

# Optimizing Diversity, Equity and Inclusion in Pragmatic Clinical Trials: Findings from the Pain Management Collaboratory

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# Disclosures

I receive grants from the National Center for Complementary and Integrative Health, the National Institute on Drug Abuse, VHA Health Systems Research, and the VHA Office of Rural Health.

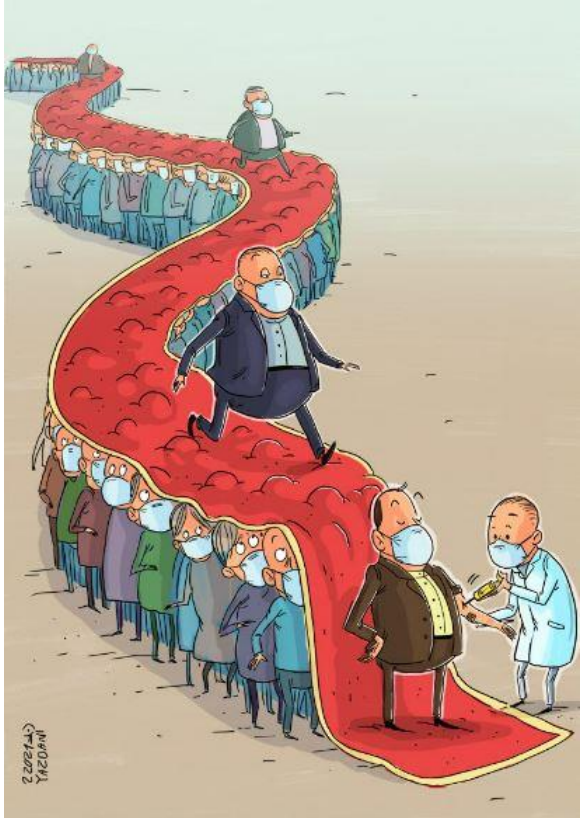
I have no conflicts with the work presented today.

I identify as a cis man of Southeast Asian, Polynesian, and Western European descent and am a first-generation college graduate. I am a licensed psychologist in the state of Oregon and co-principal investigator of one pragmatic clinical trial within the PMC.

# What we will cover in today's presentation

1. Some definitions that will be helpful
2. A brief history of pain disparities research
3. The Pain Management Collaboratory (PMC)
4. PMC study design and results
5. Recommendations for pain researchers

# Health Disparity

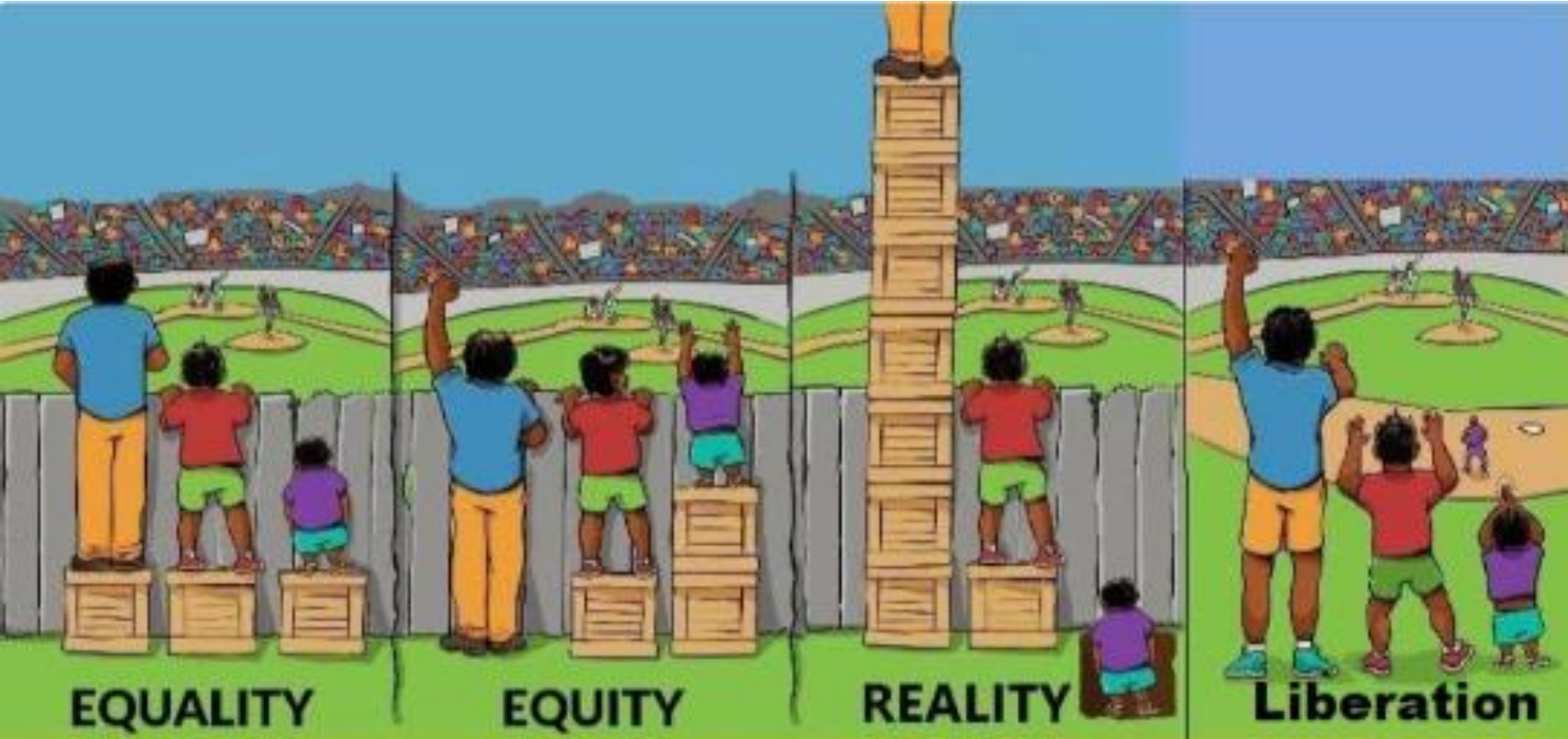


Preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health in socially disadvantaged and marginalized populations

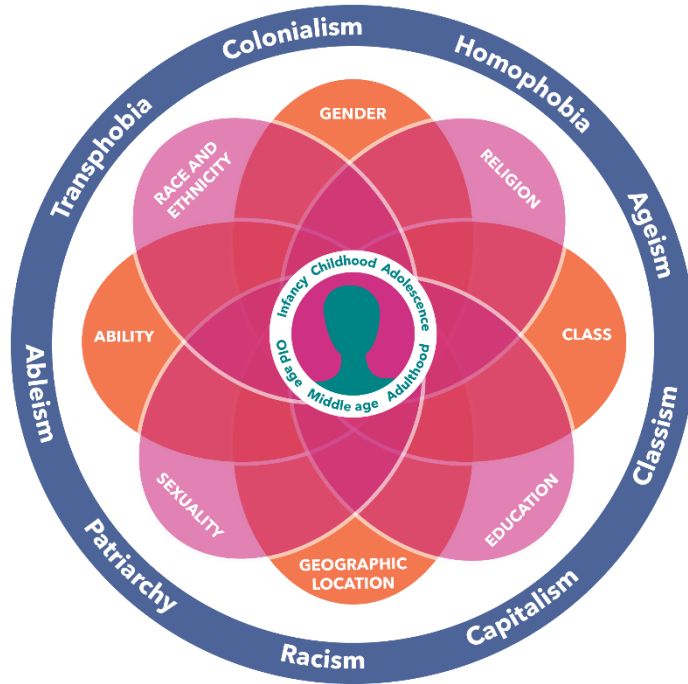
Healthy People, 2030

<https://health.gov/healthypeople/priority-areas/health-equity-healthy-people-2030>

# Health Equality, Equity, and Liberation



# Intersectionality



<https://justassociates.org/big-ideas/intersectionality/>

Cumulative ways in which multiple forms of discrimination combine, overlap, or intersect, especially in the experiences of marginalized individuals or groups

Crenshaw K. Demarginalizing the intersection of race and sex: a black feminist critique of antidiscrimination doctrine, feminist theory, and antiracist politics. University of Chicago Legal Forum 1989.

# Perspectives on the history of health disparities research

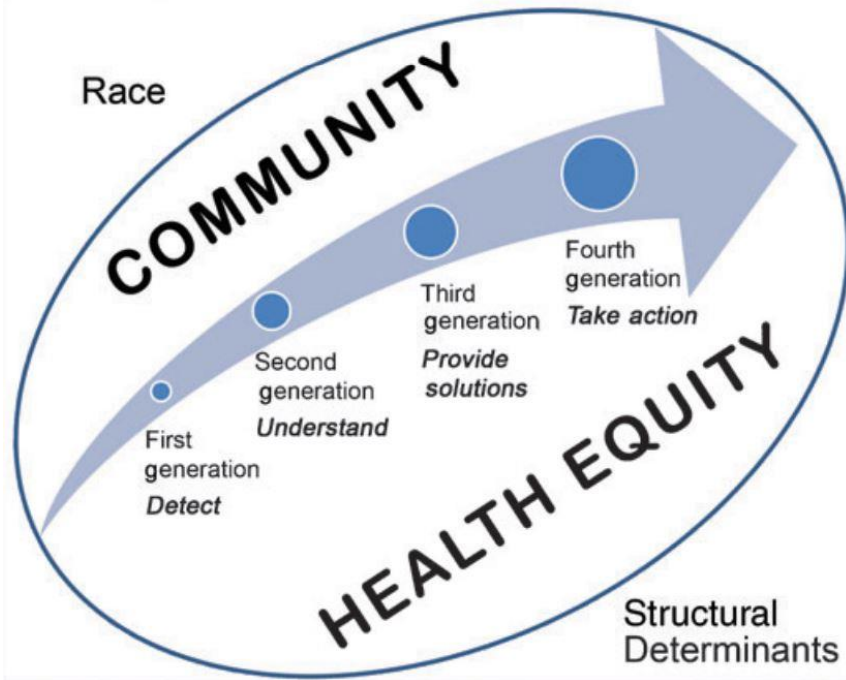
## Toward a Fourth Generation of Disparities Research to Achieve Health Equity

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Annual Review of Public Health 2011. 32:399-416  
doi: 10.1146/annurev-publhealth-031210-101136

We propose a new...generation of research grounded in public health critical race praxis, utilizing comprehensive interventions to address race, racism, and structural inequalities and advancing evaluation methods to foster our ability to eliminate disparities. This new generation demands that we address the researcher's own biases as part of the research process.



Generation 1: Do disparities exist?

Generation 2: Why do disparities exist?

Generation 3: Do interventions work?

Generation 4: Action-oriented.

- Structural determinants of health
- Social construction
- Self-awareness



# Perspectives on the history of pain disparities research

## **A historical review of pain disparities research: Advancing toward health equity and empowerment**

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## Generation 1

### Identification, Documentation, and Description

- Simple differences in assessment, treatment, and prevalence of pain primarily between Black and White Americans



## Generation 2

### Explanation

- Advancement of Biopsychosocial Model of Pain
- Multi-dimensionality of disparities



## Generation 3

### Solutions and Social Construction

- New treatments
- Introduction of SDoH, Equity, Intersectionality, & Lifecourse perspectives
- Intra-ethnic and Intra-racial investigation of pain



## Generation 4

### Liberation and Evaluation

- Transcending simple differences into complex relationships
- Multifaceted pain multi-level, multi-generational, and multi-disciplinary interventions
- Precision Medicine and Behavior Change for pain



- ✓ Classic studies on pain and culture (1968-1984)
- ✓ 1<sup>st</sup> Literature review on pain disparities by Dr. Carmen Green & colleagues (2003)

- ✓ Institute of Medicine *Relieving Pain in America* Report (2011)
- ✓ Patient Protection and Affordable Care Act (2010)- recognize pain as a public health problem and provision for pain care expansion

- ✓ Hydroxyurea introduced and effective for sickle cell disease (1995)
- ✓ National Pain Strategy (2017)- Goal 2 focuses on disparities
- ✓ Federal Pain Research Strategy (2017)- national research priorities, i.e. disparities

- ✓ 1<sup>st</sup> paper series on confronting racism in pain research published (2022) in *Journal of Pain*

War on Drugs and Imprisonment declared by Former President Nixon (1971-present): Marijuana and Cocaine/Crack (primarily impacted Black Americans)  
War on Drugs and Rehabilitation (2000-present): Opioid and illicit fentanyl crisis (primarily impacting White Americans)

# Generation 1: identification, documentation, description

- Sensitivity to pain in individuals racialized and socialized as ethnic minorities is more pronounced and severe
- Pain disparities go beyond race as the sole factor
- Systemic disparities exist in quantity and quality of pain care

## Generation 2: explanation

- Biopsychosocial model moves beyond disease states of pain and considers multiple levels of influence on the individual
- Failure to consider systemic factors that perpetuate pain disparities

# Generation 3: solutions and social construction

- Intersectionality frameworks consider permutations of identities and social experiences that impact pain
- Focus on social determinants of health—systems in which people are born, grow up, live, work, and age
- Developmental perspectives that acknowledge cumulative exposures over the life course

# Generation 4: liberation and evaluation

- Engaging people with lived pain experience
- Reshaping our thinking toward multiple systems of influence
- Striking down systems of inequity
- Fostering health empowerment and liberation

# Pain Management Collaboratory (PMC)

## Closing the Gap between Science and Clinical Practice for Pain Management.

The PMC helps to develop, promote, and implement cost-effective large-scale pragmatic clinical research on nonpharmacologic approaches to pain management among military service members and their families as well as the veteran population.

The PMC consists of 13 funded pragmatic clinical trials and a coordinating center.

### Who's Who

#### Principal Investigators:

Robert Kerns, PhD, Cynthia Brandt, MD, MPH., and Peter Peduzzi, PhD.

<https://painmanagementcollaboratory.org>

# PMC Basic Structure

## Pain Management Collaboratory





# Justice in Clinical Research

- Justice, or the fair allocation of a society's benefits and burdens, as a conduit for the *ethical inclusion* of individuals

Institute of Medicine (US) Committee on Ethical and Legal Issues Relating to the Inclusion of Women in Clinical Studies; Mastroianni AC, Faden R, Federman D, editors. Washington (DC): National Academies Press (US); 1994.

- Pragmatic clinical trials provide opportunities to increase patient representation in samples
  - Limited exclusion criteria
  - Varied clinical settings
  - Examine “real world” clinical effectiveness
  - Large samples permitting subgroup analyses

Ali J, Davis AF, Burgess DJ, et al. Justice and equity in pragmatic clinical trials: Considerations for pain research within integrated health systems. *Learn Health Syst* 2021. 6(2):e10291. doi: 10.1002/lrh2.10291

# Method

- Reviewed:
  - Human subjects worksheets submitted to the PMC<sup>3</sup>
  - Published protocol papers when available
  - NIH RePORTER
  - [clinicaltrials.gov](http://clinicaltrials.gov)
- Interviews with trial PIs and staff
  - Meaning of diversity when designing trials
  - Methods to recruit and retain diverse samples
  - Planned analyses that take into consideration diverse subgroups

	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported			Total
Race/Ethnicity	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown	
American Indian or Alaskan Native	19	53	0	12	21	0	10	31	32	178
Asian	26	104	1	33	88	0	94	166	36	548
Native Hawaiian or Pacific Islander	25	67	0	4	26	0	146	108	31	407
Black or African American	720	1314	0	124	352	0	192	361	692	3755
White or Caucasian	1257	4930	0	279	1279	0	576	1158	1617	11096
More than one race	34	100	0	36	82	0	71	118	10	451
Unknown or Not Reported	117	301	0	52	173	0	168	394	158	1363
<b>Total</b>	<b>2198</b>	<b>6869</b>	<b>1</b>	<b>540</b>	<b>2021</b>	<b>0</b>	<b>1257</b>	<b>2336</b>	<b>2576</b>	<b>17798</b>

	<b>PMC Trials</b>	<b>VA</b>	<b>DoD</b>
Female Birth Sex	22%	10%	18%
Marginalized Race and/or Ethnicity	34%	25%	31%

# Results – Diverse Samples

- Diversity is narrowly defined and targeted
  - Birth sex and/or gender identity
  - Race and ethnicity
- Other forms of diversity considered discussed
  - Rurality
  - Pain syndromes
  - Military (vs. civilian) status
- Pre-specified analyses
  - Birth sex (3)
  - Race and ethnicity (2)
  - Acute vs. chronic pain (1)

# Results – Recruitment Considerations

- Recruitment locations create expectations for diversity
  - Do specific sites drive diversity of sample?
- Partnerships inform patient-centered materials and study processes
- Recruitment approaches
  - Data-driven
  - Clinician referral
  - Patient self-referral

# Results – Retention Considerations

- The role of study coordinators
- Staff representation and training
- Removing barriers by providing real-world flexibility
- Active comparators

# 14 Recommendations

1. Patient engagement
2. Tailor definitions of diversity
3. Go beyond dichotomous categories
4. Mitigate stigma
5. Representative study teams
6. Cultural responsiveness training
7. Patient-facing materials



# 14 Recommendations

8. Site selection
9. Partner with referring clinicians
10. Consider and active comparator
11. DSMB Expertise
12. Database tracking systems
13. Setting and knowing expectations
14. Provide options

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Lovejoy TI, Midboe AM, Higgins DM, Ali J, Kerns RD, Heapy AA, Nalule EK, Pal N. Optimizing diversity, equity and inclusion in pragmatic clinical trials: findings from the Pain Management Collaboratory. *J Pain* (In Press).

 Questions?