Recruiting, Consenting & Retaining Underserved Populations in the 21st Century

Bridging the Gap Between Community Needs and Clinical Research

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...it's the only monument permitted on campus...

HONORING NOTHING—INSULTING NO ONE

Well, I find its sharp edges highly offensive to the "angularly challenged"!
Solutions

- Trust
- Respect
- Partnership
- Communication
- Flexibility
- Knowledge
WHO IS THIS SCIENTIST?
Treatment on clinical trials appears to confer significant survival advantage to patients with disseminated disease at diagnosis.

- The largest benefit is enjoyed by African-American patients. Unfortunately, several studies, including this one, have documented lower clinical trial participation rates among African-Americans.
- Our study supports recently published work suggesting that most disparities in cancer outcomes among African-Americans are eliminated when confounding factors are considered and the same treatment is provided. However, even after accounting for the disadvantage of these other factors and for the benefit of clinical-trial based therapy (not only the same therapy, but very similar care and follow-up), African-American race was associated with a 17% survival disadvantage.

Linda Elting, et.al., ASCO 2002
INSANITY: Continuing to do things the same way and expecting a different outcome.
"First they ignore you, then they ridicule you, then they fight you, then you win."

Gandhi
PERCEPTION VS REALITY

A PERSON’S PERCEPTION IS A PERSON’S REALITY WHETHER REAL OR NOT
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Looting

Finding
The Tuskegee Study
In 1932, the year the study began, the USPHS issued a paper strongly arguing for treatment of latent syphilis (Moore et al, 1932).

Every major textbook concurred in the need for treatment of latent syphilis (Brandt 1978).

Subjects were initially difficult to enroll, until they were told they would receive free treatment for their “bad blood”

Spinal taps were called “special free treatment”

“Some time ago you were given a thorough examination and since that time we hope you have gotten a great deal of treatment for bad blood. You will now be given your last chance to get a second examination. This examination is a very special one and after it is finished you will be given a special treatment if it is believed you are in a condition to stand it.

REMEMBER THIS IS YOUR LAST CHANCE FOR SPECIAL FREE TREATMENT. BE SURE TO MEET THE NURSE.”

(Letter to participants announcing the spinal tap, circa 1935)
“Deceipt was integral to the study”

Brandt 1978

- “Naturally, it is not my intention to let it be generally known that the main object of the present activities is the bringing of the men to necropsy.” (Vonderlehr to Smith, 1933)

- “They simply do not like spinal punctures….others claim they were robbed of their procreative powers (regardless of the fact that I claim it stimulates them.)” (Diebert to Vonderlehr, 1939)

- “[The doctor] wants to make a special examination to find out how you have been feeling and whether the treatment has improved your health.” (letter to study subjects, 1938)
• “Untreated” Syphilis
  – “It was difficult to hold the interest of the group of Negroes in Macon County unless some treatment was given” Dr. R. Vonderlehr, 1968. (Brandt 1978)
  – In interviews with four survivors, all remembered receiving shots, ointments, pills, or medicines. (Department of Health, Education and Welfare, 1973 - in Reverby 2000)
• Control subjects who contracted syphilis were simply switched into the “test” group.
“The legacy of the Tuskegee Study endures, in part, because the racism and disrespect for black lives that it entailed mirror black people’s contemporary experiences with medicine.” (Blendon et al. 1995)

- Negative experiences cited by African American and Latino focus groups (Thom and Campbell 1997)
  - lack of respect
  - lack of privacy
  - deaths of friends or relatives due to poor medical care

- Minorities report more communication problems with physicians (Commonwealth Fund, 2002)

- African American patients rate their visits with physicians as less participatory than whites. (Cooper-Patrick et al. 1999)

- Minorities much more likely to believe that doctors, nurses and other health professionals – whether they mean to or not – treat minority patients differently than white patients. (Harvard Forums on Health 2003)
OBSERVATIONS

• Bad outcomes may come from good goals, and Good outcomes can come from bad goals.

• Scientists and other professionals are highly motivated to seek self fulfillment through their work. To complete a major study in a field which results in publications is to achieve a certain immortality. Thus, the zeal for this study may be understood even as it crossed the line of ethics.

• White and Black institutions and professionals with high ideals are often compromised by self interests and egos. Black institutions and organizations supported this project because it furthered their goals for the race even to the disadvantage of their lesser brothers. The silence of the Black professionals on this issue is mystifying. The study was not done in secrecy, at least 36 article were published in well known journals. About 125 Black medical interns worked in the unit carrying out this study between 1947 and 1963.
After the Tuskegee Study, the government changed its research practices to prevent a repeat of the mistakes made in Tuskegee.

1974, the National Research Act was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Regulations were passed in 1974 that required researchers to get voluntary informed consent form all persons taking part in studies.

In 1974, studies using human subjects began requiring Institutional Review Boards, which decides whether they meet ethical standards.

Principles of Community-Based Participatory Research

1. Recognizes community as a unit of identity.
2. Builds on strengths and resources in the community.
3. Facilitates collaborative partnerships in ALL phases of research.
4. Integrates knowledge and action for the mutual benefit of all partners.
5. Promotes co-learning and empowering practices that address social inequities.
6. Involves cyclical process.
7. Addresses health from different perspectives.
8. Disseminates findings and knowledge gained to all partners.

(Information adapted from Israel, et al 1998)
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CLINICAL TRIALS
Barriers to Clinical Trials

• Fear of unethical treatment
• Distrust of the investigator’s motives
• An incomplete understanding of their benefits, responsibilities, risk, and the safeguards for study subjects
• The investigators’ apparent lack of respect for the subjects and their cultures.
• The history of episodic research without long-term program having, tangible benefits
• Cost and/or lack of insurance
• Lack of access to clinical trials (transportation, child care, time off of work) and
• lack of true partnerships in study design
TOP TEN REASONS WHY MINORITIES ARE NOT ENROLLED ON CLINICAL TRIALS
10. Time consuming for physicians and staff to explain and translate protocols and consent forms for patient and/or family member(s).
9. Lack of awareness of existing protocols by physicians and by the community
8. Concept of "guinea pig" still prevalent
7. Lack of bilingual providers and use of translators does not promote adequate communication between patients/families and providers
6. Time consuming for patients, who can often not afford time-off work or time away from home/children.
5. Financial constraints and requirement of costly diagnostic procedures at specific times during course of treatment.
4. Treatment protocols not available at patient's preferred treatment site (HMO, PPO, Non Medical Center site etc.)
3. Different tumor incidence in minority groups compared to whites.
2. Lack of protocols specific for cancers most often seem in minority populations or geographical area.
1. Lack of understanding of Minorities' Knowledge, Attitudes and Practices regarding cancer. Such results in poor protocol planning.
“Health in minority communities cannot be approached as a single issue. It has to be done in a holistic manner”

Lovell A. Jones, 1985
There is no genetic basis for racial classification.
WHICH ONE OF THESE INDIVIDUALS IS A GOOD CANDIDATE FOR BIDEL?
There are five elements originally written for establishing an effective cancer education program, but are relevant to addressing the enrolment of minorities in clinical trials.
1. States that a committee which plans to provide the program should include persons who represent the population targeted to be served.

2. Major items should refer to the local cancer/health plan. If one does not exist, one should be developed before proceeding.

3. Use a wide range of health education communication methods to capitalize on the strengths of each. This should be done with the community.
5. The need for sufficient funds and manpower to carry out the plan. If you don’t have this DON’T START.
* FAROS expands the Freeman model to include CHW to navigate older Latinos through screening & PN at the point of suspicious findings onward to the community and life after cancer.
MODIFIED PATIENT NAVIGATOR PROGRAM

Participant Recruitment

Clinical Findings Screening Impact on Recruitment

(-) Additional Test Enroll in the Study

(+)

Referred For Treatment Continued Follow up

Health Outcome

CHEER
Respect, Trust, & Partnership
Center for Research on Minority Health
Clinical Findings?

- Role of the Health Referral Specialist
- Receives notification of all remarkable clinical findings
- Contacts participants
- Coordinates referral to resources if needed
- Follows up with participant to assure that services were received
**Indigent Care Reimbursement**

**Traditional Approach**
- **Qualifications:**
  - Income
  - “Moms & kids” ONLY

**Disability Approach**
- **Qualifications:**
  - Income
  - Disease-based disability
    - Disability > 12 mo.
    - TERI
      - 100% Stage 3&4 Cancer
      - 70% Stage 2 Cancer
    - BMT

**Net:** < $1 Billion
Benefits & Opportunities

For the Underserved Patients

- Provides financial access to cancer care
- Improves mortality
- Provides other disability-based benefits (e.g. SSI)

For M.D. Anderson

- Increases reimbursement
- Fulfills mission by saving more lives
- Increases outreach to underserved communities

Center for Research on Minority Health

Respect, Trust, & Partnership

CHEER

Health Care Delivery System

Underserved Cancer Patients

Outreach (PUSH)

Benefits Enrollment (PULL)
Screened & Follow up
If you TRULY show that you care as much about their health as they care about their health they will come
## IMPaCT Report

**Date Range:** 09/01/2006 to 01/31/2010

### Patients Educated about CT and IMPaCT

<table>
<thead>
<tr>
<th></th>
<th>Enrolled in IMPaCT</th>
<th>Not Enrolled in IMPACT</th>
<th>Total</th>
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<tbody>
<tr>
<td>Patients Potentially Eligible for CT</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>93</td>
<td>40</td>
<td>133</td>
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### Not Yet Consented to CT (Recruitment):

<table>
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<tr>
<th></th>
<th>Enrolled in IMPaCT</th>
<th>Not Enrolled in IMPACT</th>
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<tbody>
<tr>
<td>Ineligible:</td>
<td>8 (27%)</td>
<td>14 (48%)</td>
</tr>
<tr>
<td>Pending:</td>
<td>0 (0%)</td>
<td>1 (3%)</td>
</tr>
<tr>
<td>Eligible:</td>
<td>22 (73%)</td>
<td>14 (48%)</td>
</tr>
</tbody>
</table>

#### Declined CT
- Enrolled in CT: 5 (23%)
- Currently Enrolled in CT: 2
- Completed CT: 14
- Withdrawn Self: 1

#### Enrolled in CT: 17 (77%)

### Already Consented to CT (Retention):

<table>
<thead>
<tr>
<th></th>
<th>Enrolled in IMPaCT</th>
<th>Not Enrolled in IMPACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ineligible:</td>
<td>0 (0%)</td>
<td>1 (9%)</td>
</tr>
<tr>
<td>Pending:</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Eligible:</td>
<td>63 (100%)</td>
<td>10 (91%)</td>
</tr>
</tbody>
</table>

#### Declined CT
- Enrolled in CT: 0 (0%)
- Currently Enrolled in CT: 14
- Completed CT: 43
- Withdrawn Self: 6

#### Enrolled in CT: 63 (100%)

#### Completed CT: 43 (100%)

#### Withdrawn Self: 6 (0%)
FAROS expands the Freeman model to include CHW to navigate older Latinos through screening & PN at the point of suspicious findings onward to the community and life after cancer.
Researchers too often look at community based research as something **PLACED** in the community as opposed to research truly **BASED** in the community.
PROPOSED NEW CENTER

DOROTHY I. HEIGHT CENTER FOR HEALTH EQUITY AND EVALUATION RESEARCH

- Enhancing Minority Participation in Clinical Trials (EMPaCT)
- Robert Wood Johnson Funded Children and Neighborhoods Defeat Obesity (CAN DO Houston) Project
- The Science Centers in Educational Classroom Enhancement
- Gulf Coast Trans-disciplinary Research Recovery Center on Community Health (SECURE Gulf Coast)
- Dorothy I. Height Center for Health Equity and Evaluation Research (UH/UTMDACC)
- Kellogg Health Scholars
- CMS funded Project Facilitated Assistance, Research & Outreach Services (FAROS)
- P60 Project EXPORT – Center of Excellence
- The Ovarian & Nutrition Education Study
- Bioethics Initiative for Health Equity in Health Care and Research Center
- Department on Health Disparities Research
- Health Disparities Education, Awareness Research & Training (HDEART) Consortium

Legend:
- Institutional Units
- Center Units
- Program/Project Units
Everyone Needs ...... The future generation

An ENVISIONED FUTURE

The past generation

The next generation
Do one brave thing today... then run like hell!