Is this the right time
to study use of genomic data
in health systems?

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“If you’re not at the table, you’re on the menu.”

• Whose decision is it? Who do we need to convince?
• Who is at our table? Nationally? In NYC?
• If we don’t study it, will it happen anyway?
  – If we don’t study it, who will, and in which patients ($)?
  – Our Board answer: “One needs to be vigilant. The research should proceed, but carefully.”

Culture of understanding: Reflections and suggestions from a genomics research community board. Progress in Community Health Partnerships, 2017
Can genomic-based reach diverse participants and be equitably distributed? Yes, if intentional, valued, resourced, done carefully.

“How do you advance science in a good way and not take advantage of the vulnerability of a community?”

“The statement that looking at genetic risks by ancestry works against the Black community is traditional and stereotypical. Genomics can be integrated into community health.”

Who’s rejecting who here?
Example: *APOL1* Risk Variants

- African ancestry (AA) 3x odds of kidney failure
- 1/7 AA individuals have genetic variant protective of sleeping sickness
  - 10x odds of kidney failure if hypertension
  - Explains up to 70% of racial disparity in kidney failure

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**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 CKD.
Go-No Go Research- Who decides?

– Genetic ethicist: “Don’t touch this- you will set the disparities movement back 30 years.”

– Elder Mimsie Robinson:

“Now maybe White doctors won’t judge Black people on dialysis as not caring enough or not being compliant. They’ll recognize that there’s more to disease than bad behavior.”

• Where we ended up: NHGRI RCT
  – To incorporate genomics into primary care
  – Stakeholder engaged, patient-centered

GUARDD
Genetic testing to Understand and Address Renal Disease Disparities

Race

Disparities

Ancestry
The GUARDD Study Design

- **Eligibility:** Self-reported AA; 18-70 yrs, HTN, no DM, CKD
- **Randomize:** \textit{APOL1} testing vs. delayed testing in 1y
  - GC-trained staff to test patients, return results
  - GC available for patients (never used)
  - Providers get results as BPAs in EHRs
Methods

• Community- Clinical- Academic team developed
• Began with formative research (so no surprises)
• Roadshow- introducing GUARDD, getting feedback
  – 5 fed. qualified health centers (safety net)
  – 6 neighborhood practices
  – 4 academic primary care practices
• Part of system with 4.5m patients,
  13 ac & comm hosp’s, 350 outpatient sites
  7000MDs, ~50% non-white
• Many genomics/research naïve/concerned- PCP’s like me
“A good invitation to a good party”
(BTW, who’s your invitation meant for?)

• When’s good for you? (anytime, anywhere)
• Recruiters- from/of community, build relationships, continuity, help each other
• Recruitment feels like it’s from a neighbor (it is)
• Used appropriate, language, literacy, graphics
Results: Completed Enrollment in 2y Retained 93% 3m, 90% 12m

- Difficult to Reach Population
  - Homeless/Mobile
  - Recently incarcerated
  - Competing demands
    - Food/Jobs
    - Professional Conflicts

Demographics (100% AA) | %
------------------------|-----
Age (mean, range)       | 53 (18-70)
Female (same as sample) | 67
Inadequate Health Literacy | 20
Education: ≤ HS degree  | 44
Income <$30,000         | 53
Non-adherent to BP meds | 48
Uncontrolled BP (≤140/90) | 47
<table>
<thead>
<tr>
<th>Item</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trained: Had Formal Genetics Course</td>
<td>79%</td>
</tr>
<tr>
<td>Experienced: Ordered genetic test in last year</td>
<td>36%</td>
</tr>
<tr>
<td>Prepared: For patients who had genetic test for a chronic disease</td>
<td>25%</td>
</tr>
<tr>
<td>Concerned: Re insurance discrimination</td>
<td>53%</td>
</tr>
<tr>
<td>Don’t trust genetic testing companies</td>
<td>76%</td>
</tr>
<tr>
<td>Pt Response: Motivate behavior change (prediction)</td>
<td>34%</td>
</tr>
<tr>
<td>Will try harder to control BP</td>
<td>69%</td>
</tr>
<tr>
<td>Race/Ancestry: Clue for who needs genetic test</td>
<td>75%</td>
</tr>
<tr>
<td>Genes are partly reason for racial/ethnic disparities</td>
<td>81%</td>
</tr>
</tbody>
</table>
Patient Survey (n=2052) : Genomic Beliefs, Concerns

<table>
<thead>
<tr>
<th>Item</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Had previous genetic test</td>
<td>11</td>
</tr>
<tr>
<td>Understand genetic testing</td>
<td>12</td>
</tr>
<tr>
<td>Good idea to get genetic testing to assess chronic disease risk (genes effect this risk)</td>
<td>96</td>
</tr>
<tr>
<td>Want children tested for APOL1 variants</td>
<td>78</td>
</tr>
<tr>
<td>Worried about the privacy of results</td>
<td>11</td>
</tr>
<tr>
<td>Think doctors would discriminate against people with genetic chronic disease risk</td>
<td>5</td>
</tr>
</tbody>
</table>
3 month survey (no diff. than baseline)

<table>
<thead>
<tr>
<th>Item</th>
<th>%</th>
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<tbody>
<tr>
<td>Don’t trust their doctor</td>
<td>45</td>
</tr>
<tr>
<td>Doctors don’t treat B&amp;W patients equally</td>
<td>67</td>
</tr>
<tr>
<td>B more likely to have chronic diseases than W</td>
<td>88</td>
</tr>
<tr>
<td>- Genetics contributes to this disparity</td>
<td>82</td>
</tr>
<tr>
<td>How docs view you think if disparity is genetic</td>
<td></td>
</tr>
<tr>
<td>- No change in view</td>
<td>63</td>
</tr>
<tr>
<td>- More negative</td>
<td>13</td>
</tr>
<tr>
<td>- More positive</td>
<td>24</td>
</tr>
<tr>
<td>Would get tested again</td>
<td>95</td>
</tr>
<tr>
<td>Satisfied w/timing, type, amount of info they got</td>
<td>&gt;95%</td>
</tr>
</tbody>
</table>
Study had positive results (some docs were right)

Associated with self-reported improvements in BP med use
“You want to learn about us? Include us.”

Diverse populations/sites should not be an add-on, afterthought, or funding strategy. If we MUST diversify, we will.

“The culture of understanding is far more important than the culture of fear, and the culture of understanding has no color. Our success came from willingness and ability of all stakeholders to challenge their views about race, racism, ancestry, genomics and research.”

“This voice needs to be harnessed. People will become engaged when someone who looks like them is at the helm.”
Conclusion: Do it now, do it right. 
Make diversity/engagement a priority from the get go

Thanks to, and from our Genomics Board

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Clinical Medicine
Clinical Trials, Disparities
Program Management
PGX
Genetic Counseling
Patient Engagement
Community Organizing
Faith Community
Community Health
Pediatrician, Children’s Advocate

GUA R D D
Genetic testing to Understand and Address Renal Disease Disparities
Thanks to our partners and funders

NHGRI
IGNITE
NCATS
Conduits

And thank you!