



Gulf War Era Veterans' Patterns of Enrollment in a Biorepository Project

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BACKGROUND & OBJECTIVES

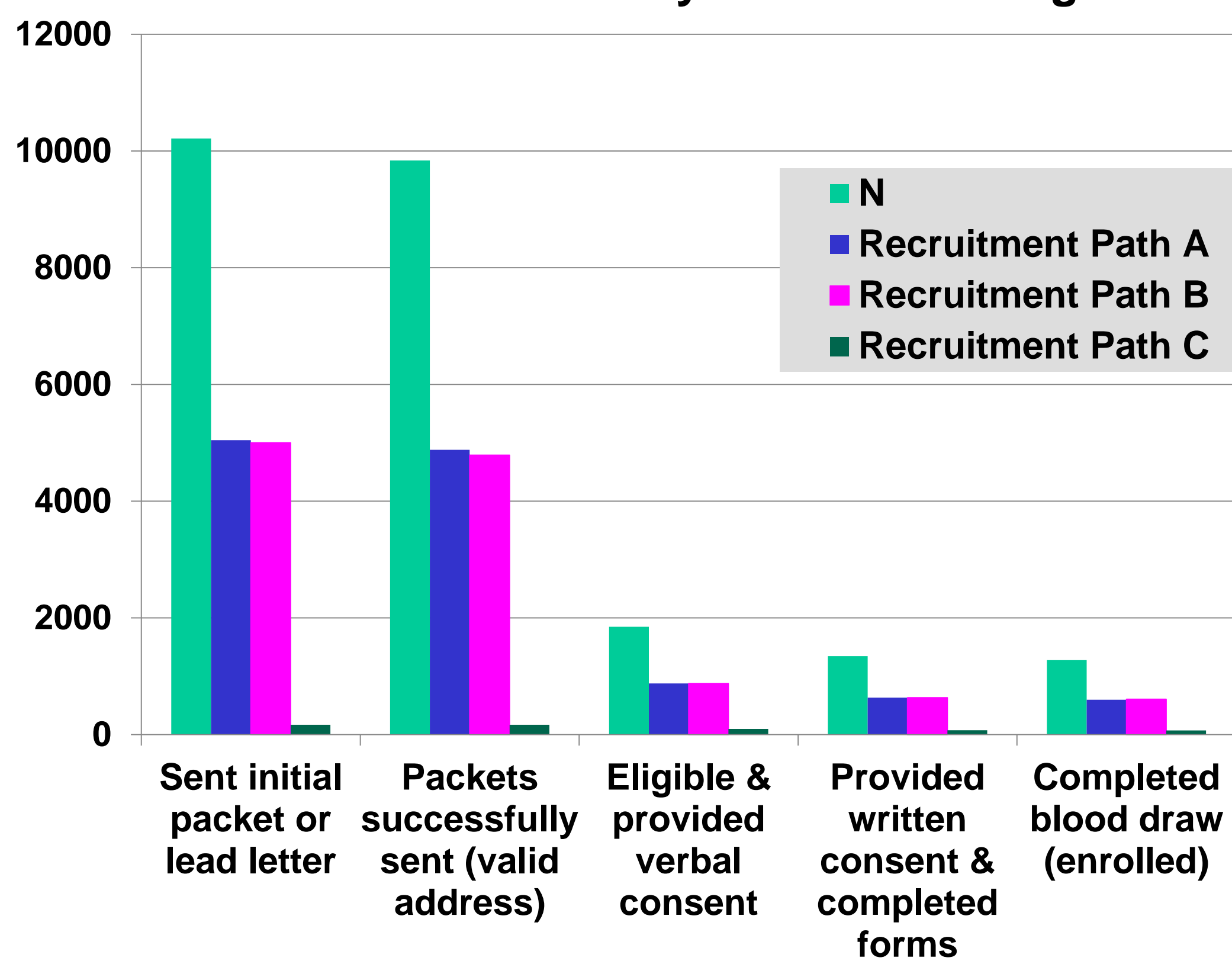
- During the 1990-1991 Gulf War Era (GWE) ~700,000 US Armed Forces deployed to Southwest Asia; 4 million served elsewhere. Many GWE Veterans experience health conditions that are poorly understood.
- The goal of **Gulf War Era Cohort and Biorepository pilot stage** was to test enrollment & data collection processes to inform wider implementation.

METHODS

Pilot project: Implemented from Sept 2014 to May 2016.
Eligibility: All Veterans who served from July 1990 - August 1991, regardless of deployment or VA user status.
Sample: Stratified random sample of 10,000 GWE Veterans from Defense Manpower Data Center sample.
Recruitment pathways: Path A: Mailed enrollment packet; Path B: Mailed introduction letter followed by enrollment packet; Path C: Veteran self-nomination
Enrollment methods: Phone follow-up & informed consent conducted by call center; field-based phlebotomists visited Veterans at their home or workplace.
Requirements: Complete mailed survey, allow access to VA & non-VA medical records, provide a blood sample.
Source of Opt-Out Information: Postcards & notes from call center staff
Analytic Approach: Content-analyzed free response opt-out information; data coded separately by two team members (80% initial agreement), then reconciled.

RESULTS

Number of Veterans by Enrollment Stage



	N	A	B	C
Sent initial packet or lead letter	10213	5046	4999	168
Packets successfully sent (valid address)	9839	4881	4790	168
Eligible & provided verbal consent	1848	875	877	96
Provided written consent & completed forms	1343	633	634	76
Completed blood draw (enrolled)	1276	598	607	71

Reason Removed from Enrollment Process

	Mail undeliverable	Bad phone #	Maximum Call attempts	Opted Out	Not Eligible	Deceased	No blood draw
N	357	888	4309	2887	284	110	64

Opt-Out Analysis

Opt-Out Reasons: Fixed Choice ¹	N ²
Not interested	2760
Do not want to give blood	264
Confidentiality concerns	360
Too sick	102
Concerns about genetic studies	131
Concerns about access to med records	293
Do not have time	505

1) Fixed choice: pre-existing answer choice selected by Veteran on postcard or by call center staff based on conversation
 2) Some Veterans provided more than one reason for opting out. Reasons are not mutually exclusive.

Common Opt-Out Themes: Free Response¹

Common Opt-Out Themes: Free Response ¹	N ²	Example Quote
Generally not interested	184	"[Veteran] stated that he just has some gut feeling & could not explain the reasoning as to why he did not want to participate..."
VA-related concerns	101	"No Faith in The V.A." "[Veteran said] ...VA has not helped him with his medical issues & it's been over 20 yrs."
Perceived ineligibility or belief that they are not a good candidate	72	"Was never deployed..." "I was there but I'm healthy; no need to do it."
Actual ineligibility	68	"Was not in the service 1990-1991"
Logistical barriers	60	"Working, can't take off."
Concern about research methods	58	"[Veteran] states that the survey is too long & if it were online she would do it." "[Veteran] said... he doesn't want his blood sitting in a bank waiting for research."
Concern about Privacy/Information	58	"Info release agreement far too broad." "The questionnaire is [too] intrusive"
Question value of project	36	"I don't think anything will come of it. It is just going to...drag along like the agent orange thing."

1) Free response: written response on postcard or verbal response recorded by call center staff
 2) As of 6/8/2016. Some Veterans provided more than one reason for opting out. Reasons are not mutually exclusive.

LESSONS LEARNED

Enrollment Patterns

- Paths A & B yielded similar enrollment rates.
- Path B required additional staff time & resources. However, sending a lead letter before an enrollment packet helped identify bad addresses & save money on subsequent mailings.

Opt-Out Analysis

Opt-out analysis highlights need to:

- Build interest, understanding, & trust around research
- Refine messaging about eligibility requirements- clarity is key!
- Address concerns about privacy & information security
- Explore ways to reduce requirements & burdens on participants (e.g. optional medical record release)
- Further explore Veterans' perspectives on research through stakeholder engagement & qualitative research activities