Diversity Enhances Scientific Discovery: Value and federal priority

Hortensia Amaro, PhD
USC Suzanne Dworak-Peck School of Social Work, and
Department of Preventive Medicine,
USC Keck School of Medicine

Navigating the University: Research & Resources Management Retreat
Huntington Library & Botanical Gardens
August 15, 2017
Hortensia Amaro Bio

HORTENSIA AMARO is Dean's Professor of Social Work and Professor of Preventive Medicine, USC Keck School of Medicine. From 2012-2017, she served as USC Associate Vice-Provost for Community Research Initiatives. Funded by over 35 federal multi-year grants, her research has focused on HIV prevention with women, drug use during pregnancy, drug use epidemiology among Latinos, and substance use and co-occurring substance use, mental health and post-traumatic stress disorders treatment. She has authored more than 150 scholarly publications, many widely-cited; and launched treatment programs for Latina and African American women. As Associate Vice-Provost for Community Research Initiatives, she conducted the first comprehensive study on conditions in communities surrounding the USC UPC and HSC and authored the 2015 USC State of the Neighborhood Report; and developed and tested a brief video-based obesity prevention intervention on healthy food shopping for low-income Latina mothers. She is currently conducting a multi-year R01 NIDA-funded randomized clinical trial on the efficacy of a mindfulness-based relapse prevention intervention and neural mechanisms in early recovery including the role of stress using fMRI and psychological measures.

Previously, Amaro was with Northeastern University for 10 years, as Associate Dean, Distinguished Professor of Health Sciences, and founder and Director of the university's Institute on Urban Health Research. For 18 years prior to that, she was Professor in the Boston University School of Public Health and School of Medicine. She served as Vice-Chair of the Boston Public Health Commission as an appointee by the late Mayor Thomas Menino for 14 years. Her service includes founding two Boston HIV prevention organizations in communities of color, three national professional organizations, and service on six National Academy of Medicine study committees.

She was elected to the National Academy of Medicine in 2010. She has received over 50 awards including two honorary doctoral degrees in humane letters, the National Elizabeth Beckman Award for Professors who Inspire their students to change the world, and the American Public Health Association’s prestigious 2015 Sedgwick Memorial Medal for Public Health Service. She currently serves as Associate Editor of the American Journal of Public Health, the Board on Population Health of the National Academy of Medicine, and the Board of Research!America. She received her doctorate in psychology from the University of California, Los Angeles, in 1982.
Update: Access and Opportunity, Diversity and Inclusion

April 20, 2016

A Message to the USC Community

April 19, 2016

Last November I wrote about efforts the university would undertake to increase access and opportunity, strengthen our commitment to diversity and equity, and ensure a campus climate that is inclusive of all. I noted that a commitment to diversity, inclusion, and equity has long been a part of USC’s history – from our...
Information about how NIH promotes a diverse scientific research workforce

Learn how diversity supports our mission, find opportunities to participate in diversity programs, meet researchers, and more. Whether you are a science student, trainee, faculty member, or someone who is interested in diversity programs, you can find what you are looking for here.

https://extramural-diversity.nih.gov/
Federal law requires women and minorities be included in all clinical research studies, as appropriate for the scientific goals of the work proposed.

For NIH-defined Phase III clinical trials, applicants must also consider whether the study can be expected to identify potential differences by sex/gender, race, and/or ethnicity and, unless there is clear evidence that such differences are unlikely to be seen, they must include plans describing how potential group differences will be evaluated.
Studying both sexes across the biomedical research continuum

THE SCIENCE: NIH Requirements

Asks investigators to examine their research questions and scientific hypotheses; consider the potential influence of sex; and address these in design, analyses, and publications.

From the very first idea about a biomedical research area to the bedside and beyond sex influences be considered, collected, and reported.
# Rigor and Reproducibility in NIH Applications: Resource Chart


NIH Website: [https://www.nih.gov/research-training/rigor-reproducibility](https://www.nih.gov/research-training/rigor-reproducibility)

<table>
<thead>
<tr>
<th>4 AREAS OF FOCUS</th>
<th>WHAT DOES IT MEAN?</th>
<th>WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scientific Premise</strong></td>
<td>The <em>scientific premise</em> for an application is the research that is used to form the basis for the proposed research question(s). Describe the general strengths and weaknesses of the prior research being cited as crucial to support the application. Consider discussing the rigor of previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources.</td>
<td>Research Strategy ➢ Significance</td>
</tr>
<tr>
<td><strong>Scientific Rigor (Design)</strong></td>
<td><em>Scientific rigor</em> is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. Emphasize how the experimental design and methods proposed will achieve robust and unbiased results.</td>
<td>Research Strategy ➢ Approach</td>
</tr>
<tr>
<td><strong>Biological Variables</strong></td>
<td><em>Biological variables</em>, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease. In particular, sex is a biological variable that is frequently ignored in animal study designs and analyses, leading to an incomplete understanding of potential sex-based differences in basic biological function, disease processes and treatment response. Explain how relevant biological variables, such as the ones noted above, are factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex.</td>
<td>Research Strategy ➢ Approach</td>
</tr>
</tbody>
</table>

*See related FAQs, blog post, examples from pilots*
Another Major Research Gap: Race and Ethnic Diversity

... and male.
• **Problem:** Default human model subject was a 70-kg male; preponderant focus on male animals in preclinical research.
  • Mostly single-sex investigations, not reported sex of animals, cells, or tissues used -- have contributed to ambiguous evidence base about sex-based influences on biology and health.

• **Past Assumption:** fundamental biology includes only molecular, biochemical, and physiologic characteristics shared, or the same, between males and females.

• However, fundamental biology encompasses characteristics that are both shared and different.

IOM committee was charged with considering biology at the cellular, developmental, organ, organismal, and behavioral levels.
• **Sex is a basic biological variable**

• Consider influence of sex in study design

• Review literature for influence of sex

• Consider influence of sex when developing research questions

• Incorporate both males and females into studies

• Analyze and report data disaggregated by sex

• Consider sex in interpretation of results

• Articulate strong justification if single sex study

• Appropriately generalize research findings
Gender refers to the socially constructed roles, behaviors and identities of female, male and gender-diverse people.

- It influences how people perceive themselves and each other, how they behave and interact and the distribution of power and resources in society.

- Gender is usually incorrectly conceptualized as a binary factor (female/male).

- In reality, there is a spectrum of gender identities and expressions defining how individuals identify themselves and express their gender.
Integrating sex and/or gender in research design and methods: Tools

• This review addresses specific research issues for:
  • basic researchers,
  • clinical investigators,
  • epidemiologists,
  • population scientists, and
  • social scientists

• Provides annotated bibliography and resource tools on how to consider sex and gender as independent variables in research design and methodology.
Sex and Gender in Research Publications
Moving toward True Inclusion of Racial/Ethnic Minorities in Federally Funded Studies
A Key Step for Achieving Respiratory Health Equality in the United States

Esteban G. Burchard
Sam S. Oh
Marilyn G. Foreman
Juan C. Celedón

1Department of Bioengineering and Therapeutic Sciences, University of California, San Francisco, San Francisco, California; 2Department of Medicine, University of California, San Francisco, San Francisco, California; 3Division of Pulmonary and Critical Care Medicine, Morehouse School of Medicine, Atlanta, Georgia; and 4Division of Pediatric Pulmonary Medicine, Allergy and Immunology, Children’s Hospital of Pittsburgh of University of Pittsburgh Medical Center, University of Pittsburgh, Pittsburgh, Pennsylvania

Table 1. U.S. Racial and Ethnic Minority Groups Share a Disproportionate Burden of Respiratory Diseases

<table>
<thead>
<tr>
<th>Group</th>
<th>Condition</th>
<th>Disparity</th>
<th>Reference(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Puerto Ricans and African Americans</td>
<td>Asthma</td>
<td>Highest prevalence, morbidity, and mortality</td>
<td>29</td>
</tr>
<tr>
<td>African Americans</td>
<td>More likely to develop COPD at an early age</td>
<td>Increased susceptibility to the detrimental effects of cigarette smoking</td>
<td>30</td>
</tr>
<tr>
<td>Puerto Rican women</td>
<td>COPD</td>
<td>Second-highest age-adjusted mortality rate among all ethnic groups</td>
<td>31</td>
</tr>
<tr>
<td>Asian Americans and Pacific Islanders</td>
<td>Influenza and pneumonia</td>
<td>Sixth leading cause of death overall and fourth leading cause of death among those 65 years and older</td>
<td>32</td>
</tr>
<tr>
<td>African American men</td>
<td>Lung cancer</td>
<td>More prone to develop and die from lung cancer, and to present with nonlocalized disease</td>
<td>33–35</td>
</tr>
<tr>
<td>Hispanics and African Americans</td>
<td>Advanced lung cancer</td>
<td>More likely to have false hope about cure from chemotherapy than whites</td>
<td>36</td>
</tr>
<tr>
<td>African American adolescents</td>
<td>Obstructive sleep apnea</td>
<td>Disproportionately affected compared to other races/ethnicities</td>
<td>37–39</td>
</tr>
<tr>
<td>African Americans</td>
<td>Sarcoidosis and acute respiratory distress syndrome</td>
<td>Substantially increased risk of dying</td>
<td>40</td>
</tr>
<tr>
<td>Asian Americans, Native Hawaiians, and Pacific Islanders</td>
<td>Tuberculosis</td>
<td>Incidence rates are highest</td>
<td>41</td>
</tr>
</tbody>
</table>

Definition of abbreviation: COPD = chronic obstructive pulmonary disease.
Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled

Sam S. Oh1, Joshua Galanter1,2, Neeta Thakur1, Maria Pino-Yanes1,3,4, Nicolas E. Barceló1, Marquita J. White1, Danielle M. de Bruin1, Ruth M. Greenblatt1,5, Kirsten Bibbins-Domingo1,6, Alan H. B. Wu7, Luisa N. Borrell8, Chris Gunter8,9, Neil R. Powe1,5,6, Esteban G. Burchard1,9

PLOS Medicine | DOI:10.1371/journal.pmed.1001918 December 15, 2015

Table 1. Insights from studies conducted in diverse race/ethnic groups.

<table>
<thead>
<tr>
<th>Trait</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancer</td>
<td>Differences in Native American ancestry at the estrogen receptor locus led to discovery of a genetic variant that was protective against breast cancer in Latinas [11].</td>
</tr>
<tr>
<td>Heart failure</td>
<td>A post-hoc analysis of clinical trials of fixed-dose combination of hydralazine and isosorbide dinitrate suggested that black, but not white patients had a significant reduction in mortality compared to placebo [12].</td>
</tr>
<tr>
<td>Increased preterm birth rate</td>
<td>Exposures to endocrine disrupting chemicals such as bisphenol-A (BPA) are more common among minorities who live in low socioeconomic strata. BPA causes epigenetic alterations of the germ line resulting in increased preterm birth rate; these alterations can pass down to future generations [13].</td>
</tr>
<tr>
<td>Stevens-Johnson syndrome</td>
<td>The risk of carbamazepine-induced Stevens-Johnson syndrome due to HLA-B*1502 is highest in populations of Southeast Asian and East Asian ancestry [14].</td>
</tr>
<tr>
<td>Kidney disease</td>
<td>Genetic variants of APOL1 have been associated with kidney disease in individuals of African ancestry whose ancestors lived in regions of Africa endemic with typanosomiasis; these renal risk variants are largely absent in individuals of European or Asian ancestry [15].</td>
</tr>
<tr>
<td>Response to efavirenz</td>
<td>Blood levels and treatment response to this antiretroviral drug are influenced by individual ancestral make up, which can be accounted for by polymorphisms of cytochrome 2B6 and genetically defined ancestry [16,17].</td>
</tr>
</tbody>
</table>

• Few biomedical studies focus recruitment on minority representation, and do not focus attention on factors most relevant to minority health.

• Since 1993, less than 2% of more than 10,000 cancer clinical trials funded by NCI included enough minority participants to meet the NIH’s own criteria and goals -- despite striking racial/ethnic disparities in cancer incidence and mortality.

• Less than 5% of NIH-funded respiratory research reported inclusion of racial/ethnic minorities.

• Similar incongruities between disease burden and representation in biomedical research exist for cardiovascular diseases and diabetes.

• Economic consequences: eliminating racial/ethnic health disparities would have reduced total medical costs during 2003–2006 by more than $1.2 trillion.
• Black applicants for NIH funding were about two-thirds as likely as White applicants to receive grants during the years 2000–06, even accounting for factors such as publication record and training (Ginther et al. Science 333, 1015–1019; 2011).

• Buchard et al found that from 1985-2013, underrepresented minorities have been awarded NIH grants at 78–90% the rate of white and mixed-race applicants every year (Am J Respir Crit Care Med, 191 (5), 514–521, 2015).

• “Positive bias” or In-group bias: the tendency for people to favor other people and institutions that they know either personally or by reputation.
NIH Programs Build Research and Science Careers

NIH supports programs to develop the biomedical, behavioral, clinical, and social sciences research workforce. Click on the boxes below to find NIH programs available at any career stage. Diversity-related programs are indicated with a highlight. You can see all current diversity-related funding opportunities here.

Cross-Cutting Programs
- Research Supplements to Promote Diversity in Health-Related Research (Admin Supp)
- National Research Mentoring Network (NRMN)
- Institutional Development Award (IDeA)
- Short Courses, Summer Institute and other research education activities

POLICY FORUM

SOCIOLOGY

Weaving a Richer Tapestry in Biomedical Science

Lawrence A. Tabak* and Francis S. Colissy*

As much as the U.S. scientific community may wish to view itself as a single garment of many diverse and colorful threads, an unflinching consideration of actual data reminds us that our nation’s biomedical research workforce remains nowhere near as rich as it could be. An analysis a

Science 2011, 333 (6045), 940-941.
References and Useful Resources to Get Started


Clayton & Tannenbaum. Reporting Sex, Gender, or Both in Clinical Research? JAMA, 2016, 316 (18), 1863-1864.


Gurhtie. Even the Rat was White. A historical view of psychology. Allyn & Bacon, 1998.


Heidari et al. Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use. Research Integrity and Peer Review, 2016; 1:2.


Mazure & Jones. Twenty years and still counting: including women as participants and studying sex and gender in biomedical research. BMC Women's Health, 2015, 15 (94).


National Institutes of Health. Funding opportunities on sex differences and women’s health research (examples):

  https://orwh.od.nih.gov/research/funded-research/scor/


Pohlbaus et al. Sex Differences in Application, Success, and Funding Rates for NIH Extramural Programs. Academic Medicine, 2011, 86 (6), 759–767.

Oh et al. Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled. PLOS Medicine | DOI:10.1371/journal.pmed.1001918 December 15, 2015.


Thank you
Hamaro@usc.edu