HISPANICS AND CLINICAL TRIALS

Jorge C. Rios MD, FACC, FACP

Professor Emeritus of Medicine
George Washington University
Sr Academic Advisor to the President
Ross University
The Issue

- Participation of Hispanics in Clinical Research and clinical trials is reported to be small in comparison to the population
  - What are the factors?
Questions to be Answered

1. Is adequate representation essential? Why?

2. Are Hispanics under-represented in clinical research?
   - Investigators
   - Participants

3. What are the potential causes of the under-representation?
   - Investigators
   - Participants

4. What does representation of Hispanics mean?

5. What are some potential strategies to address the issue?
   - Investigators
   - Participants
Question # 1: Is adequate representation important?

The following information provide some answers
Examples From Some Pharmacokinetic Studies

- 22.5% of Japanese, 17.4% Chinese and 3% Swedish metabolize poorly several drugs such as diazepam, antidepressants and GI drugs omeprazole (the enzyme CYP2C19 catalyzes the drugs).
- A study of black and white renal transplant patients found that blacks have almost a 50% lower clearance of some steroids.
- The concentration of Ibuprofen (a non steroidal antinflammatory drug,) in the presence or ranitidine increased by 54% in blacks and decreased 15% in whites.
- Chinese were less able than Caucasian to metabolize codeine
- Infusion of some drugs (i.e.Isoproterenol) raises BP two folds in black more than in whites.
- Studies have shown that for a given number of cigarettes smoked per day, blacks have higher exposure to nicotine than Caucasians and Mexican Americans
Some Examples From Clinical Trials and Clinical Observations

1. African-Americans have a lesser response to ACE inhibitors and Beta Blockers in lowering Blood Pressure

2. Some specific treatments (isosorbide dinitrate/hydralazine) confirmed a survival advantage in black populations

3. The BEST Trial showed a significant reduction in mortality with use of bucindolol in white patients only. A specific gene appear to influence the difference

4. Diuretics are more effective than ACE and angiotensin receptor blockers in preventing CV disease outcomes in African-Americans
Some Initial Conclusions

- Basic science data demonstrates ethnic differences in the metabolism of drugs
- Clinical Trials have begun to show ethnic differences in therapeutic effect and outcomes, especially in African-American hypertensives
- Information from Clinical Trials is not available from other population segments
- Some genetics studies have explained some differences in results
- The knowledge gap between Pharmacokinetics, Genetics and Clinical Trials must be narrowed in order to design trials that explore ethnic differences
Question # 2: Are Hispanics (both physicians and participants) under-represented in Clinical Research?

Some data regarding physicians and participants
Ethnic Origin Of Physicians

Source US Census Bureau 2004
SOME FACTS ABOUT THE US PHYSICIAN POPULATION

- Of 900,000 physicians in the US 25% are International Medical Graduates

- Hispanic IMG’s represent 15% of practicing physicians in the US

- The number of US born Hispanics applicants to Medical Schools is 7.1% (2005). (Hispanic Population+/- 13%)

- In 2004 US Medical Schools graduated 1,000 Hispanics or 4% of total graduates

- In 2004 4% of Hispanics were members of a Medical School faculty
Reasons Why the Number of Hispanic Physicians and Investigators Should Be Increased

1) Language and cultural issues make patients more satisfied when care is provided with physicians that share the same culture. This concept has been validated with Hispanic and African-American patients.

2) Since Hispanic physicians are likely to practice in Hispanic preponderant communities, their participation in recruiting subjects for clinical research will enhance representation.

3) Hispanic population has grown to 13% of US population.

4) It is anticipated to be 35% by 2040.
FACTORS THAT INFLUENCE THE SHORTAGE OF HISPANIC INVESTIGATORS

- Small number of Hispanic physicians
- Small number of Hispanics as U.S. graduates or U.S. medical students
- Low number of Hispanic physicians in Academic Medicine
- Preponderance of Hispanic physicians in practice, many of them in Hispanic dominant communities
- Lack of training in research methodology
- Poor communication between the “community practice” and the “academic community”
Also, to answer Question # 2, we need to understand current participation in Clinical Trials by Hispanic Participants.
Total Enrollment in Clinical Trials
1995-1999
Source F.D.A./CDER

- RACE DETERMINED: 47%
- RACE UNDETERMINED: 53%
Reporting Ethnicity in Clinical Trials

Source: Sheikh et al, BMJ vol 329, 2004

- EUROPEAN TRIALS: 7% of reports identify ethnicity

- AMERICAN TRIALS: 39% of reports identify ethnicity
  - P < 0.0001
Trial Participants by Race

- WHITE 88%
- BLACK 8%
- ASIAN 3%
- HISPANIC 1%
- AM. IND 0%
U.S. Clinical Trial Participants by Race
Source F.D.A.
% Population by Race

vs.

% Participants in Trials by Race

% US POPULATION

% PARTICIPANTS

WHITE  BLACK  HISPANIC  ASIAN  AM.IND
Question # 3: What are the causes of under-representation?
Factors That Determine Lack of Hispanic Participants in the U.S.

- Economic Status
- Limited Access to Health Care
- Legal Fears
- Communication
- Cultural Differences
- Distance/Transportation
- Cost
Question # 4: What does proper representation of Hispanics mean?

As it relates to Clinical Trials and Pharmaceutical Research, we need to have better definition of “Hispanic” or Latino sub groups in the U.S.
ISUES OF “ADEQUATE” REPRESENTATION OF HISPANICS

- Hispanics represent a cultural group but not a racially identifiable group
- Racial composition of Hispanics is very diverse
- National origin of Hispanics is very diverse
National Origin of the U.S. Hispanic Population

An example of complex racial and genetic mix

- S.AMERICAN
- C.AMERICAN
- CUBAN
- P.RICANS
- MEXICANS
Ethnic/Racial Composition of Hispanics
A complex genetic mix

- **CAUCASIAN**
  - Spanish
  - Italian
  - Nordic
  - Jewish

- **ORIENTAL**
  - Japanese
  - Chinese

- **INDIAN**
  - Caribbes
  - Aztec
  - Mayan
  - Pima

- **AFRICAN (BLACK)**
  - Kimundu
  - Kpelle
  - Nubian
  - Fula
Question #5: What are some potential strategies to address the issue?
Inter-American College of Physicians and Surgeons Strategies

- Received a grant from AstraZeneca to recruit and train Hispanic physicians to participate in Clinical Trials
- Has recruited over 200 physicians in the Miami and New York areas
- Plans are to continue recruitment in other areas with large Hispanic populations until the 1000 number is reached
- Offers training sessions for recruited physicians in how to participate in clinical trials
- Offers CME credits for participation in a distance education training course
- Created a corporate structure to allow agreements with sponsors and CRO’s to conduct clinical trials involving the ICPS participating physicians