"Indiana Genomics Implementation Opportunity for the Underserved"

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Indiana Genomics Implementation Opportunity for the UnderServed

Acronym: InGenIOUS funded by NHGRI-IGNITE

Testing the effect of pharmacogenetics genotyping on health care costs and adverse events.

Endpoints:

- Total health care costs
- Adverse events

Eskenazi & IU Health patients randomized to

- >1,312 genotype guided therapy
- >3,145 standard of care

Why target genomic medicine to underserved populations?

Routine monitoring of drug response can be more difficult for underserved patients:

- Access to monitoring may be further away for MUA's
- Days off work may mean less pay
- Transportation costs may be more significant

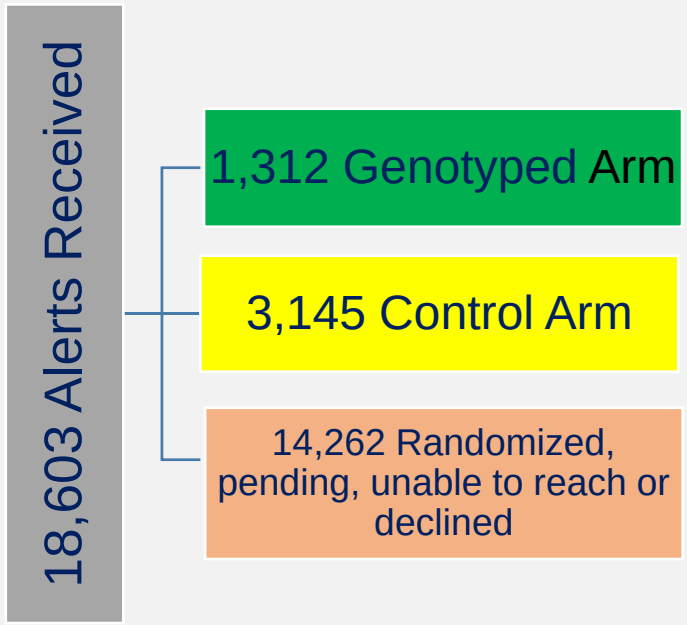
Thus, patients may not return for routine monitoring of efficacy & toxicity

Genomic testing that helps get the right drug at the right dose the first time may help

INGENIOUS Enrollment

Recruiting from 192+ clinical sites utilizing in-person and on-line methods collecting blood or saliva for genotyping

Enrollment 4/1/2015 to 4/10/2018



Eskenazi Health System
(4/1/2015 to present)

- 1 Hospital location
- 70+ in and outpatient sites
- Phone recruitment
- In-person enrollment

Indiana University Health System
(2/1/2017 to Present)

- 14 of 16 Hospital locations
- 122 outpatient clinics
- Phone recruitment
- On-line enrollment

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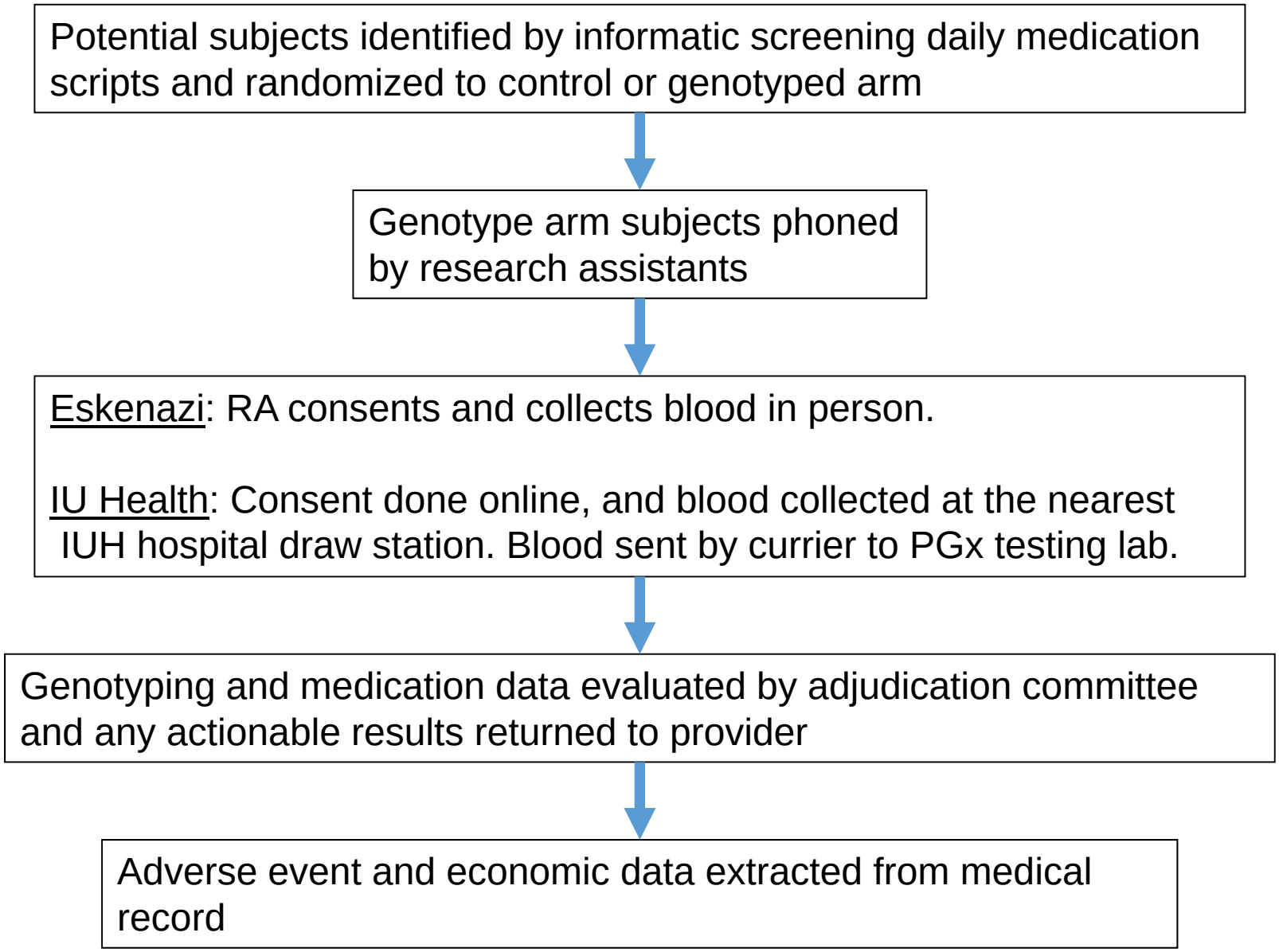
INGenious


Potential subjects identified by informatic screening daily medication scripts and randomized to control or genotyped arm
Genotype arm subjects phoned by research assistants
Eskenazi: RA consents and collects blood in person.
IU Health: Consent done online, and blood collected at the nearest IUH hospital draw station. Blood sent by currier to PGx testing lab.
Genotyping and medication data evaluated by adjudication committee and any actionable results returned to provider
Adverse event and economic data extracted from medical record

INGENIOUS Enrollment Analysis

- 1,313 subjects genotyped
- 33.1% of subjects genotyped had an actionable result
- Actionable genotype frequency varied significantly by medication
- All actionable genotypes reviewed by adjudication committee

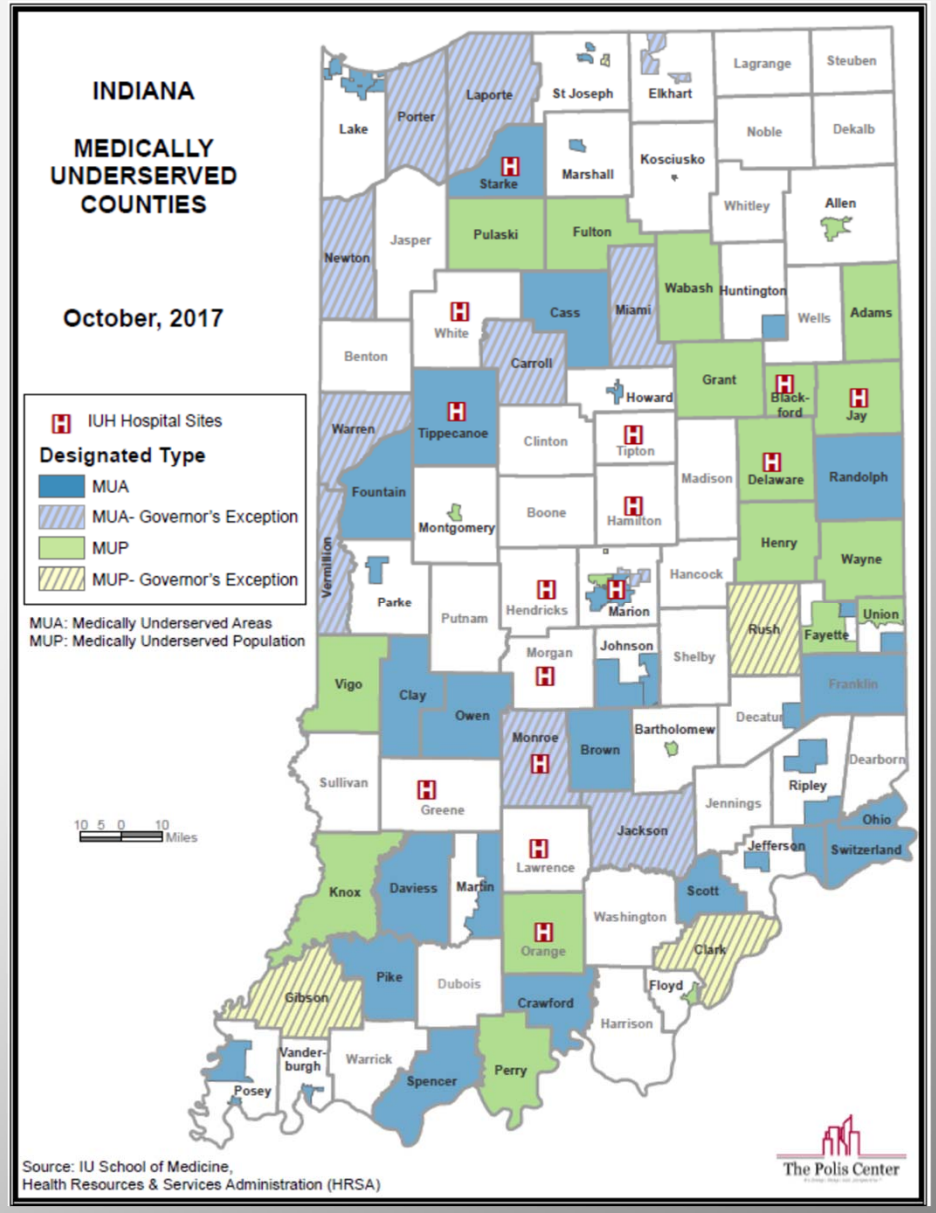
Drug	# subjects	Actionable
tramadol	233	99
Escitalopram	133	42
Amitriptyline	125	68
Codeine	107	15
Nortriptyline	88	8
Omeprazole	87	31
Pantoprazole	81	20
Clopidogrel	78	29
Citalopram	78	28
Venlafaxine	76	34
Aripiprazole	66	10
Warfarin	36	14
Esomeprazole	34	13
Simvastatin	22	7
Doxepin	14	7
Capecitabine	13	1
Atomoxetine	11	3

INGENIOUS Race Distribution

Race	Number
White	2743
Black or African American	1300
Unknown or not reported	341
More than one race	57
Asian	35
American Indian/Alaska native	10
Native Hawaii/Pacific Islander	9
Total	4495

Geographic distribution of Indiana MUA/P's

- 90-98% of patients in IU's EHR systems are ethnically/racially identified.
- > 83% are Geo-Coded so those in Medically underserved areas and populations (MUA/P's) can be identified.
- ~ 42% of IUH/Eskenazi patients reside in MUA/P's that are served by inpatient and outpatient facilities.



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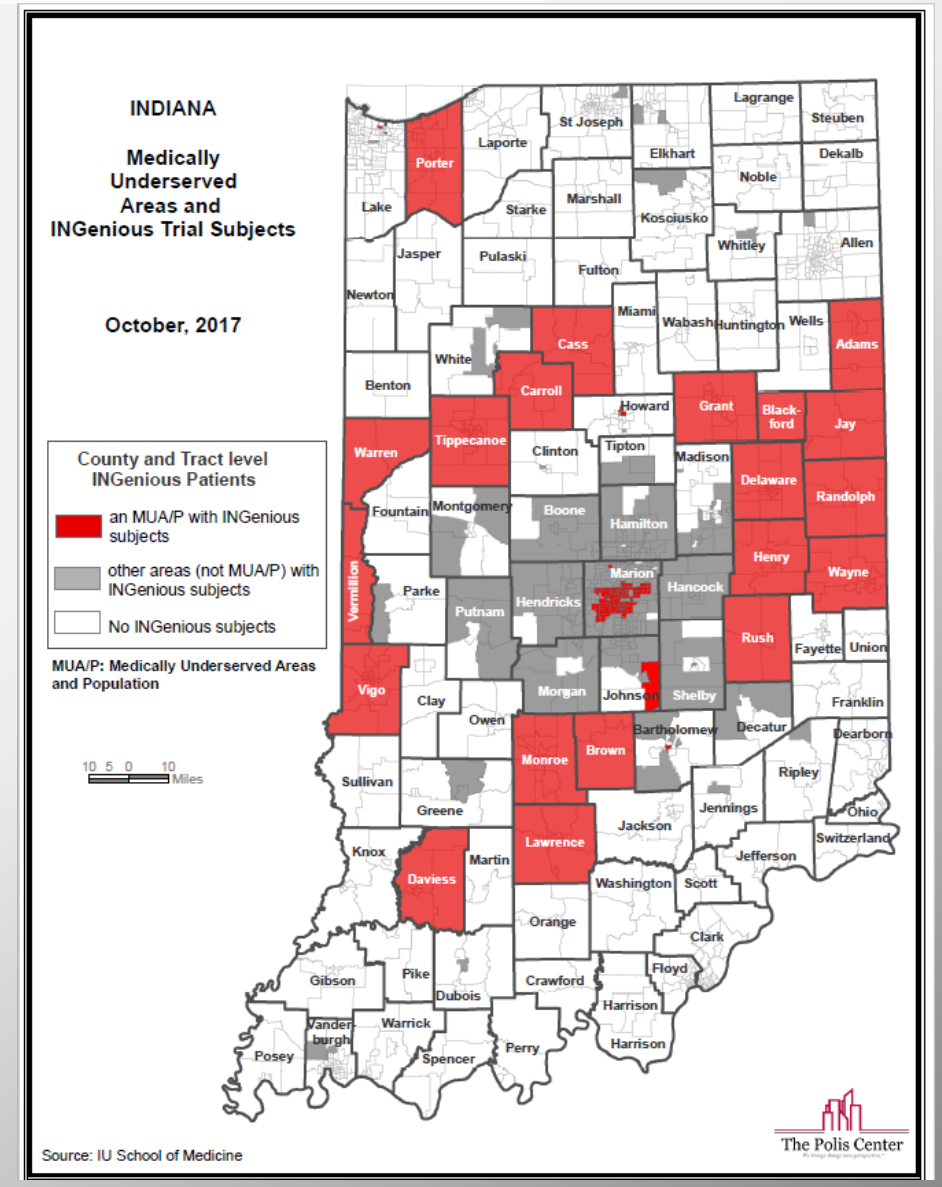
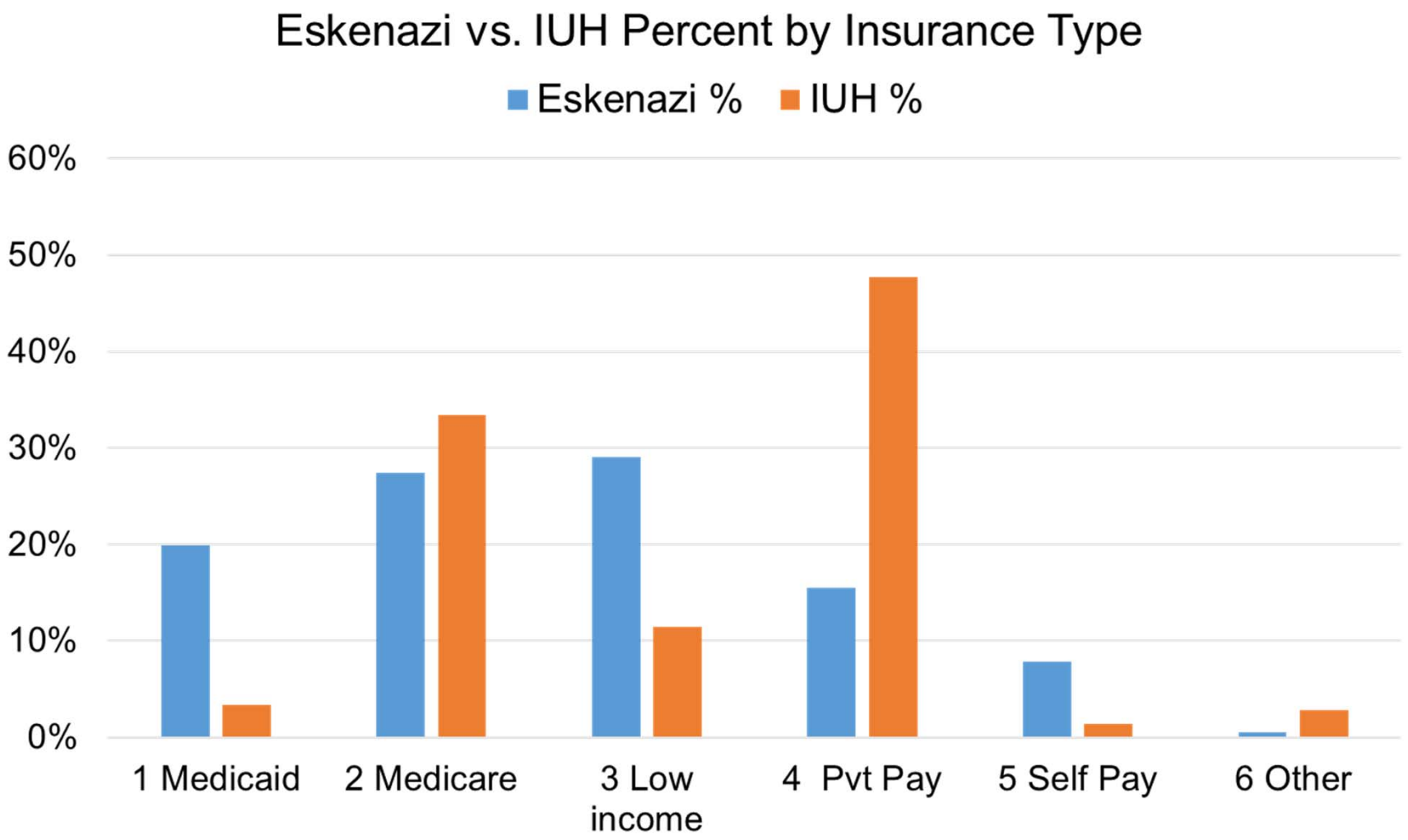
INGENIOUS patients in MUA/P's

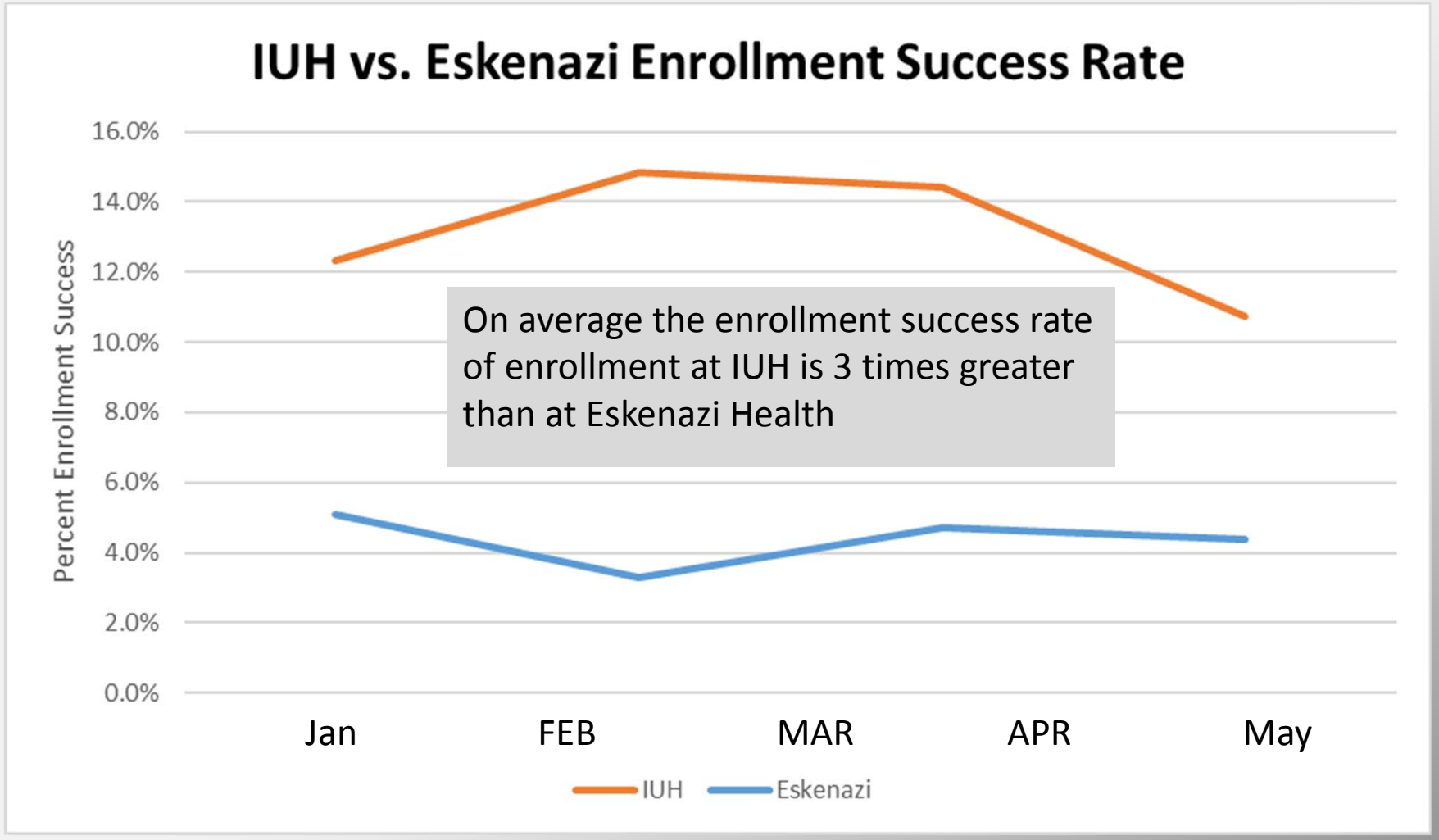
- Of the genotyped arm,
  - 37% are from MUA/P
  - 53% not from MUA/P
  - 10% unknown status



INGENIOUS Study

Control and Intervention Arms (through 8/2017)





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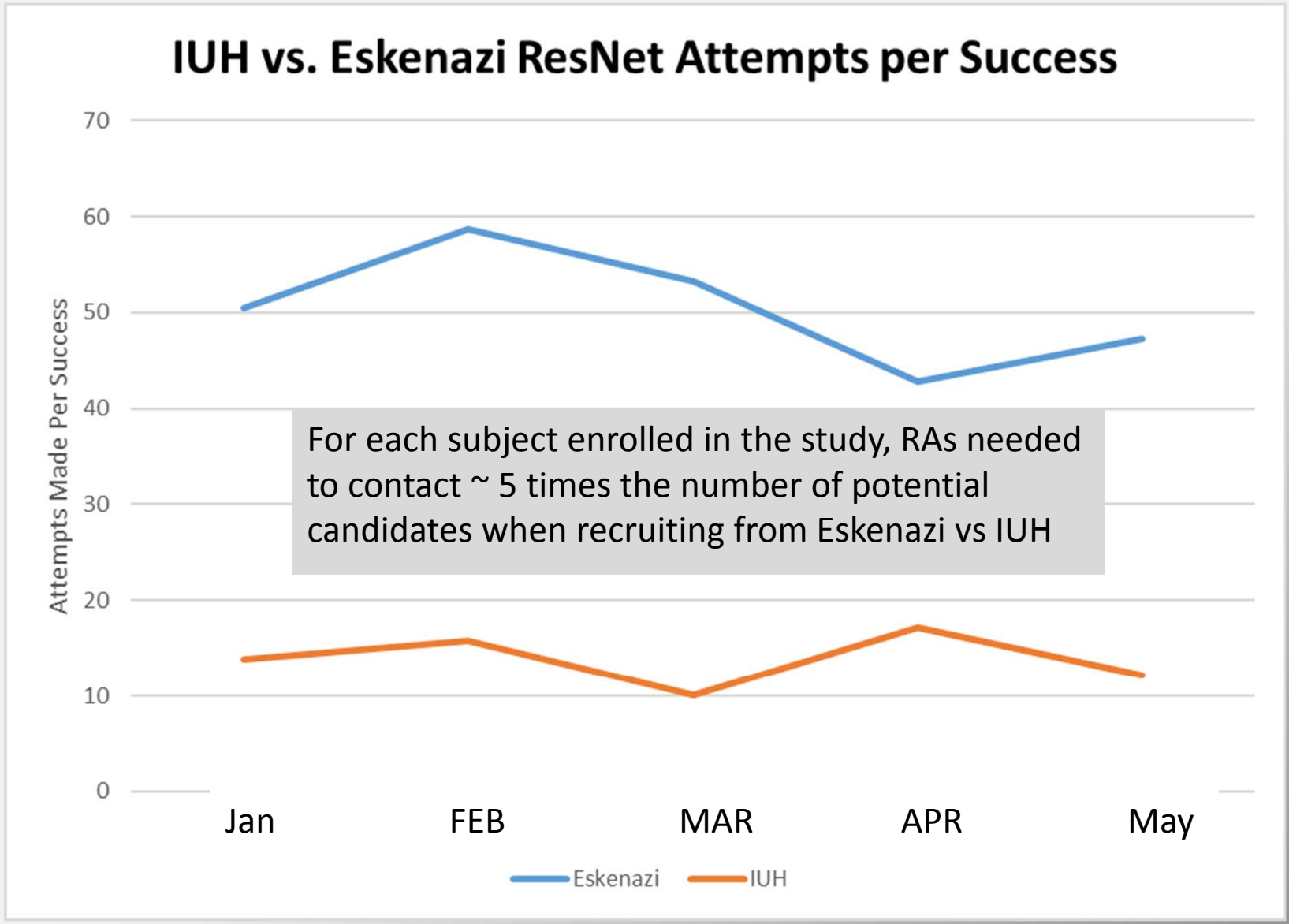

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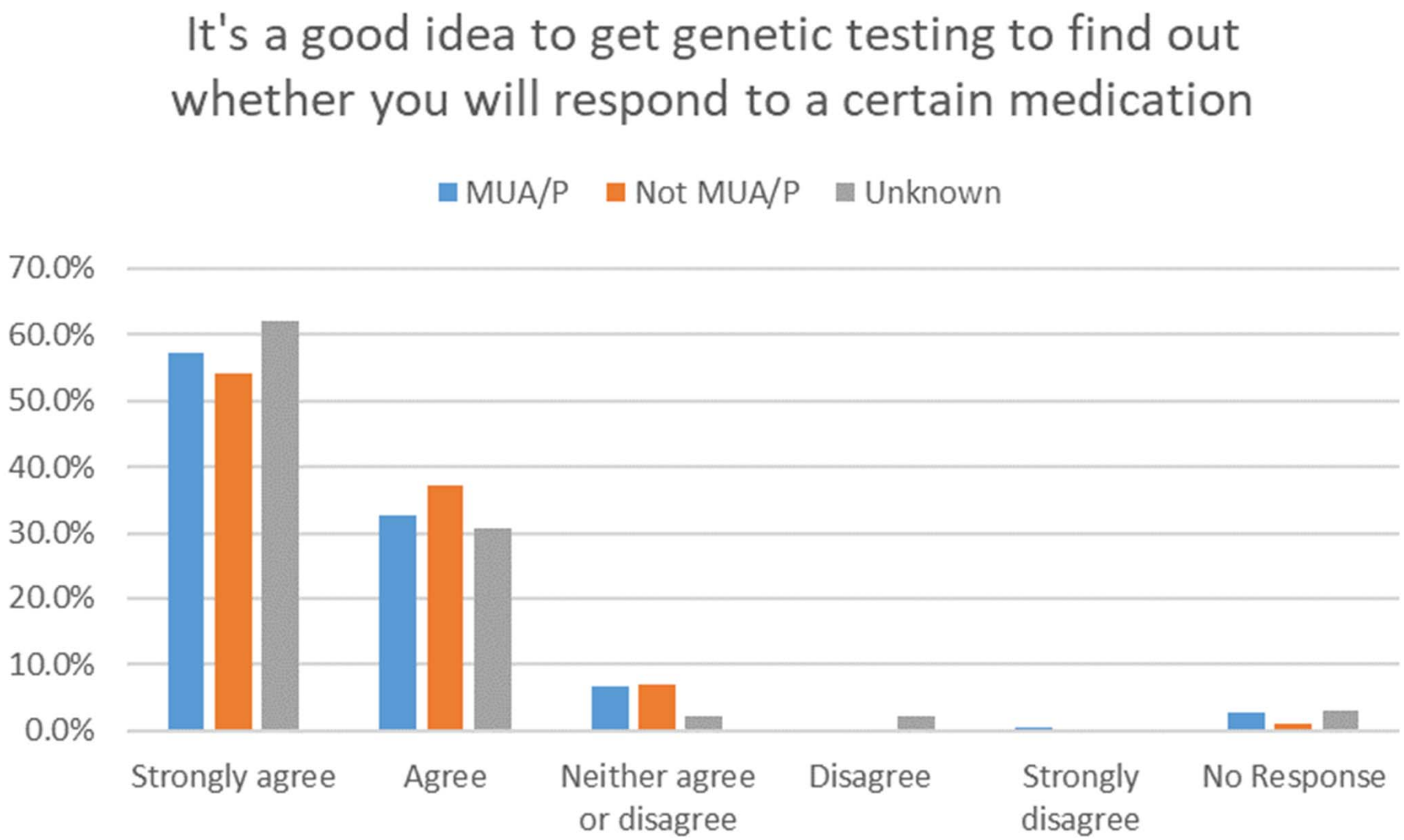
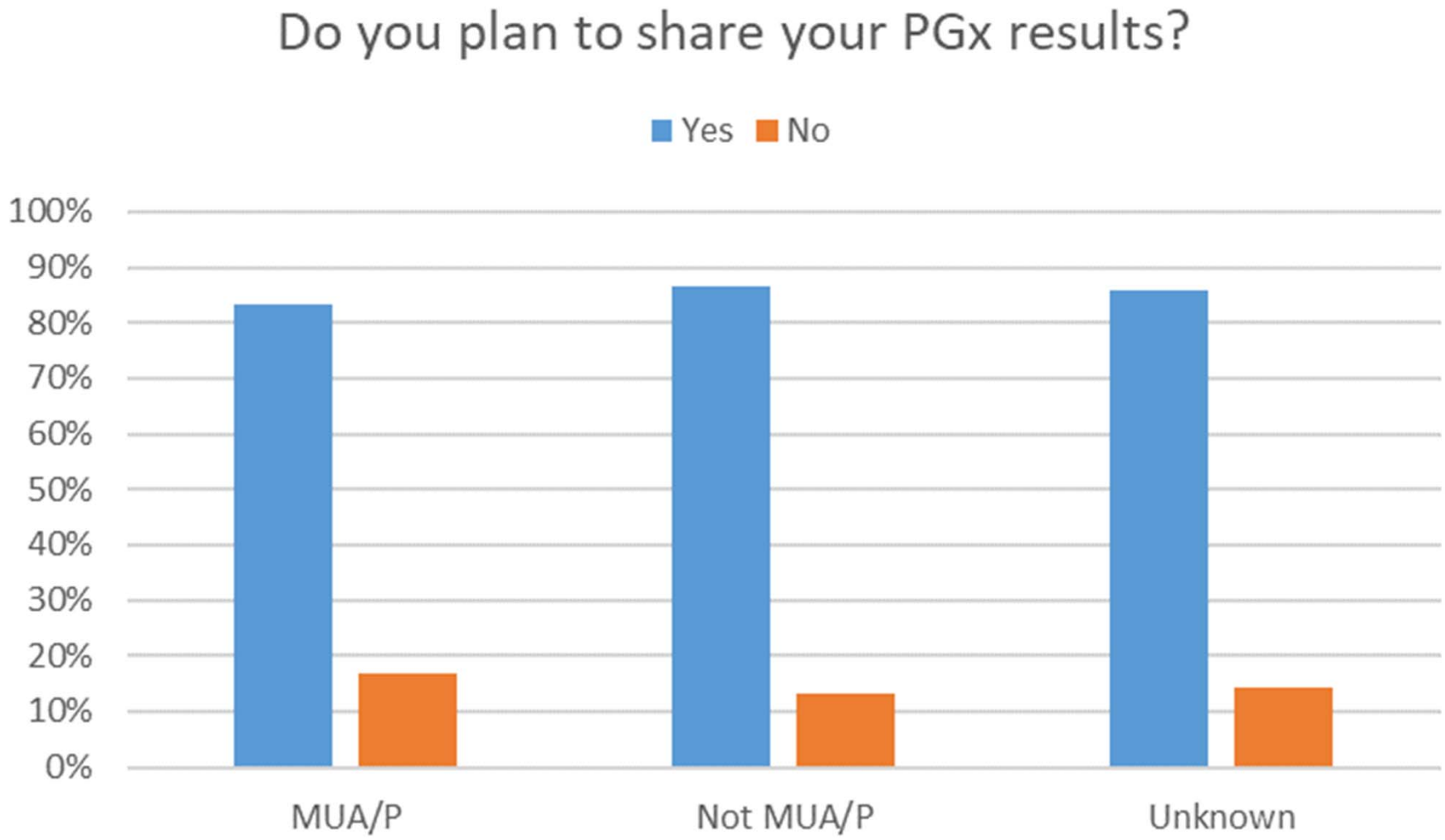
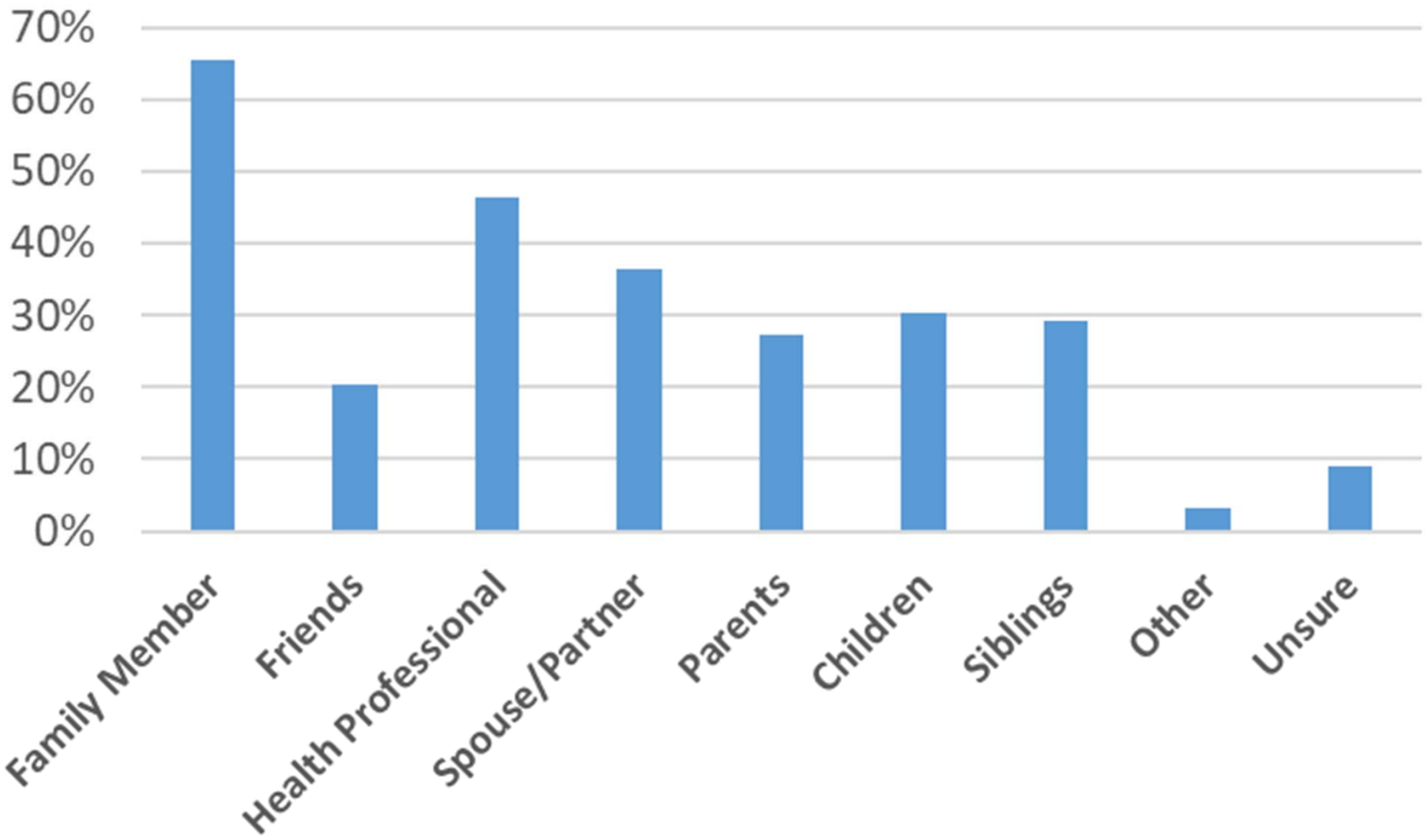

It's a good idea to get genetic testing to find out whether you will respond to a certain medication
MUA/P
Not MUA/P
Unknown
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
Strongly agree
Agree
Neither agree or disagree
Disagree
Strongly disagree
No Response


Do you plan to share your PGx results?
Yes
No
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
MUA/P
Not MUA/P
Unknown

If Yes for you plan to share, who will you share with?



Lessons learned

Remote recruitment for genomic medicine studies can successfully enroll patients and collect samples from medically underserved areas and populations.

Direct to patient recruitment can reach patients in underserved areas without needing to engage large numbers of providers.

Tools exist to identify patients in underserved areas and assure that those patients are represented in the studies.

More resources may be needed to recruit patients from safety-net hospitals.

The subjects want their genetic data and want their providers to have access to it.

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