

REPORT DOCUMENTATION PAGE

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				5c. PROGRAM ELEMENT NUMBER	
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INSTRUCTIONS FOR COMPLETING SF 298

1. REPORT DATE. Full publication date, including day, month, if available. Must cite at least the year and be Year 2000 compliant, e.g. 30-06-1998; xx-06-1998; xx-xx-1998.

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5a. CONTRACT NUMBER. Enter all contract numbers as they appear in the report, e.g. F33615-86-C-5169.

5b. GRANT NUMBER. Enter all grant numbers as they appear in the report, e.g. AFOSR-82-1234.

5c. PROGRAM ELEMENT NUMBER. Enter all program element numbers as they appear in the report, e.g. 61101A.

5d. PROJECT NUMBER. Enter all project numbers as they appear in the report, e.g. 1F665702D1257; ILIR.

5e. TASK NUMBER. Enter all task numbers as they appear in the report, e.g. 05; RF0330201; T4112.

5f. WORK UNIT NUMBER. Enter all work unit numbers as they appear in the report, e.g. 001; AFAPL30480105.

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15. SUBJECT TERMS. Key words or phrases identifying major concepts in the report.

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17. LIMITATION OF ABSTRACT. This block must be completed to assign a distribution limitation to the abstract. Enter UU (Unclassified Unlimited) or SAR (Same as Report). An entry in this block is necessary if the abstract is to be limited.

Enabling Personalized Medicine through Exome Sequencing in the U.S. Air Force

Robert C. Green, MD, MPH

Professor of Medicine, Harvard Medical School

@RobertCGreen

Director, Genomes2People Research Program

Brigham and Women's Hospital and Broad Institute



Dr. Green's Support and Disclosures

- Research: US National Institutes of Health
US Department of Defense
Broad Institute of MIT & Harvard
Franca Sozzani Fund for Preventive Genomics
- Advisory: AIA, Applied Therapeutics, Helix, Ohana
Biosciences, OptraHealth, Prudential, Verily, Veritas
- Co-Founder: Genome Medical – a company providing telegenetics expertise to patients, providers, employers and care systems
- Disclaimer: The views expressed are those of the author(s) and do not reflect the official views or policy of the Department of Defense or its Components. The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402.

The MilSeq Project: A Military-Academic Collaboration

Carrie L. Blout, MS, CGC

Ruth Brenner, MD, Lt Col, USAF

Kurt D. Christensen, PhD, MPH

Mauricio DeCastro, MD, Maj, USAF

Cubby Gardner, PhD, Maj, USAF

Robert C. Green, MD, MPH

Jacqueline Killian, PhD, Lt Col, USAF

Joel B. Krier, MD, MMSc

Matthew Lebo, PhD

Amy L. McGuire, JD, PhD

Megan D. Maxwell, MS, LCGC

Maxwell J. Mehlman, JD

Debra Neimeyer, PhD, CIV, USAF*

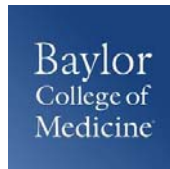
Efthimios Parasidis, JD, MBioethics

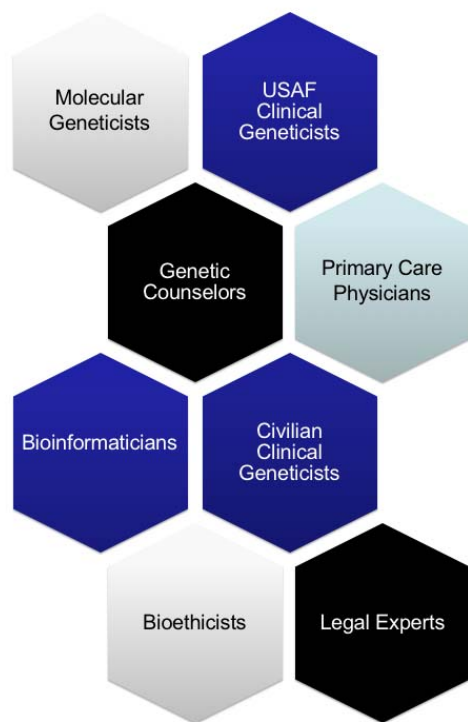
Stacey Pereira, PhD

Jill O. Robinson, MA

Jason L. Vassy, MD, MPH, SM

Jameson Voss, MD, MPH, Maj, USAF





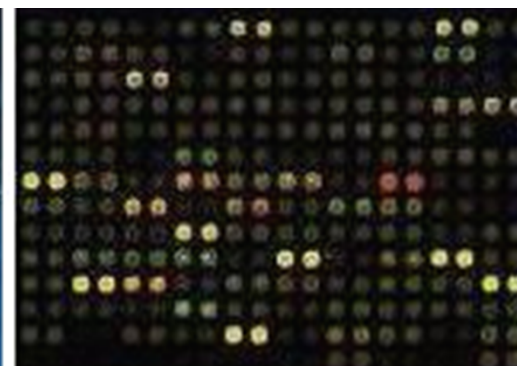
Rationale...

1. Genomics will soon become part of everyday medicine and will provide health benefits.
2. Managing genomic information will require a nimble multi-disciplinary approach.
3. Understanding genomics will be profoundly important to the military for:
 - a. Health of service members and families
 - b. Optimizing performance of the warfighter
 - c. Maintaining military security

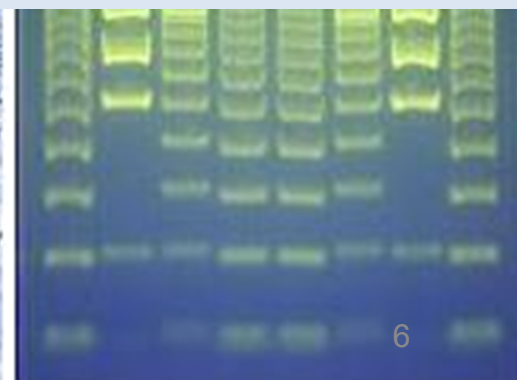


The MilSeq Project

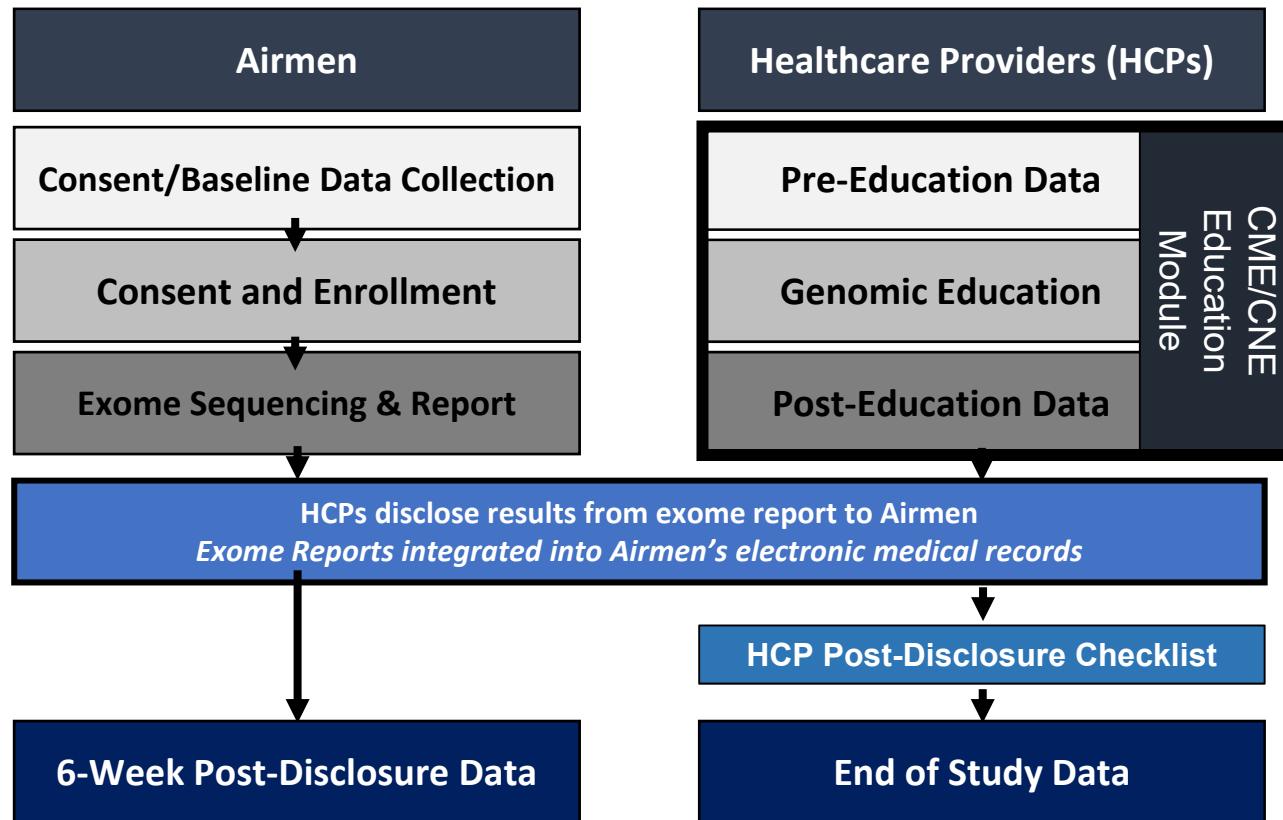
- Initially funded by the United States Air Force (USAF) through Air Force Medical Support Agency (FA8650-17-2-6704)
- Continuation funding through 59th Medical Wing (Joint Base San Antonio-Lackland Air Force Base) and 711th Human Performance Wing (Wright-Patterson Air Force Base)
- Goal is to pilot the implementation of sequencing in day-to-day medicine (consent, sample collection, sequencing, interpretation, report generation, report disclosure, follow up care)
 - Recruit 75 active-duty Airmen and 12 USAF healthcare providers at Lackland to participate in a pilot trial of implementing genomic medicine in the USAF
 - Assess short term medical, behavioral and economic impact
 - Examine the special circumstances associated with implementation of genomic medicine within the active duty military

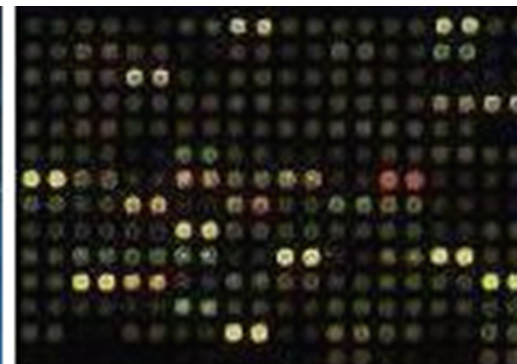


Experimental Design

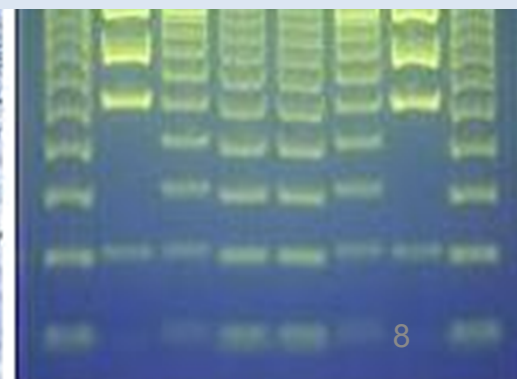


The MilSeq Project Protocol



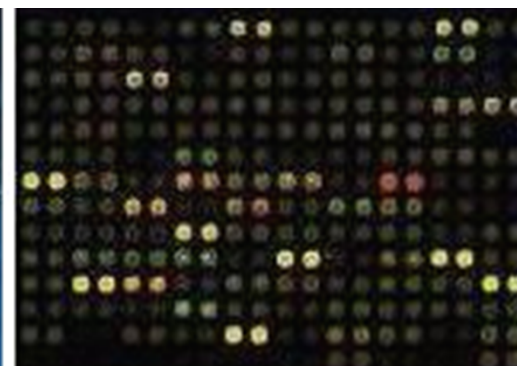


Safety of Participants

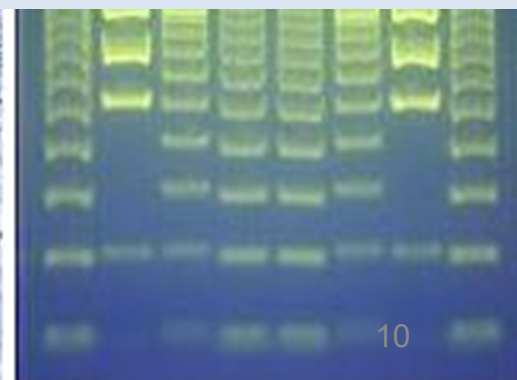


Risk Mitigation in the MilSeq Project

- IRB approved with robust consent process.
- Optional recruitment without coercive messaging.
- Entire sequencing/interpretation process is CLIA/CAP certified and positives confirmed before disclosure.
- Genetic counselor onsite with additional 24-7 availability of experts.
- Patient-HCP disclosures taped and transcribed to be reviewed by study personnel.

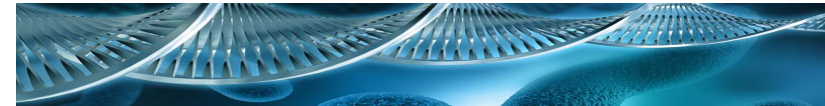


Study Recruitment



Recruitment Methods

- Brochure
- Base newsletter
- Facebook posting
- Direct coordinator approach



Calling Active Duty Airmen to Participate in the MilSeq Project, a Study of Genomic Sequencing

What is the MilSeq Project?

The MilSeq Project is a clinical research study funded by the US Air Force designed to explore how genomic sequencing can be used in the practice of medicine.

What is the purpose of the study?

Genomic sequencing may soon be available to almost everyone. The purpose of this study is to explore how military health care providers (HCPs) and active service Airmen feel about genomic sequencing information and ultimately how they use this information in healthcare.

Who may participate?

We are enrolling healthy active duty Air Force members and military health care providers.

What will happen in this study?

Interested Active duty Air Force members are invited to participate in a baseline survey asking about their thoughts about genomic sequencing. At the end of the survey, they will be asked about their interest in participating in a study where they may have the opportunity to have whole exome sequencing, a type of genomic sequencing.

Survey

-Complete a survey to tell us your opinions and feelings about genomic sequencing and how you think this type of info might impact your medical care.

-In the survey we will ask if you are interested in learning more about another part of our study that may allow you to have whole exome sequencing.

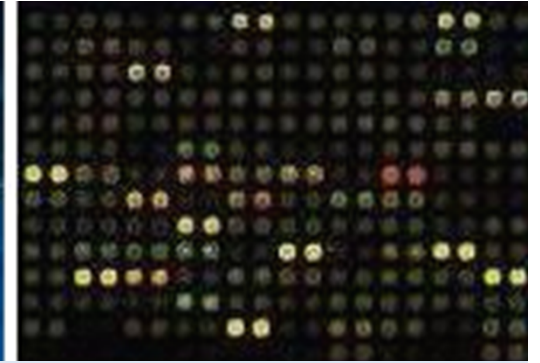
Follow-up

If you tell us you are interested in learning more about the sequencing study, our study Genetic Counselor will call or email you to provide additional information.

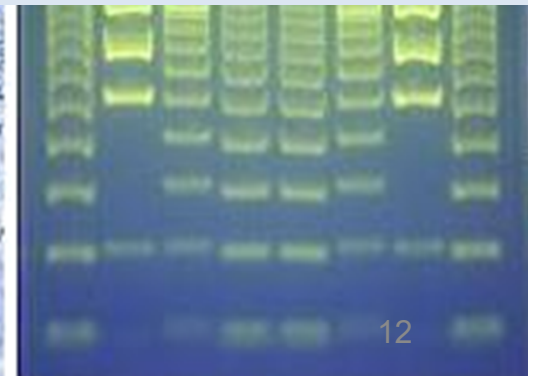
If you are not interested, your participation ends with the survey.

To Participate Use this Link:
<https://is.gd/milseq>

To learn more please contact: **Megan Maxwell** Genetic Counselor at
(210) 292-7556



Health Care Provider Preparation



HCP Education and Support

- 3-hour, military-specific didactic lecture from a genetic counselor
- Inheritance ACTion Sheets (4)

YOUR PATIENT'S FINDING

AUTOSOMAL
•
DOMINANT

Where can I find more information?

- Clinical Sequencing Exploratory Research (CSER)
- GeneReviews®
- Genetics Home Reference
- OMIM®
- Clinical Genome Resource (ClinGen)

What do I do now?
Post-test counseling

- Familiarize yourself with the features of the condition
 - If possible, assess whether the patient already has symptoms
 - If the patient does not yet have symptoms, and screenings or diagnostic tests are available for early detection and prevention, offer these tests to the patient
 - Discuss reproductive risk and whether testing of related individuals may be an appropriate consideration

Your patient's finding is associated with an autosomal dominant condition. This means:

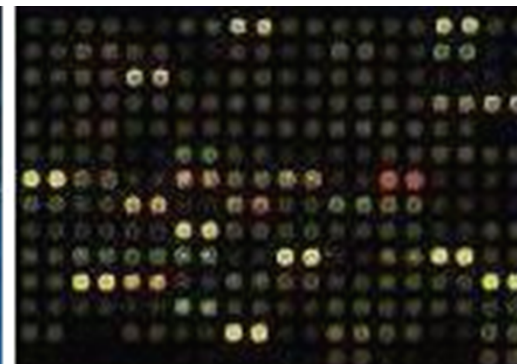
- The patient may already be symptomatic or is likely to develop symptoms in the future, unless the condition has **variable expressivity**¹ or **reduced penetrance**²
 - If the condition has variable expressivity, the patient may only exhibit minor or partial symptoms
 - If the condition has reduced penetrance, the patient may never exhibit symptoms
- If the patient has siblings, they are at risk to have the same finding
- Reproductive risk to any pregnancy is 50%, regardless of the sex of the fetus
 - In very rare circumstances, this risk can increase and also result in more severe symptoms if the patient's partner has the same autosomal dominant condition as the patient [e.g., hypercholesterolemia]

1. variable expressivity – inheriting a dominant allele for a genetic condition, but the extent to which symptoms are shown is on a spectrum (e.g., sliding light dimmer)

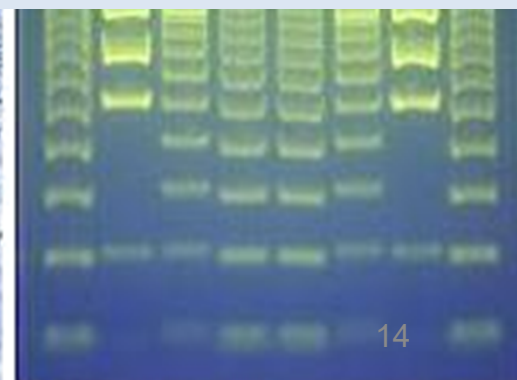
2. reduced penetrance – inheriting a dominant allele for a genetic condition, but not showing symptoms (e.g., "on/off" light switch)

U.S. National Library of Medicine

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a	aa	aa

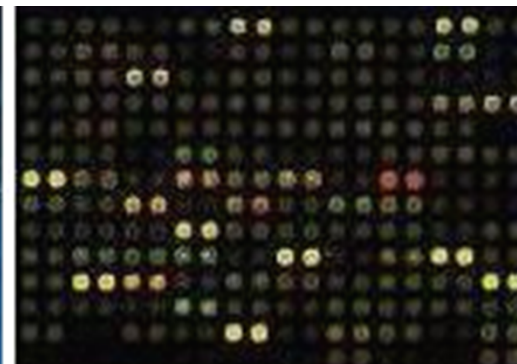


Exome Sequencing

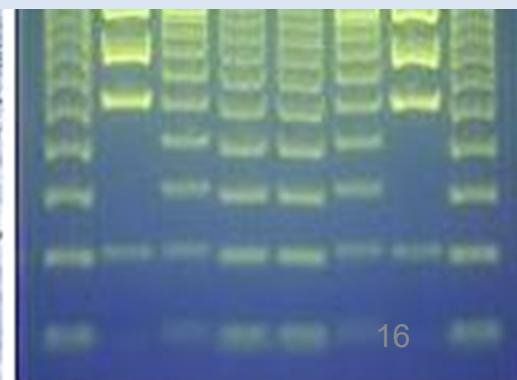


Exome Sequencing at Partners Healthcare Laboratory for Molecular Medicine





How Many Genes Were Analyzed?



All (~ 5000) known monogenic (Mendelian) genes

Dominant (e.g. *BRCA1*, *MLH1*, *MYH7*, *KCNQ1*, *RYR1*)

Recessive (e.g. *CFTR*, *HBB*)

All (~ 5000) known monogenic (Mendelian) genes

Dominant (e.g. *BRCA1*, *MLH1*, *MYH7*, *KCNQ1*, *RYR1*)

Recessive (e.g. *CFTR*, *HBB*)

Selected (9) genes with risk alleles (e.g. *APOE*, *F5*)

All (~ 5000) known monogenic (Mendelian) genes

Dominant (e.g. *BRCA1*, *MLH1*, *MYH7*, *KCNQ1*, *RYR1*)

Recessive (e.g. *CFTR*, *HBB*)

Selected (9) genes with risk alleles (e.g. *APOE*, *F5*)

Selected pharmacogenomic variants (~ 60 medications)

All (~ 5000) known monogenic (Mendelian) genes

Dominant (e.g. *BRCA1*, *MLH1*, *MYH7*, *KCNQ1*, *RYR1*)

Recessive (e.g. *CFTR*, *HBB*)

Selected (9) genes with risk alleles (e.g. *APOE*, *F5*)

Selected pharmacogenomic variants (~ 60 medications)

Genetic determinants of (~ 333) RBC/platelet antigens

All (~ 5000) known monogenic (Mendelian) genes

Dominant (e.g. *BRCA1*, *MLH1*, *MYH7*, *KCNQ1*, *RYR1*)

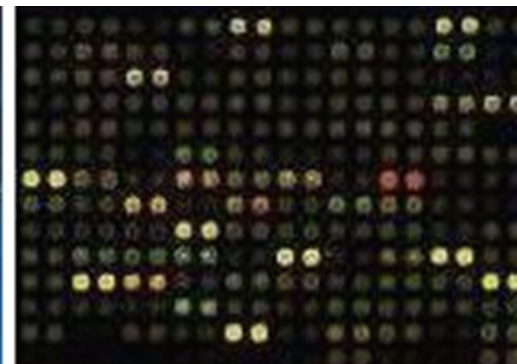
Recessive (e.g. *CFTR*, *HBB*)

Selected (9) genes with risk alleles (e.g. *APOE*, *F5*)

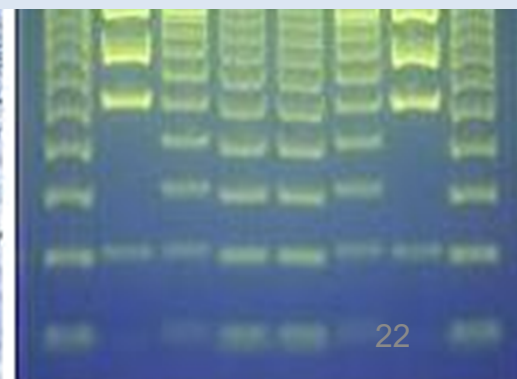
Selected pharmacogenomic variants (~ 60 medications)

Genetic determinants of (~ 333) RBC/platelet antigens

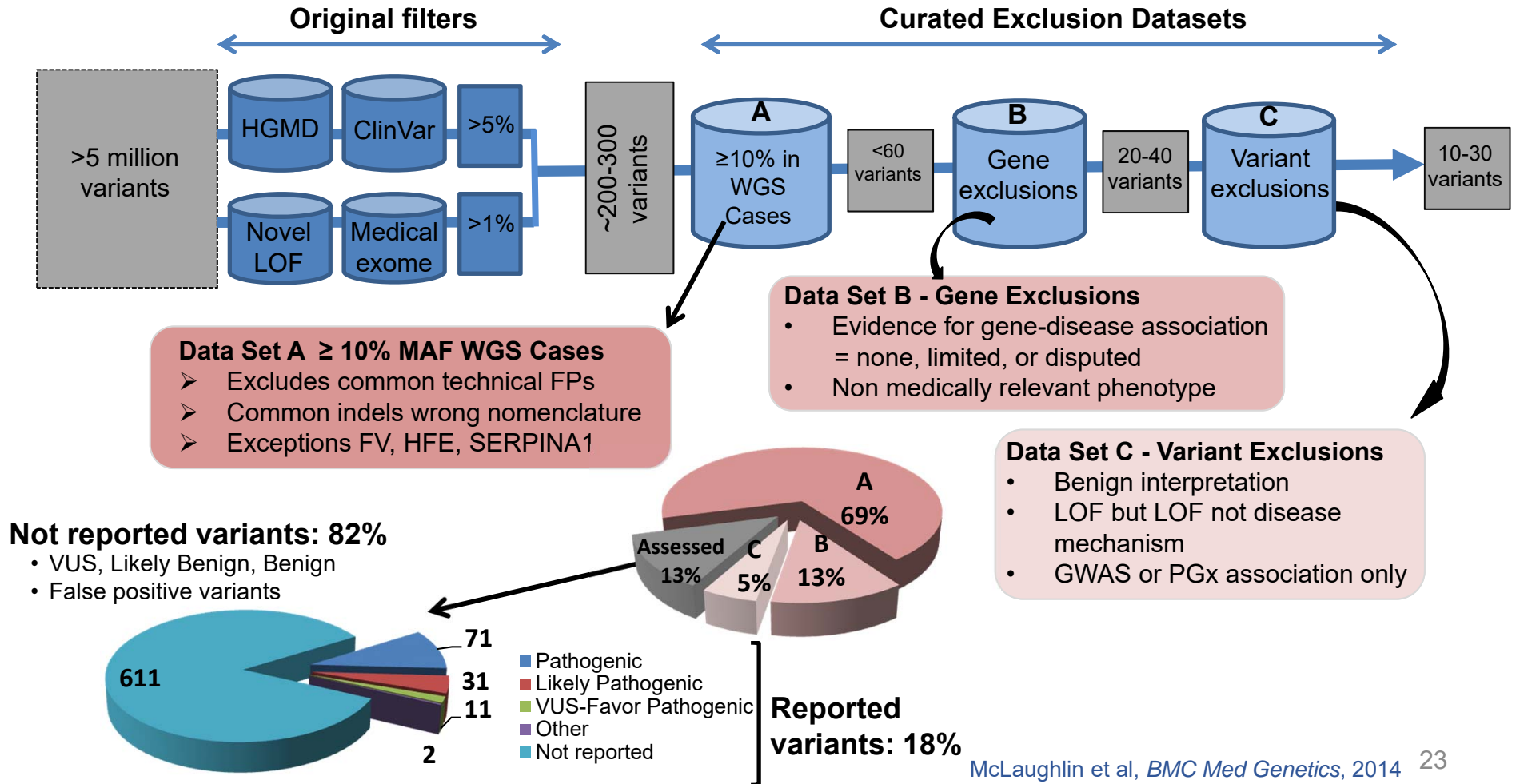
~~Polygenic Risk Scores~~



Variant Classification



MilSeq Exome Filtering Approach

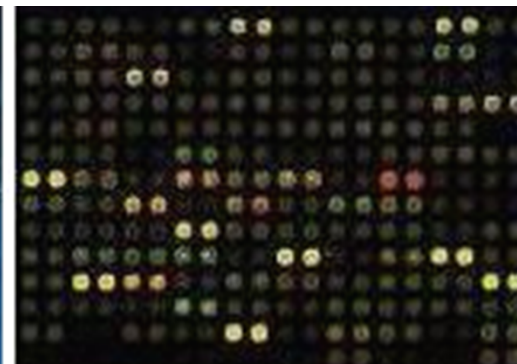


ACMG Criteria for Variant Pathogenicity and Inclusion in MiSeq Reports

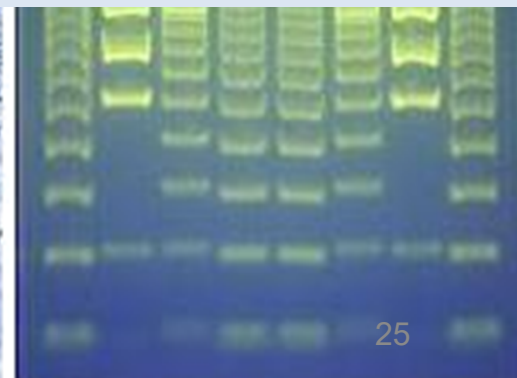
MiSeq Exome Sequencing Report



Standard Indication-Based Genetic Testing Reports



Report Design



MiSeq Project Exome Report

- Monogenic (dom) risks
- Monogenic (rec) carrier status
- Disease-associated risk alleles
- Pharmacogenomic variants
- Blood serology (not shown)

RESULT: VARIANTS OF CLINICAL SIGNIFICANCE IDENTIFIED

One variant conferring carrier status and one variant with disease-associated risks were identified

RESULT SUMMARY

Sequencing of this individual's exome did NOT identify variants with strong evidence to cause a highly penetrant disorder, but identified one variant associated with an increased risk of disease. In addition, sequencing identified carrier status for one variant that may impact disease risk in future children or other family members, depending on the carrier status of the partner(s). All results are summarized on page 1 with further details provided on subsequent pages.

INTERPRETATION SUMMARY

A. MONOGENIC DISEASE RISK VARIANTS

This test did NOT identify variants with strong evidence to cause a highly penetrant disorder.

B. CARRIER STATUS VARIANTS

This test identified carrier status for one recessive disorder. **In the heterozygous state, this variant is not known to play a role in disease, since pathogenic variants in both copies of the X gene are necessary to cause disease.**

Being a carrier of this variant does NOT put this individual at risk for disease, but it may impact disease risk in future children, depending on the carrier status of this individual's future partner(s).

Please note, we cannot conclusively rule out a pathogenic variant on the other copy of the gene given test and analysis limitations.

Disease, Inheritance	Gene Transcript	Variant	Allele state	Classification	Penetrance	Carrier Phenotype
Adenylosuccinate lyase deficiency, Autosomal recessive	ADSL NM_000026.2	c.1277G>A p.Arg426His	Heterozygous	Pathogenic	High	None reported

C. DISEASE-ASSOCIATED RISK ALLELES

This test identified one variant associated with an increased risk of developing clinical manifestations. Please see below and subsequent pages for more detailed variant information.

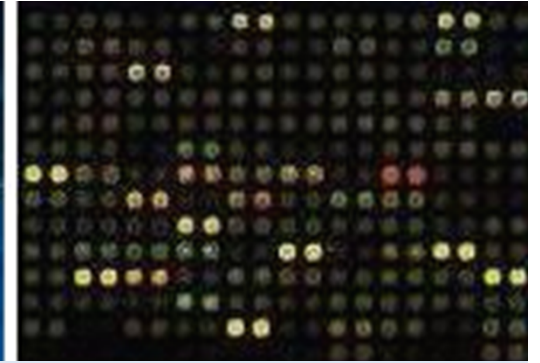
Disease, Inheritance	Gene Transcript	Variant	Allele state	Classification	Relative Risk
Pulmonary Fibrosis	MUC5B NM_002458.2	c.-3133G>T	Heterozygous	Established Risk Allele	3.7

D. PHARMACOGENOMIC ASSOCIATIONS

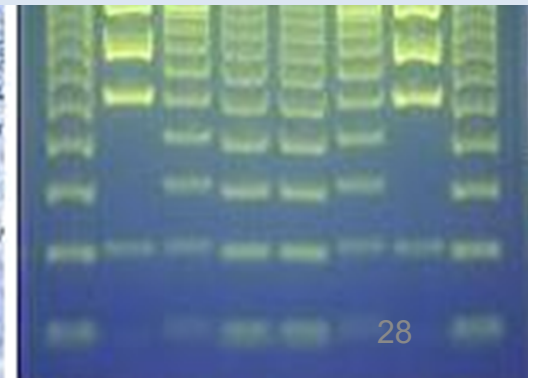
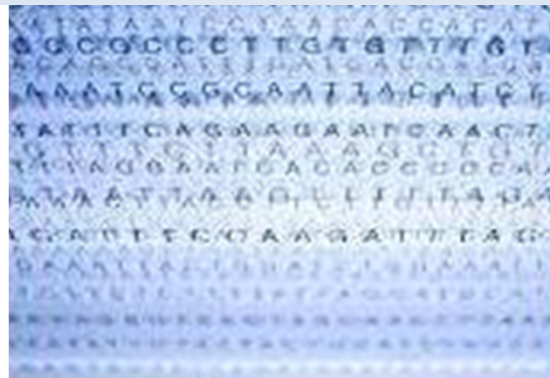
This test identified the following pharmacogenomic associations with a potential change in management. Additional pharmacogenomic associations can be found on subsequent pages.

Drug	Gene Transcript	Variant(s)	Genotype	Risk and dosing information
Clopidogrel	CYP2C19 NM_000769.1	c.[-806C(;)681G(;)636G]; c.[-806C(;)681G>A(;)636G]	*1/*2	Decreased response to clopidogrel
Digoxin	ABCB1 NM_000927.4	c.3435T>C p.Ile1145Ile	TT	Decreased metabolism and increased serum concentration of digoxin

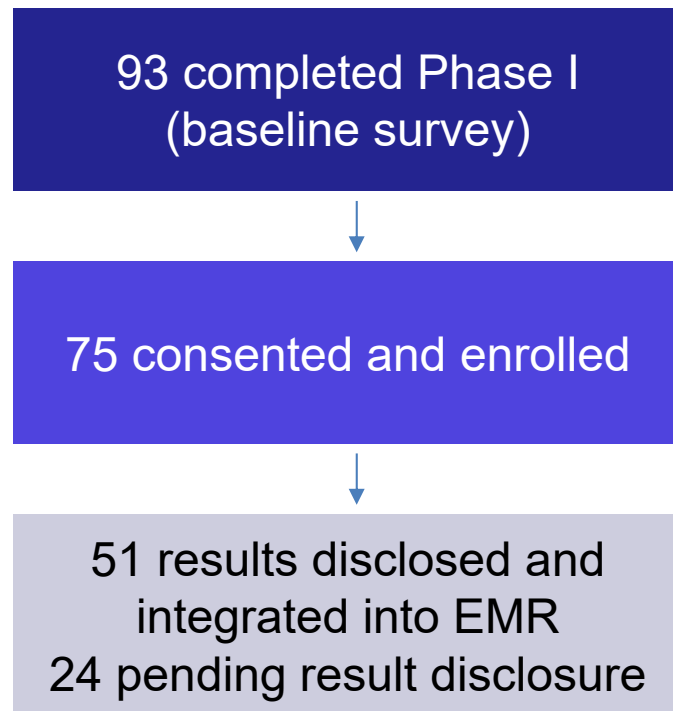




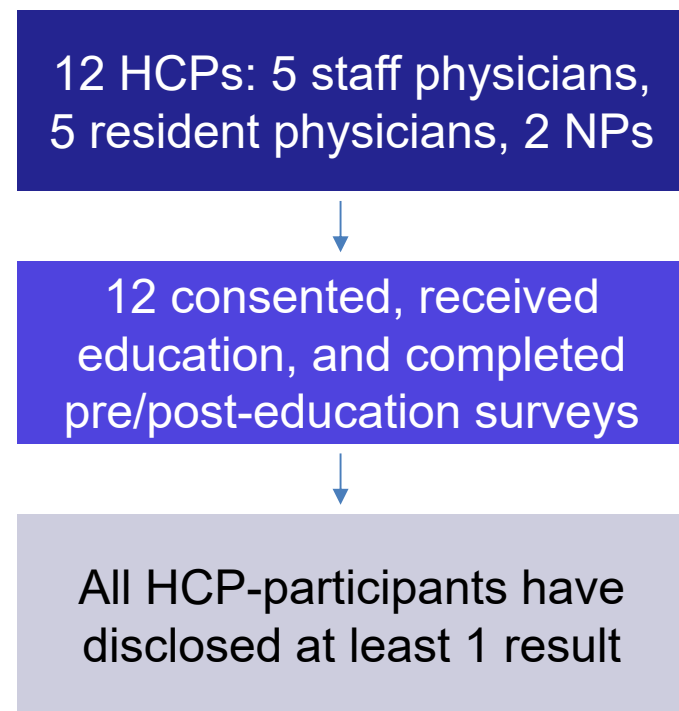
Recruitment Progress to Date

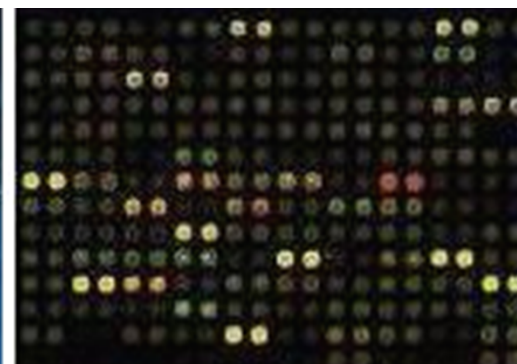


Patient-Participants

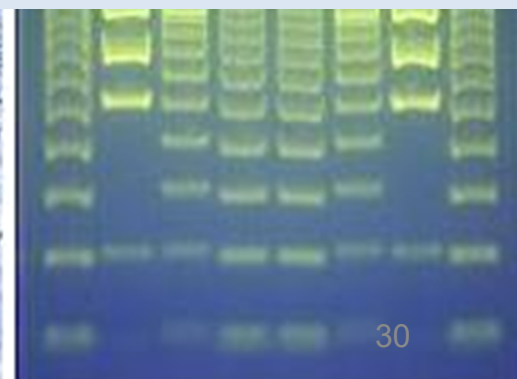


Provider-Participants

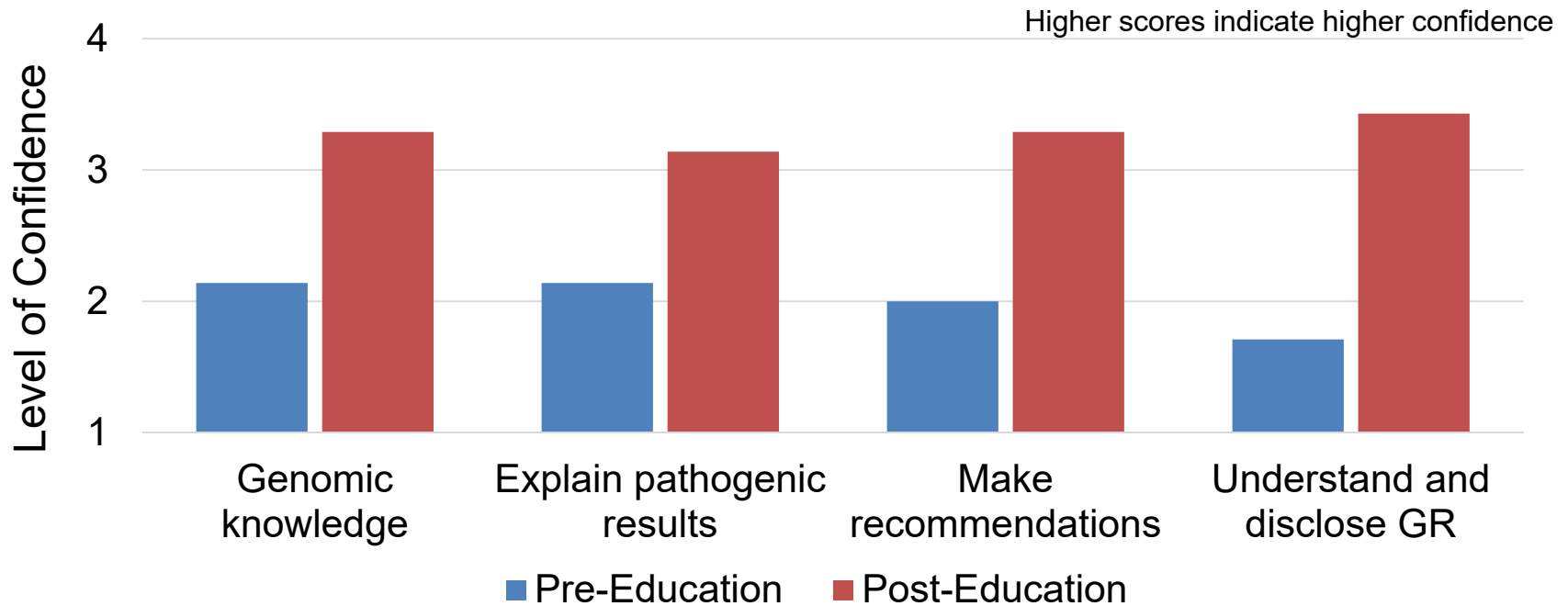




Health Care Provider Education

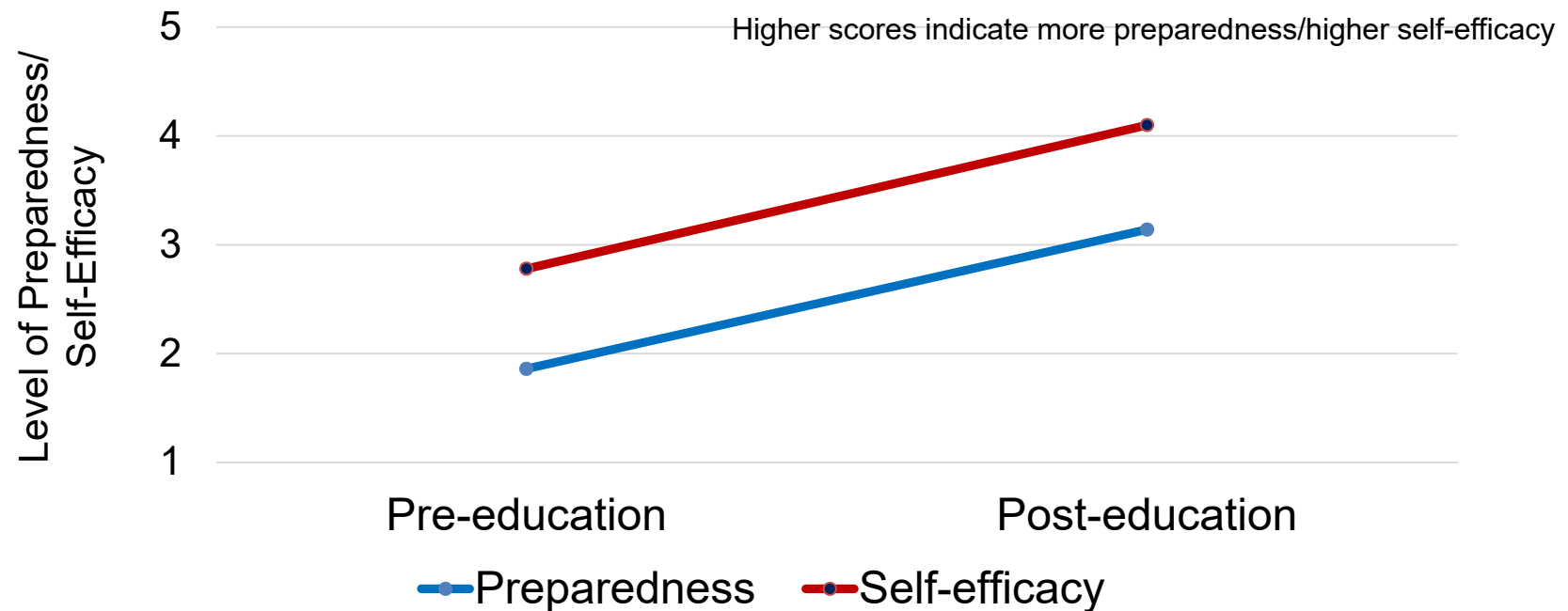


Healthcare Provider Confidence Pre- vs. Post-Education

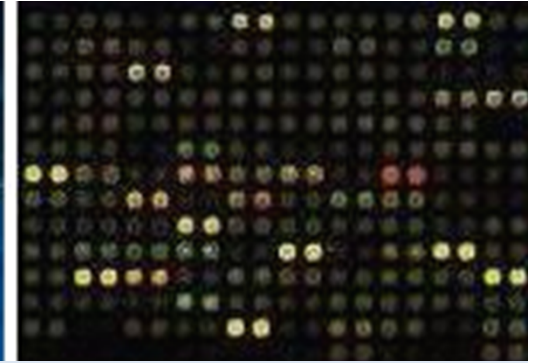


HCP's reported significantly higher feelings of confidence in each domain after attending the education session (all $p < 0.05$).

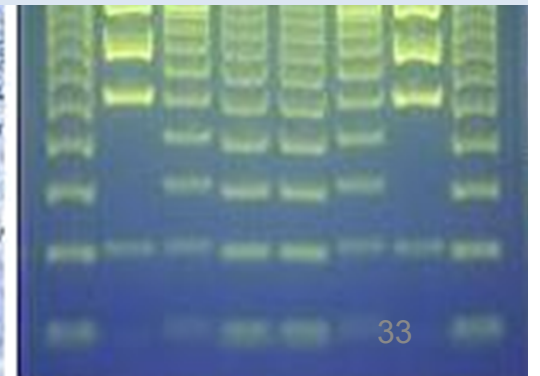
HCP Preparedness & Self-Efficacy Pre- vs. Post-Education



HCP's reported significantly higher feelings of preparedness (scale 1-4, $p=0.037$) and self-efficacy (scale 1-5, $p=0.018$) after attending the education session. ³²



Cohort Description and Baseline Data



Patient-Participant Demographics

Airmen Demographics

Characteristic – N (%) unless otherwise noted	N=93
<i>Age (n=87)</i>	
Mean in years (SD)	33.75 (±8.25)
<i>Gender (n=93)</i>	
Male	48 (51.6%)
Female	45 (48.4%)
<i>Race/Ethnicity (n=93)</i>	
Hispanic or Latino	17 (18.3%)
Non-Hispanic White	61 (65.6%)
Non-Hispanic Other*	13 (13.9%)
Prefer Not to Answer	2 (2.2%)
<i>Education (n=93)</i>	
Did not graduate from college	36 (38.7%)
College graduate or higher	57 (61.3%)
<i>Annual Household Income (n=93)</i>	
≤ \$99,999	64 (68.8%)
≥ \$100,000	29 (31.2%)

* Non-Hispanic Other includes African American, Asian, and Other

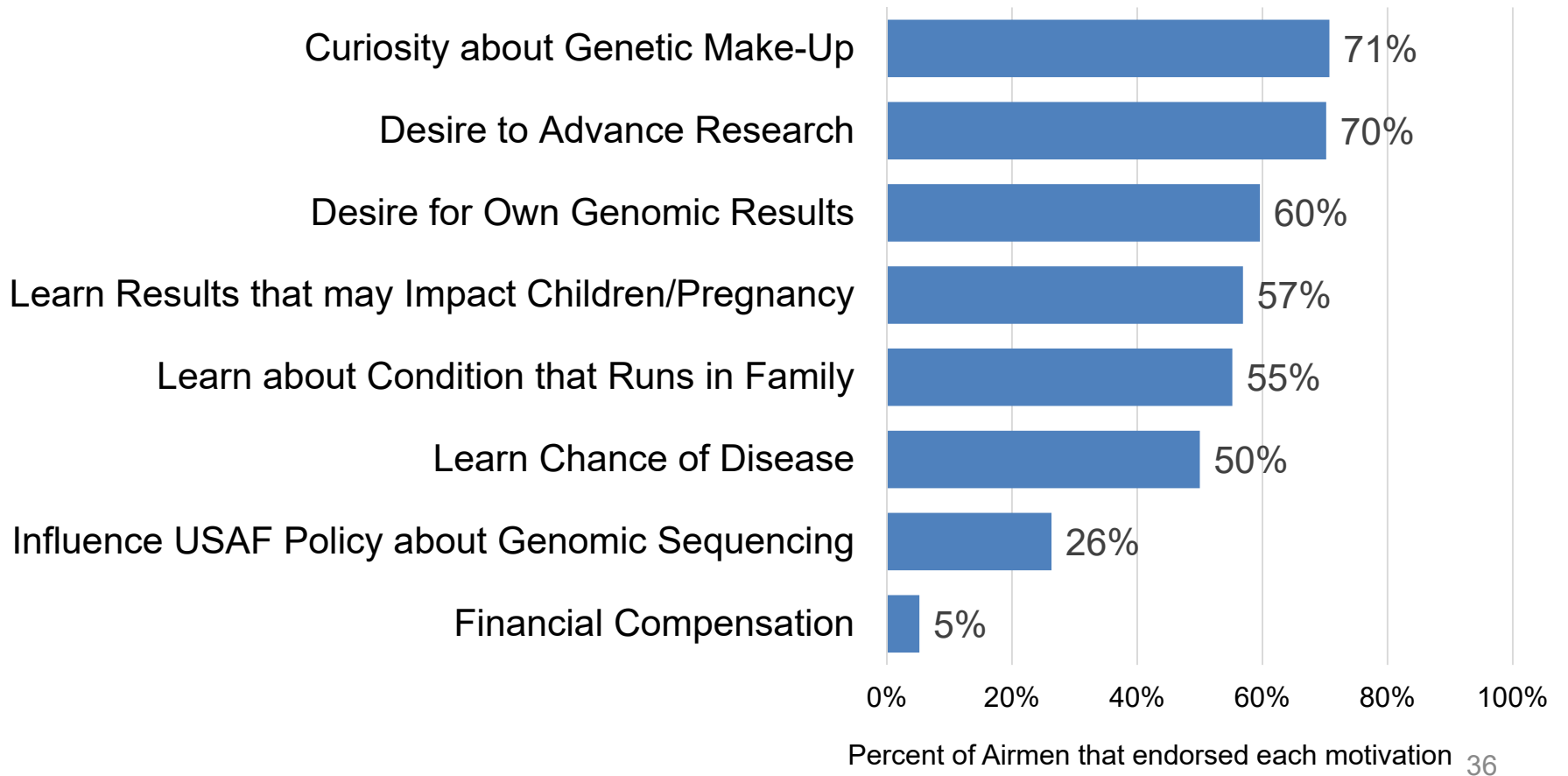
Healthcare Provider Demographics

Health Care Provider Demographics

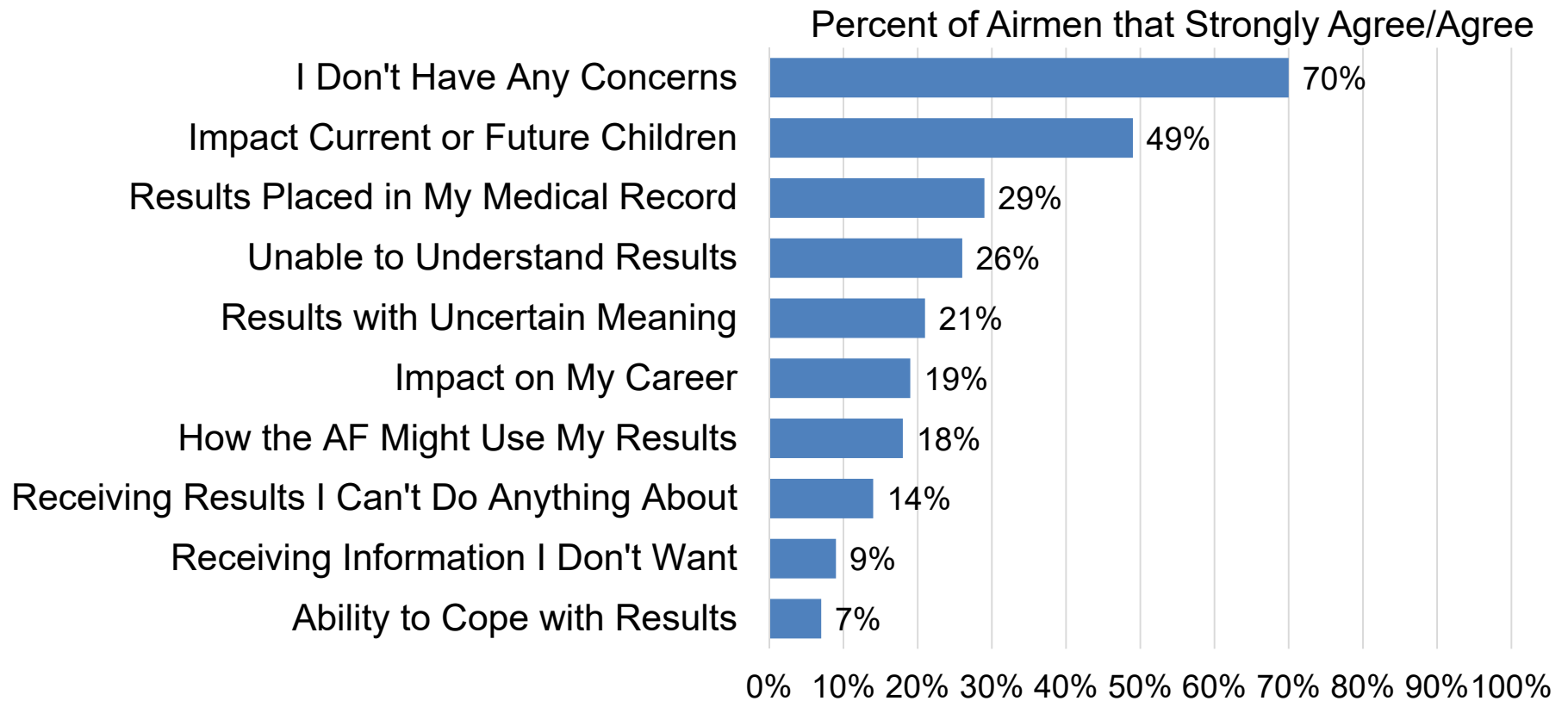
Characteristic – N (%) unless otherwise noted	N=12
<i>Age (n=11)</i>	
Mean in years (SD)	39 (\pm 9.25)
<i>Gender (n=12)</i>	
Male	8 (66.7%)
Female	4 (33.3%)
<i>Race/Ethnicity (n=12)</i>	
Hispanic or Latino	0 (0%)
Non-Hispanic White	6 (50%)
Non-Hispanic Other*	6 (50%)
<i>Years in Practice (n=12)</i>	
1-10	10 (83.4%)
21-30	2 (16.6%)
<i>Genetics Training (n=12)</i>	
No	11 (91.7%)
Yes	1 (8.3%)

* Non-Hispanic Other includes African American and Asian

Airmen's Motivations to Participate in a Genomic Sequencing Project



Airmen's Concerns about Participating in a Genomic Sequencing Project



Monogenic Disease Risk: 58 Exome Reports

- 4 participants (6.8%) with autosomal dominant findings
 - Familial hypercholesterolemia
 - Male, self-reported high cholesterol first diagnosed at 20 years of age
 - Cholesterol level of 300 on most recent lipid panel (2013)
 - Prescribed CRESTOR®* as a result of this finding
 - Dehydrated hereditary stomatocytosis I
 - Male, normal CBC, splenectomy contraindicated for affecteds
 - Familial exudative vitreoretinopathy
 - Female, no visual symptoms reported
 - Nonsyndromic hearing loss
 - Female, no hearing impairment reported

Carrier Status Variants: 58 Exome Reports

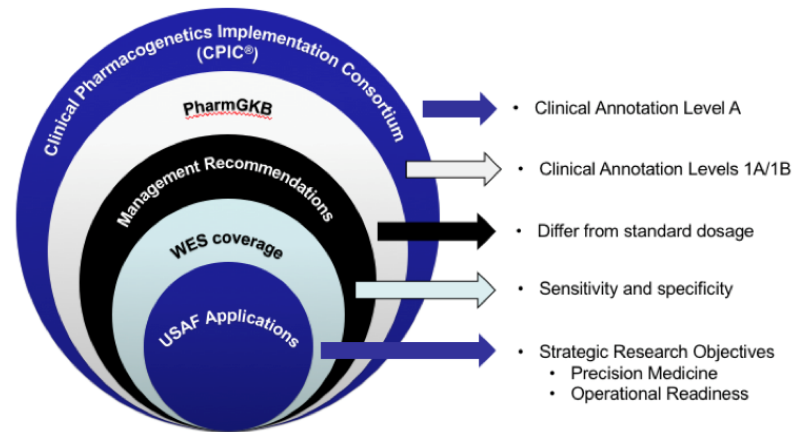
- 50 participants (86%) identified as carriers
 - Range: 0-6 per report; average: 2 per report
- Repeated findings:
 - Hereditary hemochromatosis: n=17
 - Stargardt disease: n=5
 - Primary ciliary dyskinesia: n=4
 - Thrombocytopenia with absent radius syndrome: n=4
 - Nonsyndromic autosomal recessive hearing loss: n=3

Carrier Status Variants: 58 Exome Reports 13 Possible Manifesting Heterozygotes!

- Congenital hypothyroidism: n=2
- Cystinuria: n=2
- Fanconi anemia: n=1
- Hypogonadotropic hypogonadism: n=1
- Myotonia congenita: n=1
- Nijmegen breakage syndrome: n=1
- Pseudocholinesterase deficiency: n=3
- Rippling muscle disease: n=1
- Sickle cell: n=1

All Participants have at Least One Atypical Pharmacogenomic Variants

Selection Criteria



PGx Panel Classifications & USAF Applications

Analgesic*

- Combat casualty care
- Chronic pain management for combat-related disability
- Musculoskeletal training injury

Anticoagulant

- Combat casualty care
- Prophylaxis for post-amputation deep vein thrombosis

Anesthetic

- Combat casualty care
- Continuum of care for subsequent surgical interventions

Anticonvulsant

- Combat casualty care
- Traumatic brain injury

Psychiatric*

- Post traumatic stress disorder
- Combat-related depression and anxiety
- Sleep disturbances

**CYP2D6* variants are salient for informing pain management and mental health treatments in the USAF. WES may not be reliable for the detection of *CYP2D6* whole-gene duplications (decreased sensitivity). Therefore, supplemental CNV analysis is performed for inclusion in the MilSeq Project PGx panel.

Lessons from the MilSeq Study

- Multi-disciplinary team has demonstrated that sequencing can be integrated into the practice of military medicine
- Substantial number of Airmen interested in sequencing and are not deterred by thorough informed consent process.
- Participants are not distressed, even for positive findings.
- High motivation to learn about their own health (personal and reproductive)
- HCPs do not initially rate themselves as prepared but the 3-hour education module modestly improves their self-perceived level of preparedness
- Surprising amount of information pertinent to operational readiness (disease risk, performance vulnerabilities, pharmacogenomics, rapid and accurate typing for blood transfusion)

MiSeq Project Publications

npj | Genomic Medicine

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PERSPECTIVE OPEN

Genomic medicine in the military

Mauricio De Castro¹, Leslie G Biesecker², Clesson Turner³, Ruth Brenner⁴, Catherine Witkop⁴, Maxwell Mehlman^{5,6}, Chris Bradburne⁷ and Robert C Green⁸

Molecular Genetics & Genomic Medicine

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INVITED COMMENTARY

Military genomics: a perspective on the successes and challenges of genomic medicine in the Armed Services

Mauricio J. De Castro¹  & Clesson E. Turner²

¹United States Air Force Medical Genetics Center, 81st Medical Group, Keesler AFB, Mississippi 39534

²Division of Genetics, Department of Pediatrics, Walter Reed National Military Medical Center, Bethesda, Maryland 20889

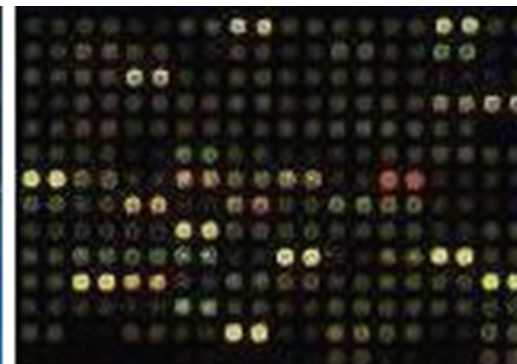
MilSeq Project Scientific Conference Presentations

2017

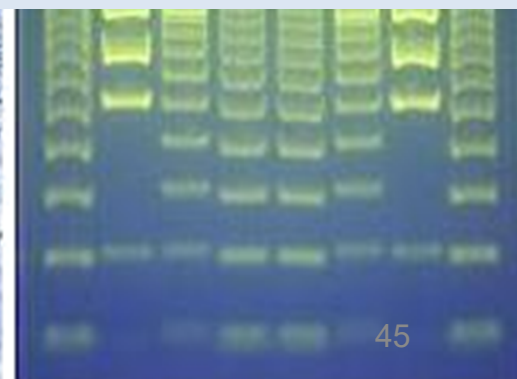
- Military Operational and Readiness Precision Medicine
- American Society of Human Genetics

2018

- Law and the Biosciences
- American Society of Law, Medicine and Ethics
- American College of Medical Genetics and Genomics
- Military Health System Research Symposium
- American Society for Bioethics and Humanities
- American Society of Human Genetics
- National Society for Genetic Counselors
- US Army Center for Environmental Health Research Science
- Integrative and Collaborative Biomedical Research



Future Potential



Potential Benefit to Warfighter

- Health and morale of warfighters and their families
- Identification of rare donors for blood transfusions
- Awareness of increased occupational risks
- Leveraging of genetic advantages
- Countermeasures for security vulnerabilities

The MilSeq Project – Future Potential

- Evaluate scalability by expanding the number of active duty military in MilSeq Project
 - Improve overall health of service members and families
 - Tailor warfighter performance with genetic/physiological strengths
 - Identify rare blood donors and recipients for transfusion
- Utilize existing DNA repositories and create DHA biobanks to improve knowledge base
- Contribute to ongoing security discussions

Thank you !

Carrie L. Blout, MS, CGC

Ruth Brenner, MD, Lt Col, USAF

Kurt D. Christensen, PhD, MPH

Mauricio DeCastro, MD, Maj, USAF

Cubby Gardner, PhD, Maj, USAF

Robert C. Green, MD, MPH

Jacqueline Killian, PhD, Lt Col, USAF

Joel B. Krier, MD, MMSc

Matthew Lebo, PhD

Amy L. McGuire, JD, PhD

Megan D. Maxwell, MS, LCGC

Maxwell J. Mehlman, JD

Debra Neimeyer, PhD, CIV, USAF

Efthimios Parasidis, JD, MBioethics

Stacey Pereira, PhD

Jill O. Robinson, MA

Jason L. Vassy, MD, MPH, SM

Jameson Voss, MD, MPH, Maj, USAF

Clifton Dalgard, PhD, USUHS

Lydia Hellwig, ScM, CGC

Luis Rohena, MD, Maj, US Army

Clesson Turner, MD, Lt Col, US Army

Jacqueline Killian, PhD, Lt Col, USAF: jacqueline.m.killian.mil@mail.mil

Robert Green, MD, MPH: rcgreen@bwh.harvard.edu

Megan Maxwell, MS, LCGC: mdmaxwell@bwh.harvard.edu