

VA's Million Veteran Program

Ronald M. Przygodzki, MD

Associate Director, Genomic Medicine Program

Acting Director, Biomedical Laboratories Research & Development

Office of Research & Development

US Department of Veterans Affairs



July 2013



Let's go build ourselves a program...

- There seemingly is never enough information
- The sample sizes available are usually suboptimal to answer questions
- Genomic studies are statistically underpowered
- The phenotype (composite of an organism's observable characteristics or traits) is skimpy or not standardized
- There is never enough money to do it all

- The “silent” question...



How do we know if anyone supports or cares?

- How do we find out whether the Veteran “wants” this to begin with?
- Most importantly, never assume – rather refute or reaffirm...

**Normal is an illusion.
What is normal for the spider,
is chaos for the fly**

— *Charles Addams*



Veteran Consultation Project



- In 2007, VA launched a consultation project to assess Veterans' knowledge and attitudes about genomic medicine
 - Interagency agreement with National Human Genome Research Institute and conducted under a cooperative agreement by the Genetics and Public Policy Center at Johns Hopkins University
 - PI Kathy Hudson
 - Focus Groups, Pilot, and Survey
- 10 focus groups in five locations with diverse participants (Fall 2007)
 - Solicit a wide range of perspectives
 - Identify themes and issues
- Surveyed 931 participants (Spring 2008)
 - To test themes and messages from focus groups



Veteran Consultation Project: Findings

- 83% said program should be done
- 71% said they would participate
- 61% also said they would:
 - Attend a ½ day exam
 - Allow medical records from non-VA health care to be added to the database
 - Have follow up exams over time
- Participation associated with:
 - Attitudes about helping and history of previous “altruistic behaviors”
 - Attitudes about research
 - Curiosity about genetics
 - Satisfaction with VA
 - Demographic differences

ARTICLE

Veterans' attitudes regarding a database for genomic research

David Kaufman, PhD¹, Juli Murphy, MS¹, Lori Erby, PhD², Kathy Hudson, PhD¹, and Joan Scott, MS, CGC¹

Purpose: Large cohort studies to investigate interactions between genes, environment, and lifestyle require large representative samples of the population. The Department of Veterans Affairs health care system is uniquely positioned to carry out such research, with a large patient population and a sophisticated system of electronic medical records. As the Veterans Affairs considers establishing a large database of genetic information and medical records for research purposes, a survey of 931 Veterans Affairs patients was carried out to measure their willingness to participate, what their concerns would be, and their preferences about

Some link genomic and other exposure data to electronic medical records, which can streamline data collection but may limit the information available to that recorded within a particular medical records system. Others perform standardized health exams and collect medical histories at baseline and follow-up intervals.⁷⁻⁹ This approach may lead to more complete data, but also may require more time and expense. All such studies face the challenge of accurately and efficiently measuring participants' environmental exposures.



Veteran Consultation Project: Findings (Cont'd)

- Prior to the launch of MVP:
 - Online survey of 451 Veterans to understand attitudes toward opt-in and opt-out models of enrollment
- Most respondents were willing to participate under both opt-in (80%) and opt-out (69%) models
- Stronger preferences for the opt-in approach were expressed among younger Veterans and Hispanic Veterans

©American College of Medical Genetics and Genomics | ORIGINAL RESEARCH ARTICLE | Genetics in Medicine

Prefrences for opt-in and opt-out enrollment and consent models in biobank research: a national survey of Veterans Administration patients

David Kaufman, PhD¹, Juli Bollinger, MS¹, Rachel Dvoskin, PhD¹ and Joan Scott, MS, GCG²

Purpose: In 2006, the Department of Veterans Affairs launched the Genomic Medicine Program with the goal of using genomic information to personalize and improve health care for veterans. A step toward this goal is the Million Veteran Program, which aims to enroll a million veterans in a longitudinal cohort study and establish a database with genomic, lifestyle, military-exposure, and health information. Before the launch of the Million Veteran Program, a survey of Department of Veterans Affairs patients was conducted to measure preferences for opt-in and opt-out models of enrollment and consent.

Methods: An online survey was conducted with a random sample of 451 veterans. The survey described the proposed Million Veteran Program database and asked respondents about the acceptability of opt-in and opt-out models of enrollment. The study examined differences in responses among demographic groups and relationships between beliefs about each model and willingness to participate.

Results: Most respondents were willing to participate under both opt-in (80%) and opt-out (69%) models. Nearly 80% said they would be comfortable providing access to residual clinical samples for research. At least half of respondents did not strongly favor one model over the other; of those who expressed a preference, significantly more people said they would participate in a study using opt-in methods. Stronger preferences for the opt-in approach were expressed among younger patients and Hispanic patients.

Conclusion: Support for the study and willingness to participate were high for both enrollment models. The use of an opt-out model could impede recruitment of certain demographic groups, including Hispanic patients and patients under the age of 55 years.

Genet Med 2012;14(9):787-794

Key Words: biobank; genetics; informed consent; opt-out; recruitment; research ethics



Recruitment: Status

Current strategies:

- Primary method is centralized, mail-based recruitment
- Augmented by:
 - Walk-ins: Veterans who present to MVP study location without a scheduled appointment
 - Co-recruitment via other Cooperative Studies Program initiatives
- Enrollment rates are ~20%

Future strategies:

- There is room to grow!
 - Not all strategies have been taken advantage of
 - On-line
 - Social media

Thank you!

