Paving the Way to Health Care Access

Everyone Play a Role in the Clinical Trials Education

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Ana Marin
American Cancer Society
Beth Israel Deaconess Medical Center

Karen Burns White
Initiative to Eliminate Cancer Disparities
Dana-Farber/Harvard Cancer Center

Karen Winkfield, MD, PhD
Assistant Professor, Harvard Medical School
Department of Radiation Oncology
Massachusetts General Hospital
Learning Objectives

- Cancer 101
- Examine the history and context of health disparities and inequities
- Describe clinical trials and how they work
- Identify barriers and solutions to minorities participating in clinical research
- Design and practice an approach that engages interpreters in the clinical trial conversation
Cancer, Health Disparities and Clinical Trials –

- What comes to your mind....
First things first......

- What is cancer – Basic Facts...
  - # 2 cause of death
  - Nearly 1 in 4 death
Normal versus Cancer Cell Growth

Normal: regulated cell growth

Cancer: uncontrolled cell growth
Malignant versus Benign Tumors

Benign (not cancer) tumor cells grow only locally and cannot spread by invasion or metastasis.

Malignant (cancer) cells invade neighboring tissues, enter blood vessels, and metastasize to different sites.

Time
Invasion and Metastasis

1. Cancer cells invade surrounding tissues and blood vessels
2. Cancer cells are transported by the circulatory system to distant sites
3. Cancer cells reinvade and grow at new location
What Causes Cancer?

BACTERIAL AND VIRAL

CHEMICALS

RADIATION

LIFESTYLE, HORMONES, HEREDITARY
Different Types of Cancer

- Throat Cancer
- Cancer of the Oesophagus
- Lung Cancer
- Stomach Cancer
- Bowel Cancer
- Cancer of the Bladder
- Prostate Cancer
- Testicular Cancer
- Skin Cancer

- Ovarian Cancer
- Cancer of the Uterus or Cervix
- Skin Cancer
Cancer Treatments

- Surgery
- Chemotherapy
- Radiation Therapy
- Hormone Therapy
- Targeted Agents
- Clinical Trials
Cancer Screenings

- Lung - Low-dose CT Scan
- Breast - Mammogram
- Cervix - Pap Test
- Colorectal - Colonoscopy
- Prostate - prostate specific antigen/rectal exam
Health Disparities & Inequities in Health Care
What are Health Disparities?

National Institutes of Health

“What Health Disparities are the differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions that exist among specific populations groups in the United States”
Health DISPARITIES ≠ Health INEQUITIES

**DISPARITIES** are differences in health status and mortality rates that exist among specific population groups.

**INEQUITIES** are differences in health status and mortality rates across population groups that are systemic, avoidable, unfair, and unjust.
Leading National Health Disparities

- Cardiovascular Disease
- Cancer
- Diabetes
- HIV/AIDS
- Infant Mortality
- Asthma
- Mental Health
Pop Quiz....
On average, which of the following is the best predictor of one’s health?

A. whether or not you smoke  
B. what you eat  
C. whether or not you are wealthy  
D. whether or not you have health insurance  
E. how often you exercise

**ANSWER:** Whether or not you are wealthy
Generally speaking, which group has the best overall health in the U.S.?

A. Recent Latino immigrants
B. Non-Hispanic Whites
C. Native-born Latinos
D. Native-born Asian Americans

**ANSWER:** Recent Latino immigrants
Racial Segregation in Boston
Poverty Concentration
When it comes to your health...

...your **zip code** may be more important than your **genetic code**.
Social Determinants of Health
**Food Environment**

**Food desert**: large geographic area with no or distant grocery stores.

- imbalance of food choice,
- fast food
- convenience stores, and liquor stores

Research show that residents living in food deserts suffer **worse diet-related health outcomes**, including diabetes, cancer, obesity, heart disease, and premature death.
Black Americans are 5 times less likely to live in census tracts with supermarkets than White Americans.

Nationally, 50% of Black neighborhoods lack access to a full service grocery story or supermarket.

The fruit and vegetable intake of Black residents increased an average of 32% for each Supermarket in their census tract (Morland, Wing, and Diez Roux, 2002)
“The health inequities we see are the embodied expressions of social inequality. They are not about just individual bad choices: they are about things not being fair.”

Dr. Nancy Krieger
Harvard School of Public Health
<p>| Cancer Incidence and Death Rates* by Site, Race, and Ethnicity†, US, 2004-2008 |
|---------------------------------|---------------------------------|-------------------------------|-------------------------------|---------------------------------|-------------------------------|
| Incidence                       | White                          | African American             | Asian American or Pacific Islander | American Indian or Alaska Native† | Hispanic/Latino               |
| All sites                       |                                |                               |                               |                                 |                               |
| Male                            | 545.0                          | 626.2                         | 332.4                         | 427.8                           | 423.4                         |
| Female                          | 420.8                          | 394.2                         | 284.0                         | 362.1                           | 333.5                         |
| Breast (female)                 | 122.3                          | 116.1                         | 84.9                          | 89.2                            | 92.3                          |
| Colon &amp; rectum                  |                                |                               |                               |                                 |                               |
| Male                            | 54.6                           | 66.9                          | 42.4                          | 51.5                            | 48.6                          |
| Female                          | 40.3                           | 49.7                          | 32.7                          | 41.5                            | 34.2                          |
| Kidney &amp; renal pelvis           |                                |                               |                               |                                 |                               |
| Male                            | 20.8                           | 22.6                          | 9.9                           | 27.4                            | 19.4                          |
| Female                          | 10.9                           | 11.7                          | 4.9                           | 16.8                            | 11.2                          |
| Liver &amp; intrahepatic bile duct  |                                |                               |                               |                                 |                               |
| Male                            | 8.6                            | 14.1                          | 21.7                          | 15.8                            | 17.0                          |
| Female                          | 2.9                            | 4.0                           | 8.2                           | 7.6                             | 6.4                           |
| Lung &amp; bronchus                 |                                |                               |                               |                                 |                               |
| Male                            | 83.7                           | 102.7                         | 49.8                          | 71.0                            | 46.8                          |
| Female                          | 57.2                           | 51.4                          | 28.1                          | 51.7                            | 27.0                          |
| Prostate                        | 142.8                          | 230.8                         | 79.7                          | 101.2                           | 126.7                         |
| Stomach                         |                                |                               |                               |                                 |                               |
| Male                            | 8.5                            | 16.4                          | 16.8                          | 13.9                            | 13.8                          |
| Female                          | 4.0                            | 8.2                           | 9.4                           | 6.8                             | 8.4                           |
| Uterine cervix                  | 7.7                            | 10.6                          | 7.4                           | 9.8                             | 12.2                          |</p>
<table>
<thead>
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<th>Mortality</th>
<th>White</th>
<th>African American</th>
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<td>15.1</td>
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<td>Colon &amp; rectum</td>
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<tr>
<td>Male</td>
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<tr>
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<td>Stomach</td>
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<td>Male</td>
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<td>10.7</td>
<td>9.2</td>
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<td>3.4</td>
<td>3.1</td>
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*Per 100,000, age adjusted to the 2000 US standard population.
†Race and ethnicity categories are not mutually exclusive; persons of Hispanic origin may be of any race.

**Source:** Incidence: NAACCR, 2011. Data are collected by cancer registries participating in the National Cancer Institute’s SEER program and the Centers for Disease Control and Prevention’s National Program of Cancer Registries. Mortality: National Center for Health Statistics 2011.
Disparities and gaps in treatment are complex issues

Public-policy – Resource allocations decisions – multi-prong and multi-faceted (political, economic, and social systems)

Strategies to achieving equity:

- Promote equal health care access and quality
- Improve workforce diversity
- Empower patients and communities
What are Clinical Trials?

- A research study answers important questions
- Look for new ways to prevent, detect or treat disease
Different Types of Trials

- Prevention
- Diagnostic
- Screening Trials
- Quality of Life
Clinical Trial Protocol

- Written, detailed, scientific action plan
- Ensures consistency of research procedures, scientific validity of results and protects patients
- Must be reviewed and approved by an Institutional Review Board (IRB) before the clinical trial can begin
Why Participate in Clinical Research

- Gain insights and answers about the safety and effectiveness of new therapies
- Find ways to diagnose, prevent, treat, or cure diseases
- One size does NOT fit all!
# Clinical Trial Phases

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<tr>
<th>Models</th>
<th>Clinical phases</th>
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<tr>
<td>Pre-clinical</td>
<td><strong>Clinical phases</strong></td>
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<tr>
<td>In vitro studies</td>
<td>Phase I: Safety – Tolerability – Pharmacokinetic / dynamics – Dose-response</td>
</tr>
<tr>
<td>In vivo studies</td>
<td>Phase II: Dosing – Efficacy</td>
</tr>
<tr>
<td>Process development</td>
<td>Phase III: Efficacy compared to gold standard treatment</td>
</tr>
<tr>
<td>GMP production</td>
<td>Phase IV: Post-marketing surveillance - Pharmacovigilence</td>
</tr>
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# General Clinical Trials Times and Costs

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<tr>
<th></th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>NDA review</th>
<th>Phase 4</th>
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<tr>
<td><strong>Years</strong></td>
<td>1-1.5</td>
<td>2</td>
<td>3-3.5</td>
<td>0.6-2.5</td>
<td>11-14</td>
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<tr>
<td><strong>Test population</strong></td>
<td>20-80 healthy volunteers</td>
<td>100-300 patients</td>
<td>1000-3000 patients</td>
<td></td>
<td></td>
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<tr>
<td><strong>Purpose</strong></td>
<td>Determine safety and dosage</td>
<td>Evaluate effectiveness, look for side effects</td>
<td>Confirm effectiveness, monitor adverse reactions for long term use</td>
<td></td>
<td>Additional post-marketing testing</td>
</tr>
<tr>
<td><strong>Cost (mm)</strong></td>
<td>$32.3</td>
<td>$37.7</td>
<td>$96.1</td>
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</tbody>
</table>
WHAT IS THE PROCESS?

Clinical Trials in a Nut Shell

- Approved Protocol
- Investigator selection
- Approval Process
- Statistical Analysis
- Data Entered and reviewed
- Patient recruitment and participation
- Presentation and publication of report
- Data filed and registration obtained
Barriers to Participation

- Psychosocial/socioeconomic issues
- History/past experiences
- Resources/Financial considerations

Barriers to Participation

▪ Research System Issues

▪ Researcher Bias

▪ Issues in Research Method, Design, Management

Recruitment Strategy

Educate, educate, educate….

- Use outreach workers from the targeted population (cultural insider)
- Faith-Based/Community-Based Organizations such as community health centers
- Health-Care Delivery systems –
  - Clinical research staff – Cultural competency education
  - Interpreters – Clinical research/clinical trials education
Institutional change is a MUST!

- Require cultural competency training!
- Create a welcoming environment
- Hire minority staff
- Develop new partnerships
- Work with a community advisory board
- Modify study material as needed
My Personal Story

- BIDMC/ACS Patient Navigator program is very important for patients and families because it’s a direct connection between providers, nurses and staff of the medical facility.

- The Patient Navigator program, has earned the providers/RN’s and staff recognition as a valuable and trustworthy source of information, and connection to resources from ACS, the medical facility and the community in general.

- Having been a medical interpreter you know the vital role as expert communicators between patients, providers and of course, researchers.

- LEP patients need to have access and knowledge about clinical trials.
The American Cancer Society – Patient Navigation role and Clinical Trials

“Patient navigators remove barriers to care,” said Rian Rodriguez, MPH, director of the American Cancer Society Patient Navigator Program. “They ensure that patients don’t fall through the cracks so they can complete their treatment and have a more successful health outcome.”
Clinical Trials Matching Service

- The American Cancer Society Clinical Trials Matching Service - a partnership with Eviti, Inc.,

- Free, confidential program that helps patients, their families and health care workers find cancer clinical trials most appropriate to a patient's medical and personal situation.

- ACS can help find research studies that are testing new drugs or methods to prevent, detect or treat cancer
Clinical Trials - The role of Medical Interpreters

At BIDMC:

- In communicating accurate health related information to patients, families and communities

- For many patients, a clinical trial may be an option of treatment for cancer or other serious illnesses

- Orientation at BIDMC includes researchers (PI) learning the guidelines of interpreter services.
Medical Interpreter Role, and Clinical Trials at BIDMC

Plan accordingly:

- Clinical trials can take a long time to be explained
- The consent form is lengthy
- For Limited English Patients (LEP) appropriate planning and allowed time to explain clinical trials is necessary and very important
Thank you
Ana C. Marin, ACS/BIDMC Cancer Patient Navigator
617-667-3429
1-800-227-2345
amarin@bidmc.harvard.edu
ana.marin@cancer.org
www.cancer.org
EVITI, Inc. – 1.800.303.5691