

Ethics of Community Engaged Research: Background and Lessons Learned in NYC

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Overview

- You all have a working knowledge of community engaged research
 - And how this approach may benefit populations
- Today, we will:
 - Address ethics in community engaged research
 - Explore an example from a collaborative perspective
 - Race/Ancestry, Genetics & Kidney Disease

But first, a reminder...

- We partner with each other- multiple communities:
 - Local community, clinical, academic, private sector, public health leaders
- Because there are inequities
 - Unjust differences in health, quality of life and lifespan based on factors that should not fate any of us to suffering or death
 - It's our job as researchers, clinicians, patients to fix that
- Community engagement
 - Grounded in principles of community organizing
 - Justice, fairness, empowerment, self-determination, participation

Ethics of Community Engagement

(5 principles adapted from Belmont Report)

- 1. Respect: Bidirectional Communication/Understanding**
 - Constructive sharing/addressing ideas, risks, concerns
- 2. Beneficence: Equity, Mutual Legitimacy**
 - Ideas, decision-making, agenda setting, responsibility, money
- 3. Justice: Investment**
 - In partnership infrastructure, operations, funding
 - In relationships, capacity building, in communities themselves
- 4. Informed Consent: Transparency**
 - Elicit and share priorities, constraints
 - Concerns re coercion, violations of privacy, data misuse
- 5. Actionability: Translation and Dissemination**
 - Legitimate, serious, partnered dissemination plan
 - Mutual ownership of research products, successes

Ethical Challenges

1. **Respect: Communication/Understanding**

- Whose idea was the study? The research plan? Who's it designed for and by? Is this just for your research career?

2. **Beneficence: Equity, Mutual Legitimacy**

- Am I a volunteer? Subject? Rubber stamp? Partner?
- Don't paternalize poor, non-white people, this isn't charity.

3. **Justice: Investment**

- Why is the whole study built/run out of your ivory tower?
- Will we learn from/with each other (capacity building)?

4. **Informed Consent: Transparency**

- Are you manipulating me? Listening to me? Can I trust you?
- Need to share each others' goals, timelines, limitations.

5. **Actionability: Translation and Dissemination**

- Will you tell us what you learned? Will anything change?
- Will we use data to inform policies and systems?

To Collaborate

We First Must Understand Each Other

	Researcher/Industry	Participant/Local Community
Purpose	Clear, Important	“Earned Skepticism”
Timeline	now, Now, NOW!!!	What’s the hurry?
Benefit	Obvious- career, grants, knowledge, health, it’s for their own good	Unclear- drive-by, or helicopter research
Risks	Minimal & Tuskegee- ages ago!	Unacceptable if benefit iffy, historic abuses
Attitude to Research	Needed to gain knowledge	Problems are apparent, resources are lacking
Participants Should	Agree, comply	Question, contribute

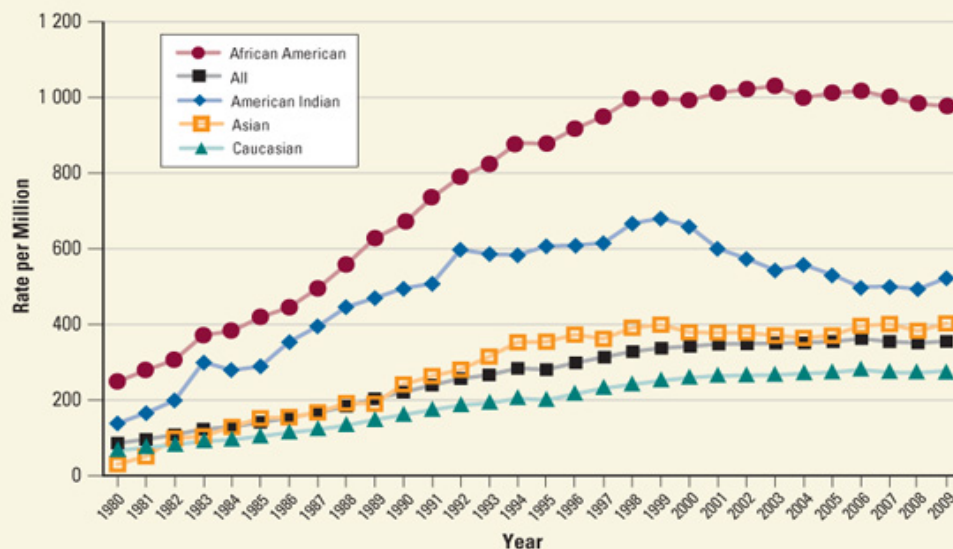
An Example Navigating Ethics and Engagement

Ancestry, Genetics, Kidney Failure

- Chronic kidney disease affects 26m US adults.
 - Most commonly associated w/diabetes (40%) & hypertension (28%)
- African Americans/Blacks are:
 - 2-3 x more likely to develop kidney failure compared to Whites.
 - 5 x more likely to develop kidney failure from HTN than Whites.
- Why? Lots of reasons, access, quality of care, and...



Adjusted Incident Rates of ESRD by Race



<http://kidney.niddk.nih.gov/kudiseases/pubs/kustats/#6>
Grams et al. 2013
National Kidney Foundation



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Genetic testing to Understand and
Address Renal Disease Disparities

Genetics...

What we Learned at a Partnership Board meeting

- *APOL1* variant (mutation) confers protection against sleeping sickness
 - Similar to malaria/sickle cell
 - But this variant increases risk for kidney failure 5x
 - May explain up to 70% of excess prevalence of kidney failure in AA's.
- Prevalence:
 - African Ancestry 1 in 7
 - Eur. Ancestry < 1 in 200

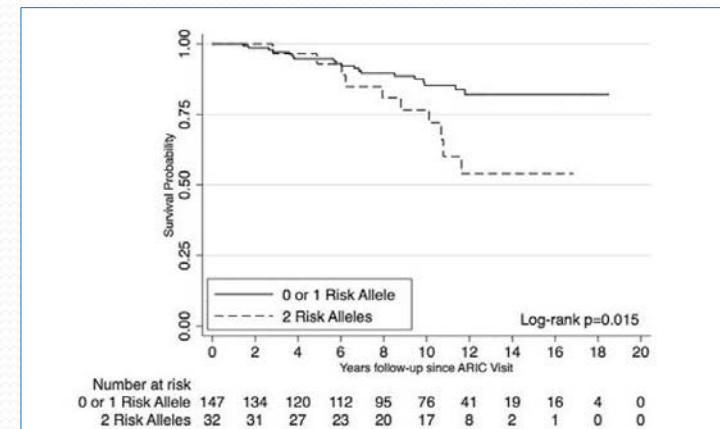


Figure 1. Participants with CKD and two *APOL1* risk alleles progressed faster to ESRD than participants with CKD and zero or one *APOL1* risk allele. Kaplan-Meier survival curves for ESRD-free survival by number of *APOL1* risk alleles among participants with prevalent CKD (n=179).

So What?

- Variant that increases risk for a common chronic disease (new!)
 - And a differential risk in people with specific ancestry.
 - Race is a social construct, but ancestry has genetic component.
- Initial reactions:
 - Genetic ethicist: **“Don’t touch this - you will set the disparities movement back 30 years.”**
 - Leader of Harlem church: **“Now maybe white doctors won’t judge black people on dialysis as not caring enough or not being compliant. They will recognize that there’s more to disease than bad behavior.”**
- Who’s view matters? Who do we listen to?
- What do we do with this information that will help and not harm?
- How do we chart a course?



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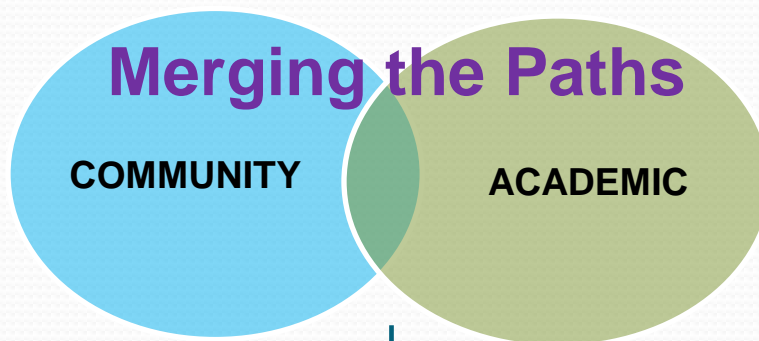
Centers for
Community
and Academic
Research Partnerships

Approach: Community Engaged Research

Randomized Trial

- Impact of testing for APOL1/returning results on patient outcomes (blood pressure, kidney disease testing, psycho-behavioral results for patients/clinicians)
- At FQHCs and academic centers in NYC- Harlem, S. Bronx

Residents,
Clergy, Clinicians,
Community Educators
APOL1 + patients



Researchers



**A COMMUNITY-ACADEMIC
BOARD**

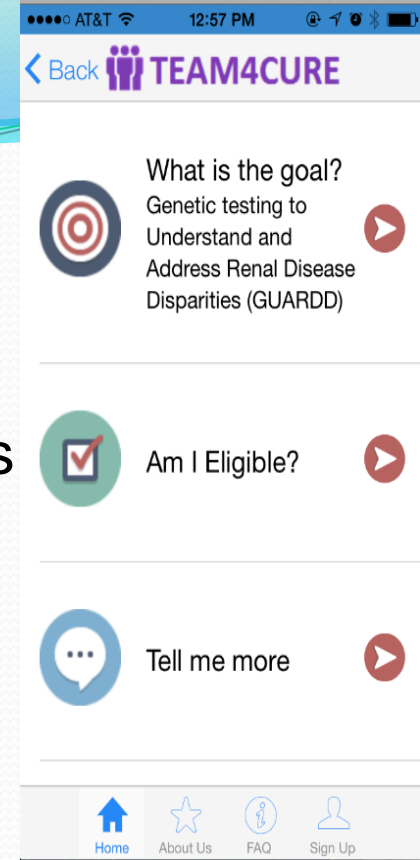


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Community Board: Inclusive Approach

- Formative research, piloting every step
- Study design w/stakeholder engagement
 - Co-wrote/developed consent, recruitment strategies
 - Got us to change design, IRB to genomics regs
- Intensive capacity building for research
 - And for researchers to understand CBPR
- Patient/Clinician-Centered Approaches
 - Enroll, calls, texts, letters, app, intercepts
 - Defined race/ancestry
 - Chose who would deliver results
 - Results: EHR-enabled CDS
- Results: going well so far!
 - 100 people/month joining



Did you know that people of African ancestry who have high blood pressure are more likely to develop serious kidney problems?

A simple blood test can help you find out if you are at higher risk.



Contact us if you are an adult of African descent with high blood pressure and are interested in taking part in a study to find out if you are at higher risk for kidney disease.

You will receive \$120 in gift cards if you take part.

Please call (212) 659-9571 for more information.



Potential Benefits from Community Engagement

- Community knowledge, expertise → new hypotheses, more relevant research questions, data interpretation, programs
 - Improved data quantity, quality, validity, reliability
 - More accurate, culturally appropriate interpretation of findings
 - Novel, effective recruitment, retention
- Builds trust between academics and communities
 - Lower barriers for researchers to gain entry into communities and vice versa.
 - Avoid mistakes- better safeguarding of privacy, reduced risks
- Research more likely leads to tangible health & community benefits
 - Don't waste time/resources
 - Funding, work enhances local capacity, assets and sustainability



Remember

- Always look through a participant lens
 - Be open to other ideas.
- Design studies with inclusiveness in mind at every step- no one is less important
 - Not even academics, we all have critical strengths.
 - This will work if we all pony up and speak up.
- Work to find magic- CBP (participation), R (rigor)
- Contribute to change
 - Share results with participants/communities.
 - Democratize data (all should have access to it).
 - Provide community benefit (employment, capacity).

Thanks

- Community, Clinical and Research Partners
- Funders:
 - NIMHD
 - NCATS
 - NHGRI



And thank you from our team!

