
THE UNIVERSITY OF CHICAGO

# Pharmacogenomics-guided Prescribing and Opportunities for Promoting Health Equity

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No disclosures or conflicts of interest to report

# Agenda

- Pharmacogenomics in diverse populations
- Current and Future Research

# Pharmacogenomics (PGx)

Field that examines the relationships between genetic makeup and drug response.

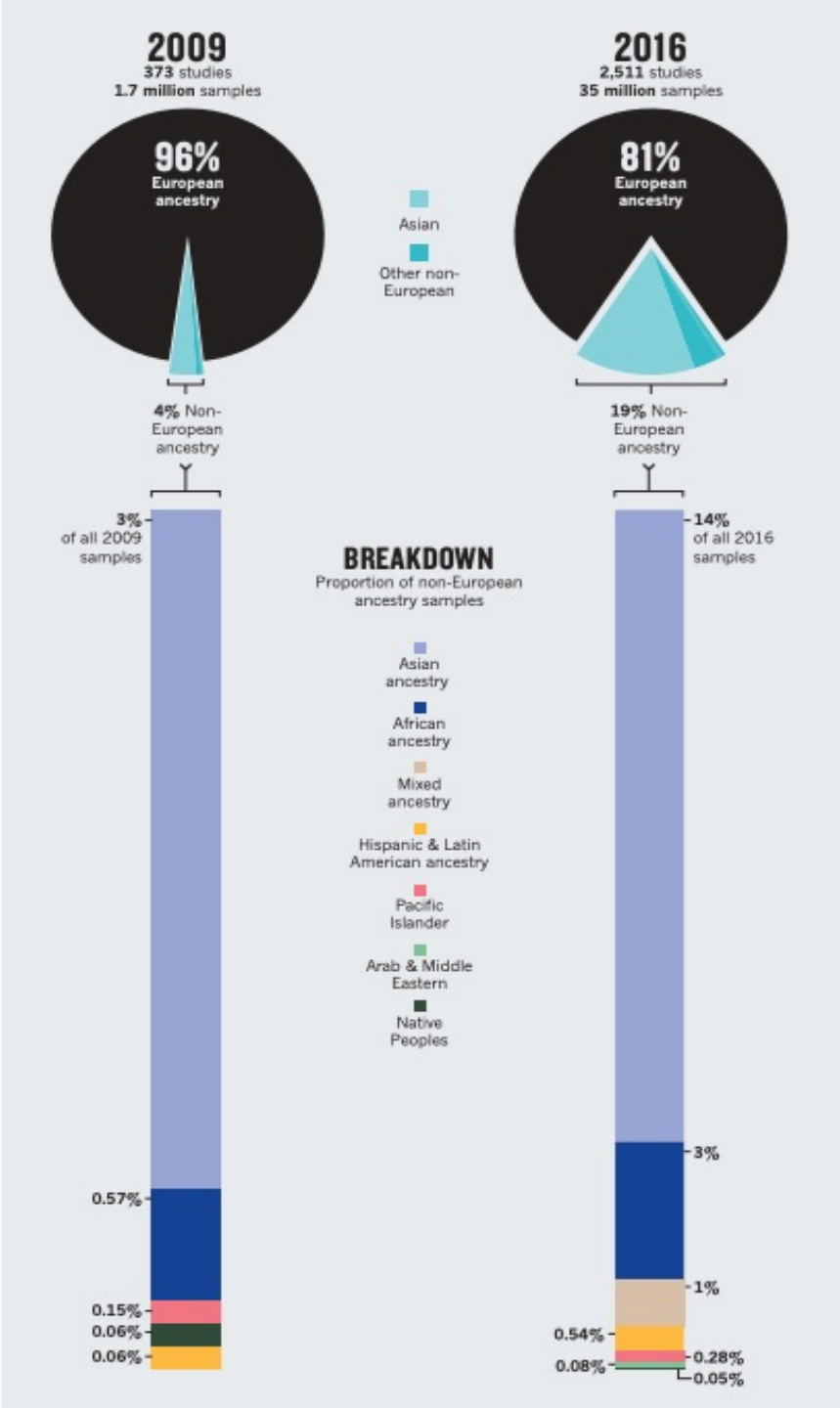
Combines pharmacology and genomics.

PGx tests for genetic inheritance have lifelong implications for directing drug treatment for a range of health conditions.

# Benefits of Personalized Prescribing

- Trial and error prescribing
- Cost of adverse drug events (medical expenditures, morbidity/toxicities, mortality)
- Improve health outcomes

In spite of improvements, the vast majority of data from Genome Wide Association Studies (GWAS) are from European populations




Popejoy and Fullerton et al *Nature* 2016

# Concern that ethnically diverse populations are being excluded from the benefits of personalized prescribing because:

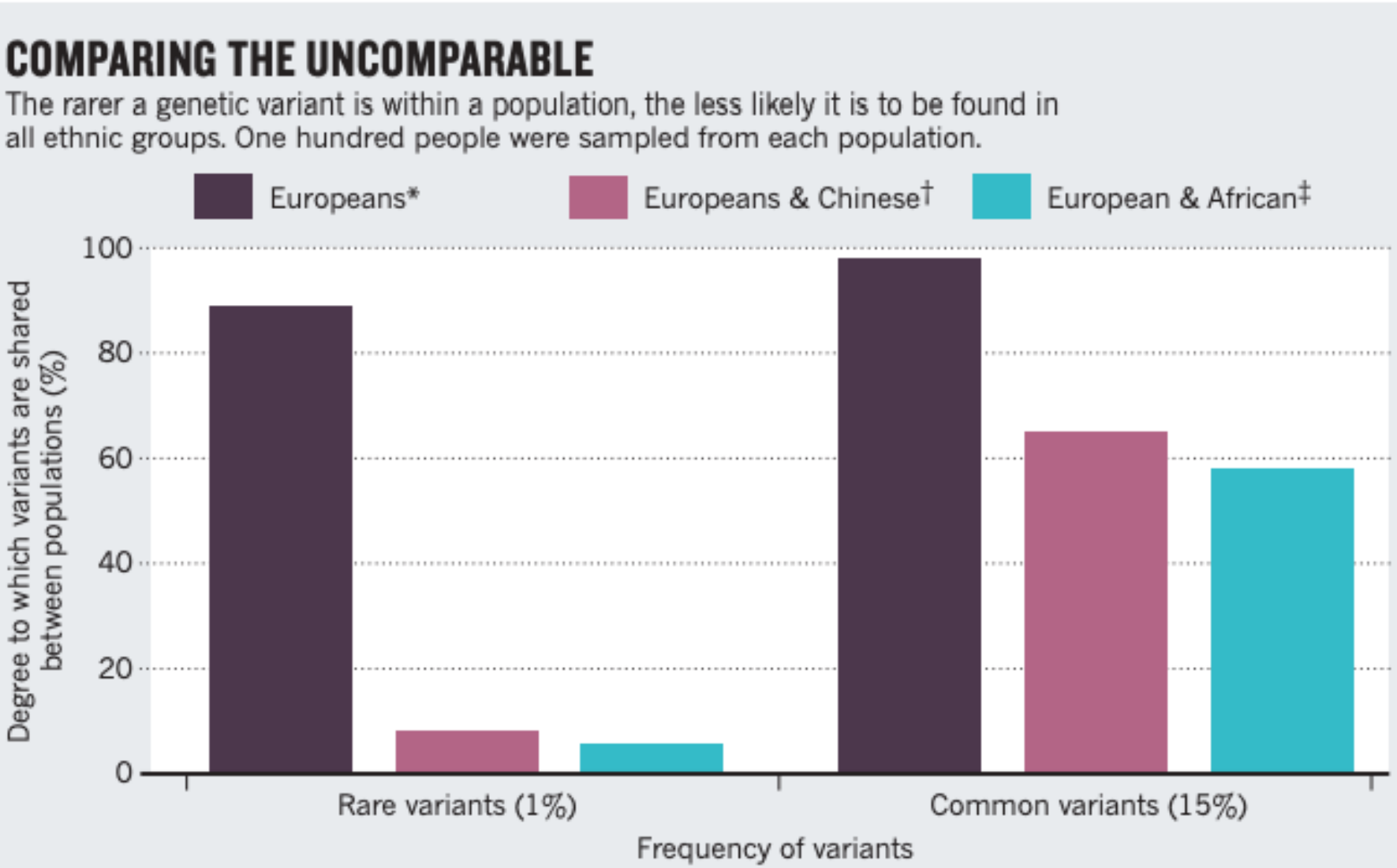
Dearth of genetic information collected from these populations

↓

Underrepresentation in PGx studies

↓

Uncertainty of clinical utility in minority populations




Bustamante et al *Nature* 2011

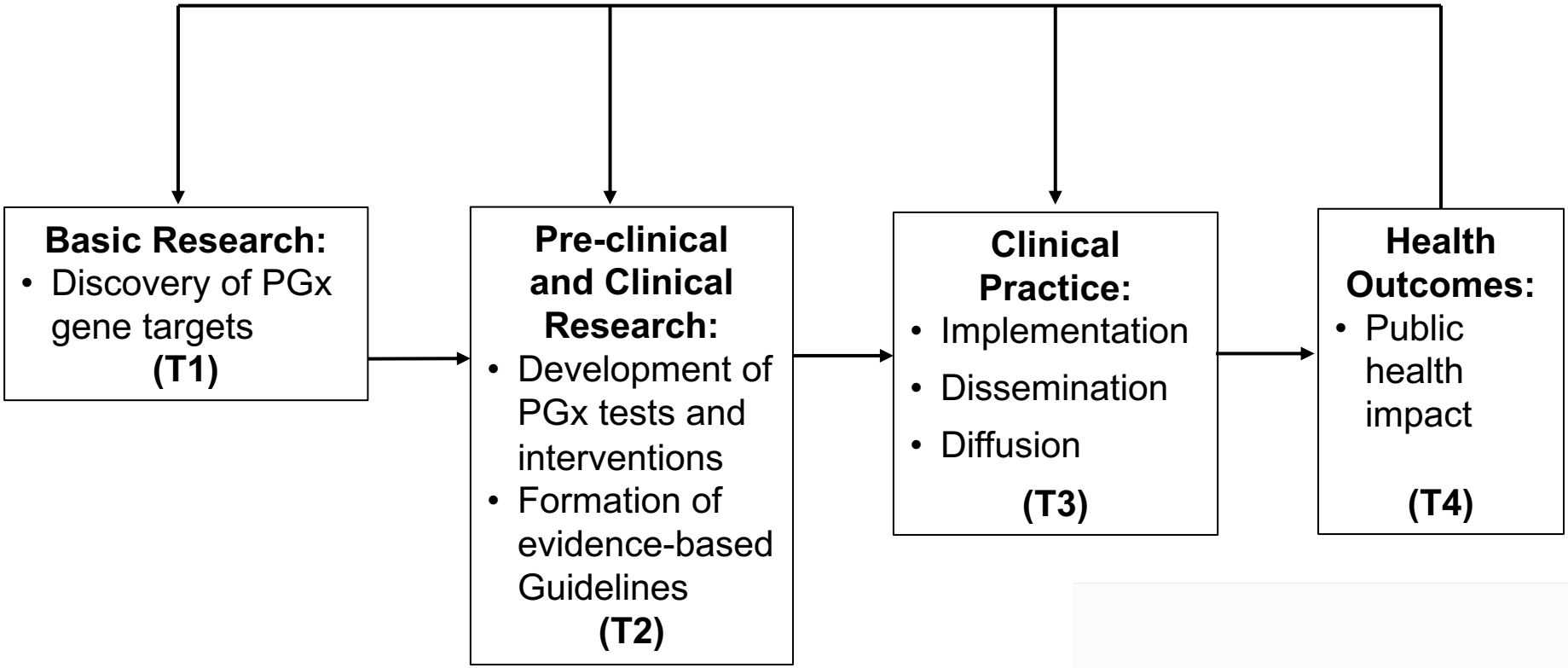
# Criticisms for the use of race in clinical decision-making

- *Scientific basis and definition of race is disputed*
    - Arbitrary categorization under influence of social construction and discrimination
    - 'Racial' categories do not apply in a global context, being heavily influenced by national/local sociopolitical factors
    - Genetics may be conflated with race fueling discrimination based in genetic predeterminism

- *Self-reported race vs. genetic ancestry*

Seguin et al *The Pharmacogenomics Journal* 2008

# Translational Cycle of Pharmacogenomics (PGx) Research



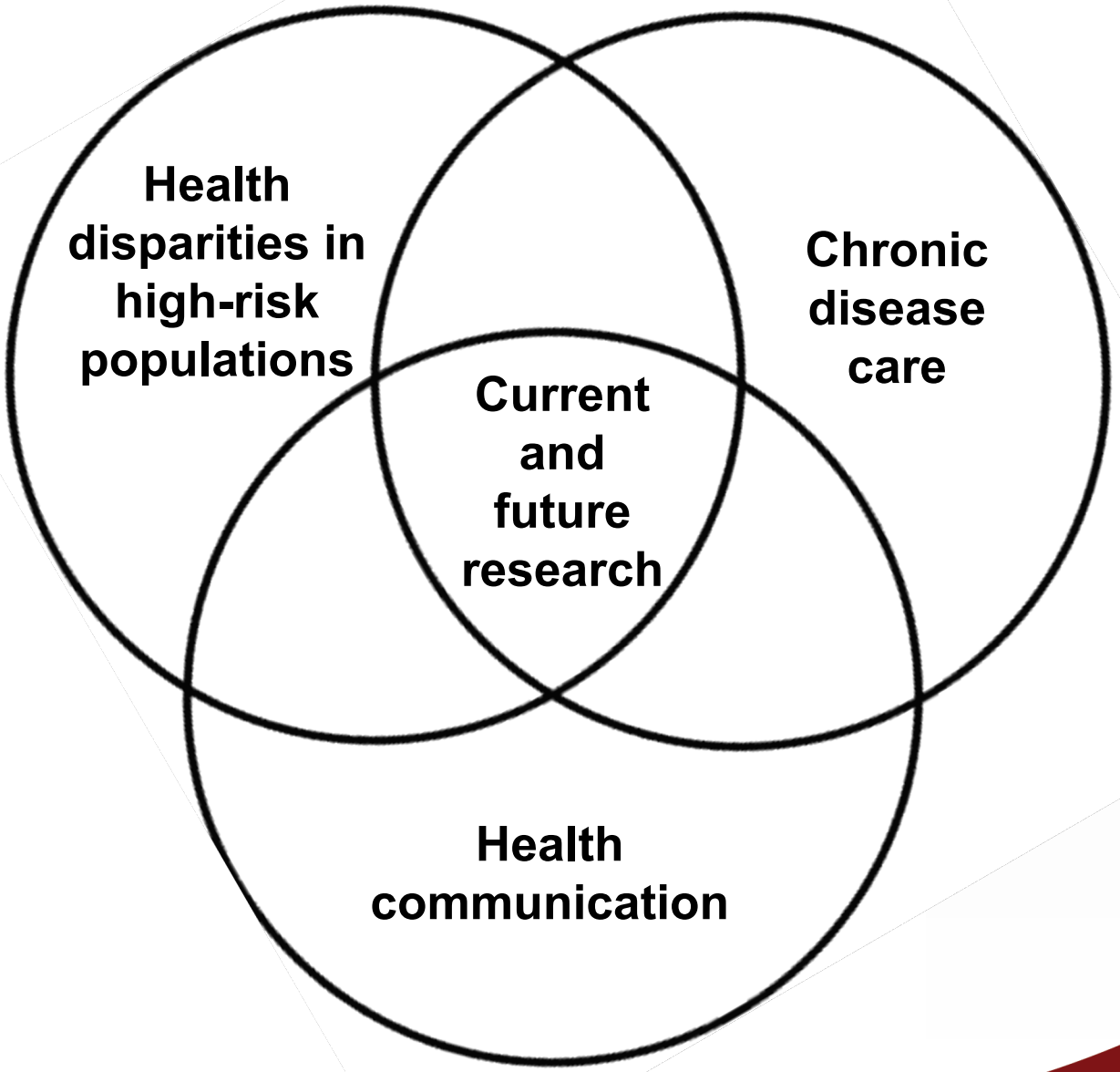

**Across translational stages, patients from ethnically diverse populations may experience greater risk for experiencing health disparities.**

Adapted from Khoury et al *Genetics in Medicine* 2007

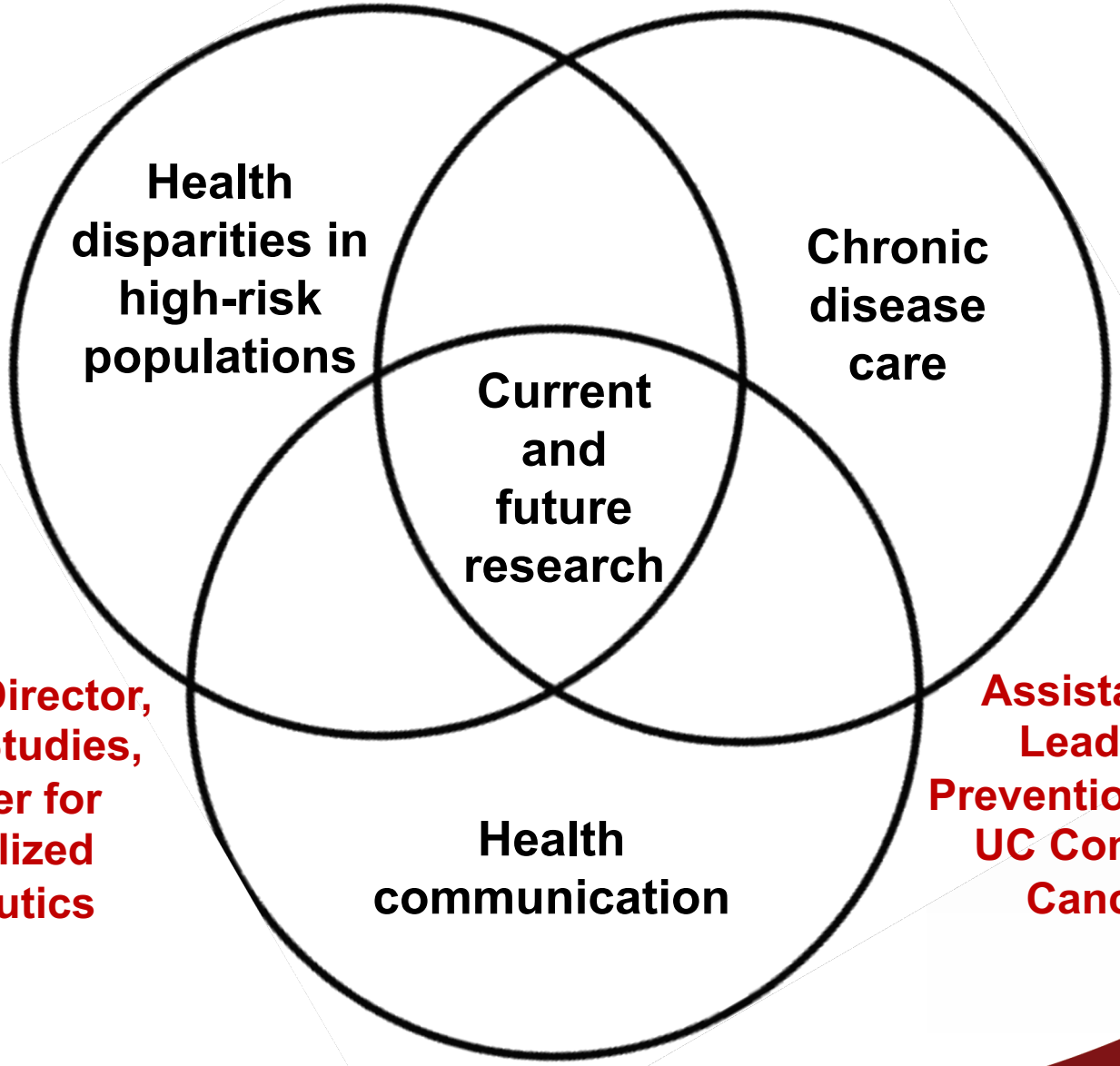
A systematic review of the literature found a documented shortage of evaluations on the impact of pharmacogenomics on health disparities.

Martin et al *Pharmacogenomics* 2017

# Health Policy and Health Services Research



# Health Policy and Health Services Research




**Assistant Director, Diversity Studies, UC Center for Personalized Therapeutics**

**Assistant Program Leader, Cancer Prevention and Control, UC Comprehensive Cancer Center**

# Translation of pharmacogenomics (PGx) to underserved and underrepresented patient populations at risk for experiencing health disparities

1) Patient experience with PGx

2) PGx implementation outcomes in minority patient populations

3) PGx and social vulnerability (i.e. social determinants of health)

1) Patient experience with PGx

# Underrepresented patient views and perceptions of personalized medication treatment through pharmacogenomics

Saulsberry et al. *NPJ Genom Med* 2021

# Study Objectives

1) Evaluate the reported views and perceptions of care received among genotyped African-American, or Black, and White patients participating in a large institutional pharmacogenomic implementation program.

2) Include education as a key covariate because it reflects the availability of resources (e.g. income and health insurance), the ability to process various types of information, and multiple socioeconomic indicators including social and cultural factors

***We particularly focused on self-reported race to define the populations in our study as self-identified race is used to direct pharmacogenomic clinical guidelines as well as clinical decision-making more generally in healthcare settings

# Hypothesis

We hypothesized that patients' attitudes and perceptions about pharmacogenomics with respect to their medical care would significantly differ based on self-reported race.

# Data and Study Setting

- 1200 Patients Project (UChicago Center for Personalized Therapeutics)
- Patient surveys completed following outpatient clinical visits
- Surveys provided self-reported demographic information along with patient views/perceptions of care during their most recent health encounter

# Methods and Analysis

- Comparison of survey measures between self-reported Black and White study participants
- Multiple surveys collected over time for a single individual
- Statistical analysis involved chi-square tests of independence with the level of statistical significance set at $P<0.05$ without adjustment for multiple comparisons

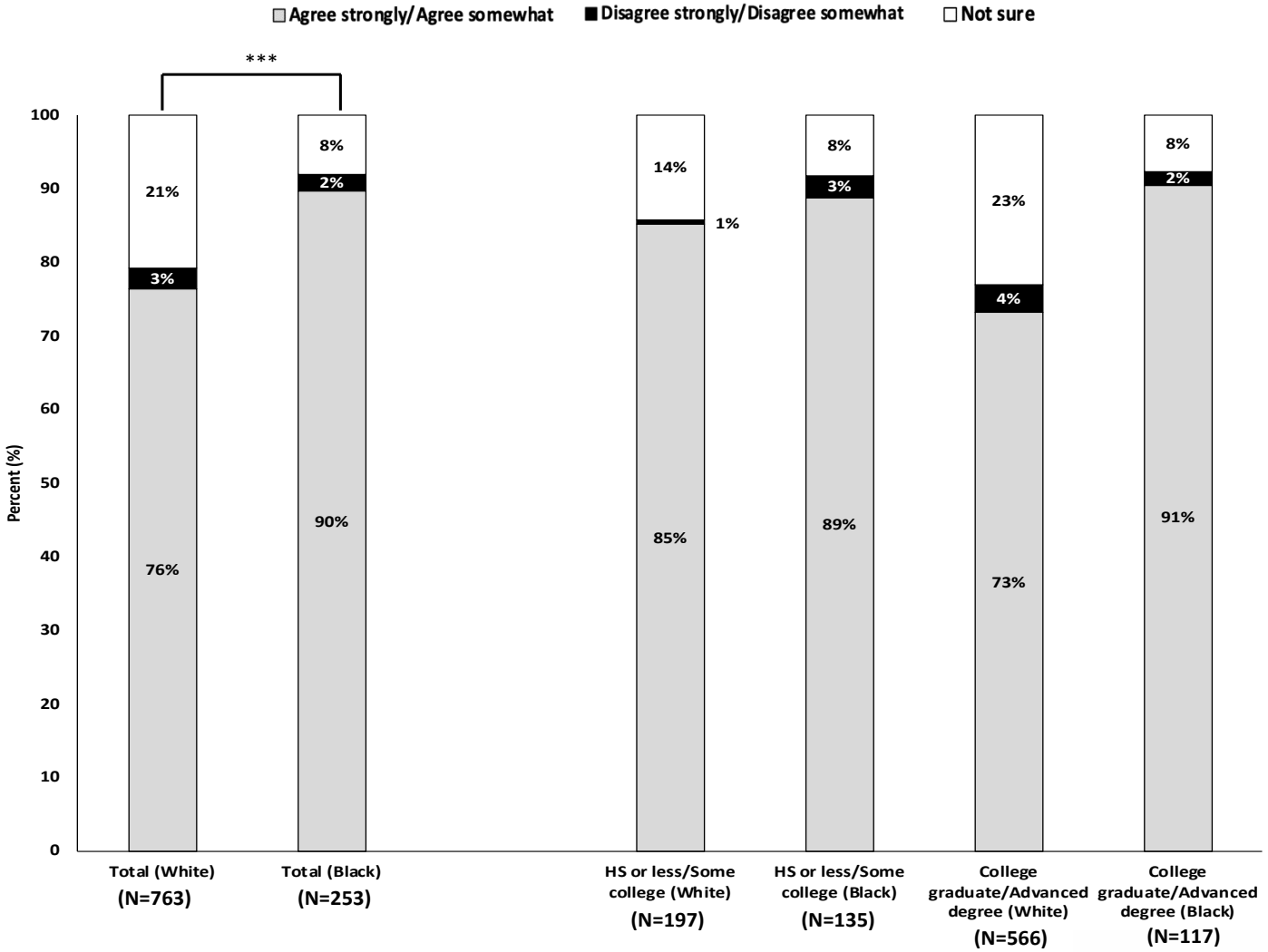
# Study Population

| | Race | | | | | | |
|---|---|---|---|---|---|---|---|
| | White | | | Black | | | |
| **Educational attainment** | **Total[a]** | **HS or less/ Some college** | **College graduate/ Advanced degree** | **Total[b]** | **HS or less/ Some college** | **College graduate/ Advanced degree** | **p-value[†]** |
| Total survey respondents [N(%)] | 332(72) | 86(26) | 246(74) | 131(28) | 74(56) | 56(43) | |
| Gender [N(%)] | | | | | | | |
| Female | 138(42) | 44(51) | 94(38) | 94(72) | 51(69) | 43(77) | <0.0001*** |
| Age [N(%)] | | | | | | | |
| Mean (range) | 60(19-90) | 63(19-90) | 59(20-87) | 61(19-95) | 61(19-89) | 61(26-89) | |
| 18-25 years | 8(2) | 2(2) | 6(2) | 1(1) | 1(1) | -- | |
| 26-39 years | 26(8) | 3(3) | 23(9) | 9(7) | 6(8) | 3(5) | |
| 40-50 years | 33(10) | 5(6) | 28(11) | 21(16) | 10(14) | 11(20) | 0.306 |
| 51-64 years | 122(37) | 33(38) | 89(36) | 43(33) | 22(30) | 21(38) | |
| 65+ years | 143(43) | 43(50) | 100(41) | 57(44) | 35(47) | 21(38) | |
| Total surveys returned evaluating clinical visits (after enrollment) [N(%)] | 790(75) | 207(26) | 583(74) | 265(25) | 145(55) | 119(45) | |
| Surveys returned per patient (after enrollment) [N(%)] | | | | | | | |
| Mean (range) * | 2(1-16) | 2(1-16) | 2(1-14) | 2(1-7) | 2(1-7) | 2(1-6) | |
| 1 | 149(45) | 40(47) | 109(44) | 66(50) | 41(55) | 24(43) | |
| 2 | 73(22) | 17(20) | 56(23) | 30(23) | 15(20) | 15(27) | 0.512 |
| 3-4 | 75(23) | 18(21) | 57(23) | 26(20) | 12(16) | 14(25) | |
| 5+ | 35(11) | 11(13) | 24(10) | 9(7) | 6(8) | 3(5) | |
| Self-reported health [N(%)][‡] | | | | | | | |
| Excellent/Very good | 479(61) | 101(50) | 378(65) | 105(40) | 42(30) | 63(53) * | |
| Good | 235(30) | 73(36) | 162(28) | 108(41) | 63(44) | 45(38) | <0.0001*** |
| Fair/Poor | 68(9) | 30(15) | 38(7) | 48(18) | 37(26) | 10(8) | |
| N= | 782 | 204 | 578 | 261 | 142 | 118 | |

*$P \leq .05$. **$P \leq .01$. ***$P \leq .001$.

***Receptivity to a greater role for personalized prescribing may be more broadly distributed across the Black patient population as Black respondents across education levels indicated similarly high levels of this desire.***

*I think knowledge of my personal genetic information should have a greater role in my healthcare provider's treatment decisions about me*




*$P \leq .05$. **$P \leq .01$. ***$P \leq .001$.

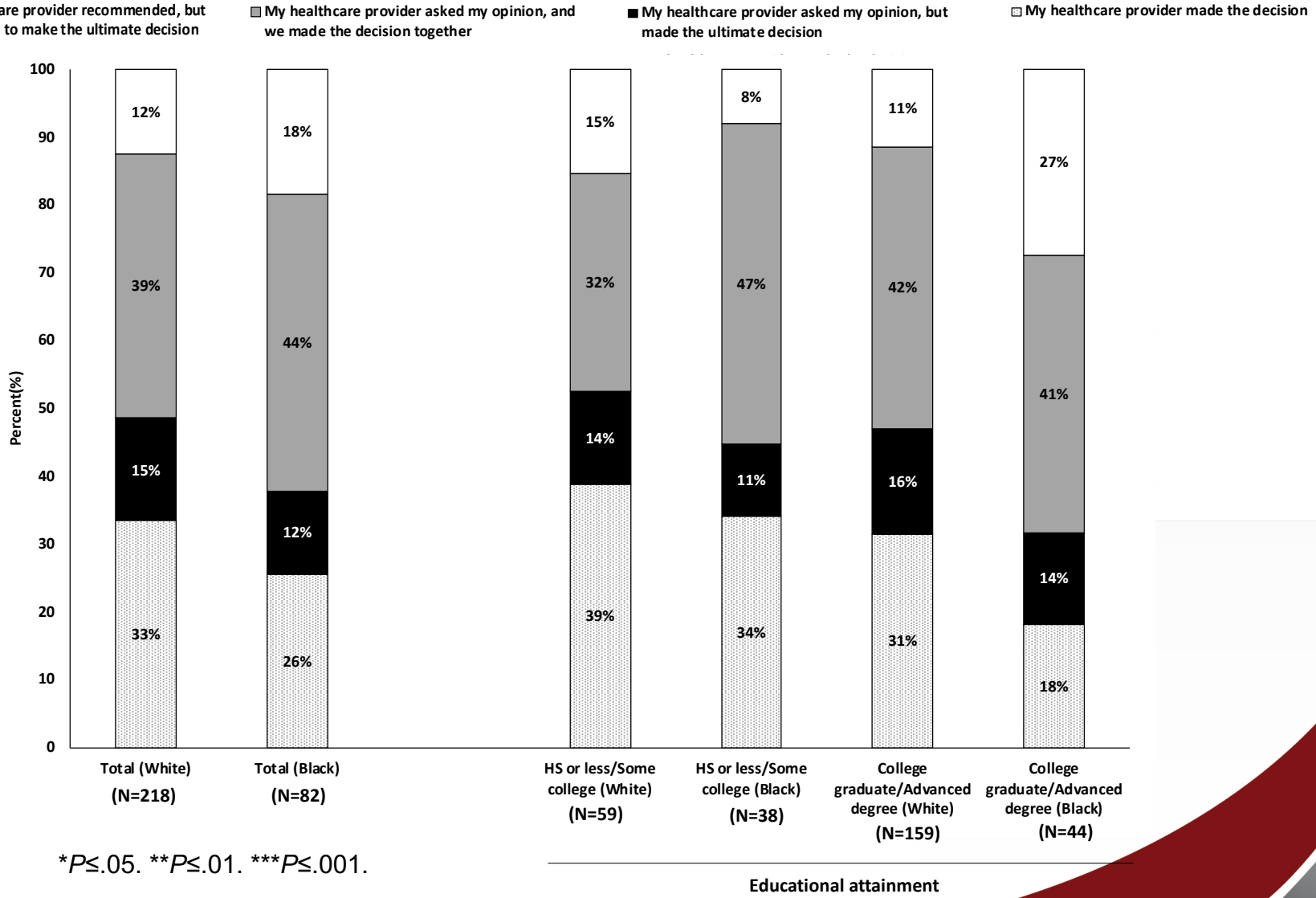
## *Black patients reported initiating discussions about the impact of personal make-up (genetics) on medication response with their provider far less frequently than White patients.*

| | Race | | | | | | |
|---|---|---|---|---|---|---|---|
| | White | | | Black | | | |
| Survey measure/question | Total[a] N(%) | HS or less/ Some college N(%) | College graduate/ Advanced degree N(%) | Total[b] N(%) | HS or less/ Some college N(%) | College graduate/ Advanced degree N(%) | p-value[†] |
| *Did your healthcare provider stop or change one of your medications today, or start a new medication?* | | | | | | | |
| Yes | 237(31) | 61(31) | 176(31) | 87(33) | 41(28) | 46(40) | |
| No | 532(69) | 136(69) | 396(69) | 170(65) | 101(70) | 68(59) | 0.273 |
| Unsure | 5(1) | 1(1) | 4(1) | 4(2) | 2(1) | 2(2) | |
| N= | 774 | 198 | 576 | 261 | 144 | 116 | |
| ***If yes to did your healthcare provider stop or change one of your medications today, or start a new medication…*** | | | | | | | |
| *Did your healthcare provider discuss specific factors about you or your personal make-up which would suggest that you were more likely or less likely than other patients to benefit from the medication change or new medication?* | | | | | | | |
| Yes | 128(59) | 43(75) | 85(53) | 43(49) | 18(46) | 25(52) | |
| No | 77(35) | 12(21) | 65(41) | 29(33) | 12(31) | 17(35) | 0.005** |
| Unsure | 12(6) | 2(4) | 10(6) | 15(17) | 9(23) | 6(13) | |
| N= | 217 | 57 | 160 | 87 | 39 | 48 | |
| *If yes, who initiated the discussion about individual factors regarding you and your response to the medication change or new medication?* | | | | | | | |
| I was the one who asked about individual factors | 20(15) | 7(16) | 13(15) | 2(4) | 0(0) | 2(7) | |
| My healthcare provider was the one who brought up individual factors | 88(67) | 34(76) | 54(63) | 42(86) | 18(86) | 24(86) | 0.037* |
| Unsure | 23(18) | 4(9) | 19(22) | 5(10) | 3(14) | 2(7) | |
| N= | 131 | 45 | 86 | 49 | 21 | 28 | |

*$P \leq .05$. **$P \leq .01$. ***$P \leq .001$.

***More than half of Black and White patients reported being asked their opinion about medication changes during clinical visits, with at least 40% of each patient group reporting being asked their opinion and making the decision together with their provider.***

*Regarding the medication change or new medication discussed, please choose one of the following:*




*$P \leq .05$. **$P \leq .01$. ***$P \leq .001$.

# Conclusions

- Our results suggest an opportunity for enhanced patient-provider communication, especially for self-reported Black patients, around the role of genetic results during prescribing.

- Given the significance of patient-provider communication in influencing patient behaviors and outcomes, tailored communication strategies may need to be developed and employed which address Black patients' perceptions of receiving personalized treatments and help with the interpretation of pharmacogenomic information by providers for minorities and less educated patients.

# Health Equity and Risk Communication in Pharmacogenomics

NIH NHGRI K08 Career Development Award

**Aim 1: Where might health disparities arise as the use of pharmacogenomics becomes more widespread within the U.S. health system?**

Publicly available nationally representative dataset of prescription drug use

**Aim 2: What are the views, values, and preferences of minority populations and their providers in relation to pharmacogenomics?**

Qualitative interviews

**Aim 3: How might communication about PGx impact minority patient views and care preferences?**

Survey experiment with hypothetical clinical vignettes

**Aim 3: How might communication about PGx impact minority patient views and care preferences?**

Survey experiment with hypothetical clinical vignettes (*Health Expect* 2015; *JGIM* 2017)

Exposure to a hypothetical clinical vignettes (Pharmacogenomic risk for adverse drug response)

Responses to measures within a survey instrument

# 2) PGx implementation outcomes in minority patient populations

# Applicability of Pharmacogenomically Guided Medication Treatment during Hospitalization of At-Risk Minority Patients

Saulsberry et al. *J Pers Med*. 2021

# Study Objectives

1) Conduct a multi-site inpatient pharmacogenomic implementation program among self-identified African-Americans (AA; *n* = 135) with numerous rehospitalizations (*n* = 341) from 2017 to 2020.

2) Evaluate the point-of-care availability of patient pharmacogenomic results to healthcare providers via an electronic clinical decision support tool.

# Hypothesis

We hypothesized that evidence-based pharmacogenomic information would be particularly relevant to the medications used in this setting for hospitalized African American patients.

# Data and Study Setting

- ACCOuNT (African American Cardiovascular Pharmacogenomics Consortium) Translational Project evaluated the clinical translation of pharmacogenomics to minority patients historically excluded from genomic studies.

- The University of Chicago, the University of Illinois Chicago, and Northwestern University.

# ACCOuNT Consortium (Translational Project)

Impact on genetic biomarkers on:

- Drug selection
- Dosing
- Clinical outcomes

# The University of Chicago

Pre-emptive genotyping of enrolled patients.

Genomic Prescribing System (GPS)- decision support by translating patients' genotypic results into individualized PGx summaries.

Patient PGx information is available and delivered to healthcare providers at the point of the patient encounter to guide prescribing decisions.

# Hospitalizations

Medication prescribing frequently occurs during hospitalizations.

With a higher disease burden, AA are a high-risk population with frequent hospitalizations:

Several studies have examined patterns of hospitalization due to ambulatory care-sensitive conditions by race/ethnicity, generally finding higher rates of hospitalization for blacks compared to whites

(Decker et al. 2009; Chang et al. 2008; Howard et al. 2007; Laditka 2003; Oster and Bindman 2003; Pappas et al. 1997; Parket and Schoendorf et al. 2000; Shi et al. 1999 )

Acute care setting vs. Routine care settings

- Alongside multiple studies, the lab has demonstrated the critical relevance of PGx-guided prescribing for patients enrolled to study through outpatient clinics who were subsequently hospitalized (Lee et al 2019 *Pharmacogenetics and Genomics*).

AA: African-American

# Methods and Analysis

- Patients who were hospitalized at any of these 3 institutions were approached for enrollment and collection of a blood sample for broad pharmacogenomic genotyping.

- Then, results were made available for subsequent hospitalizations to enrolled treating providers (physicians, advance practice providers, and pharmacists) via an electronic decision support tool, and prescribing during the hospitalization and at discharge were evaluated.

- Statistical analysis involved chi-square tests of independence with the level of statistical significance set at $P<0.05$ without adjustment for multiple comparisons

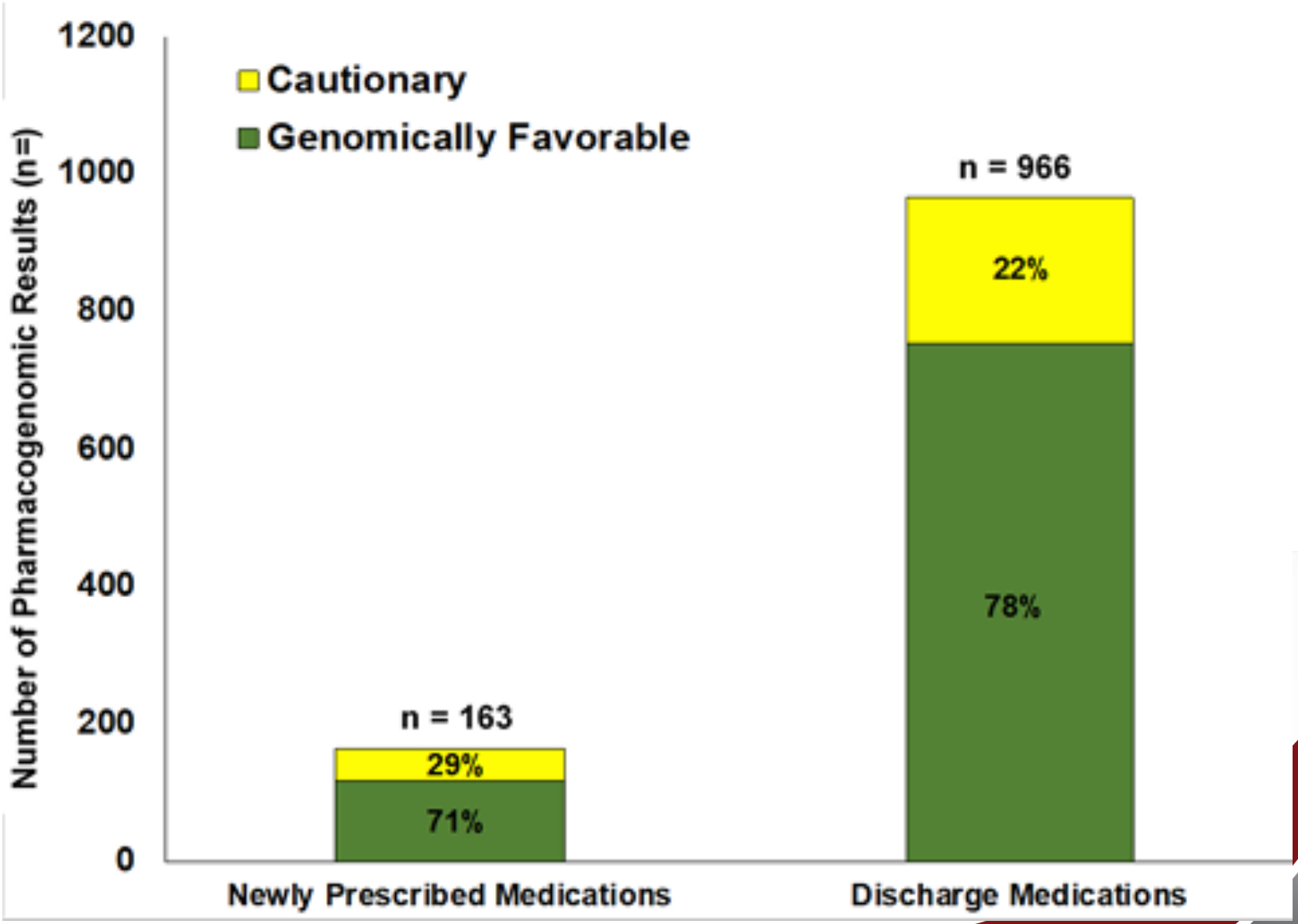
# Patient Study Population

- The population was predominantly female (61%) with a mean age of 53 years (range 19-86).
- The majority of the population (80%) had an educational attainment of HS or less/some college.
- Mean number of comorbidities reported was 7 (range of 1-19).
- Mean number of prescription drugs was 12 (range of 1-28)
- On average, six medications were newly prescribed during each individual hospital admission.

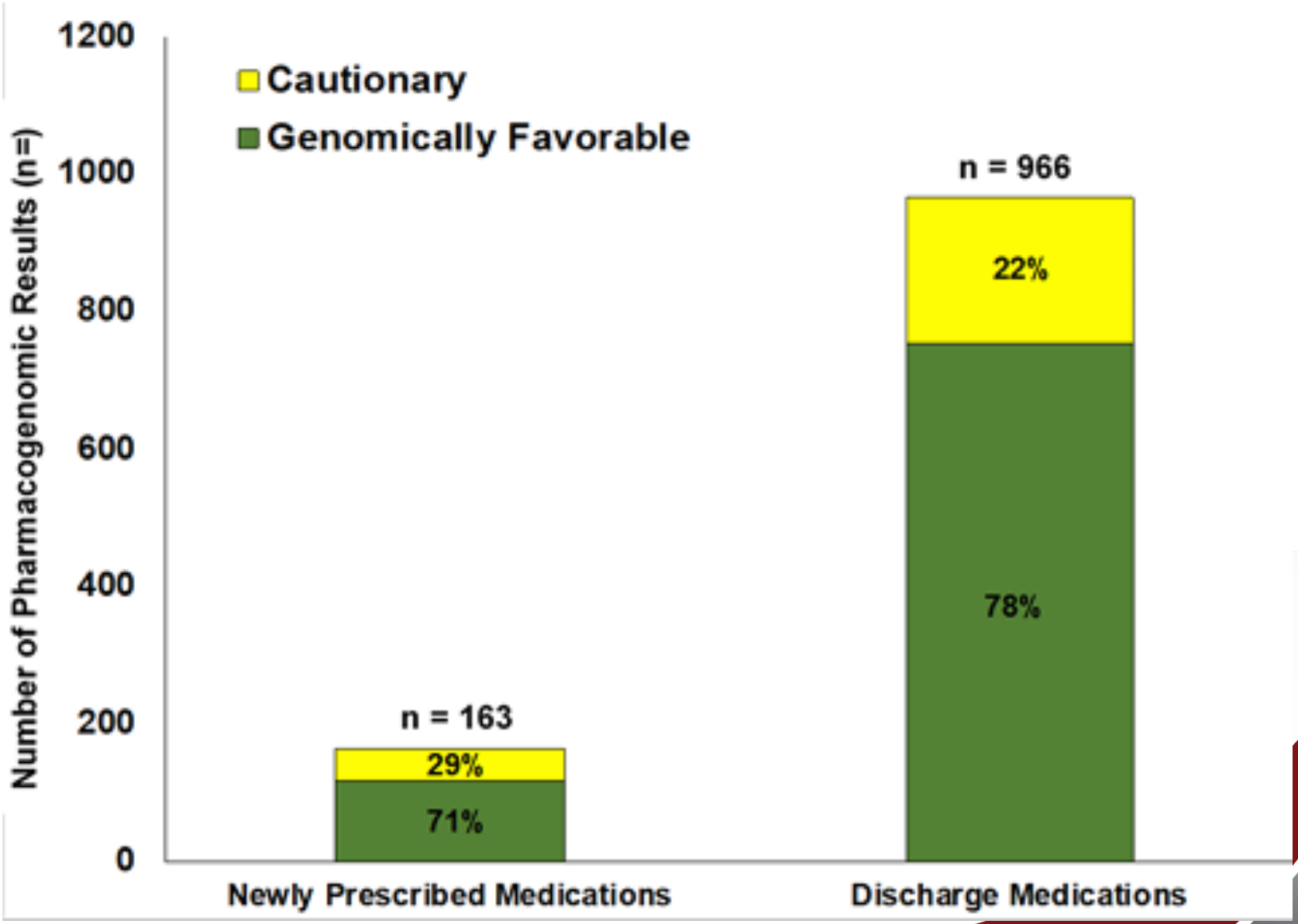
# ACCOuNT Study Population: Providers

| | Number of Providers (n=261) |
|---|---|
| **Characteristic** | |
| **Provider Type** | **n (%)** |
| MD (Hospitalist Physician + Primary Care) | 158 (61) |
| PA | 14 (5) |
| APN | 16 (6) |
| PharmD (Hospitalist Pharmacist + PP_Pharmacist) | 73 (28) |
| **Years in practice (mean ± SD)** | 8 ± 7 |
| **Institution (all providers)** | **n (%)** |
| UChicago | 128 (49) |
| Northwestern | 89 (34) |
| UIC | 44 (17) |

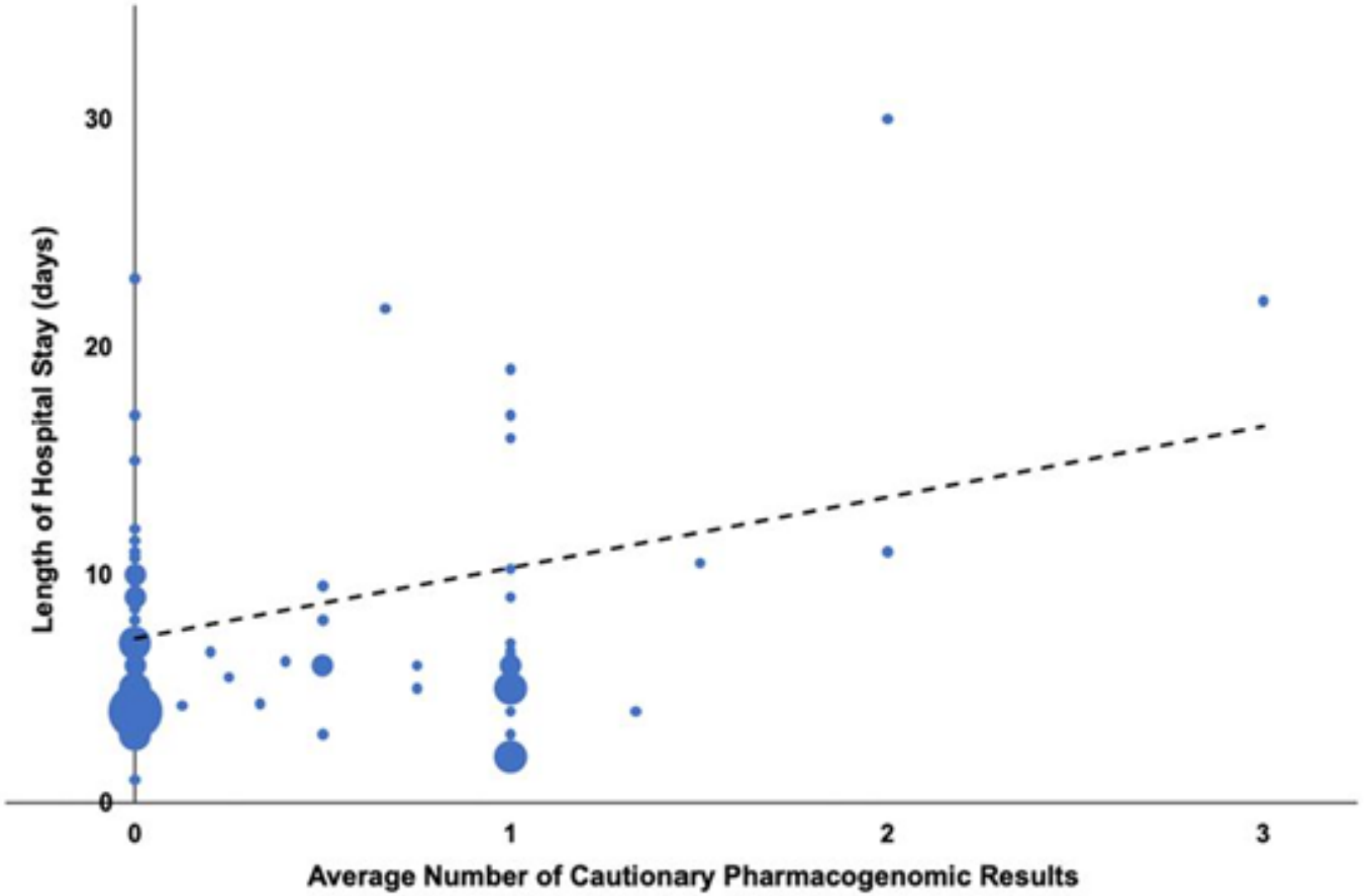
***Most results indicated genomic favorability, although nearly 29% of newly prescribed medications indicated increased genomic caution (increase in toxicity risk/suboptimal response).***



***More than one of every five medications prescribed to AA patients at hospital discharge were associated with cautionary pharmacogenomic results.***



***Positive relationship between the per-patient average number of cautionary pharmacogenomic results associated with newly prescribed medications during hospitalizations and length of hospital stay.***



# Conclusions

- Our results indicated that high-risk pharmacogenomic results (genomic contraindication) were exceedingly rare in our hospitalized AA study population.

- We conclude that the applicability of pharmacogenomic information during hospitalizations for vulnerable populations at-risk for experiencing health disparities is substantial and warrants continued prospective investigation.

# 3) PGx and social vulnerability (i.e. social determinants of health)

# Effect Modification by Social Determinants of Pharmacogenetic Medication Interactions on 90-Day Hospital Readmissions within an Integrated U.S. Healthcare System

Saulsberry et al. *J Pers Med*. 2022

# Study Objective

Investigate the association between pharmacogenetic interactions and 90-day readmission in a diverse study population.

# Hypothesis

We hypothesized that social determinants were important contributors to readmission and that there would be effect modification of the gene-x-drug interactions on risk of 90-day readmission, particularly by medical complexity.

# Data and Study Setting

- Evaluated 90-day hospital readmission (primary outcome) for 19,999 adults from 2010 through 2020 who underwent testing with a 13-gene pharmacogenetic panel.

- For genes with evidence of variation in drug response, genetic indicators (genotype-based phenotypes) were collected and annotated for:
  *CYP2B6*, *CYP2C19*, *CYP2C9*, *CYP2D6*, *CYP3A5*, *CYP4F2*, *DPYD*, *IFNL3*, *NUDT15*, *SLCO1B1, TPMT, UGT1A1, VKORC1*.

- The NorthShore University HealthSystem

# Methods and Analysis

Univariate logistic regression analyses demonstrated that strongest associations with 90-day hospital readmissions were the number of medications prescribed within 30 days of a first hospital admission that had Clinical Pharmacogenomics Implementation Consortium (CPIC) guidance.

# Study Population

**Table 1.** Overall Study Population Sociodemographic and Clinical Characteristics ($n$ = 19,999).

| $n$ (%) √ | Inpatient Admissions 2010–2020 [a] | | | | 90-Day Hospital Readmission [b] | | |
|---|---|---|---|---|---|---|---|
| | | | | | $n$ = 4740 | | |
| | Overall 19,999 (100) | No 15,259 (76) | Yes 4740 (24) | | No 4120 (87) | Yes 620 (13) | |
| **Age, median (IQR)** | 53 (42–64) | 53 (42–63) | 54 (41–68) | * | 52 (41–67) | 62 (46–72) | * |
| **Age group (years)** | | | | | | | |
| 18–39 | 4097 (20.5) | 3128 (76.3) | 969 (23.7) | | 877 (90.5) | 92 (9.5) | |
| 40–49 | 4275 (21.4) | 3208 (75) | 1067 (25) | | 976 (91.5) | 91 (8.5) | |
| 50–64 | 6849 (34.2) | 5679 (82.9) | 1170 (17.1) | | 1011 (86.4) | 159 (13.6) | |
| 65 or above | 4778 (23.9) | 3244 (67.9) | 1534 (32.1) | | 1256 (81.9) | 278 (18.1) | |
| **Gender** | | | | * | | | * |
| Female | 12,852 (64.3) | 9324 (72.5) | 3528 (27.5) | | 3106 (88) | 422 (12) | |
| Male | 7147 (35.7) | 5935 (83) | 1212 (17) | | 1014 (83.7) | 198 (16.3) | |
| **Race** | | | | * | | | * |
| White | 13,961 (69.9) | 10,292 (73.7) | 3669 (26.3) | | 3172 (86.5) | 497 (13.5) | |
| Black/African American | 612 (3.1) | 437 (71.4) | 175 (28.6) | | 131 (74.9) | 44 (25.1) | |
| Asian | 1293 (6.5) | 1020 (78.9) | 273 (21.1) | | 254 (93) | 19 (7) | |
| American Indian/Alaska Native | 37 (0.2) | 28 (75.7) | 9 (24.3) | | 8 (88.9) | 1 (11.1) | |
| Pacific Islander/Hawaiian Native | 18 (0.1) | 16 (88.9) | 2 (11.1) | | 2 (100) | 0 (0) | |
| Other | 3751 (18.8) | 3157 (84.2) | 594 (15.8) | | 537 (90.4) | 57 (9.6) | |

***Health insurance was not associated with risk of 90-day readmission.***

**Table 4.** Unadjusted and Adjusted Logistic Regression Analysis of 90-day Hospital Readmissions Among Patients Prescribed a CPIC Medication Within 30 days of Inpatient Admission ($n = 4404$).

| | uOR (95% CI) | *p*-Value | aOR (95% CI) | *p*-Value |
|---|---|---|---|---|
| **Age Group** | | | | |
| 18–39 | *Reference* | | *Reference* | |
| 40–49 | 1.05 (0.75–1.47) | 0.001 | 1.04 (0.74–1.47) | 0.529 |
| 50–64 | 1.73 (1.27–2.35) | 0.026 | 1.28 (0.93–1.78) | 0.104 |
| 65 or above | 2.35 (1.77–3.12) | <0.0001 | 1.14 (0.80–1.65) | 0.783 |
| **Gender** | | | | |
| Female | *Reference* | | *Reference* | |
| Male | 1.47 (1.21–1.80) | 0.0001 | 1.11 (0.89–1.38) | 0.371 |
| **Race *** | | | | |
| White | *Reference* | | *Reference* | |
| Black/African American | 2.12 (1.47–3.07) | <0.0001 | 2.12 (1.42–3.17) | <0.0001 |
| Asian | 0.43 (0.26–0.70) | <0.0001 | 0.62 (0.37–1.03) | 0.002 |
| **Ethnicity** | | | | |
| Non-Hispanic | *Reference* | | | |
| Hispanic/Latino | 1.10 (0.54–2.26) | 0.975 | | |
| **Marital status** | | | | |
| Unmarried | *Reference* | | - | - |
| Married | 0.60 (0.49–0.72) | 0.441 | | |
| **Employment status **** | | | | |
| Employed | *Reference* | | *Reference* | |
| Unemployed | 2.19 (1.82–2.64) | <0.0001 | 1.74 (1.39–2.18) | 0.007 |
| **Insurance status** | | | | |
| Commercial | *Reference* | | *Reference* | |
| Government | 1.81 (1.50–2.20) | 0.307 | 1.04 (0.81–1.34) | 0.6605 |
| Out-of-pocket (self-pay) | 1.67 (0.47–5.90) | 0.736 | 1.48 (0.41–5.32) | 0.5742 |

***The odds of 90-day readmission for patients with one or more identified gene-x-drug interactions after adjustment for these covariates was attenuated by 10%***

**Table 4.** Unadjusted and Adjusted Logistic Regression Analysis of 90-day Hospital Readmissions Among Patients Prescribed a CPIC Medication Within 30 days of Inpatient Admission ($n = 4404$).

| | uOR (95% CI) | *p*-Value | aOR (95% CI) | *p*-Value |
|---|---|---|---|---|
| **Median household income in relation to US median household income ***** | | | | |
| Less than $64,994 | *Reference* | | *Reference* | |
| $64,994 or more | 1.33 (0.86–2.05) | 0.203 | 1.63 (1.03–2.58) | 0.035 |
| **BMI, range 13.3–79.2** | 1.03 (1.02–1.04) | <0.0001 | 1.01 (1.00–1.03) | 0.050 |
| **Smoking status** | | | | |
| No | *Reference* | | *Reference* | |
| Yes | 1.38 (0.87–2.18) | 0.176 | 1.26 (0.78–2.04) | 0.347 |
| **COVID status** | | | | |
| Yes vs. No | 0.56 (0.17–1.84) | 0.341 | | |
| **Number of comorbidities ****** | | | | |
| 0 | *Reference* | | *Reference* | |
| 1 | 1.57 (1.24–1.98) | 0.018 | 1.28 (0.99–1.64) | 0.044 |
| 2 | 2.54 (1.91–3.39) | 0.006 | 1.83 (1.33–2.52) | 0.070 |
| 3 or more | 3.36 (2.61–4.32) | <0.0001 | 2.23 (1.66–3.02) | <0.0001 |
| **Number of CPIC medications prescribed within 30 days prior to inpatient admission** | | | | |
| 1 | *Reference* | | | |
| 2 | 1.14 (0.82–1.58) | <0.0001 | - | - |
| 3 | 2.50 (1.77–3.53) | 0.417 | - | - |
| 4 | 3.07 (2.13–4.41) | 0.008 | - | - |
| 5 or more | 7.66 (5.45–10.77) | <0.0001 | - | - |
| **Gene-x-drug interactions within 30 days prior to inpatient admission** | | | | |
| Absent | *Reference* | | *Reference* | |
| Present | 1.41 (1.18–1.70) | 0.0002 | 1.31 (1.08–1.59) | 0.006 |

# Conclusions

Our results highlight the major contribution of social determinants and medical complexity to risk for hospital readmission, and that these determinants may modify the effect of gene-x-drug interactions on rehospitalization risk.

# Future Research

HSR Health Services Research

RESEARCH ARTICLE | Open Access

## The social vulnerability metric (SVM) as a new tool for public health

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# Future Research (continued)

**Improve health outcomes for underserved and underrepresented populations through precision prescribing**

- Tailoring PGx implementation across clinical settings and therapeutic areas
- Evolve PGx clinical decision support tools at the point-of-care to best support targeted care delivery (e.g. patient-provider communication on PGx results and prescribing decisions)
- Aligning PGx care to patient preferences

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