G2P
GENOMES TO PEOPLE

the Franca Fund

The Path to Preventive Genomics

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BRIGHAM HEALTH
BWH BRIGHAM AND WOMEN'S HOSPITAL
Mass General Brigham
BROAD INSTITUTE

Support and Disclosures

Research:	National Institutes of Health NHGRI, NIA, NICHD, NHLBI, NCATS Department of Defense Broad Institute of MIT & Harvard Snite Foundation Franca Sozzani Fund for Preventive Genomics
Advisory:	AIA, Genomic Life, Grail, Humanity, Plumcare, OptumLabs, Verily, VibrentHealth
Co-Founder:	Genome Medical

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What is the Genomes2People Research Program?

Bringing genomics into evidence-based patient care…

Genomes2People creates virtual teams for each funded project

Population Sequencing (Framingham/Jackson) Study Team, National Heart Lung and Blood Institute Grant R01 HL143295

The PeopleSeq Consortium Team, National Human Genome Research Institute Grant R01 HG009922

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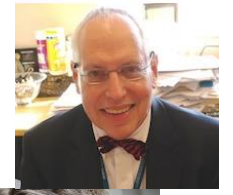
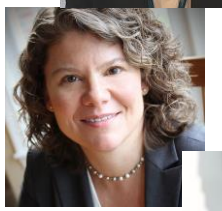
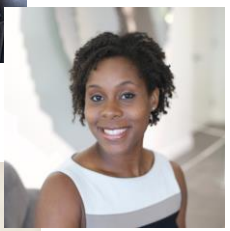
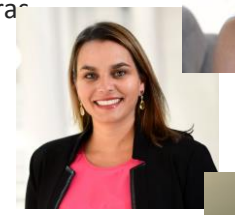
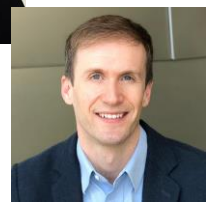
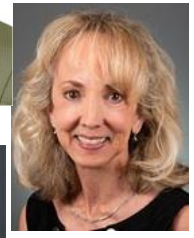
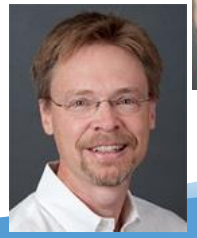
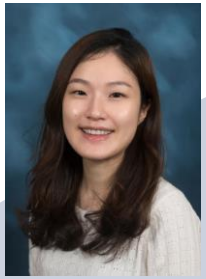
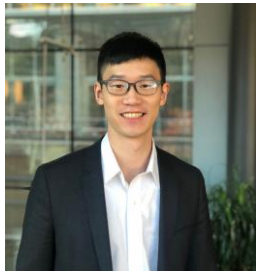
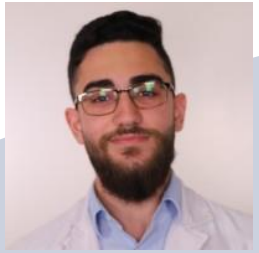






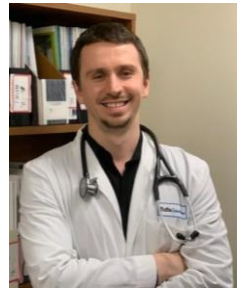



Mentoring trainees at every level







College students

Graduate and Medical school students

Postdoctoral Physicians and Scientists

High school students

35 trainees hosted from 2019 - 2020

G2P Research Portfolio

REVEAL

PGen

MedSeq

BabySeq

MilSeq

PeopleSeq

PopSeq

AllofUs Research Program

MGB Biobank / eMERGE III/IV

Verily Project Baseline

Committed to promoting diversity in genomic medicine

National Center for Advancing Translational Sciences

First to offer WGS to African American and Hispanic newborns

National Human Genome Research Institute

First to offer subsidized elective sequencing to health adults

National Heart, Lung, and Blood Institute

First to return genomic research results to African Americans in Jackson Heart Study





The MedSeq Project :

…the world's first pilot randomized trial of comprehensive genome sequencing in healthy individuals

The MedSeq Project: A randomized controlled trial of WGS and comprehensive interpretation

Primary care physicians and their healthy middle-aged patients

Family History Review	Family History Review + Genome Report

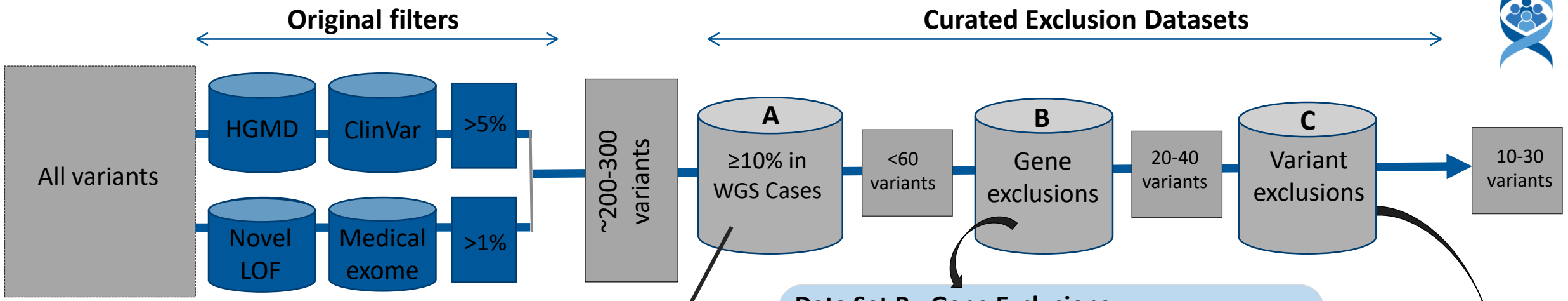
Physician reviews family history information and discloses results from Genome Report
Results added to patient's electronic medical record

Medical Record Review

Patient and physician outcomes

Vassy et al. Trials, 2014; Roberts et al. Genet Med, 2018; Vassy et al. Ann Intern Med, 2017; Vassy et al. JGIM, 2018; Krier et al. Dialogues Clin Neurosci 2016

Standardizing variant interpretation



Data Set A ≥ 10% MAF WGS Cases

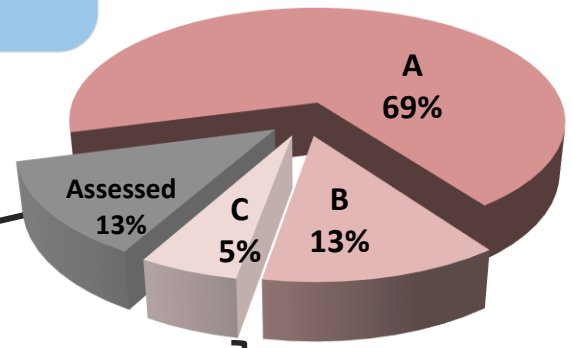
- Excludes common technical FPs
- Common indels wrong nomenclature
- Exceptions FV, HFE, SERPINA1

Data Set B - Gene Exclusions

- Evidence for gene-disease association = none, limited, or disputed
- Non medically relevant phenotype

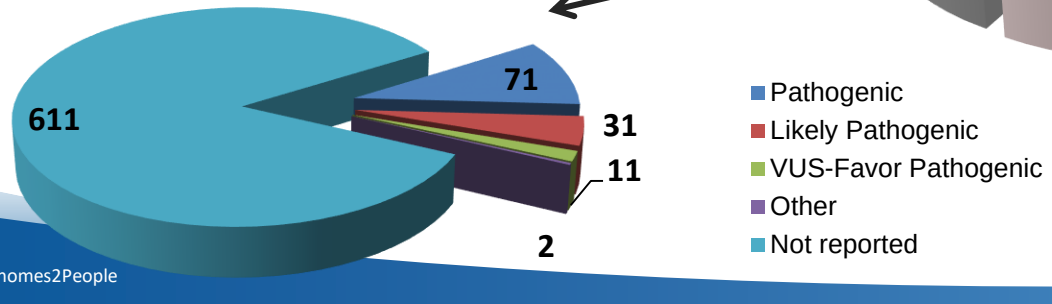
Data Set C - Variant Exclusions

- Benign interpretation
- LOF but LOF not disease mechanism
- GWAS or PGx association only



Not reported variants: 82%

- VUS, Likely Benign, Benign
- False positive variants



Reported variants: 18%

McLaughlin et al, BMC Med Genetics, 2014

The MedSeq Project: Building a one page report for PCPs

Returned Results

- Monogenic Risk
- Polygenic Risk
- Carrier Variants
- Pharmacogenomic Variants
- Blood Types

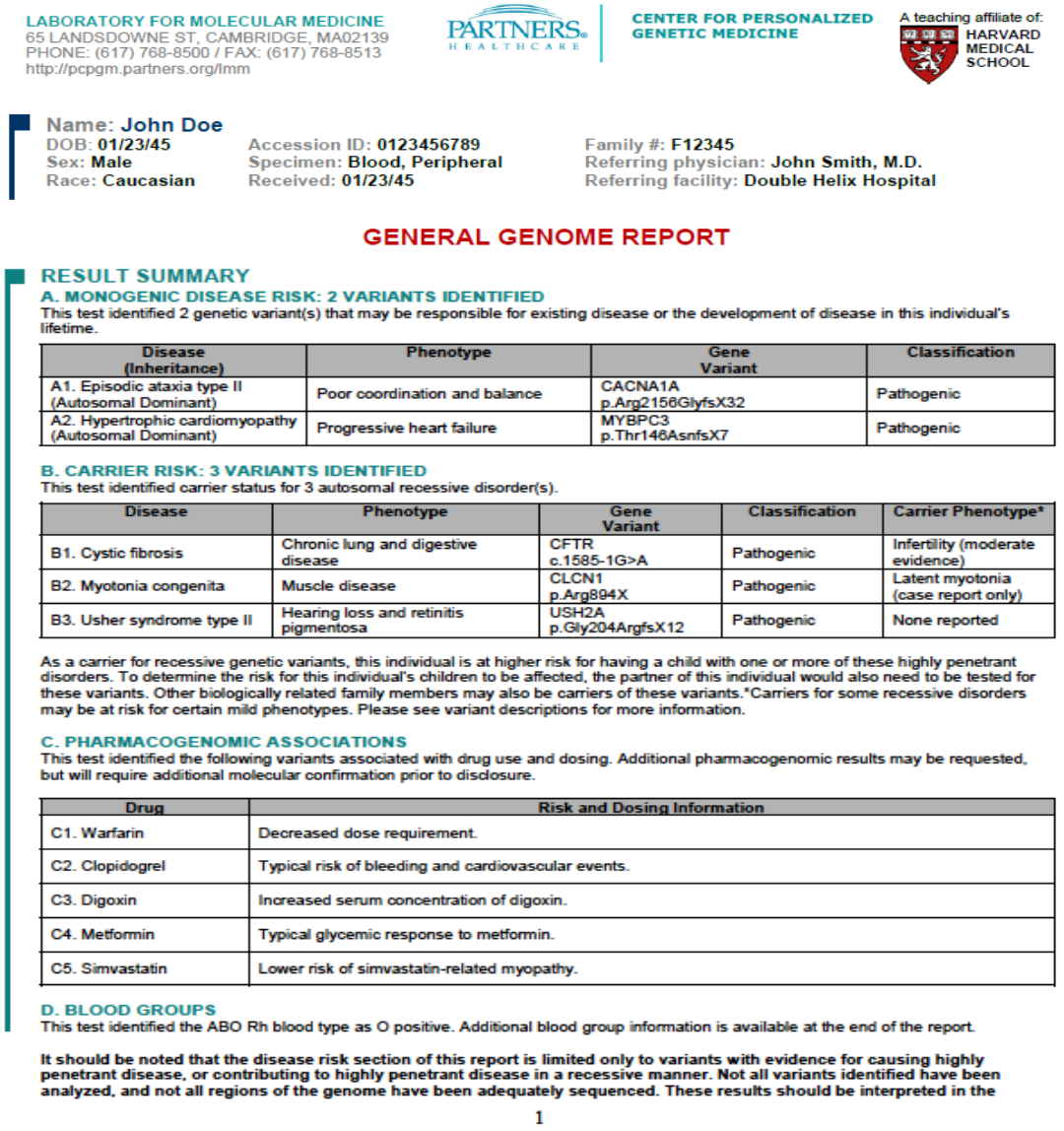
Additional Information

Structured Variant Data

Disease/Inheritance

Variant Evidence

Supporting References



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65 LANDSDOWNE ST, CAMBRIDGE, MA02139
PHONE: (617) 768-8500 / FAX: (617) 768-8513
http://pcpgm.partners.org/lmm

PARTNERS HEALTHCARE | CENTER FOR PERSONALIZED GENETIC MEDICINE

A teaching affiliate of: HARVARD MEDICAL SCHOOL

Name: John Doe
DOB: 01/23/45
Sex: Male
Race: Caucasian
Accession ID: 0123456789
Specimen: Blood, Peripheral
Received: 01/23/45
Family #: F12345
Referring physician: John Smith, M.D.
Referring facility: Double Helix Hospital

GENERAL GENOME REPORT

RESULT SUMMARY

A. MONOGENIC DISEASE RISK: 2 VARIANTS IDENTIFIED

This test identified 2 genetic variant(s) that may be responsible for existing disease or the development of disease in this individual's lifetime.

Disease (Inheritance)	Phenotype	Gene Variant	Classification
A1. Episodic ataxia type II (Autosomal Dominant)	Poor coordination and balance	CACNA1A p.Arg2156GlyfsX32	Pathogenic
A2. Hypertrophic cardiomyopathy (Autosomal Dominant)	Progressive heart failure	MYBPC3 p.Thr146AsnfsX7	Pathogenic

B. CARRIER RISK: 3 VARIANTS IDENTIFIED

This test identified carrier status for 3 autosomal recessive disorder(s).

Disease	Phenotype	Gene Variant	Classification	Carrier Phenotype*
B1. Cystic fibrosis	Chronic lung and digestive disease	CFTR c.1585-1G>A	Pathogenic	Infertility (moderate evidence)
B2. Myotonia congenita	Muscle disease	CLCN1 p.Arg894X	Pathogenic	Latent myotonia (case report only)
B3. Usher syndrome type II	Hearing loss and retinitis pigmentosa	USH2A p.Gly204ArgfsX12	Pathogenic	None reported

As a carrier for recessive genetic variants, this individual is at higher risk for having a child with one or more of these highly penetrant disorders. To determine the risk for this individual's children to be affected, the partner of this individual would also need to be tested for these variants. Other biologically related family members may also be carriers of these variants.*Carriers for some recessive disorders may be at risk for certain mild phenotypes. Please see variant descriptions for more information.

C. PHARMACOGENOMIC ASSOCIATIONS

This test identified the following variants associated with drug use and dosing. Additional pharmacogenomic results may be requested, but will require additional molecular confirmation prior to disclosure.

Drug	Risk and Dosing Information
C1. Warfarin	Decreased dose requirement.
C2. Clopidogrel	Typical risk of bleeding and cardiovascular events.
C3. Digoxin	Increased serum concentration of digoxin.
C4. Metformin	Typical glycemic response to metformin.
C5. Simvastatin	Lower risk of simvastatin-related myopathy.

D. BLOOD GROUPS

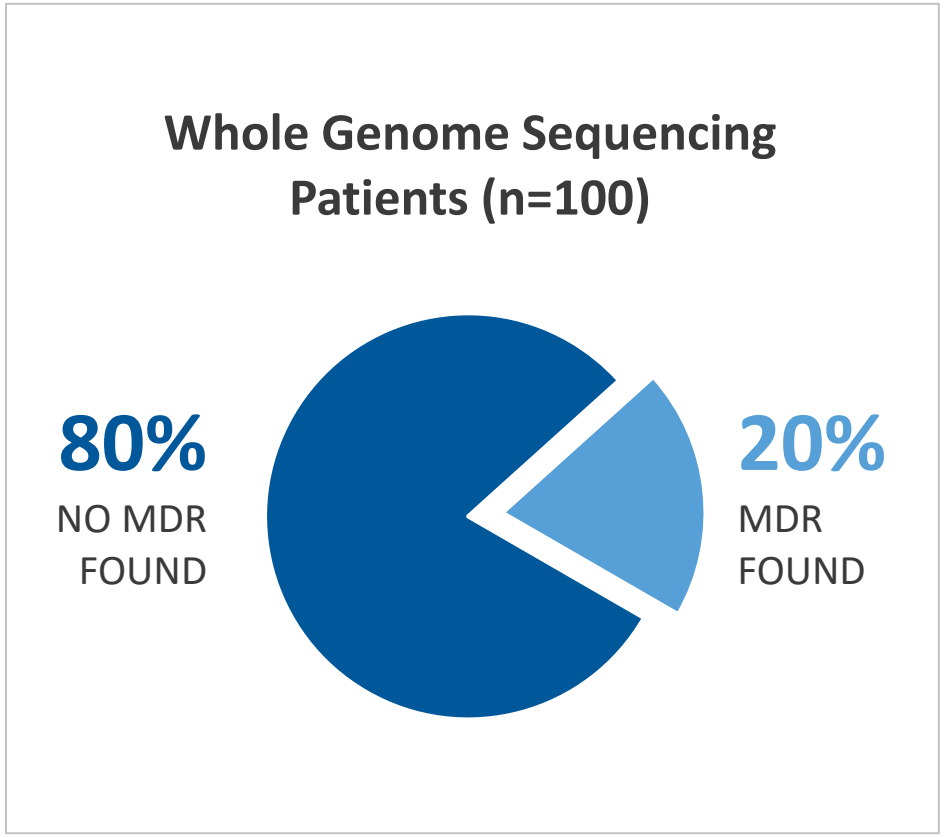
This test identified the ABO Rh blood type as O positive. Additional blood group information is available at the end of the report.

It should be noted that the disease risk section of this report is limited only to variants with evidence for causing highly penetrant disease, or contributing to highly penetrant disease in a recessive manner. Not all variants identified have been analyzed, and not all regions of the genome have been adequately sequenced. These results should be interpreted in the

1

Vassy et al, Trials, 2014; McLaughlin et al, BMC Med Genetics, 2014

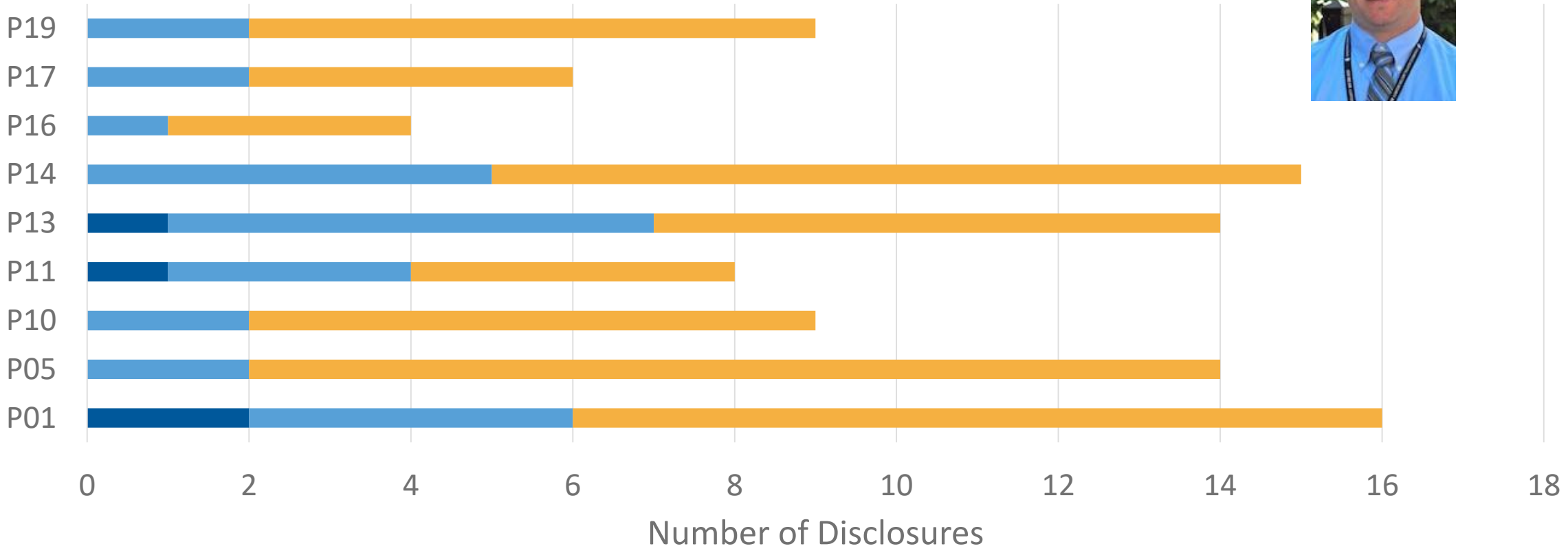
The MedSeq Project: Unanticipated monogenic findings



Gene	Condition	Phenotypic evidence
EYA4	Postlingual hearing loss; *AD*	Yes
PPOX	Variegate porphyria; *AD*	Yes
RDH5	Fundus albipunctatus; AR	Yes
HFE	Hereditary hemochromatosis; AR	Yes
APP	Alzheimer's disease, late-onset; *AD*	Family history
ELN	Supravalvular aortic stenosis; *AD*	No
CHEK2	CHEK2-related cancer risk; *AD*	No
SQSTM1	Paget disease of the bone; *AD*	No
F5	Factor V Leiden thrombophilia; *AD*	No
LHX4	Combined pituitary hormone deficiency; *AD*	No
ANK2	Ankyrin-B related cardiac arrythmia; *AD*	No
COL2A1	Spondyloepiphyseal dysplasia congenita; *AD*	No
KCNQ1	Romano-Ward syndrome; *AD*	No
TTN2	Hypertrophic cardiomyopathy; *AD*	No
ARSE	Chondrodysplasia punctate; XL	No
F5	Factor V Leiden thrombophilia; *AD*	No

Vassy et al Ann Int Med, 2017; Christensen et al, Genet Med, 2018

The MedSeq Project: PCPs make no serious communication errors discussing genomic information



No High Risk Errors!

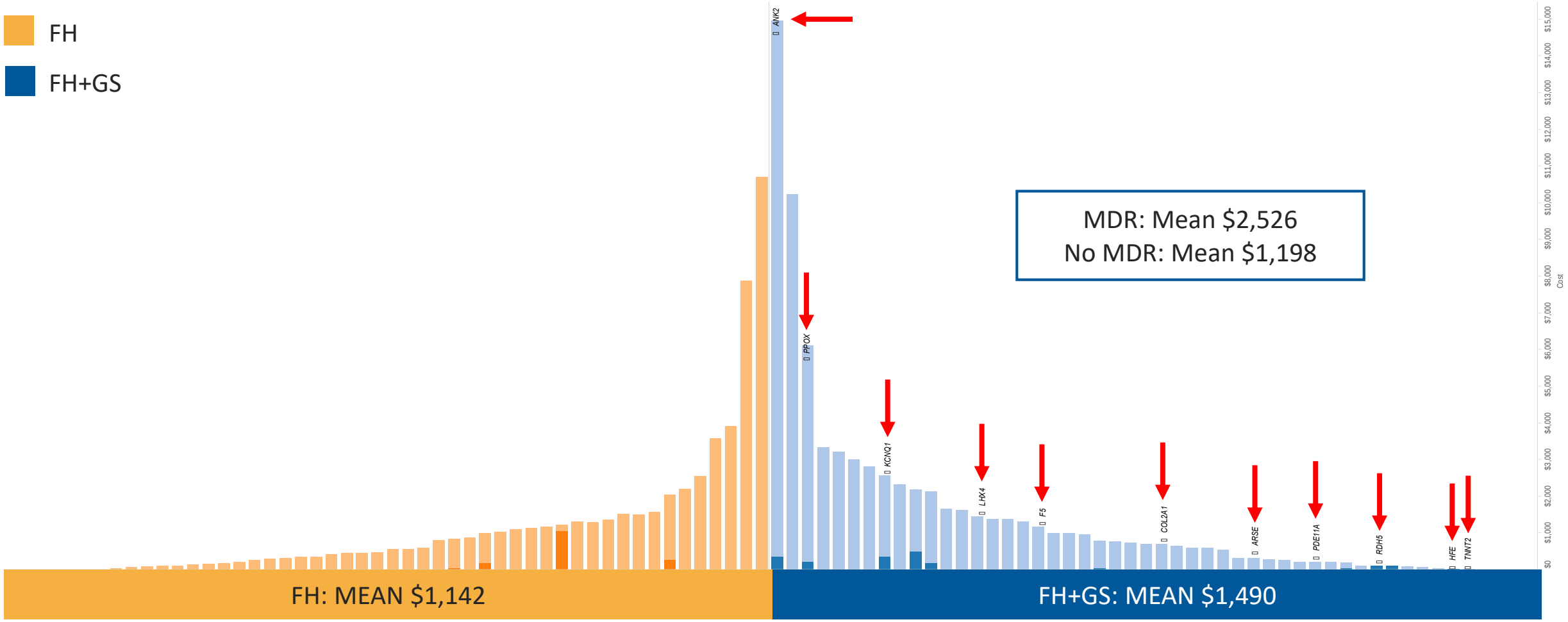
■ Medium Risk Error **(4 disclosures)**

■ Low Risk Error **(26 disclosures)**

■ No Errors **(64 disclosures)**

Vassy et al., JGIM 2018

The MedSeq Project: 6-month healthcare spending



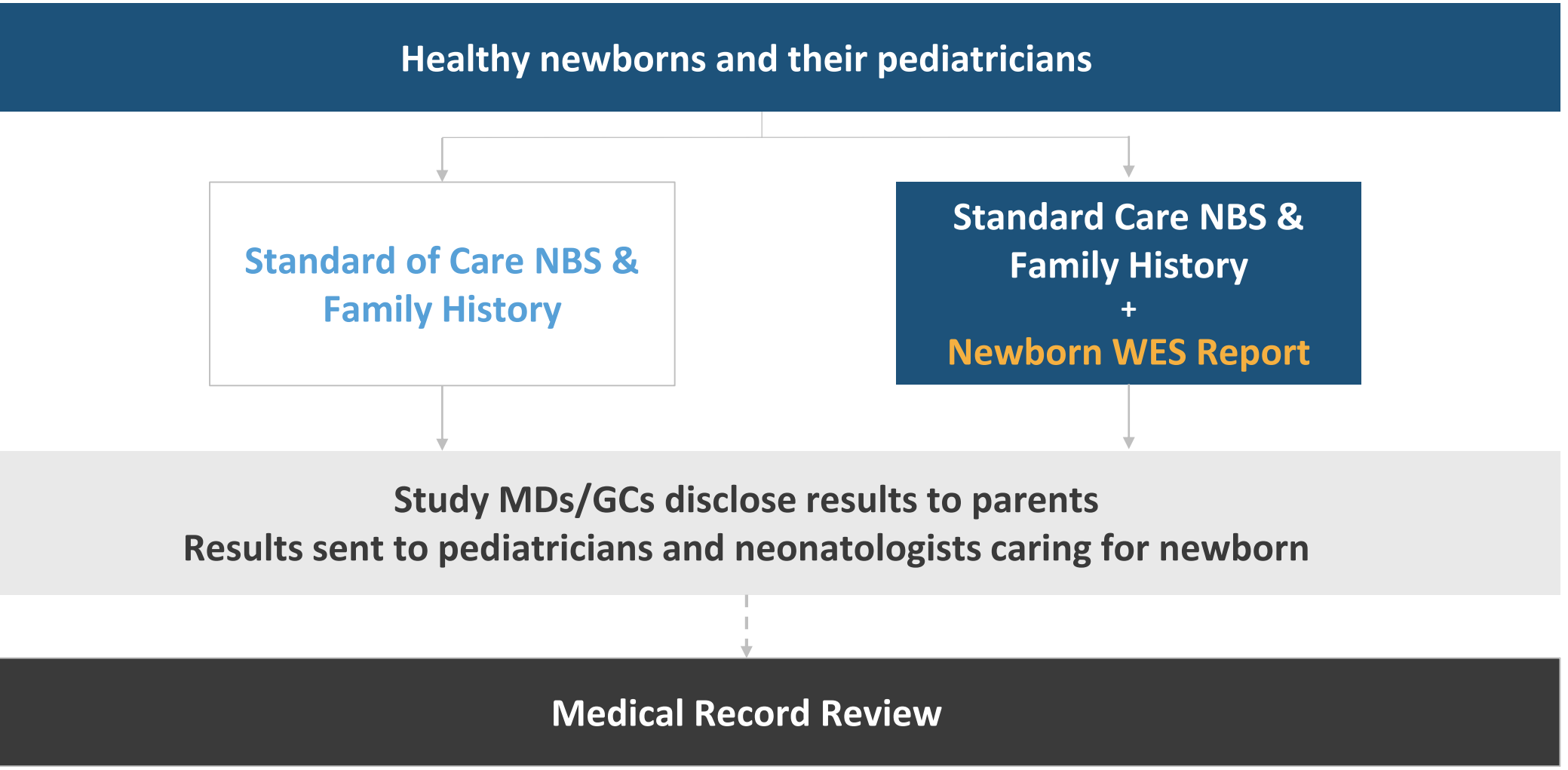
Christensen et al., GIM 2018

The BabySeq Project

"…whether you like it or not, a complete sequencing of newborns is not far away"
Francis Collins, 2012

Mass General Brigham

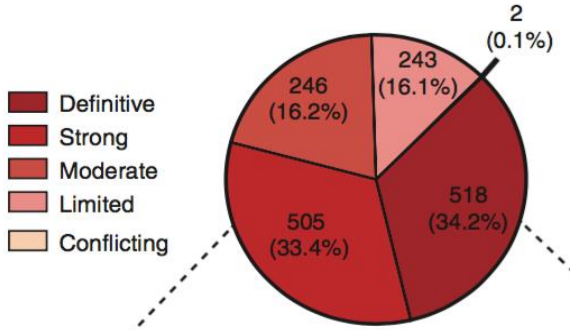
The BabySeq Project: A controlled trial of WES and comprehensive interpretation



Holm IA, et al.. The BabySeq project: implementing genomic sequencing in newborns. BMC Pediatr. 2018 Jul 9;18(1):225. doi: 10.1186/s12887-018-1200-1. PMID: 29986673; PMCID: PMC6038274.

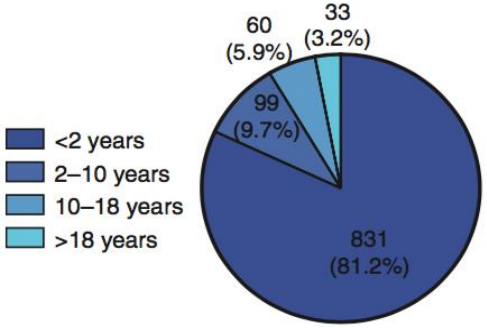
Curating the BabySeq Gene List

Gene-disease validity *(n=1,514)*

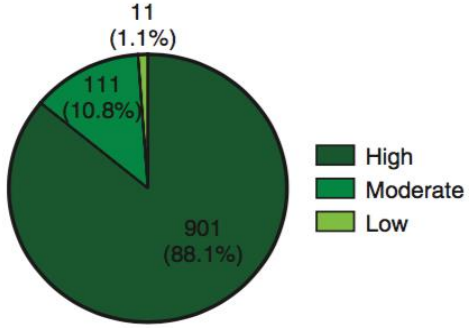


Genes with strong and definitive evidence *(n=1,023)*

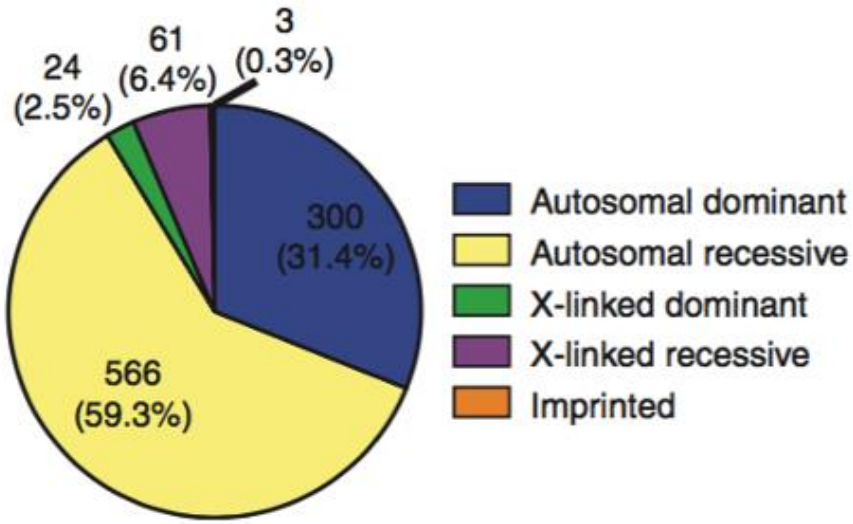
Age of onset



Penetrance



Inheritance pattern of genes meeting BabySeq reporting criteria (954)



Genes with highly penetrant, childhood onset disease *(i.e. Duchenne muscular dystrophy, n=884)*

+

Genes with high actionability *(i.e. cancer predisposition syndromes, n=70)*

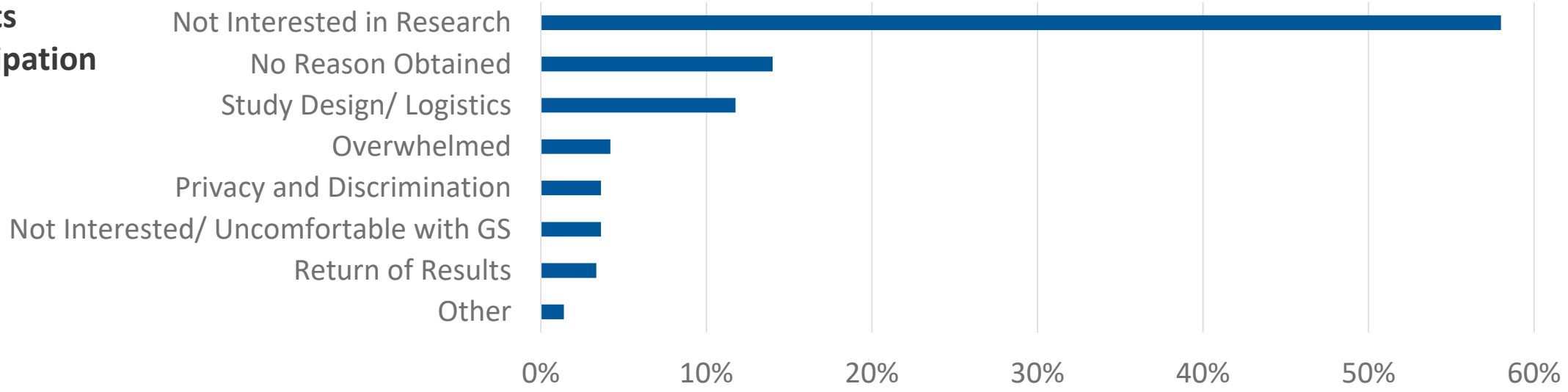
=

954 genes meet BabySeq reporting criteria

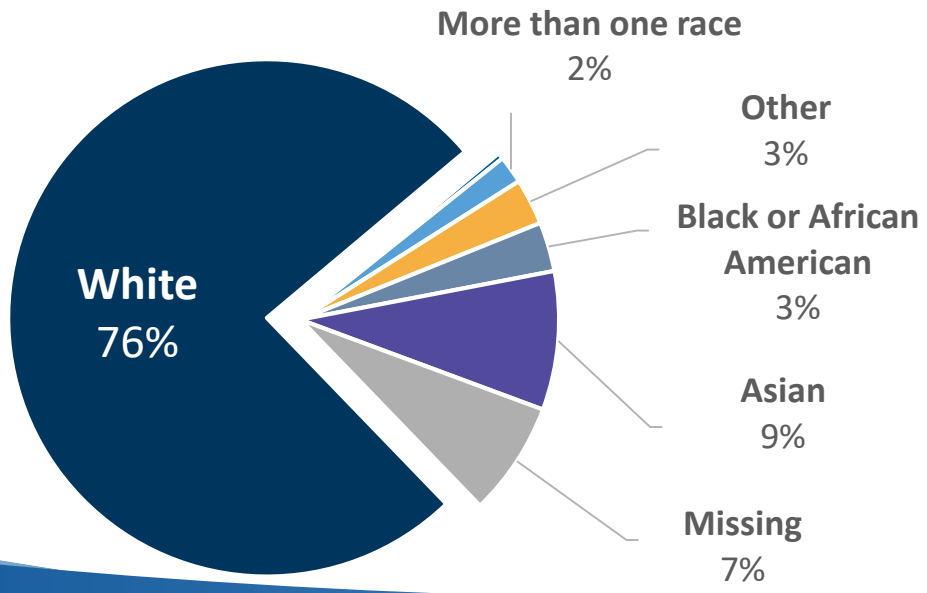
Ceyhan-Birsoy et al. *Genetics in Medicine*, 2017.

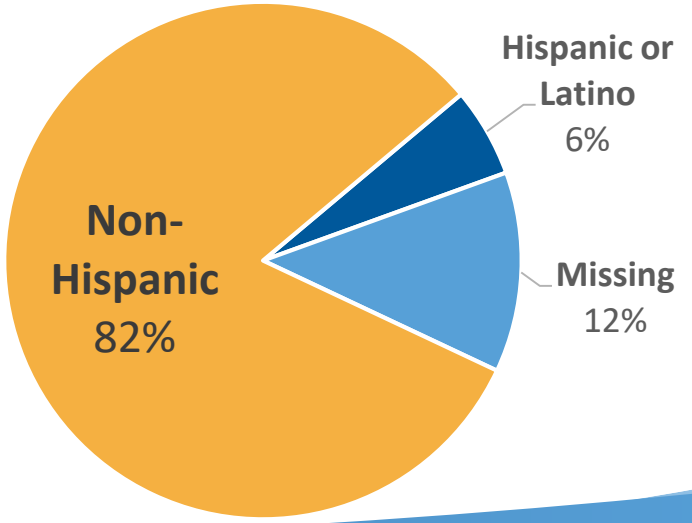
Recruitment uptake and demographics

Reasons parents declined participation



Race and Ethnicity of enrolled parents

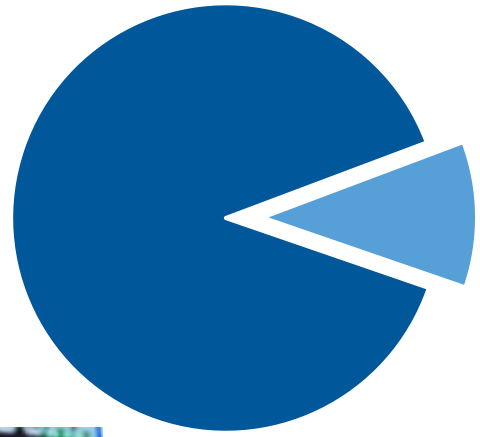




Genetti, C.A., et al,. *Genet Med* 2019

Unanticipated Monogenic Findings

Whole Exome Sequencing Infants (N=159)



89% NO MDR FOUND

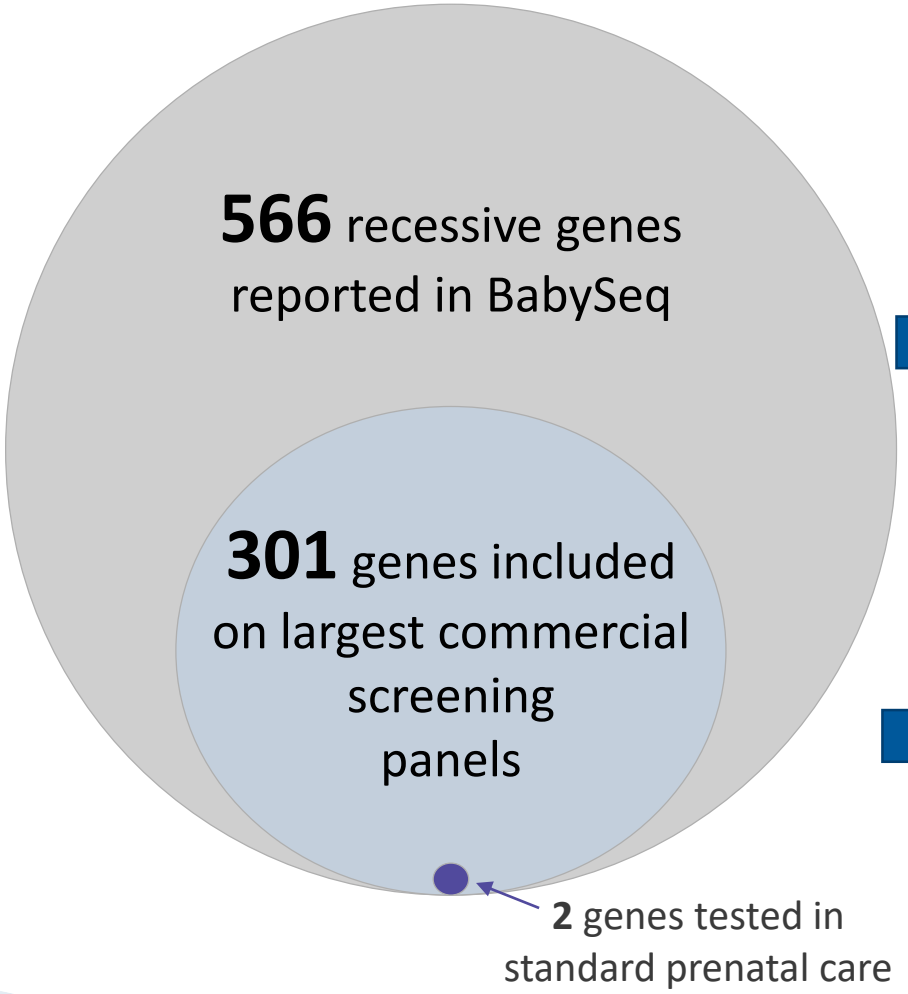
11% MDR FOUND

Gene	Condition	Phenotypic evidence
ANKRD11	KBG syndrome; *AD*	Yes
BTD	Biotinidase deficiency; *AR*	Yes
ELN	Supravalvular aortic stenosis; *AD*	Yes
GLMN	Glomuvenous malformations; *AD*	Yes
KCNQ4	Non-syndromic hearing loss; *AD*	Family history
SLC7A9	Cystinuria; *AR*	Family history
TTN (4)	Dilated cardiomyopathy; *AD*	Family history (2/4)
BRCA2 (2)	Hereditary breast and ovarian cancer; *AD*	Family history
MSH2	Lynch syndrome; *AD*	Family history
MYBPC3	Hypertrophic cardiomyopathy; *AD*	No
VCL	Dilated cardiomyopathy; *AD*	No
CD46	Atypical hemolytic-uremic syndrome; *AD*	No
CYP21A	Congenital adrenal hyperplasia due to 21-hydroxylase deficiency; *AR*	No
G6PD	Glucose-6-phosphate dehydrogenase deficiency; *XL*	No

Ceyhan-Birsoy et al. *Am J Hum Genet*, 2019.

Comparison with Conventional Carrier Screening

88% of infants had at least 1 PV/LPV for a recessive carrier condition



47% of reported variants would have been missed by commercial "expanded screening" panels

INVITAE | GoodStart Genetics

sema4

HerediT UNIVERSAL

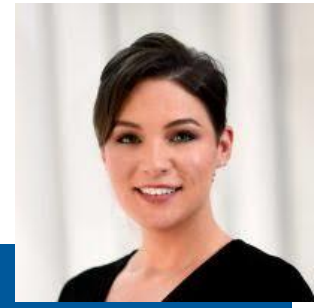
Counsyl

99% of reported variants would have been missed by routine care

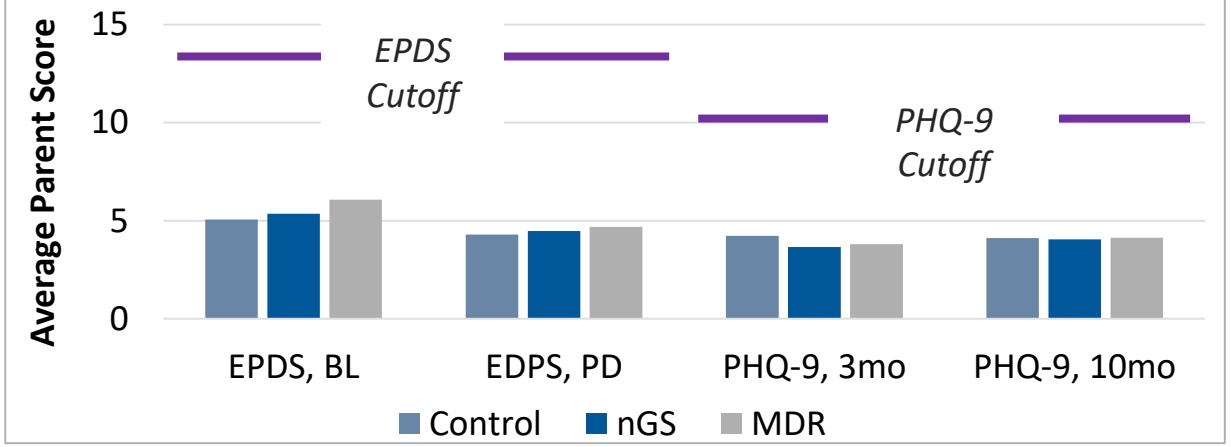
horizon™ natera carrier screen

VanNoy et al. *Pediatrics*, 2018.

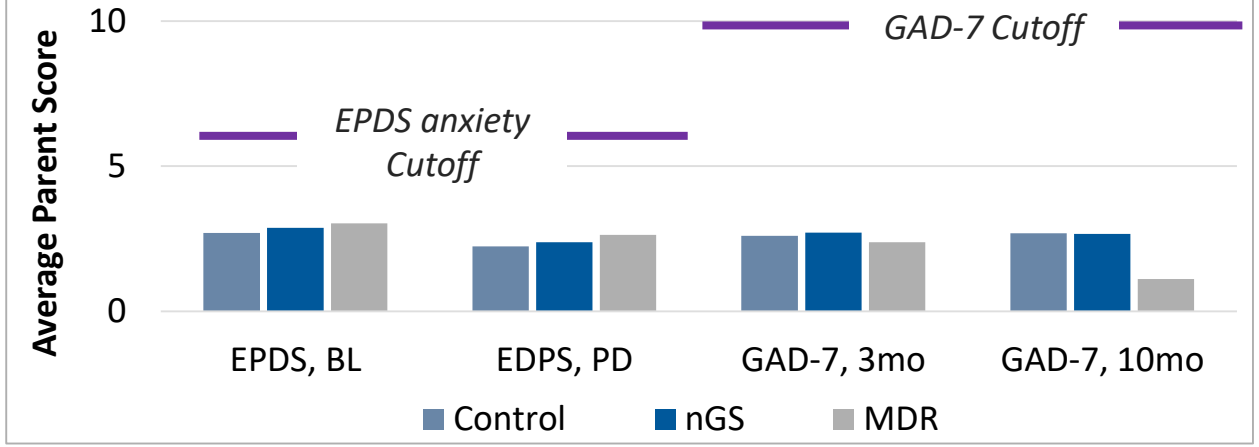
No Increased Depression/Anxiety, Self-Blame, or Relationship Dysfunction



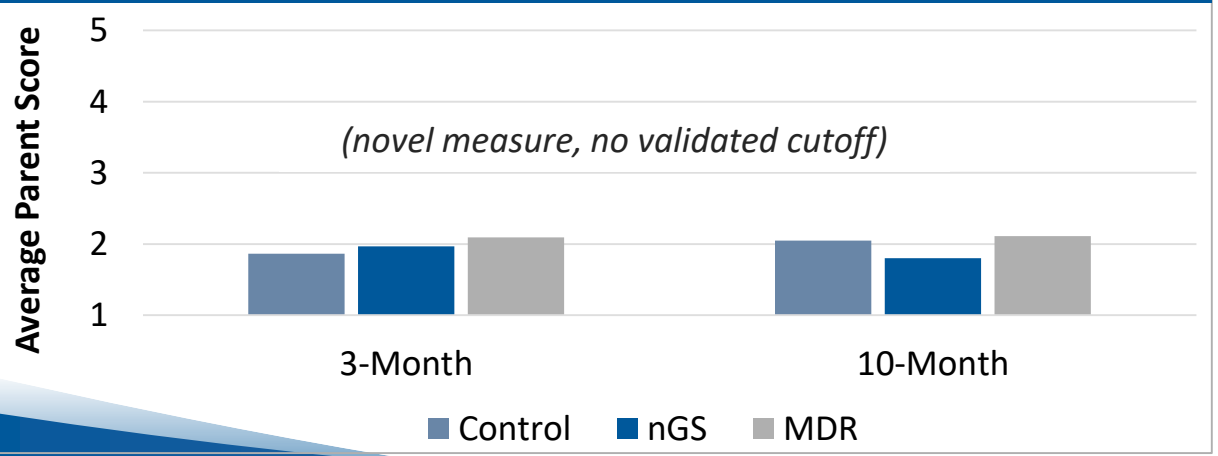
Parental depression



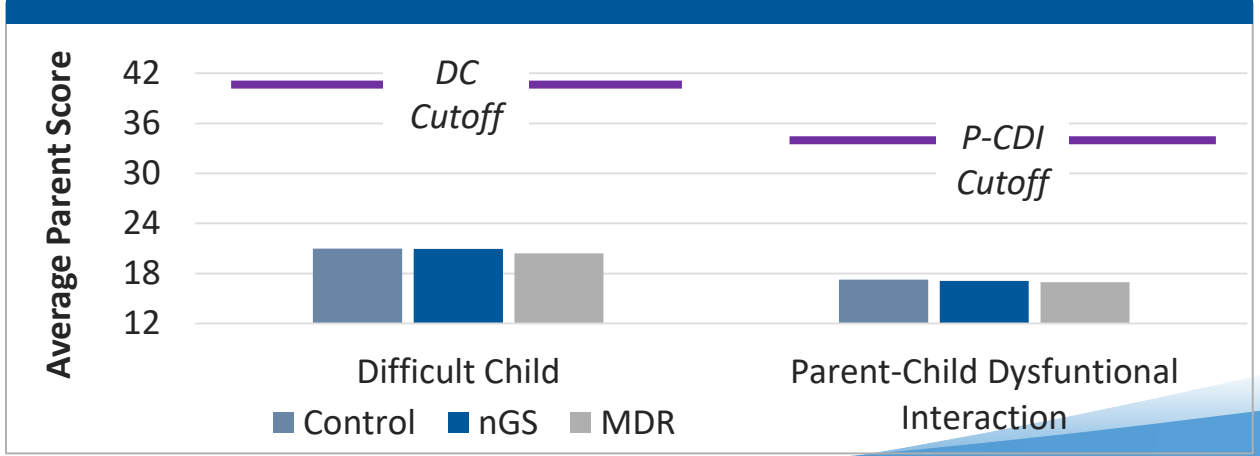
Parental anxiety



Parental self-blame



Parental perception of child & relationship



Pereira et al. in submission.

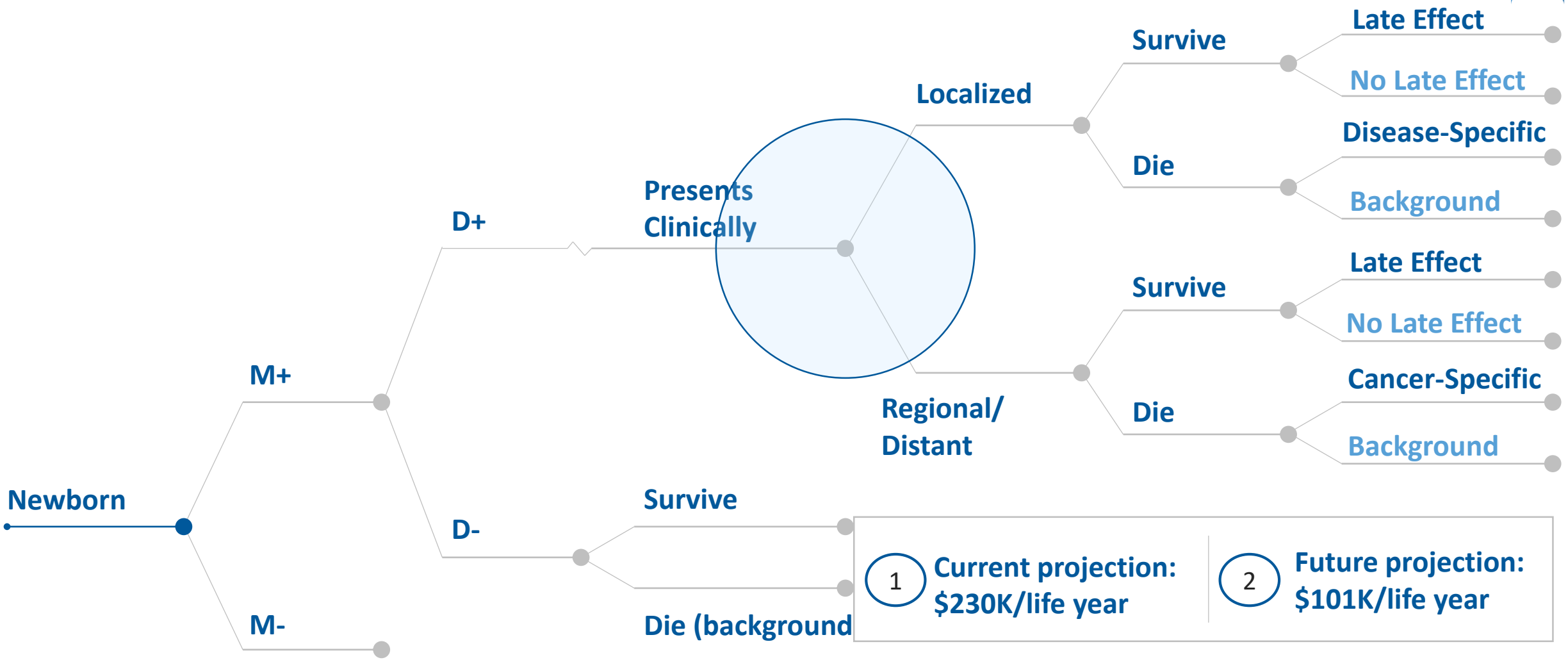
No Increase in Health Care Spending

Median

Christensen et al., in preparation.

Modeling Lifetime Benefits and Costs

(slide courtesy Kurt Christensen)



Christensen et al., in preparation.

Inherited Cancer Disorders

Hereditary Breast and Ovarian Cancer
Li-Fraumeni Syndrome
Peutz-Jeghers Syndrome
Lynch Syndrome
Familial adenomatous polyposis
Von Hippel Lindau syndrome
Retinoblastoma
WT1-related Wilms tumor
Neurofibromatosis type 2
Tuberous Sclerosis Complex
Multiple Endocrine Neoplasia Type 1
Multiple Endocrine Neoplasia Type 2
Familial Medullary Thyroid Cancer (FMTC)
PTEN Hamartoma Tumor Syndrome
Polyposis/Juvenile polyposis; Colorectal adenomas; FAP
Hereditary Paraganglioma-Pheochromocytoma Syndrome

ACMG POLICY STATEMENT | Genetics inMedicine

ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing

Robert C. Green, MD, MPH[1,2], Jonathan S. Berg, MD, PhD[3], Wayne W. Grody, MD, PhD[4–6], Sarah S. Kalia, ScM, CGC[1], Bruce R. Korf, MD, PhD[7], Christa L. Martin, PhD, FACMG[8], Amy L. McGuire, JD, PhD[9], Robert L. Nussbaum, MD[10], Julianne M. O'Daniel, MS, CGC[3], Kelly E. Ormond, MS, CGC[11], Heidi L. Rehm, PhD, FACMG[2,12], Michael S. Watson, PhD, FACMG[13], Marc S. Williams, MD, FACMG[14] and Leslie G. Biesecker, MD[15]

Cardiac Disorders

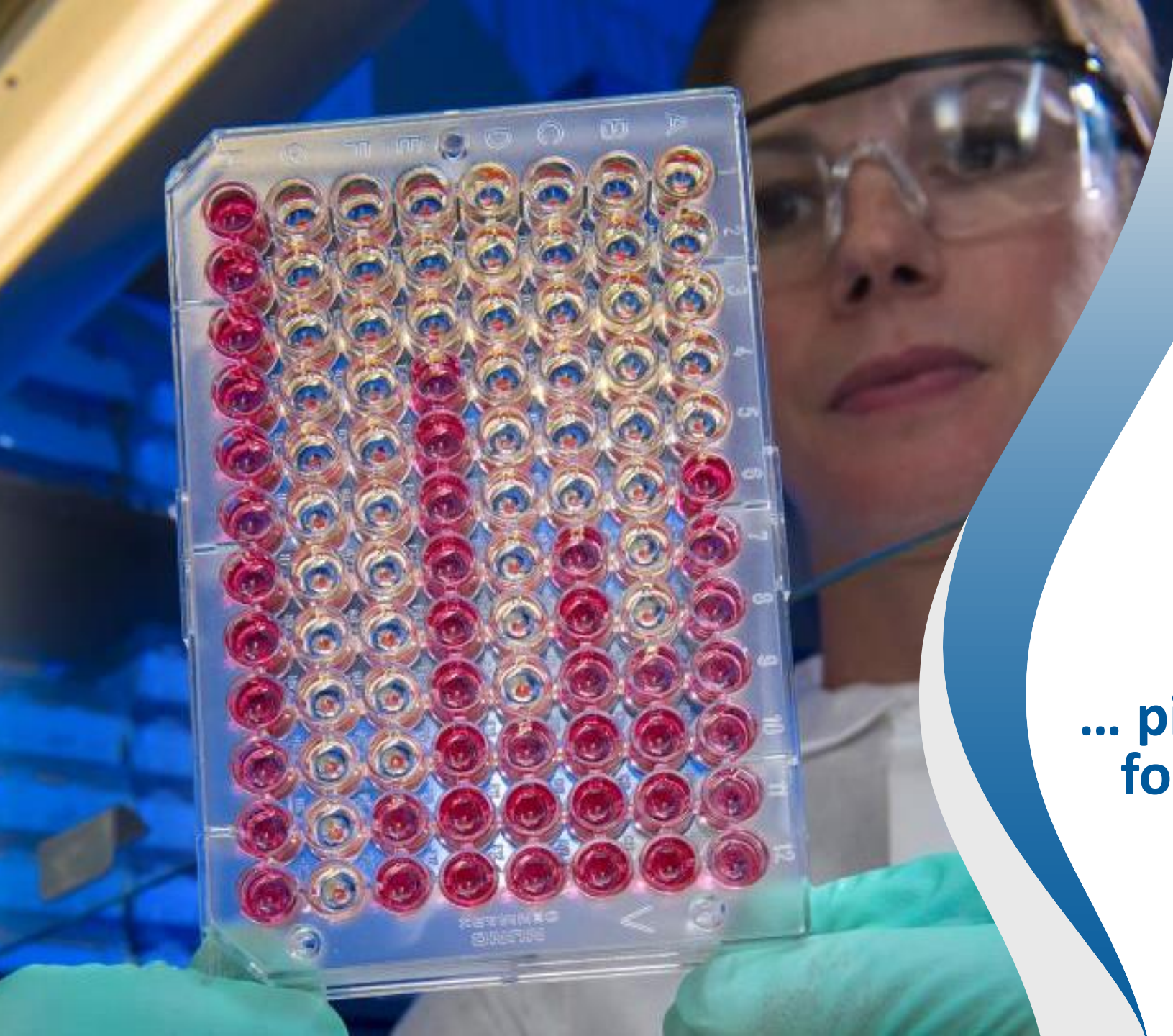
EDS - vascular type
Hypertrophic cardiomyopathy
Dilated cardiomyopathy
Catecholaminergic polymorphic ventricular tachycardia
Arrhythmogenic right ventricular cardiomyopathy
Romano-Ward Long QT Syndromes, Brugada Syndrome
Marfan Syndrome, Loeys-Dietz, Familial Thoracic Aortic Aneurysms

Other:Wilson Disease, OTC, Malignant hyperthermia susceptibility, Familial hypercholesterolemia

SPECIAL ARTICLE | Genetics inMedicine

Recommendations for returning genomic incidental findings? We need to talk!

Wylie Burke, MD, PhD[1], Armand H. Matheny Antommaria, MD, PhD[2], Robin Bennett, MS, CGC[3], Jeffrey Botkin, MD, MPH[4], Ellen Wright Clayton, MD, JD[5], Gail E. Henderson, PhD[6], Ingrid A. Holm, MD, MPH[7–9], Gail P. Jarvik, MD, PhD[3], Muin J. Khoury, MD, PhD[10], Bartha Maria Knoppers, JD, PhD[11], Nancy A. Press, PhD[12], Lainie Friedman Ross, MD, PhD[13], Mark A. Rothstein, JD[14], Howard Saal, MD[15], Wendy R. Uhlmann, MS, CGC[16], Benjamin Wilfond, MD[17], Susan M. Wolf, JD[18] and Ron Zimmern, FRCP, FFPHM[19]



Returning genomic results in the Mass General Brigham Biobank

… piloting genomic screening for actionable conditions in research biobank

MGB Biobank gRoR Protocol

PARTNERS HEALTHCARE | PERSONALIZED MEDICINE

Genotyping with MEGA Chip

Gene sequencing

ACMG59 result identified

Letter to participant: "research result… that may be important to your health"

Phone call with GC to discuss result category & option to confirm

Opt-Out

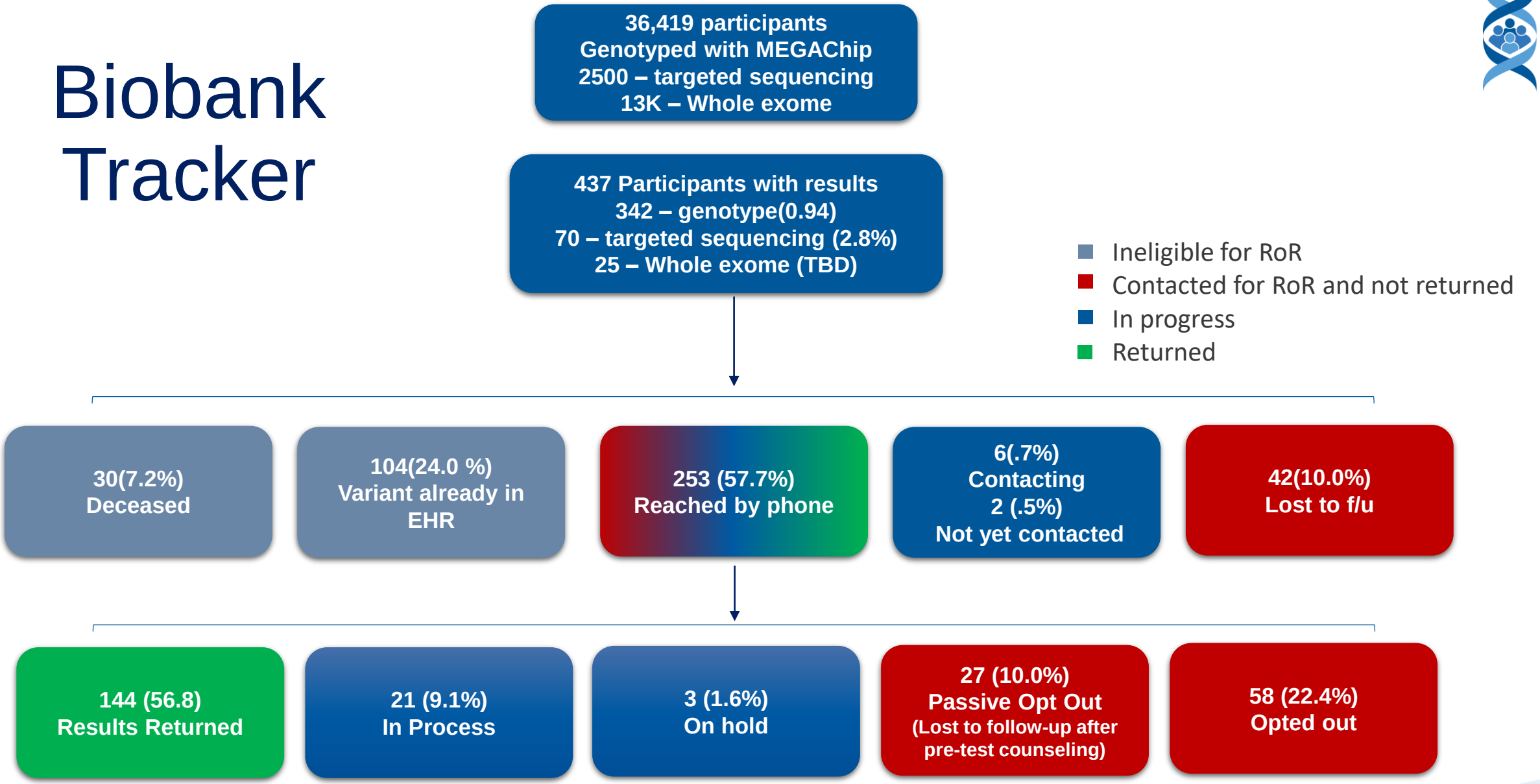
Resample and confirmatory (CLIA) testing

In-person disclosure by specialist or participant's own MD

Results entered into electronic medical record

Blout, Machini, Shah et al, in preparation

Biobank Tracker



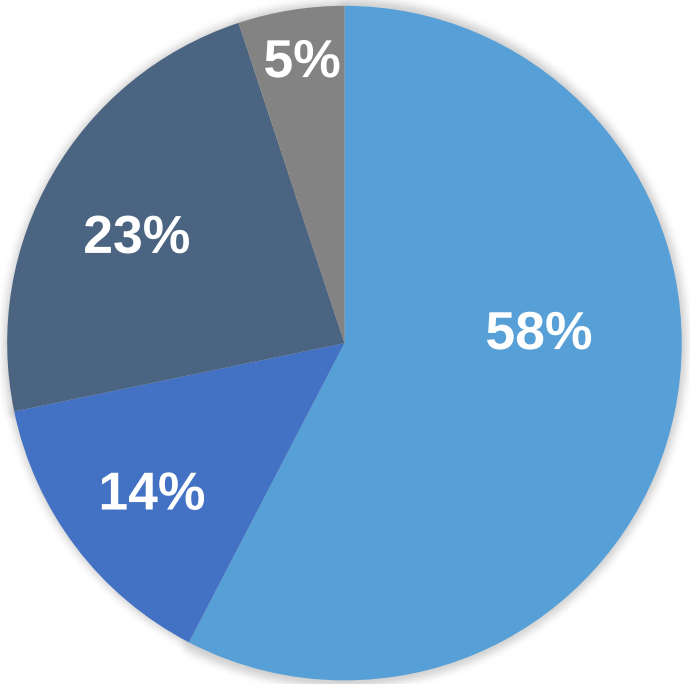
Cancer	#
APC	7
BRCA1	49
BRCA2	68
MLH1	2
RET	1
TP53	3
MUTYH	1
MSH6	1
SDHB	1
SDHC	4
VHL	4

Cardiac	#
FBN1	2
KCNQ1	15
MYBPC3	14
MYH7	11
MYL3	3
LMNA	1
SCN5A	8
GLA	1
PKP2	5
TNNI3	5
TNNT2	1

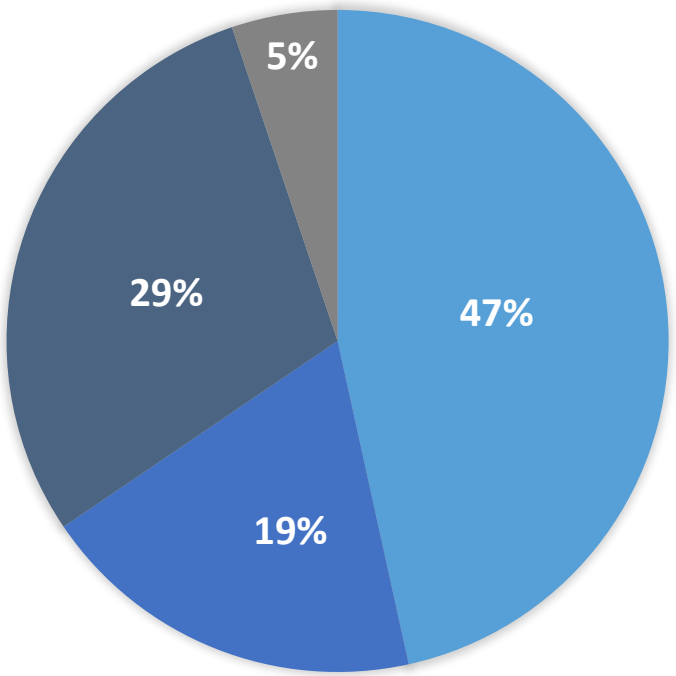
Cholesterol	#
APOB	17
LDLR	19

Other	#
RYR1	11

MEGA Chip



Sequencing



Cancer Cholesterol Cardiac Other

Cancer	#
APC	3
BRCA1	6
BRCA2	5
MSH2	2
MSH6	2
MUTYH	1
PTEN	1
PMS2	5
RET	1
SDHD	1
TP53	1
VHL	3

Cardiac	#
FBN1	4
GLA	1
KCNQ1	3
MYBPC3	3
SCN5A	2
MYL3	1
MYH7	2
LMNA	2
PKP2	1
SMAD3	1
TNNI3	1

Cholesterol	#
APOB	1
LDLR	10

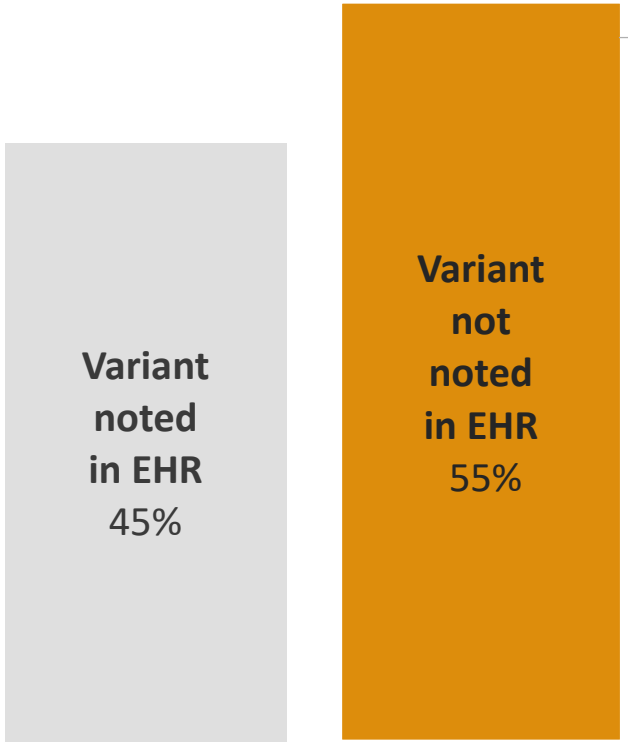
Other	#
RYR1	2
TSC1	1

Blout, Machini, Shah et al, in press

Over half of the MGB biobank participants with genetic cancer risk had not been tested, and half of those met current expert criteria for genetic testing

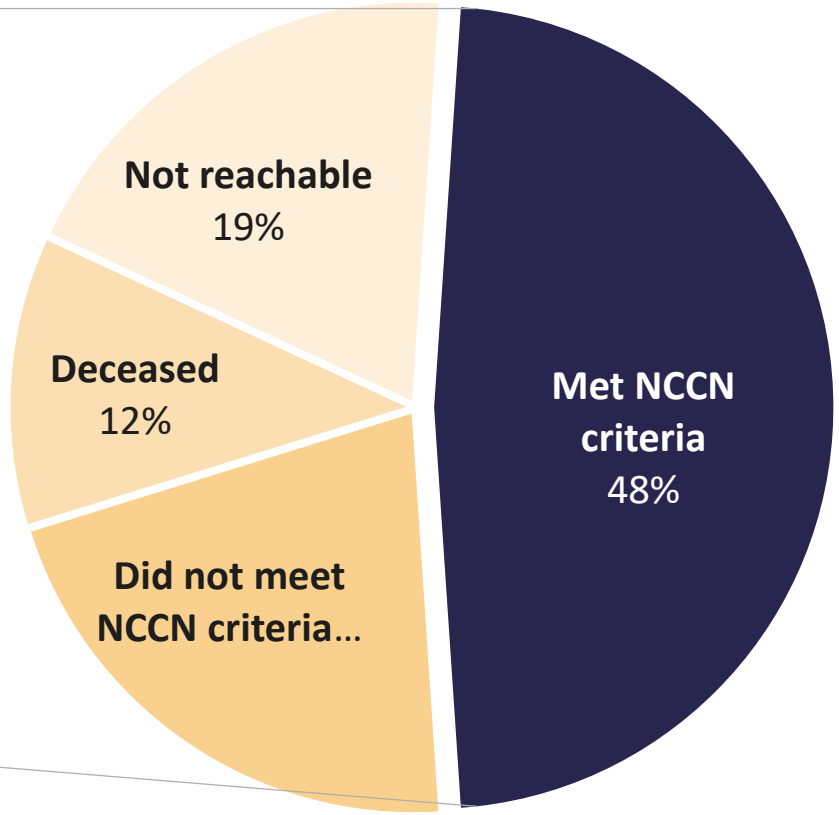
How many with variant were already in the EHR?

n = 170



Of those who did not know they carried a cancer risk variant, how many met NCCN criteria for genetic testing?

n=94

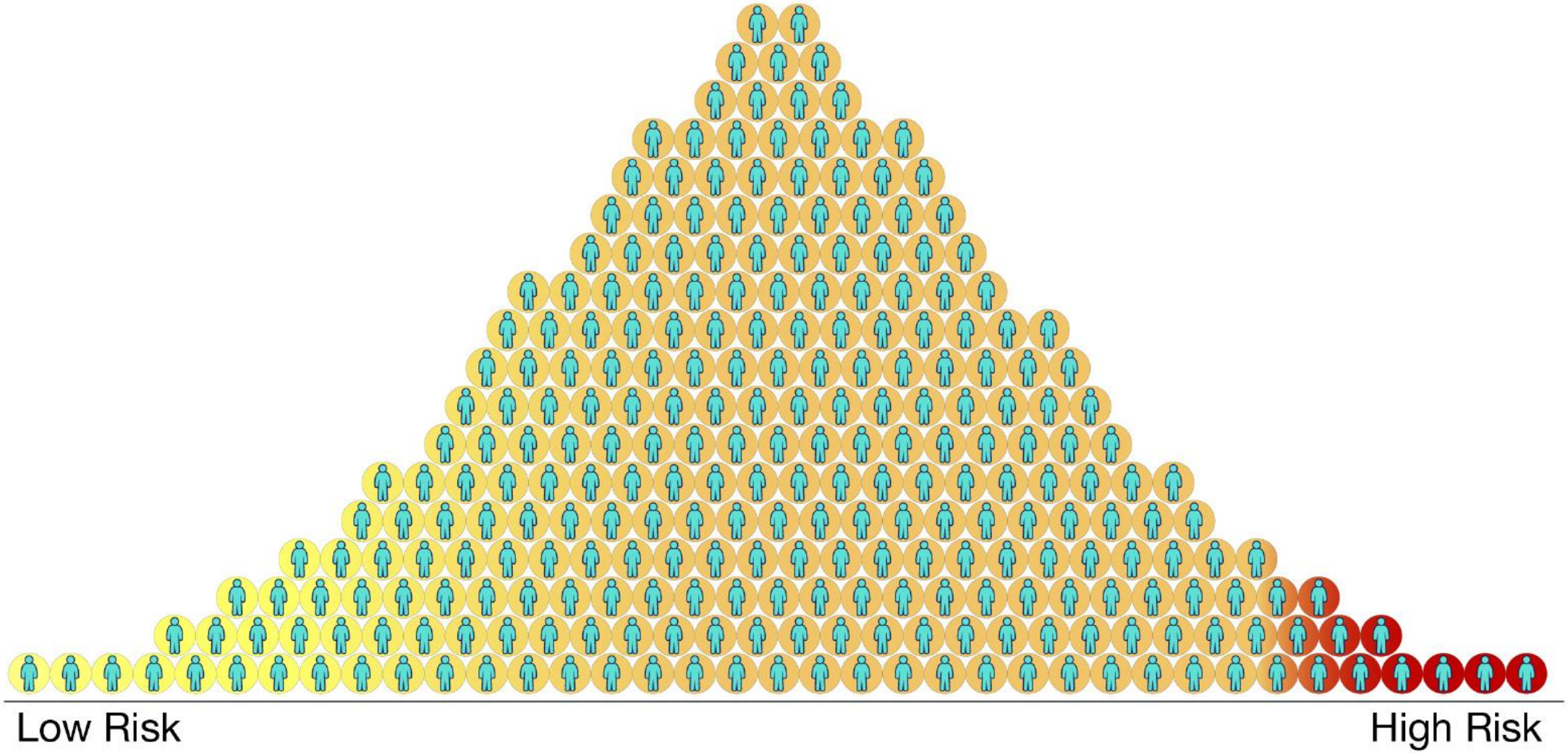


Blout, Machini, Shah et al, in preparation

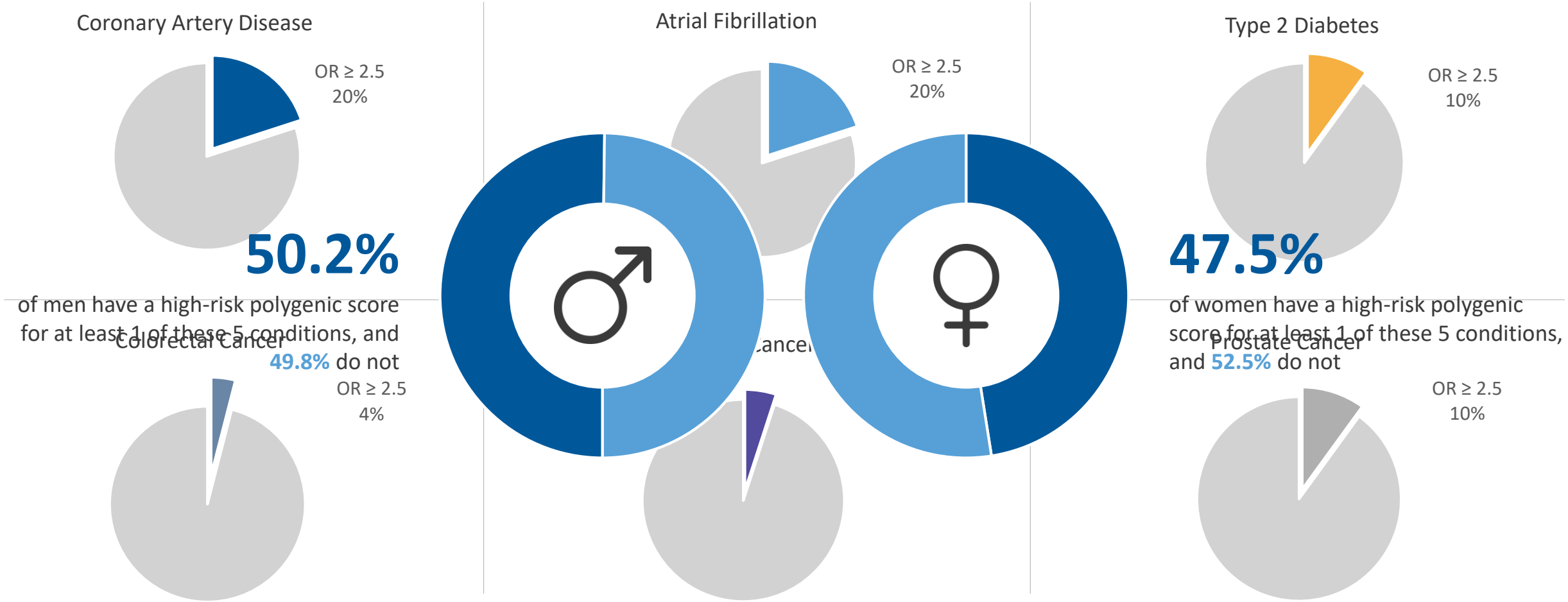
Implementing polygenic risk scores

…combining thousands of low-effect variants to stratify risk for common disease

Polygenic Risk Scores



Reported prevalence of high-risk polygenic scores



Frampton et al, 2016; Khera et al, 2018; Mahajan et al, 2018
Schmit et al, 2018; Schumacher et al, 2018; Seibert et al, 2018

Randomized Trial of PRS Scores

DETAILED GENOMIC RESULTS

A. POLYGENIC DISEASE RISK

Polygenic risk describes the chance of developing certain health conditions based on a large number of genetic variants across the genome. This test assessed the risk for developing the following conditions: atrial fibrillation, breast cancer, colorectal cancer, coronary artery disease and type II diabetes.

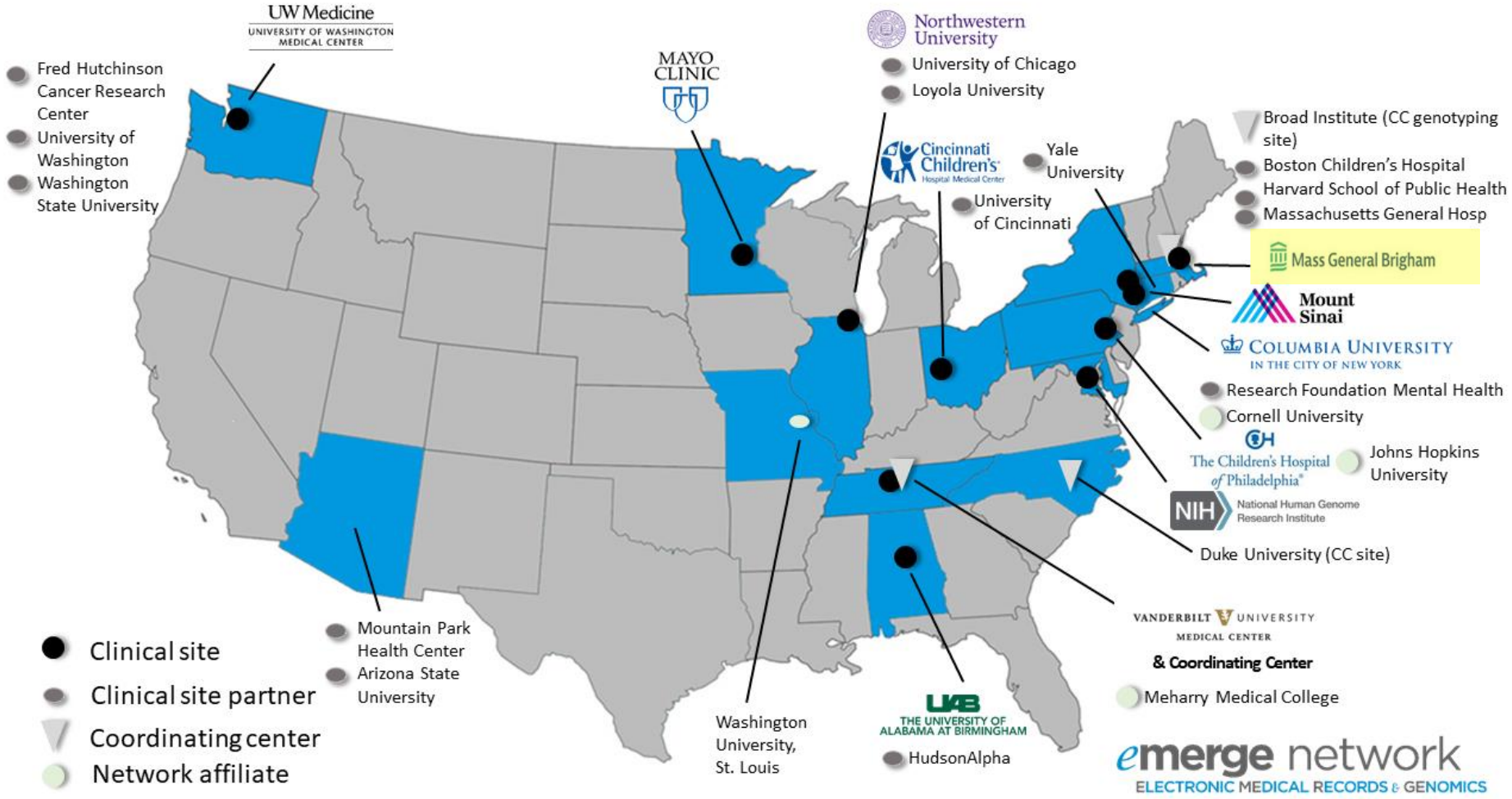
This test identified an increased polygenic risk for Prostate cancer (see methodology for complete description of the analysis). It did NOT indicate increased polygenic risk for the remaining conditions.

Atrial fibrillation	Average Polygenic Risk
Colorectal cancer	Average Polygenic Risk
Coronary artery disease	Average Polygenic Risk
Prostate cancer	Increased Polygenic Risk
Type 2 diabetes	Average Polygenic Risk

GenoVA

Genomic Medicine at VA

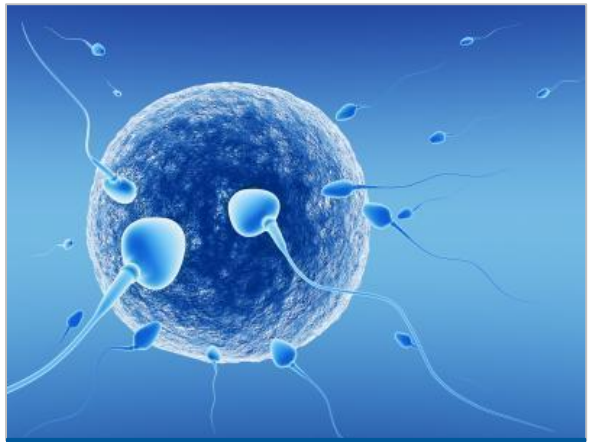
eMERGE IV sites



The number of people carrying variants for monogenic diseases depends upon how many genes are analyzed

Criterion	Number of Genes	% w Pathogenic Variants in High Impact Dominant Conditions
“CDC Tier 1”	10	1-2%
ACMG59 (15 cancer only)	15	1.2%
ACMG59	59	2-3%
Invitae Health Screen	147	6.2%
MedSeq/BabySeq/MilSeq	~ 5000	15-21%[§]

Results in healthy adults and infants from MedSeq/BabySeq/MilSeq Projects + polygenic risk estimates



91% with recessive mutations

80% with atypical responses to meds

15% with dominant mutations

50% With elevated polygenic risk in at least one condition

Christensen et al GIM, 2018; Vassy et al Annals 2017; Ceyhan-Birsoy et al. AJHG, 2019; Frampton et al, 2016; Khera et al, 2018; Mahajan et al, 2018; Schmit et al, 2018; Schumacher et al, 2018; Seibert et al, 2018

Population screening debate intensifies

- Diagnosis of unsuspected genetic disease
- Risk stratification for surveillance and prevention
- Knowledge and personal utility

- Rare conditions with low prior probability could identify many at-risk who do not manifest the condition
- Unproven value: clinical utility and cost-effectiveness
- Inadequate expertise in the medical workforce

Brigham Preventive Genomics Clinic – Now available for telemedicine

HARVARD MEDICAL SCHOOL

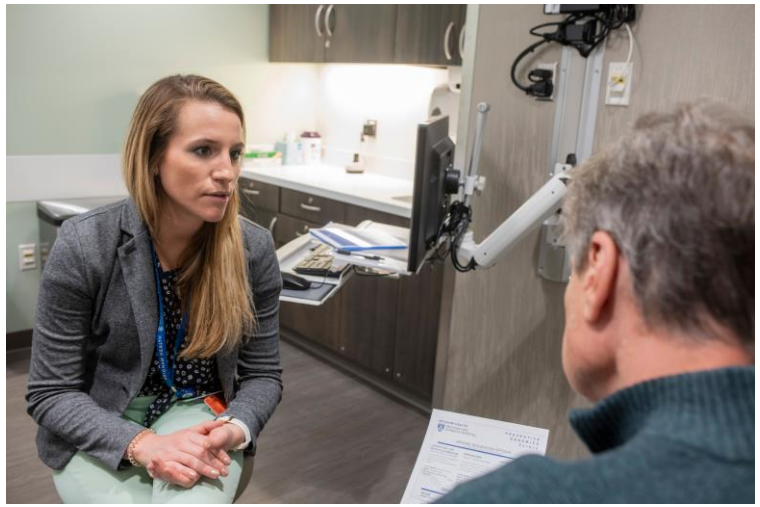
genomeweb

BRIGHAM HEALTH
BWH BRIGHAM AND WOMEN'S HOSPITAL

Brigham and Women's Hospital Opens Preventive Genomics Clinic

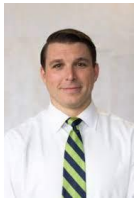
Aug 16, 2019 | staff reporter

NEW YORK – Brigham and Women's Hospital announced today that it has opened the Preventive Genomics Clinic, an academically affiliated clinical service to provide comprehensive DNA sequencing, interpretation, and reporting of disease-associated genes for healthy adults and their children who want to understand and mitigate their risk of future disease.



Video stories: People who benefited from preventive genomics

Full videos here



Precision Population Health

GenoVA
Genomic Medicine at VA

Harvard Pilgrim HealthCare

BROAD INSTITUTE
Medical and Population Genetics

PARTNERS HEALTHCARE | BIOBANK

HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH

BRIGHAM HEALTH
BWH BRIGHAM AND WOMEN'S HOSPITAL

ARIADNE LABS

BRIGHAM HEALTH
BRIGHAM AND WOMEN'S HOSPITAL

HARVARD MEDICAL SCHOOL

Thank You!

genomes2people.org

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@genomes2people

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Please contact me for confidential details on obtaining genome sequencing for yourself or your family members.