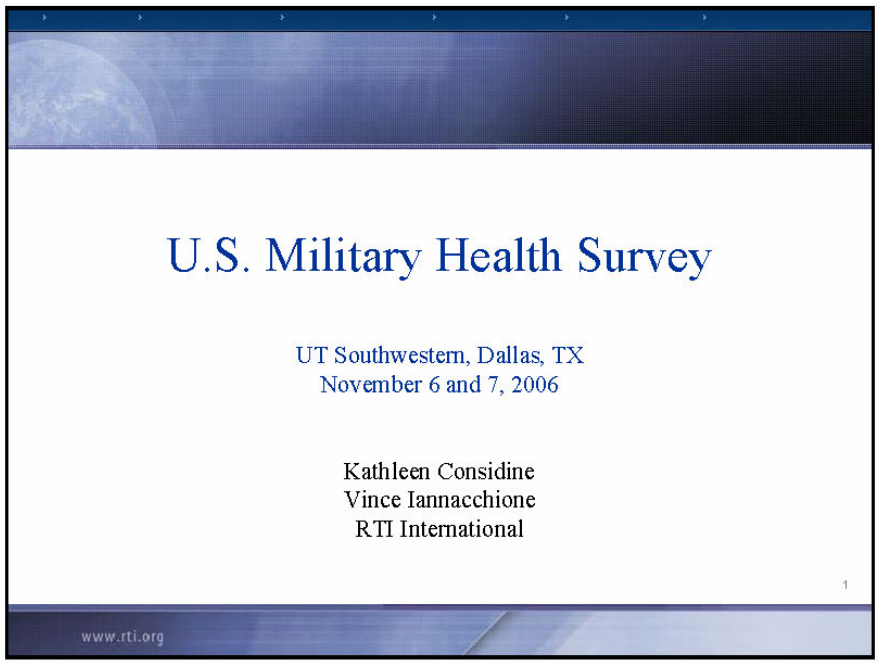
Presentation 2 - Kathleen Considine and Vince Iannacchione



Primary Analytic Objectives

Among Gulf War Era Veterans

- Estimate the prevalence of:
  - any Haley syndrome
  - each of the three primary Haley syndromes
- Test for differences between those who were:
  - Deployed to *Kuwaiti Theater of Operations* (KTO)
  - Not deployed to KTO (but deployable)

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Secondary Analytic Objectives

- Validate and refine the factor analysis model used to derive original Haley syndromes
- Estimate magnitude of the "Healthy Warrior Effect"

  "Bias caused by the disproportionate concentration of pre-war illness in the non-deployed population."

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Study Design Overview

Three-Phase Study of Gulf War Era (1990-91) Veterans

Phase 1: Approximately 8,000 Telephone Interviews (CATI)

Phase 2: Approximately 2,000 Blood Specimens

Phase 3: Approximately 400 Clinic Exams

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Components of the Interview Phase

- CATI Questionnaire Development
- CATI Programming
- Telephone Interviewing Protocol
- Quality Assurance

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Phase 1 – CATI Questionnaire

Questionnaire includes three modules

- Symptoms (771 questions)
- Exposures (244 questions)
- Family Issues (76 questions)

Average length of interview

- 60 minutes for those healthy and not deployed to KTO
- 2.5 hours for those deployed with health issues

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CATI Questionnaire

Symptoms Module contains questions regarding:

- Case definitions of Haley, Steele, Fukuda, Kang, CFS (CDC), FM (survey) and MCS (Iris Bell's Chemical Odor Intolerance scale).
- Physical and mental functional status (SF-12)
- Physician-diagnosed conditions
- Medical assessments of vision and balance disturbance
- Postwar driving abilities and record
- Health problems before the war
- Treatments tried and assessments of their effectiveness
- Time course of post-war symptoms

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CATI Questionnaire

Exposures Module contains questions regarding:

- Chemical weapons alarms, Khamisiyah
- Use of insect repellents, pesticide-treated uniforms, flea collars
- Took pyridostigmine bromide (PB) and resulting side effects
- Vaccinations, medicines taken before and during deployment
- Exposure to oil fire smoke, jet fuel, other petroleum products
- Exposure to depleted uranium (CHPPM categories)
- Combat exposure scales (Keane; Haley)
- Individual location/date information if separated from unit
- Sexual harassment/assault

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CATI Questionnaire

Family Issues Module contains questions regarding:

- Fertility
- Outcome of each pregnancy
- Birth defects
- Evidence of learning disorders in children

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CATI Questionnaire

Methodological Issues in Questionnaire Development

- Focus groups
- Adapt from paper-and-pencil (PAPI) to CATI
- Revisions based on other validated questions
- Methods for asking sensitive questions
- Techniques to minimize recall bias
- Identify programming and question wording issues
- Timing Test
- Procedures to alleviate mental fatigue

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CATI Programming

During the interview, the CATI program must be able to

- Calculate Haley, Steele, and Fukuda syndrome scores
- Match a veteran's unit with the Troop Location Data Base
- Schedule a continuation call
- Select a random sub-sample of non-syndromic veterans for blood specimens

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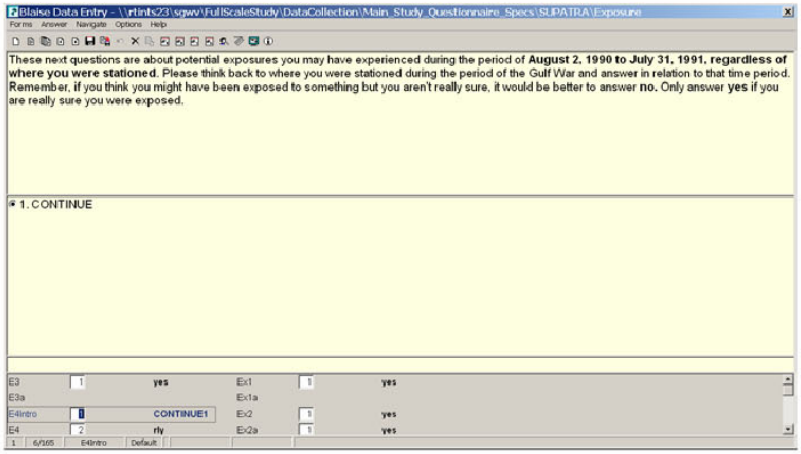
CATI Programming



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Telephone Interviewing Protocol

Locating Veterans

- Initial batch tracing for all sample members
- Interactive tracing for unlocatable sample members

Training CATI Interviewers

- 4 day-long interviewer trainings
- Interviewer training on dealing with refusals
- Interviewers must pass 2 certifications prior to beginning work

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RTI Call Center

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Endorsements and Study Clearances

Endorsements

- Veterans Service Organizations

Clearances

- IRB Approval from RTI and UT-Southwestern
- HSRRB (DoD) clearance from Ft Detrick
- Certificate of Confidentiality from NIEHS

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Telephone Interviewing Protocol

Advance Materials

- Lead Letter
  - Participation is important but voluntary
  - $50 for completing CATI questionnaire
  - Location of study website
- Letters of Endorsement
- Map of KTO
- Document containing FAQs and Answers

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Study Website

US Military Health Survey

Home
Study Overview
Confidentiality
Endorsements
Interview Materials
FAQs

A survey of 8,000 men and women from all branches of the United States Armed Forces serving on active duty, ready reserve, or the National Guard.

Click here to learn about your rights as a study participant.

Last Modified: November 1, 2006 11:06 AM

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Quality Assurance

Questionnaire

- Real-time silent monitoring
- Quality circle meetings with interviewers

Interviewer Retraining

- Re-emphasize original training, address new issues

Pilot Study

- Tested all facets of the design including data analysis

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Phase 2 – Blood Specimens

Purpose

- Determine association between Haley syndromes and PON level

Protocol

- Phase 2 participants selected from CATI respondents
  - *All* identified as syndromic using Haley definition or from groups of special interest
  - A random sub-sample from others
- Contract with EMSI to collect samples
- Samples sent to UT-Southwestern for analysis

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Phase 3 – Clinic Exam

Purpose

- *Clinical verification of Haley syndromes*

Protocol

- Phase 3 selected after Phase 2 completed from respondents
  - Case/control sample balanced on characteristics
- RTI will recontact Veterans by phone to gain cooperation
- UTSW will finalize appointments/transportation
- Clinic exam will take place at UTSW and will last 2 full days

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Time Line

Submitted HSRRB clearance for Pilot:	Nov, 2003
Received HSRRB clearance for Pilot:	Oct, 2004
Conducted CATI phase of the Pilot Survey:	Jan, 2005 – Apr, 2006

Conduct blood phase of the Pilot:	Nov – Dec, 2006
Obtain clearances for Main Study:	Dec, 2006
Conduct Main Study:	Jan – Dec, 2007

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Survey Population

Target Population

3.75 million Gulf War Era veterans on active duty or in the reserves

- 752K veterans who were deployed to KTO
- 3M non-deployed veterans

Sampling Frame

- Created by Defense Manpower Data Center (DMDC)
- Updated KTO deployment status from CHPPM

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Stratified Sampling Design

Strata for CATI Phase

Deployed to KTO	Location in KTO
Age Group	Gender
Race	Active or Reserve status
Special Strata	

Strata for Blood Specimen Phase

Syndromic/Non-Syndromic

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Stratified Sampling Design

Special Strata

- 24th Reserve Naval Construction Battalion
- Parents of children with Goldenhar Complex
- Twin Pairs
- Air crew members
- Aircraft maintenance personnel

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Design Optimization

Objective

Detect true differences between major reporting domains with acceptable statistical power.

Procedure

We will use the Sample Planning Tool developed by RTI staff for cost/variance optimization.

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Sampling Weights

Sampling weights needed to adjust sample estimates for

- Selection bias
- Nonresponse bias

Weights calculated in a two-step process

1. Initial weight = inverse of selection probability
2. Nonresponse adjustment applied to initial weight

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Preliminary Sample Sizes

Selected:	13,000	
Located:	11,400	(88%)*
Eligible:	11,000	(97%)*
CATI Participants:	8,000	(73%)*

* Pilot study results

For methodological use only. Estimates are not statistically significant.

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Recommendations to Improve Response Rates

For the main survey, we will

- Use IRS information to help locate veterans
- Remove 'Gulf War' from the study title
- Address legal concerns about participating
- Maintain a web site for the study
- Promote survey in VSO publications
- Welcome other ideas!

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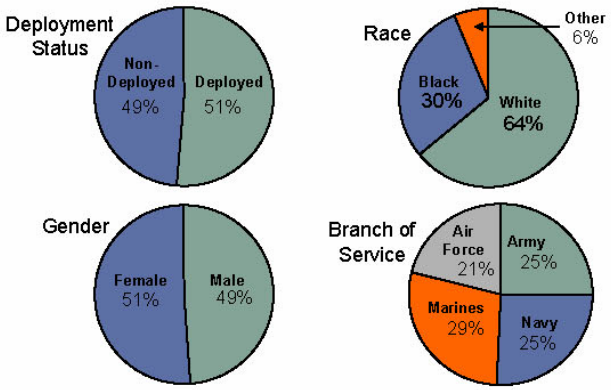
Pilot Study Demographics

118 respondents with a mean age at time of interview of 47 years



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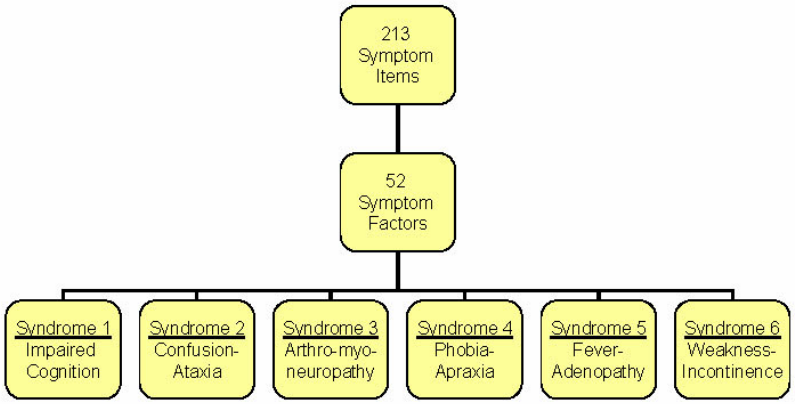
Scoring of Haley Syndromes



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Prevalence of Three Case Definitions by Deployment Status

	Overall	Deployment status	
		Deployed	Non-Dep
Total subjects	118	60	58
Fukuda	39%	53%	24%
Steele	14%	22%	7%
Any Haley Syndrome	15%	22%	9%

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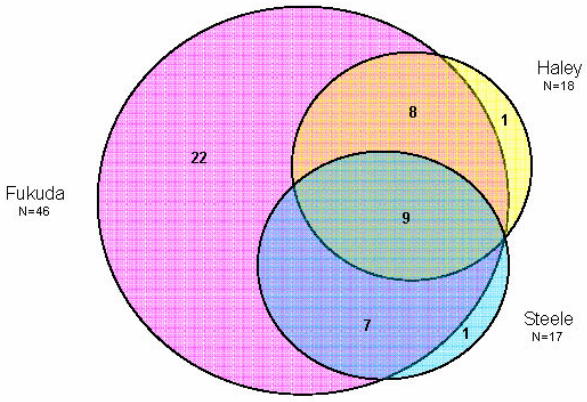
Overlap of Haley Syndromes with Alternative Case Definitions



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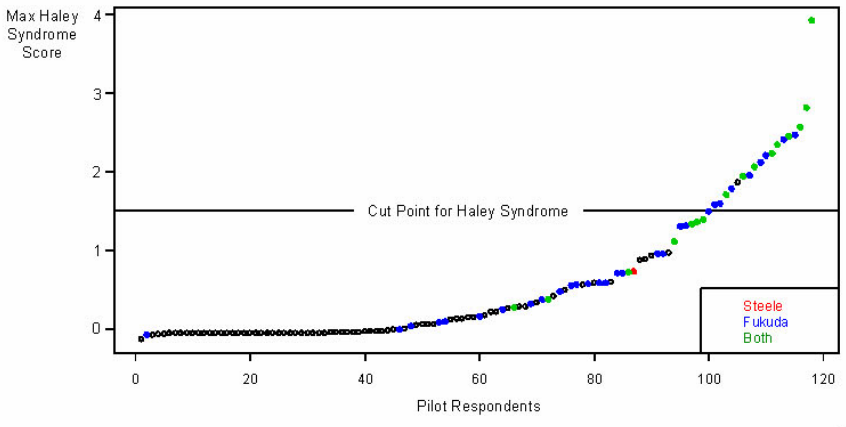
Comparison of Haley/Steele/Fukuda Syndrome Scores



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Healthy Warrior Effect

Two Reasons for Non-Deployability

1. **Medical**: An illness or physical condition (other than pregnancy) that prevented deployment to KTO.
2. **Job Related**: Military job not usually deployable or unit not fully prepared for deployment.

Pilot Study Respondents Not Deployed to KTO

Deployable:	19 (33%)
Non-Deployable:	
Medical	5 (9%)
Job Related	34 (58%)

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Pilot Respondents with Any Haley Syndrome

Deployment Status	Total #	Any Haley Syndrome	
		#	% (wgt'd)
Deployed	60	13	17%
Non-Deployed			
Deployable	19	2	5%
Job Non-Dep	34	1	5%
Medical Non-Dep	5	2	15%

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Case Definitions of Other Conditions by Deployment and Any Haley Syndrome

	Deployment status		Any Haley Syn*	
	Deployed	Nondep	Yes	No
Total subjects	60	58	13	47
Fibromyalgia (ACR screening def.)	10%	3%	46%	0%
Chemical Odor Intolerance (Bell)	10%	3%	23%	6%
MCS Screener (ATSDR)	27%	12%	54%	19%
Severe MCS	3%	0%	8%	2%
Chronic Fatigue Syndrome	1%	0%	0%	2%

**In deployed only*

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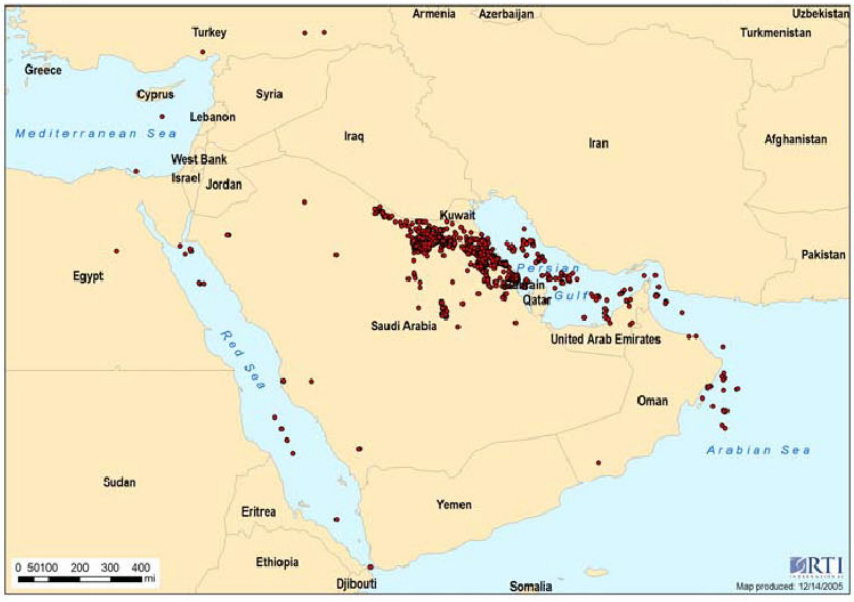
Troop Locations – Start of Desert Shield Air War – January 16, 1991



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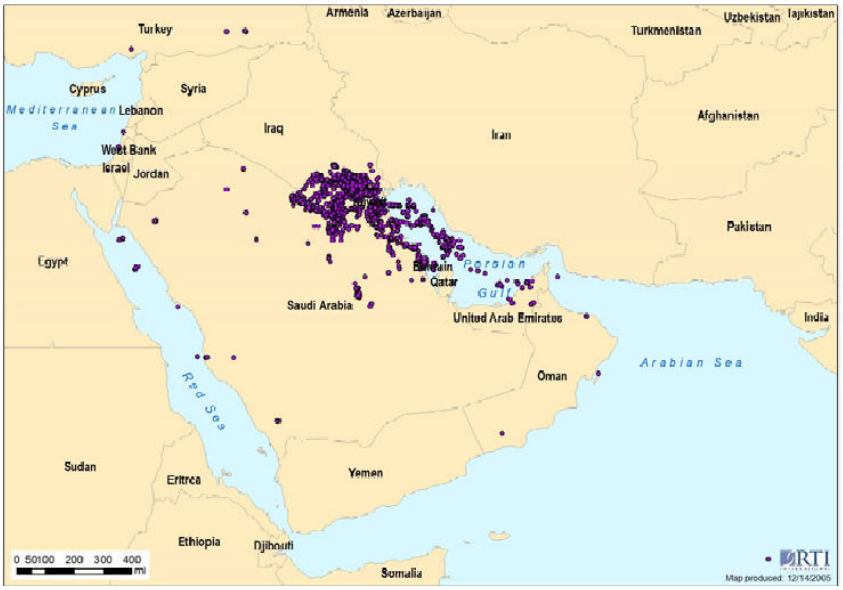
Troop Locations – End of Desert Storm – February 27, 1991



For methodological use only. Estimates are not statistically significant.

Alternative Case Definitions by Location in KTO

Location	# Persons*	Any Haley	Steele	Fukuda
In Iraq/Kuwait	13	49%	43%	56%
Elsewhere in KTO	22	18%	27%	65%

* Army and Marine Corps personnel.

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