faced limited treatment options. Although a clinical trial for a potentially groundbreaking therapy was available at a nearby research institution, he was unable to enroll due to financial barriers and lack of access to a comprehensive healthcare network.
2 People, Same Zip Code, Different Outcomes
2 People, Same Zip Code, Different Outcomes

Socioeconomic Factors
- Education
- Job Status
- Family Social Support
- Income
- Community Safety

Physical Environment

Health Behaviors
- Tobacco Use
- Diet & Exercise
- Alcohol Use
- Sexual Activity

Health Care
- Access to Care
- Quality of Care

Source: Institute for Clinical Systems Improvement, Going Beyond Clinical Walls: Solving Complex Problems (October 2014)
Social Determinants of Health

These circumstances are shaped by the distribution of money, power and resources at global, national and local levels.
Profound racial and ethnic inequities in health and health care exist across and within states.

Health system performance scores, by state and race/ethnicity

All

Race/Ethnicity
- AANHPI
- AIAN
- Black
- Latinx/Hispanic
- White

Notes: Scores are based on the percentile distribution of each group’s final composite score across all indicators/dimensions, rank-ordered by score of state’s highest group. The 50th percentile represents the median health performance score among all the groups measured. Summary performance scores not available for all racial and ethnic groups in all states; missing data for a particular group indicate that there are insufficient data for that state. AANHPI = Asian American, Native Hawaiian, and Pacific Islander; AIAN = American Indian/Alaska Native.

Data: Commonwealth Fund 2021 Health System Performance Scores.

Source: David C. Radley et al., Achieving Racial and Ethnic Equity in U.S. Health Care: A Scorecard of State Performance (Commonwealth Fund, Nov. 2021)
How do we Obtain Health Equity?

- Health equity provides everyone with a fair and just opportunity to be as healthy as possible.
- Removing obstacles to health such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and healthcare.
“Of all the forms of inequality, injustice in health care is the most shocking and inhuman.”
Oncology Clinical Trial Disparities

• Disparities in cancer mortality and morbidity between BIPOC and NHW populations

• Clinical trials = advancement of treatment and outcomes

• <5% of eligible adult cancer survivors participate in cancer trials

• BIPOC = lower enrollment rates

Clinical Trial Participants

76.3% Whites
18.3% Asians
6.1% Blacks
3.1% Hispanics

Barriers to Clinical Trial

- Clinician Barriers
- Patient Barriers
- Trial Barriers
- Institutional Barriers
- Biomarker Testing Uptake Barriers

Clinician Barriers

- Personal bias
- Costs to clinicians
- Limited time
- Support and staff
- Awareness of trials
- Resources to search for trials

Patients/Caregiver Barriers

- Attitudes towards clinical trials
- Knowledge of trials
- Side effects/toxicities
- Burden
- Financial limitations (direct & indirect)
- Location of trials

Trial Barriers

• Overly stringent eligibility criteria
• Onerous participation requirements

Institutional Barriers

• Trial Location
• Availability and diversity of research and support staff
• Lack of access to care
• Limited health insurance uptake

Biomarker Testing Barriers

• Comprehensive biomarker testing increases clinical trial options\(^1\)
• Only 50% of eligible cancer patients in the U.S. receive recommended biomarker tests\(^2\)
• Older, Black, uninsured patients are less likely to get comprehensive biomarker tests\(^3-6\)
• Over 25% of patients skipped biomarker testing due to uncovered costs\(^7\)

Global Recommendations to Increase CT Enrollment

The National Cancer Institute and the American Society of Clinical Oncology Clinical Trial Symposium recommend:

• Culturally tailored education tools, including videos and reading materials

• Promoting health literacy and participation among BIPOC through tailored materials

PHARMACISTS, PHARMACISTS, PHARMACISTS!!

Effective Strategies in Treatment Clinical Trial Enrollment Relatable to Pharmacists
<table>
<thead>
<tr>
<th>Study characteristics</th>
<th>Participant characteristics</th>
<th>End points</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study type:</strong> Single arm</td>
<td>N = 332</td>
<td>Primary: (1) Patient navigation utilization (2) Potential impacts on clinical care (treatment interruptions and clinical trial enrollment)</td>
<td>22% recruited (compared with the average in the literature of &lt;1%)</td>
</tr>
<tr>
<td><strong>Study setting:</strong> Rural cancer institute</td>
<td>Cancer type: Mixed Demographics: 100% Native American</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intervention:</strong> Patient navigation</td>
<td>Clinical trial type: Therapeutic and nontherapeutic</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Length:</strong> 5 y</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Guadagnolo et al., 2011: Strategies

• Patient navigators helped with coordinating appointments, addressing insurance issues, following up on tests, obtaining medications, arranging transportation and lodging, and offering psychosocial support.

• The program also involved community research representatives who provided cancer education, connected with local health resources, and served as liaisons between the cancer center, patient navigators, and patients or tribal governments.

<table>
<thead>
<tr>
<th>Study characteristics</th>
<th>Participant characteristics</th>
<th>End points</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study type:</strong> Single arm</td>
<td>N = 59</td>
<td>Primary: Clinical trials recruitment</td>
<td>86% recruited institutionally. Recruitment rates of Black patients to clinical trials increased from 3% to 7%</td>
</tr>
<tr>
<td><strong>Study setting:</strong> Suburban community physician offices</td>
<td>Cancer type: Breast Demographics: 100% Black Clinical trial type: Not specified</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intervention:</strong> Nurse navigator</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Length:</strong> 2 y</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Collaborations were established with 6 private practice surgical oncologists, breast surgeons, and medical oncologists practicing.

The nurse navigator:

- Made weekly visits to each community physician’s office to coordinate referrals of newly diagnosed breast cancer patients.
- Provided counseling and education to patients, assessed their understanding of diagnoses and treatment options, and educated them about available clinical trials.
- Prospectively evaluated patients for eligibility and clinical trial enrollment.

Robinson et. al., 2017: Overview

<table>
<thead>
<tr>
<th>Study characteristics</th>
<th>Participant characteristics</th>
<th>End points</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study type: Single arm</td>
<td>N = 200</td>
<td>Primary: Clinical trials recruitment</td>
<td>13.5% of sample recruited to trial, 7.5% increase in recruitment from the institution's 2012 baseline of 6%</td>
</tr>
<tr>
<td>Study setting:</td>
<td>Cancer type: Breast</td>
<td>Secondary: Intervention's influence on population's (1) intentions to participate in a clinical trial and (2) attitudes toward clinical trials</td>
<td></td>
</tr>
<tr>
<td>Urban/suburban mix, hospitals, and cancer institutes</td>
<td>Demographics: 100% Black</td>
<td>Clinical trial type: Therapeutic</td>
<td></td>
</tr>
<tr>
<td>Intervention: 15- min culturally tailored enrollment barriers video</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length: 1.5 y</td>
<td>Clinical trial type: Therapeutic</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Robinson et. al, 2017: Strategies

- Eligible participants were identified through electronic clinical schedules, medical records, referrals from healthcare professionals, and support services staff at several hospital sites.

- The study required participants to allocate at least an hour for initial on-site procedures, including completing a demographic survey to assess attitudes and intent to enroll in therapeutic clinical trials before and after a video intervention.

- Patients were followed for 6 months to track consent and enrollment in therapeutic clinical trials.


<table>
<thead>
<tr>
<th>Study characteristics</th>
<th>Participant characteristics</th>
<th>End points</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study type:</strong> Single arm</td>
<td>N = 272</td>
<td>Primary: Clinical trials recruitment</td>
<td>Recruitment increased from 9% to 16% between 2007 and 2014</td>
</tr>
<tr>
<td><strong>Study setting:</strong> Urban NCI Comprehensive Cancer Center</td>
<td>Cancer type: Mixed Demographics: 100% Black</td>
<td>Clinical trial type: Therapeutic</td>
<td></td>
</tr>
<tr>
<td><strong>Intervention:</strong> Patient navigation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Length:</strong> 7 y</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
In-service presentations were conducted for clinical research nurses and principal investigators to introduce them to the patient navigation initiative.

Patients were identified through clinic schedules, patient charts, and referrals.

Patient Navigators

- Contacted patients by phone before scheduled clinic appointments to offer navigation support and obtain informed consent.
- Offered services including clinical trial education, support for enrollees, needs assessment, assistance with transportation and lodging, appointment reminders, referrals to social workers, peer support, and regular communication with clinic staff.

### Study characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study type:</strong></td>
<td>Single arm</td>
</tr>
<tr>
<td><strong>Study setting:</strong></td>
<td>Community cancer network</td>
</tr>
<tr>
<td><strong>Intervention:</strong></td>
<td>Remote oncology clinical pharmacist</td>
</tr>
<tr>
<td><strong>Length:</strong></td>
<td>6 months</td>
</tr>
</tbody>
</table>

### Participant characteristics

- N = 103
- Cancer type: NSCLC
- Demographics: XXX
- Clinical trial type: Treatment

### End points

- Primary: Monthly clinical trials enrollment rate

### Outcome

- 367 potentially eligible patients, recommended 325 patients for enrollment, and ultimately consented and enrolled 103 patients (32%).

---

Koselke et al. 2022: Strategy

- An oncology-trained clinical pharmacist remotely reviewed chemotherapy regimen orders and a weekly custom recruitment report within six community network practices (n = 149 physicians).
- The ClinReview pharmacist identified, screened, and assisted with recruitment of eligible patients for enrollment in the MYLUNG study.

### Pharmacists’ role in Biomarker Testing for CT Enrollment

<table>
<thead>
<tr>
<th>Educate</th>
<th>Review</th>
<th>Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educate both clinicians and patients about the benefits of comprehensive biomarker testing</td>
<td>Review pharmacogenomic testing results for all patients diagnosed with targetable cancers and refer to clinical trial specialists (i.e., GO2)</td>
<td>Conduct research to explore the reason for the lack of biomarker testing uptake within the population you serve</td>
</tr>
</tbody>
</table>
GO2 for Lung Cancer LungMatch

- Clinical Trial Matching
- Biomarker analysis report
- Education and Awareness

ACCESSING LUNGMATCH IS EASY

- Call us at 1-800-298-2436
- Email your questions to support@go2foundation.org
- Visit www.lungmatch.org

Call our treatment specialists at 1-800-298-2436 or visit www.lungmatch.org.
Case Study Closing Remarks

• The cases of Maria and Robert, neighbors in zip code 33311, emphasize the profound impact of healthcare disparities on access to clinical trials and health outcomes.

• Addressing these disparities requires systemic changes in healthcare access, affordability, and outreach, particularly for underserved populations.

• Achieving health equity means ensuring that all individuals, regardless of their zip code or socioeconomic status, have equal opportunities for participation in clinical trials and access to innovative treatments that can improve their lives and chances of survival.
In your opinion, do you believe pharmacists could play a significant role in improving clinical trial enrollment rates?

- Yes, I strongly believe pharmacists have a significant role.
- Yes, I believe pharmacists have some role.
- No, I don't think pharmacists play a significant role.
- I am unsure.
Thank you

Shanada Monestime
smonestime@go2.org
650-226-5492