Practical Approaches to Improving Diversity in Clinical Trials

Wednesdays
11AM – 12noon ET
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The MRCT Center is supported by voluntary contributions (www.MRCTCenter.org) and grants.
Practical Approaches to Improving Diversity in Clinical Trials

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Recording available
Community Awareness, Access, Knowledge
October 28, 2020
Workforce Development
November 18, 2020
Study Design, Eligibility, Site Selection & Feasibility
December 9, 2020
Study Conduct (Recruitment, Retention)
January 13, 2021
Data Standards and Analysis
January 27, 2021
Stakeholder Roles and Responsibilities
February 10, 2021
Role of Data in Diversity: Genetics & Real World Data
Today’s topic

WORKFORCE DEVELOPMENT
October 28, 2020
11AM –12noon ET

Luther T. Clark, MD
Moderator
Deputy Chief Patient Officer,
Merck

Sarah A. White, MPH
Moderator
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Racquel W. Bruton
Guest Speaker
Senior Clinical Operations Lead,
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LEANING IN: A WEBINAR SERIES
Practical Approaches to improving Diversity in Clinical Trials
Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
Achieving Diversity, Inclusion, and Equity in Clinical Research

Guidance and Toolkit

mrctcenter.org/diversity-in-clinical-trials

Released 6 August 2020
Leadership

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And the invaluable contributions of >50 workgroup members, representing:

• Patients, Patient Advocates
• Academia
• Pharmaceutical companies
• CROs
• Non-profit organizations
• Trade associations
• Government agencies
• Research institutes

Each serving in their individual capacity.
• Multi-stakeholder contributions and consensus
• Practical and actionable recommendations
• Accountability section considers how each stakeholder can change the paradigm
• Toolkit provides adaptable resources not easily found elsewhere

[Link: mrctcenter.org/diversity-in-clinical-trials]
Who comprises the Clinical Research Workforce?

• Clinicians
• Investigators
• Research team members
• Referring physicians
• Sponsors
• CROs
• Patient recruitment vendors
• …anyone who is directly or indirectly involved in the research study

 Ø Broadly inclusive
 Ø Needs may differ
Workforce development

- Sensitizing the clinical research workforce to issues of diverse participation
- Building the number of underrepresented minority investigators and study staff
- Provide cultural competence and implicit bias training of all staff
- Support diversity with health literacy and clear communication
- Involve physicians in community healthcare settings and ensure they understand clinical research
Lack of Diverse Workforce impacts research

Growing the Pipeline of Diverse HIV Investigators: The Impact of Mentored Research Experiences to Engage Underrepresented Minority Students

Jonathan Fuchs, Aminta Konyate, Liz Kroboth & Willi McFarland

AIDS and Behavior 20, 249–257 (2016) | Cite this article

Mentoring Programs for Underrepresented Minority Faculty in Academic Medical Centers: A Systematic Review of the Literature

Health Promotion Practice

Increasing the Number of Underrepresented Minority Behavioral Health Researchers Partnering With Underresourced Communities: Lessons Learned From a Pilot Research Project Program

Theresa H. Cruz, PhD, Matthew E. Borrego, PhD, Janet Page-Reeves, PhD

First Published February 28, 2020 | Research Article | Check for updates

28 October 2020
Leaning In Webinar Series

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Concordance of race between doctor and patient improves compliance and health.

Effect increases with “invasiveness” of tests for preventive care.

Training of the workforce

Culturally Competent Strategies for Recruitment and Retention of African American Populations into Clinical Trials

Jane Otado, Ph.D.¹, John Kwagyan, Ph.D.¹, Diana Edwards, Ph.D.¹, Alice Ukaegbu, M.S.N., F.N.P.-B.C.¹, Faun Rockcliffe, B.A.¹, and Nana Osafo, M.S.¹

![Diagram showing recruitment strategies and their frequency]

**Figure 1.** Recruitment strategies data indicate number of response.
Minimum expectations of workforce development

Commitment to recruiting and training a diverse clinical research workforce
Training research professionals, staff, and others in cultural and linguistic competency

Implicit bias training and respect of potential populations
Commitment to health literacy

Workforce Development
The safety and efficacy of medical treatments are assessed primarily by clinical research; such research should reflect the population for whom the treatment is intended. [The organization] is committed to inclusion of diverse populations, including people of varying age, race, ethnicity, sex, gender, and other potential effect modifiers, to better reflect the population for whom the treatment is intended, in order to advance better health outcomes for all.

- Organizations should develop a model statement of commitment
- Statement can be aspirational (e.g., “…working towards inclusion”) and modified as progress occurs

Cultural Considerations

- Cultures undergo change over time
- A workforce that creates and sustains a culturally informed and respectful environment will:
  - Understand the background and cultures included in the study population
  - Learn about diverse cultural heritages, norms, lifestyles
  - Develop preferred and respectful ways to communicate with intended populations
  - Be comfortable asking and listening as well as informing and talking
- Iterative process that is most effective if modeled by leaders in all stakeholder groups
Address in advance how to accommodate the enrollment of individuals of the Islamic faith:

• Times and places of prayer
• Participation during Ramadan
• Dress requirements and interactions between women and male clinician
• If a study visit requires Muslim participants to be at the clinic, ask how you can accommodate them.
• Healthcare providers play a key role
  o Raise awareness of clinical research and specific clinical trials
  o Trusted resource to patients, explain research in context of patients’ condition
  o Critical referral agent, essential collaborator, and participant supporter

• Healthcare providers face barriers
  o Limited time
  o Limited information about ongoing clinical trials
  o Limited knowledge regarding clinical trials, especially complex protocols
  o Fail to receive information about referred patients
A well-trained study team / research staff can relieve clinical burden and enhance participant recruitment.

A few essential elements for comprehensive diversity training:

- Clinical research training
- Privacy and confidentiality training
- Trust and relationship building
- Implicit bias training
- Mindfulness tools for cultural considerations
Every stakeholder is responsible for increasing opportunities and improving mentorship and training of diverse investigators and study staff.

Examples:

- NIH Scientific Workforce Diversity Toolkit
- National Heart, Lung, and Blood Institute’s (NHLBI) PRIDE Program
- Eli Lilly and Company in partnership with Center for Drug Development and Clinical Trials at Roswell Park Cancer Institute
- American Society of Clinical Oncology (ASCO)
• Factors that influence an individual’s health literacy:
  o Economic status
  o Education
  o Race
  o Ethnicity
  o Age
  o Disability

• The communicator is responsible for developing and sharing health information that is understandable to the listener

• Clear communication is important for successful engagement and inclusion of diverse populations
Health literacy best practices

- Use of plain language
- Images relating to specific population
- Multi-format explanations of numeric information
- Application of clear design principles
- Translations and additional cultural considerations that contribute to the creation of materials that are designed specifically for a heterogeneous population.

All information
- Education about research
- Informed consent documents
- Research procedures

Communications
- Written
- Oral

For more information and examples, see the MRCT Center’s Health Literacy in Clinical Research website at https://mrctcenter.org/health-literacy/
The MRCT Center Launched a "Health Literacy in Clinical Research" Website

www.mrctcenter.org/health-literacy
## Recommendations for stakeholders

**RECOMMENDATIONS**

For Sponsors, Investigators, Providers, Clinical Research Sites and Healthcare Institutions:

- Develop a comprehensive workforce training and development program as part of the organization’s strategic plan to recruit, train, and mentor a diverse workforce to achieve better intercultural responsiveness.

- Create and expand mentoring opportunities, including satellite or sister offices and connection networks, that are available for new investigators and study teams from underrepresented groups.

- Intentionally guide the clinical research team on the skills necessary to support, understand, and communicate with a diverse participant population through a comprehensive training plan that includes trust /relationship building, and training in implicit bias detection and reduction and in cultural competence and humility.

- Improve and encourage the career development and leadership opportunities available for people with diverse backgrounds.

- Establish a workforce that is able to adopt and implement health literacy best practices in clinical research to ensure an inclusive environment.
Key Performance Indicators

The importance of metrics

Progress takes time

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**Workforce Development – Potential Key Performance Indicators (KPIs)**

**Output indicators**

- Public statement endorsing workforce D&I principles available
- D&I council established within organization
- D&I council develops comprehensive workforce D&I strategy
- Employee resource groups available at organization
- Number of employees that received a comprehensive D&I training annually
- Career development programs for underrepresented groups available at organization

**Outcome indicators**

- High attendance of D&I programs across employee type
- D&I principles cited in departmental SOPs
- Increased proportion of leadership from underrepresented demographics
- Increased self-reported understanding of cultural humility, social identity and implicit bias on company-wide survey
- D&I principles cited in commercial strategy
Today’s speakers

Racquel W. Bruton
Senior Clinical Operations Lead
Biogen
• Listen, Learn, and Engage in diverse communities to move toward more inclusive research
• Increase in our current trial participation numbers
• Building sustained transparent trustworthy relationships with the community.
• Formed a Global Clinical Operations (GCO) UP Champions team
• These community outreach events drew over 1,700 attendees across the U.S. in 2019.
• Collaborations with the Center for Information and Study on Clinical Research Participation (CISCRP) & the National Minority Quality Forum (NMQF).
“The success of any given workforce development program, however, is evident only through measuring improvement over time, which could be indicated by a shift in research study enrollment numbers, a value change in implicit association bias results, and/or through a statement of commitment from the executive level at an organization”

https://mrctcenter.org/diversity-in-clinical-trials/ pg. 132

Areas of Focus:

2019:
• Community Engagement & Awareness
• Patient & HCP Insights
• Regulatory/Industry Working Groups
• Internal Awareness & Education

2020:
• Community Engagement With Trusted Partners
• Study level plans
• Protocol Design
• Site Selection
• Departmental UP Champions
• Strategy Build-out:
  o Incorporate epidemiology data into US recruitment
  o Each study after 2020 will have an epidemiology goal prior to study start-up
  o Align engagement goals with external vendors
    ▪ CRO
    ▪ 3rd party vendor
    ▪ Community Advisory Board consisting of African Americans and Latinx members
    ▪ Investigator meetings
  o Percentage analysis for all measured metrics
Background...

• For Lupus we know it predominantly affects women and disproportionately affects women of color who identify as Black, African American, Hispanic, Afro Hispanic, Latino/Latina and Indigenous American.

• Goal:
  • FEASIBILITY & SITE SELECTION
  • PATIENT INSIGHTS
    • Patient Advisory Board Insights
  • STUDY DESIGN
  • RECRUITMENT MATERIALS AND COMMUNITY ENGAGEMENT

• Lessons learned
  • Previous trial info
  • Patient journey and social listening
  • Findings are applicable to a diverse population.
  • Lupus UP Engagement Plan requires a robust multifaceted strategy including:
    • ACCESS: Improving access and opt-in rates of clinical trials
    • EMPATHY: Addressing the lack of trust
    • ACTION: Investigators and staff of color in communities of color
      • Strategy starts before the study activation.
THANK YOU!
Workforce Diversity & Improving Access to Clinical Trials

Karen Winkfield, MD, PhD
Health Equity Consultant
KW Health Equity Consulting, LLC
Executive Director, Meharry-Vanderbilt Alliance

Leaning in: A Webinar Series
Multi-Regional Clinical Trials Center
October 28, 2020
Cancer Disparities

### Incidence and Mortality

#### Lung and Bronchus
- **White**: 56.0 (Incidence), 41 (Mortality)
- **Black**: 54.8 (Incidence), 42.3 (Mortality)
- **Asian/Pacific Islander**: 36.2 (Incidence), 22.2 (Mortality)
- **Am. Indian/Alaska Nat.**: 38.1 (Incidence), 33.4 (Mortality)
- **Hispanic**: 29.0 (Incidence), 17.6 (Mortality)

#### Colon and Rectum
- **White**: 37.8 (Incidence), 13.6 (Mortality)
- **Black**: 43.6 (Incidence), 18.5 (Mortality)
- **Asian/Pacific Islander**: 31.8 (Incidence), 9.6 (Mortality)
- **Am. Indian/Alaska Nat.**: 39.0 (Incidence), 15.8 (Mortality)
- **Hispanic**: 33.7 (Incidence), 11.1 (Mortality)

#### Female Breast
- **White**: 131.3 (Incidence), 19.8 (Mortality)
- **Black**: 124.8 (Incidence), 27.6 (Mortality)
- **Asian/Pacific Islander**: 102.9 (Incidence), 11.4 (Mortality)
- **Am. Indian/Alaska Nat.**: 79.5 (Incidence), 14.6 (Mortality)
- **Hispanic**: 99.1 (Incidence), 14 (Mortality)

#### Prostate
- **White**: 175.2 (Incidence), 17.9 (Mortality)
- **Black**: 102.3 (Incidence), 37.9 (Mortality)
- **Asian/Pacific Islander**: 56.7 (Incidence), 8.6 (Mortality)
- **Am. Indian/Alaska Nat.**: 54.6 (Incidence), 18.7 (Mortality)
- **Hispanic**: 92.0 (Incidence), 15.8 (Mortality)

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By Cancer Site and Race/Ethnicity
Health Disparities: Nature vs. Nurture

Biologic determinants
- Genetics
- Biology
- Comorbidities

Social determinants
- Socioeconomic status
- Access to care
- Sociocultural barriers
THE UNEQUAL BURDEN OF
CANCER
An Assessment of NIH Research and Programs for Ethnic Minorities and the Medically Underserved
The Charge for the IOM Committee (1998)

1. Review the status of cancer research relative to minorities and medically underserved populations within the NIH

2. Examining how well research results are communicated and applied to cancer prevention and treatment programs for minorities and medically underserved populations, and the adequacy of understanding of survivorship issues that uniquely affect minority and underserved communities

3. Examining the adequacy of NIH procedures for equitable recruitment and retention of minorities in clinical trials
Report: What Should the NIH Do??

• Burden – resources to SEER
• Research – Office of Research on Minority Health
• Priority setting across NIH programs – increase representation
• Clinical Trials – report on recruitment/retention of minorities
• Survivorship - plan to address the needs of minorities
• Monitoring - increase NIH accountability to the U.S. Congress and public constituencies

"...increasing ethnic diversity among physicians may be the most direct strategy to improve health care experiences for members of ethnic minority groups"

What About Clinical Trials??

Among All Clinical Trials

Black/African American

- White participants represent about 78.6% of all clinical trial participants.
- Asian, Black/African American, and other groups represent 11.8%, 5.4%, and 3.8%, respectively.

When looking at specific therapeutic areas, Black/African Americans only represent 2.5% cardiovascular and 2.74% of oncology trial participants from 2015-2016 (FDA Global Trial Participation 2015-16) despite the prevalence of cardiovascular disease and aggressive cancers in this minority (Coakley, Fadiran et al. 2012).
Workforce Diversity: 
*Improving access to care*

“Patients seeing physicians of their own race rate their physicians' decision-making styles as more participatory... Providing patients with access to a diverse group of physicians may lead to more patient involvement in care, higher levels of patient satisfaction, and better health outcomes.”

Diversity, Inclusion, and Representation: It Is Time to Act

Johnson B. Lightfoote, MD, MBA, FACR, Curtiland Deville, MD, Loralie D. Ma, MD, PhD, Karen M. Winkfeld, MD, PhD, Katarzyna J. Macura, MD, PhD, FACR

Abstract
Although the available pool of qualified underrepresented minority and women medical school graduates has expanded in recent decades, their representation in the radiological professions has improved only marginally. Recognizing this deficit in diversity, many professional medical societies, including the ACR, have incorporated these values as core elements of their missions and instituted programs that address previously identified barriers to a more diverse workforce. These barriers include insufficient exposure of underrepresented minorities and women to radiology and radiation oncology; misperception of these specialties as non–patient care and not community service; unconscious bias; and delayed preparation of candidates to compete successfully for residency positions. Critical success factors in expanding diversity and inclusion are well identified both outside and within the radiological professions; these are reviewed in the current communication. Radiology leaders are positioned to lead the profession in expanding the diversity and improving the inclusiveness of our professional workforce in service to an increasingly diverse society and patient population.

Key Words:
Diversity, underrepresented minorities, health disparities, health policy, radiology, radiation oncology, leadership, women in medicine, health equity

J Am Coll Radiol 2016; - - - - - - - . Copyright © 2016 American College of Radiology

Since its inception in 2013, the ACR Commission for Women and General Diversity (the "Commission") has taken the lead in changing the face of radiology [1]. The Commission formulated a strategic plan consonant with the ACR Strategic Plan of 2014, in response to its goal of increasing diversity and inclusion in the radiological professions [2]. In 2015, the ACR Council adopted Resolution 14, affirming that diversity is central to our mission, strengthens our organization, and should be measured [3]; ACR members now voluntarily report their ethnicity at membership renewal. The Commission and members have published many peer-reviewed and informal communications, in these pages and elsewhere, to expand the awareness of challenges and opportunities in diversity and inclusion, and has sponsored presentations, forums, and discussions in venues ranging from ACR 2015 and ACR 2016 to university training programs and state radiology societies. Projects pending implementation include pipeline enhancement; focused research on the barriers to improving diversity and inclusion in radiology; and diversity, inclusion, and cultural proficiency training for top leadership.

CURRENT STATE AND TRENDS IN DIVERSITY OF THE RADIOLOGICAL PROFESSIONS

Women and individuals from backgrounds underrepresented in medicine (URM) — historically, Blacks, American Indians, Alaska Natives, Native Hawaiians, Pacific Islanders, and Hispanics — are underrepresented in the diagnostic radiology [4,5] and radiation oncology (RRO) physician workforce at all levels, including practicing physicians, academic faculty, and trainees. Both specialties rank near the bottom in female and URM representation.

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The authors have no conflicts of interest related to the material discussed in this article.

ª 2016 American College of Radiology
1546-1440/16/$36.00 http://dx.doi.org/10.1016/j.jacr.2016.08.008

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Volume 35 - Number 22 - August 1, 2017

JOURNAL OF CLINICAL ONCOLOGY - ASCO SPECIAL ARTICLE

American Society of Clinical Oncology Strategic Plan for Increasing Racial and Ethnic Diversity in the Oncology Workforce

Diversity in Oncology Initiative

- Medical Student Rotation
- Resident Travel Award
- Diversity Mentoring Program
- Virtual Mentoring Program
- Oncology Scholars Rotation
- Bias Training for Scientific Reviewers
Brief Opinion

Why Racial Justice Matters in Radiation Oncology

Christina Hunter Chapman MD, MS a, b, Darlene Gabeau MD, PhD c, Chelsea C. Pinnix MD, PhD d, Curtiland Deville Jr. MD e, Iris C. Gibbs MD f, Karen M. Winkfield MD, PhD g, h, i

https://doi.org/10.1016/j.adro.2020.06.013

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Role of Cultural Competency in Reducing Cancer Disparities

Collection: Cultural Competence for Oncology Practice

This course reviews basic definitions of culture, race, and ethnicity. Essential elements of cultural competence are described and practical strategies for achieving cultural competence are provided. The course includes discussion of bi-culturalism, cultural pluralism, cultural sensitivity and specificity, and linguistic competence.

Credit Expires: 9/30/2020  |  Max Credits: 0.5  |  Available Certificates: Continuing Pharmacy Education (CPE) Certificate, CME Certificate, Continuing Nursing Education (CNE) Certificate, Certificate of Completion, Certificate of Participation

Learning Objectives:

- Distinguish between the following terms that relate to culture: race vs. ethnicity, inequality vs. inequity, and health disparity vs. health care disparity.
- Describe essential elements for cultural competence.
- Discuss consequences that stem from a lack of cultural awareness.
- Share strategies for creating a culturally competent health care environment.
- Examine examples that highlight cultural differences.
Assembling the Right Team

- Social Workers
- Nurses/APPs
- Financial Counselors
- Navigators
- Community Health Workers
- Volunteers

Engage the Community!!
Operational strategies in US cancer centers of excellence that support the successful accrual of racial and ethnic minorities in clinical trials

Jeanne M. Regnante, Nicole Richie, Lola Fashoyin-Aje, Laura Lee Hall, Quita Highsmith, J'Aimee Louis, Kenneth Turner, Spencer Hoover, Simon Craddock Lee, Evelyn González, Erin Williams, Homer Adams, Coleman Obasaju, Ify Sargeant, Jovonni Spinner, Christopher Reddick, Marianne Gandee, Madeline Geday, Julie Dang, Rayneisha Watson, and Moon S. Chen

Abstract

Background

Study populations in clinical research must reflect US changing demographics, especially with the rise of precision medicine. However, racial and ethnic minority groups (REMGs) have low rates of participation in cancer clinical trials.
Thank you!!

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