Myths and Realities Regarding the Participation of Ethnic Minorities in Clinical Trials

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Examples of Different Effects of Drugs in Minorities

- **Aspirin® (Bayer):** In men it reduces risk of AMI without increasing stroke; in females it reduces risk of stroke without affecting risk of AMI.

- **Crestor® (Astra-Zeneca):** Asian more sensitive, start lower dose; African-American less responsive, it may require higher dose.

- **Iressa® (Astra-Zeneca):** Failed to extend survival of lung cancer and caused lung toxicity (IPF) in large phase III trial; in Asians increased survival by 66% but also more pulmonary toxicity (IPF) observed.

- **Aricept® (Pfizer):** Slightly higher effectiveness in African American patients with Alzheimer’s.

- **Bi-Dil® (Nitromed):** Approved by FDA for Rx of CHF in African-American patients in 2006.

- **DG-031 (deCODE genetics):** ACS/AMI in patients expressing Hep-K gene (30% of population). African-Americans higher risk than non-Hispanic whites.

- **Exforge® (Novartis):** Novartis announced May 14, 2008 that Exforge® significantly reduced blood pressure in difficult-to-treat black patients.
Many Diseases Disproportionally Affect Ethnic Minorities. The most important...

- Type II Diabetes
- Cardiovascular disease (CHF, AMI)
- Hypertension
- Stroke
- Infectious Diseases (HIV/AIDS, PV, STDs)
- Different types of cancer (colon, prostate, cervix, lung, etc.)
- Neuropsychiatric illnesses (schizophrenia, depression, bipolar disorder)
**FDA Experience 1995 to 1999***
185 NMEs; 2,581 trials; 493,347 pts; Ethnicity reported: 53% or 263,704 pts

**U.S Diabetes Trials Participants**

**FDA Experience 2000-2004: N=7,979**

*Represents 80% of known U.S. diabetes trials participants. Race/ethnicity could not be determined from the integrated summaries for the remaining 20%.*

Epidemiology of Diabetes
Incidence* (New Cases): United States 2005

N: 850,000/year

- White: 36%
- Black: 24%
- Hispanic: 37%
Top 10 Reasons Why Minorities Do Not Participate in Clinical Trials

1. Mistrust in healthcare system: lack of consent
2. It will delay the clinical trial
3. Retention is poor
4. Compliance is poor
5. It will add complexity
6. It will add significant cost
7. Do not have the time (childcare, lost wages, etc.)
8. Language barriers (Hispanics, Asian, others)
9. Ignorance/lack of education...
10. It is a cultural thing...
Are Racial and Ethnic Minorities Less Willing to Participate in Health Research?

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ABSTRACT

Background

It is widely claimed that racial and ethnic minorities, especially in the US, are less willing than non-minority individuals to participate in health research. Yet, there is a paucity of empirical data to substantiate this claim.

Methods and Findings

We performed a comprehensive literature search to identify all published health research studies that report consent rates by race or ethnicity. We found 20 health research studies that reported consent rates by race or ethnicity. These 20 studies reported the enrollment decisions of over 70,000 individuals for a broad range of research, from interviews to drug treatment to surgical trials. Eighteen of the twenty studies were single-site studies conducted exclusively in the US or multi-site studies where the majority of sites (i.e., at least 2/3) were in the US. Of the remaining two studies, the Concordia study was conducted at 74 sites in the United Kingdom.
## Consent Rate by Race/Ethnic Group

### Twenty Biomedical Research Studies

<table>
<thead>
<tr>
<th>Type of Study</th>
<th>Non-Hispanic White</th>
<th>African American</th>
<th>Hispanic</th>
<th>All Minorities</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Offered Enrollment</td>
<td>Consent Rate</td>
<td>Offered Enrollment</td>
<td>Consent Rate</td>
</tr>
<tr>
<td>Interview, non-Intervention (3)</td>
<td>46,713</td>
<td>83.5%</td>
<td>12,614</td>
<td>82.2%</td>
</tr>
<tr>
<td>Clinical Intervention Trials (10)</td>
<td>6,724</td>
<td>41.8%</td>
<td>1,604</td>
<td>45.3%</td>
</tr>
<tr>
<td>Surgical Intervention Trials (7)</td>
<td>7,756</td>
<td>47.8%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Subtotal: Total</td>
<td>61,193</td>
<td>74.4%</td>
<td>14,218</td>
<td>15,052</td>
</tr>
</tbody>
</table>

Minority Physicians Play a Key Role in the Health Care of Minority Patients

SPECIAL ARTICLE

THE ROLE OF BLACK AND HISPANIC PHYSICIANS IN PROVIDING HEALTH CARE FOR UNDERSERVED POPULATIONS

Miriam Komaromy, M.D., Kevin Grumbach, M.D., Michael Drake, M.D., Karen Vranizan, M.A., Nicole Lurie, M.D., M.S.P.H., Dennis Keane, M.P.H., and Andrew B. Bindman, M.D.

Abstract  Background. Patients who are members of minority groups may be more likely than others to consult physicians of the same race or ethnic group, but little is known about the relation between patients’ race or ethnic group and the supply of physicians or the likelihood that minority-group physicians will care for poor or black and Hispanic patients.

Methods. We analyzed data on physicians’ practice locations and the racial and ethnic makeup and socioeconomic status of communities in California in 1990. We also surveyed 718 primary care physicians from 51 California communities in 1993 to examine the relation between the physicians’ race or ethnic group and the characteristics of the patients they served.

Results. Communities with high proportions of black and Hispanic residents were four times as likely as others to have a shortage of physicians, regardless of community income. Black physicians practiced in areas where the percentage of black residents was nearly five times as high, on average, as in areas where other physicians practiced. Hispanic physicians practiced in areas where the percentage of Hispanic residents was twice as high as in areas where other physicians practiced. After we controlled for the racial and ethnic makeup of the community, black physicians cared for significantly more black patients (absolute difference, 25 percentage points; P<0.001) and Hispanic physicians for significantly more Hispanic patients (absolute difference, 21 percentage points; P<0.001) than did other physicians. Black physicians cared for more patients covered by Medicaid (P=0.001) and Hispanic physicians for more uninsured patients (P=0.03) than did other physicians.

Conclusions. Black and Hispanic physicians have a unique and important role in caring for poor, black, and Hispanic patients in California. Dismantling affirmative-action programs, as is currently proposed, may threaten health care for both poor people and members of minority groups. (N Engl J Med 1996;334:1305-10.) ©1996, Massachusetts Medical Society.
Experience in 10 Type 2 Diabetes Trials
(1162 Patients Recruited from 2006-2010)

Patient Recruitment in Type 2 DM Trials

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Patient Recruitment</th>
</tr>
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<tbody>
<tr>
<td>3 months ahead</td>
<td>200</td>
</tr>
<tr>
<td>2 months ahead</td>
<td>300</td>
</tr>
<tr>
<td>1 month ahead</td>
<td>450</td>
</tr>
<tr>
<td>On time</td>
<td>100</td>
</tr>
<tr>
<td>1 to 3 months late</td>
<td>10</td>
</tr>
</tbody>
</table>
Race & Ethnicity in 10 Type 2 Diabetes Trials
(1162 Patients Recruited from 2006-2010)
Anaclim’s Observations

- **Recruitment**: On time or ahead of time
- **Retention**: Minorities = Non-Minorities
- **Compliance**: Minorities = Non-Minorities
- **Complexity** driven by protocol design; (inclusion/exclusion criteria) not by inclusion of minorities
- **Cost**: on average about 3% higher
- Extensive *translation services* drives cost (Hispanics and Asians)
- **Minorities understand** the importance of participation: an issue of *access*
A Full-Service Contract Research Organization focusing on the inclusion of ethnically-balanced patient populations in clinical trials

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