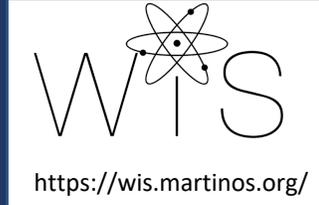


Panel & Discussion on Health Disparities and Community Engagement for Inclusive Research and Recruitment



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Dr. James Morrill MD, PhD, Medical Director of the MGH Charlestown HealthCare Center, Primary Care Physician and Assistant Professor of Medicine at MGH.



Juliana Ison, Research Program Coordinator from MGH's Community Access, Recruitment and Engagement (CARE) Research Center



Dr Angie Sanchez, MDm Assistant director, MGH Community Access, Recruitment and Engagement CARE Research Center, Research Fellow, Harvard Medical School

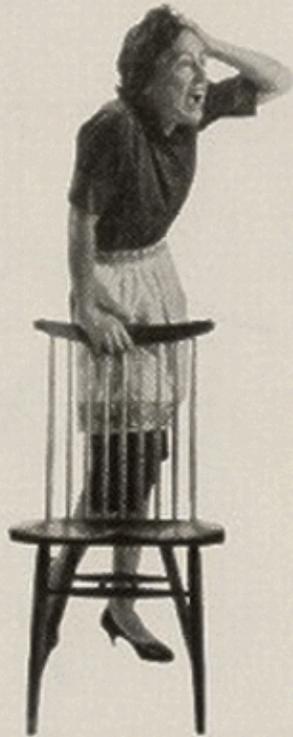
Mental health inequities can be seen in:

Prevalence

Outcomes

for prompt and sustained relief from
severe mental and

emotional stress



THORAZINE* SPANSULE*

chlorpromazine, S.K.F.

sustained release capsules, S.K.F.

30 mg. 75 mg. 150 mg. 200 mg. 300 mg.

 Smith Kline & French Laboratories

ATM Reg. U.S. Pat. Off.

Assaultive and belligerent?



Cooperation often begins with **HALDOL** (haloperidol) a first choice for starting therapy

Acts promptly to control aggressive, assaultive behavior

Several studies have reported the special effectiveness of HALDOL (haloperidol) in controlling disruptive and dangerously assaultive behavior.^{1,2} Even the number of violent assaults committed by a group of criminal psychotics "resistant to maximal doses of phenothiazines" was reduced substantially during treatment with HALDOL.³ Symptom control can be achieved rapidly, frequently within a few hours when the intramuscular form is used for initial control of acutely agitated psychotic states.⁴

Usually leaves patients relatively alert and responsive

Although some instances of drowsiness have been observed, marked sedation with HALDOL (haloperidol) is rare. In a report on a study with criminal psychotics the investigator states, "The patients remained alert and more amenable to psychotherapeutic intervention."⁵ Another investigator reports that HALDOL "normalizes" behavior and produces a sensitivity to the environment that allows more effective use of the social milieu and the therapeutic community.⁶

Reduces risk of serious adverse reactions

HALDOL (haloperidol), a butyrophenone, avoids or minimizes many of the problems associated with the phenothiazines. Hypotension is rare and severe orthostatic hypotension has not been reported. There is also less likelihood of adverse reactions such as liver damage, ocular changes, serious hematologic reactions and skin rashes.

The most frequent side effects of HALDOL (haloperidol)—extrapyramidal symptoms—are usually dose-related and readily controlled.

References: 1. Darling, H.F.: *Dis. Nerv. Syst.* 32:31 (Jan.) 1971. 2. Man, P.L., and Chen, C.H.: *Psychosomatics* 14:59 (Jan-Feb.) 1973. 3. Palestine, M.L., and Alatorre, E.: Paper presented Amer. Ass. Family Practitioners Annual Meeting, N.Y., Sept. 25-28, 1972. 4. Meschie, R.W.: *Dis. Nerv. Syst.* 35:112 (Mar.) 1974. 5. Howard, L.R.C.: *Clin. Trials*, 2:135 (May) 1965.

For information relating to Indications, Contraindications, Warnings, Precautions and Adverse Reactions, please turn page.

McNeil Laboratories, Inc., 1974

Why?

- Racism impacts the development and treatment of mental illnesses
- Culture impacts the development and treatment of mental illness
- Not enough culturally-focused research
 - Race/ethnicity being treated as a “nuisance variable”
 - Assessments – use and interpretation
- Not enough culturally-tailored treatment and systems of care
- Lack of representation



joking

insisting



amused

relaxed

irritated

thoughtful



encouraging

sympathetic

jealous

panicked



arrogant

hateful

sarcastic

stern



suspicious

dispirited

CARE

at Massachusetts General Hospital

Overall Mission: to increase the diversity of those who participate in research

- *How do we do this?*
 - *Consultations*
 - *Community Outreach and Events*
 - *Research*

- *Research coordinating = research + relationships*

General Advice for Increasing Diversity and Inclusion in Research

- **Build in multi-layered benefits**

- Direct Payment, study-wide newsletters, return of results to community, referrals to other research in/or around clinic, etc.

- **Build relationships with...**

- The community, local Community Health Centers/local providers, research participants

- **Build participant engagement and recruitment into your budget and study timeline**

- Ensure your study has the resources it needs to actualize these engagement and recruitment goals

- **Address barriers to research**

- Barriers to research disproportionately affect marginalized communities. Reducing and eliminating these barriers whenever possible will help your research become more representative and thus, more generalizable

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April 30 2021

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Of all forms of *inequality*,
injustice in *healthcare* is the
most *shocking* and *inhuman*.

—Martin Luther King, Jr.



Tuskegee – the origin of diverse recruitment

SHORT LIST OF MEDICAL ABUSES AGAINST BLACK COMMUNITY MEMBERS

Samuel Cartwright (1840s) - *coined drapetomania and dysthaesthesia aethiopica to justify slavery*

Marion Sims (1850s) - *learned to repair prolapsed uteri on Black slaves without anesthesia*

Joseph Goldberger (1912) - *induced pellagra in prisoners*

American South (1920s) - *medical use of “idiot,” “imbecile,” & “moron” to force sterilization of Blacks*

George Gey (1951) - *took Henrietta Lacks’ cells without consent, created HeLa immortal cell line*

Chester Southam (1952, 1963) - *injected cancer cells in prisoners*

Vertus Hardiman (1925) - *skull dissolved after being irradiated as 5 year old, parents deceived*

Ebb Cade (1941) - *injected with plutonium, denied medical care after severe car accident*

Eugene Saenger (1960-1971) - *forged consent documents, irradiated patients*

Johns Hopkins (1970) - *misled participants, looking for genetic predisposition to crime*

Centers for Disease Control (1990) - *experimental measles vaccines for babies without consent*

Columbia University (1997) - *broke sealed juvenile records, specifically excluded Whites*

MEDICAL ABUSES AGAINST OTHER GROUPS

Law 116 in 1937 – Forced sterilization in Puerto Rico

1960s – Mexican American women were sterilized in California

– Forced sterilization at ICE detection centers

Germany & Japan (World War II) – Vivisection

– Nazi human experimentation

John Charles Cutler (1940s) – The syphilis experiments in Guatemala

Perry Hudson (1950s) – Skid Row Cancer Study, prostate biopsy in homeless men

THE BELMONT REPORT (1979)

Respect for Persons

Must provide informed consent

Beneficence

Do no harm

All parties must understand and accept risks/benefits

Justice

Fair distribution of costs and benefits

HOW DO FEDERAL RESEARCH GUIDELINES ENCOURAGE INCLUSION?

Numerous aspirational policies; all fell short

NIH Revitalization Act of 1993

NIH Policy - Inclusion of Women and Minorities 2001

Establishment of Special Populations offices within ICs at NIH

NIH Inclusion Across the Lifespan 2019

Many, many, many FDA strategies, guidelines, declarations

- Including new draft guidance from late June 2019

But why is diversity important for research?

Is it a social justice thing?

Table 1. Percent Participation in Clinical Trials by Subpopulation* for New Molecular Entities and Therapeutic Biologics Approved in 2020

	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 AND OLDER	UNITED STATES
AVERAGE	56%	75%	8%	6%	11%	30%	54%

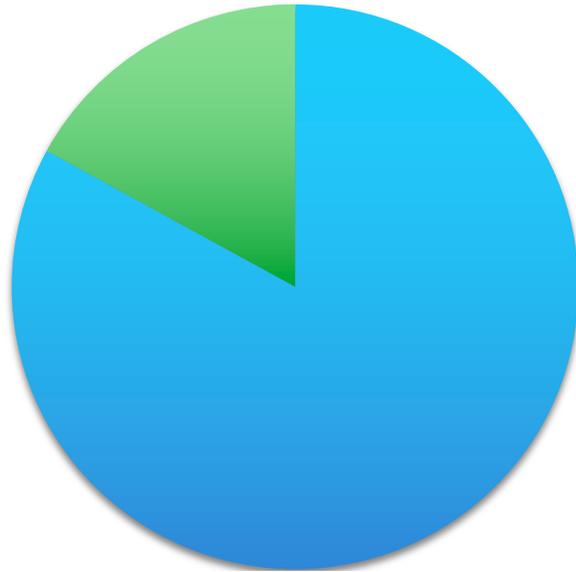
Est US pop 50.8% 76.5% 13.4% 5.9% 18.3% 16.0%

Median CTS 55% 78% 3% 5% 8% 11.5% 36%

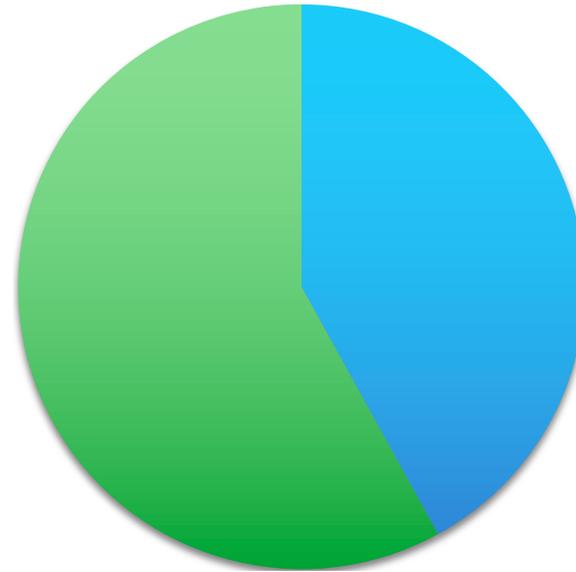
CoV CTS
(SD / mean) 0.47 0.35 1.64 1.44 0.85 1.10 0.80

WHY YOU SHOULD CARE ABOUT RECRUITMENT (PLANS)

MGH



Boston



2018 - Research Participation

WHO IS CONSIDERED TO PROVIDE DIVERSITY IN CLINICAL TRIALS?

Ethnic and Racial minorities

Rural population

Low socioeconomic status

Low income, low education

Women

LGTBQ+

WHY CAN'T WE RECRUIT DIVERSELY?

1. Lack of awareness of research opportunities
2. Deep mistrust of healthcare system and research studies
3. Confusion and concern over what research is
4. Limited transportation options / times
5. Inclusion / exclusion criteria (e.g., lumbar puncture, study partner)
6. Lack of plain language use in documents
7. Fear of placebo / fear of intervention
8. Health insurance coverage
9. Limited diversity on study staff
10. Insufficient return of value

Selected references:

Bonevski 2014 | BMC Med Res Method
Ejiogu 2011 | The Gerontologist
George 2004 | Am J Public Health
Gul & Ali 2009 | J Clin Nursing
Jackson Moy Evans 2016 | The Oncologist
Oh 2015 | PLoS Medicine
Otado 2015 | Clin Trans Sci
Probstfield & Frye 2011 | JAMA
Robinson & Trochim 2007 | Ethn Health

DIVERSITY AS A WORKFLOW PROBLEM

Sampling frame

Lack of awareness of research opportunities

Awareness

Deep mistrust of healthcare system and research

Engagement/Trust

Confusion and concern over what research is

Interest/Education

Limited transportation options / times

Return of Value

Inclusion / exclusion criteria

Screening

Lack of plain language use in documents

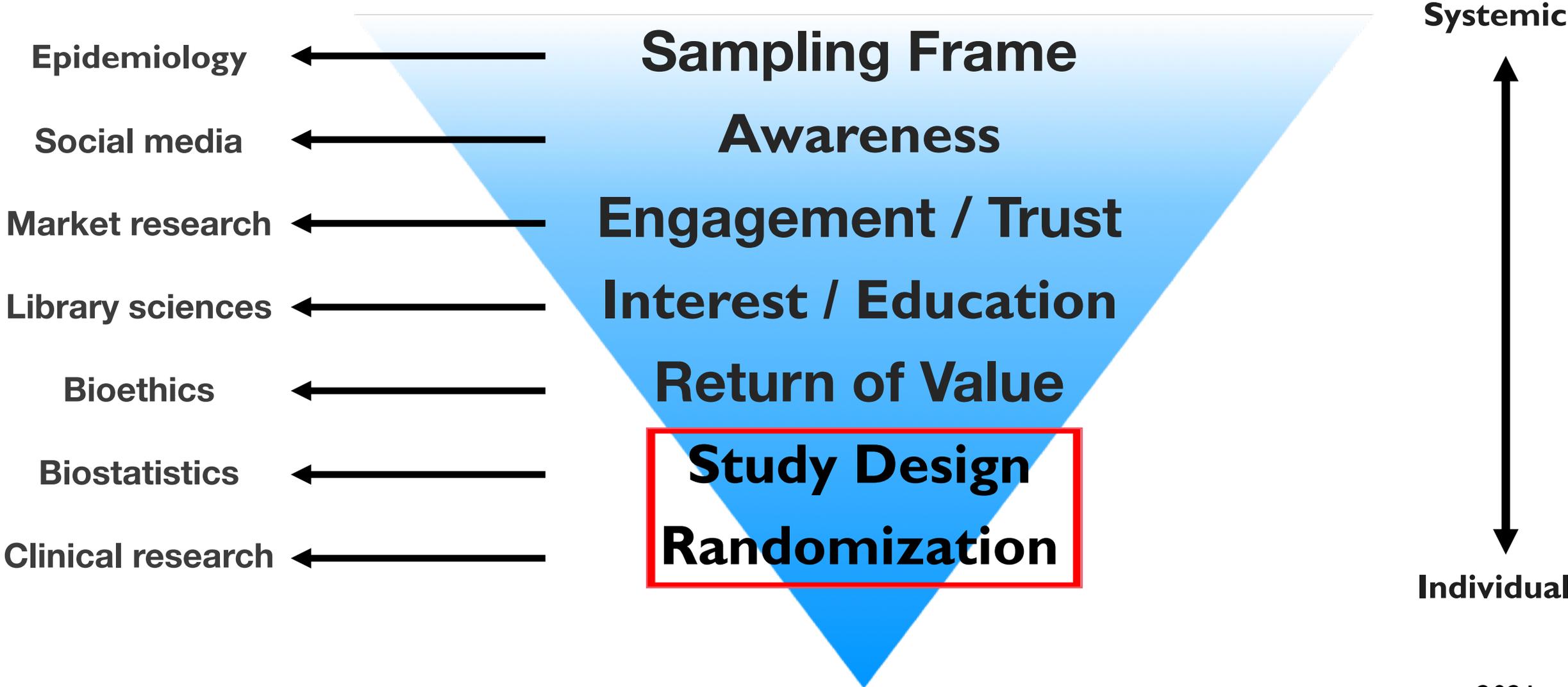
Fear of placebo / fear of intervention

Randomization

Health insurance coverage

Limited diversity on study staff

Insufficient return of value



Here's a little concrete advice

- Use plain language for everything, including your ICF
- Language equity shouldn't be the problem it is, but let's at least get English right
- Aim for 5th grade reading level, but no higher than 8th
- Use clinician champions and research ambassadors
- This becomes easier if you have a solid clinic / community presence
- Think about what you can offer clinicians to support research (hint: your expertise)
- Design for a strong return of value
- Beyond return of results - make it easy / free / fun to participate
- If you can't return any results or decent compensation, do participant celebrations
- Sustained community entrenchment works but takes time
- Can't float in and out, magic number seems to be around 7 years
- Talk to communities and families, not just prospective participants

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Angie Sanchez, MD

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