Clinical Research and the Minority Physician: Why you should be involved

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Disclosures

- Shareholder in Procter and Gamble, and other healthcare companies
- Strategic Medical Associates (management services consulting and business development firm)
- No products will be the subject of my presentation
Agenda

- Why you need to be concerned
- Traditional Barriers
- Charting a new course
Modern diagnostic, preventive or therapeutic medical practice is based on evidence gained primarily through controlled clinical trials.

Minority representation in clinical trials is generally inadequate, thus compromising the quality and validity of clinical trial findings used to guide the treatment of minority patients.

Underrepresentation contributes to health disparities.

All physicians have a role in addressing the issue.
Why We Should be Concerned About Clinical Trial Diversity

- Genetic, geographic ancestry, nutrition, environment, lifestyle can influence drug absorption, metabolism, receptor-binding, ultimately response
- Unbalanced clinical trials may select for therapies which are “out of touch” with the needs of the American population
- Low minority presence in the “evidence” for evidence-based medical practice
Reasons you should be concerned (cont’d)

- Limited guidance on use of therapeutic interventions in diverse patient populations
- Barrier to personalized medicine
- Your patients are being targeted for recruitment with or without you
Cases of Drug Response Variation

- Primaquin use in Southeast Asia (Birth of pharmacogenetics)
- Trial of Seravent
- BiDil approval in 2005
- Plavix relabeling last year
Benlysta: A glimpse of the future?

- Benlysta approved for the treatment of Systemic Lupus Erythematosi
- First drug in over 50 years for this indication
- SLE incidence in African–American women 3 times the rate in white women
- Few African–American women in clinical trial
- Those African–Americans who were in did not respond
- Inadequate number to provide conclusion
- Drug associated with higher mortality than placebo
- Data on manifestation of therapeutic target in disease of AA women unavailable
Regulatory Progression

- 1988 NDA Clinical and Statistical Guidelines
- 1993 NIH Revitalization Act
- 1997 FDA Modernization Act
- 2005 FDA Guidelines for Documentation of Race and Ethnicity
- What’s happening now: Trends in Policy Proposals– Extending market exclusivity
Population Shifts
Race/Ethnicity of Clinical Trial Participants from 185 New Drug Applications (NDAs)*

Total Enrolled 1995-1999 (n=493,347)

47% Race Determined
53% Race Undetermined

* From Medical Reviewers Reports

Clinical Trials Participants by Race for NDAs 1995–1999*

(n=263,704)*

- 88% White
- 0% Black
- 3% Hispanic
- 1% Asian
- 0% Am. Ind.

* From medical reviewers comments. Excludes 229,643 patients where race/ethnicity was not described

Enrollment by Race and Ethnicity
National Cancer Institute, Publicly Funded Cancer Clinical Trials
(Phase I-III Treatment Studies)
January 1, 2003 – June 30, 2005

Race:
- White, 88.6%
- Asian/Pacific Islander, 2.8%
- Multiple, 0.1%
- Black/African American, 8.0%
- Native American/Alaska Native, 0.5%

Ethnicity:
- Non-Hispanic/Latino, 94.4%
- Hispanic/Latino, 5.6%

Sponsor’s Dilemma

- Growing need for investigators
- 70% of investigators underperform
- 15% to 20% don’t recruit a single patient
- 40% of new investigators never do a second trial
- As much as $50,000 to initiate each investigational site
- Timeline encourage re-use of same sites over and over
- Concerns for possible increase costs, delays to achieve ethnic balance
Measures of Investigator Training in Clinical Trials

Percentage of investigators responding

- All: 75% Yes, 25% No
- Prior Participation: 57% Yes, 43% No
- Never Participated: 92% Yes, 8% No

Source: Thomson CenterWatch 2005 survey of 7,342 physicians
Relation of the Race or Ethnic Group of Physicians to Patients in Their Practices

Why do physicians participate in clinical research?

- The opportunity to be at the cutting edge of research
- Provide better patient care
- Revenue generation
- Publication
Traditional Barriers to Community Physician Participation

- Not enough time
- Fear of losing patients, patient trust
- Understanding what is involved
  - getting training
  - getting started
  - getting trials
  - financial investment and getting a return
Situating Mistrust

- Slavery and the aftermath in the African-American population - the Jim Crow Era
- The Tuskegee Experience
- Sterilization research in the American Latino population
- A perspective on research from the Native American community (Helicopter Doctors)
- Mistrust in clinical trials exists in Asian communities, but culture creates a barrier to sharing.
The Investigator–Prescriber Effect

Rate of Total Prescriptions Written Above Control Group Level at 18 months

- Phase III Investigators: 92%
- Phase IIIb/IV Investigators: 58%

Source: Glass, 2002; 18 months after drug launch for phase III and after trial completion for phase IIIb/IV.
Developed to identify ways to increase minority patient and physician involvement in all aspects of clinical research and clinical trials.

Project IMPACT includes physician and consumer education, and training activities to facilitate minority physician clinical trial participation.