

CSPEC-Durham Data and Specimen Repository & the ALS Registry

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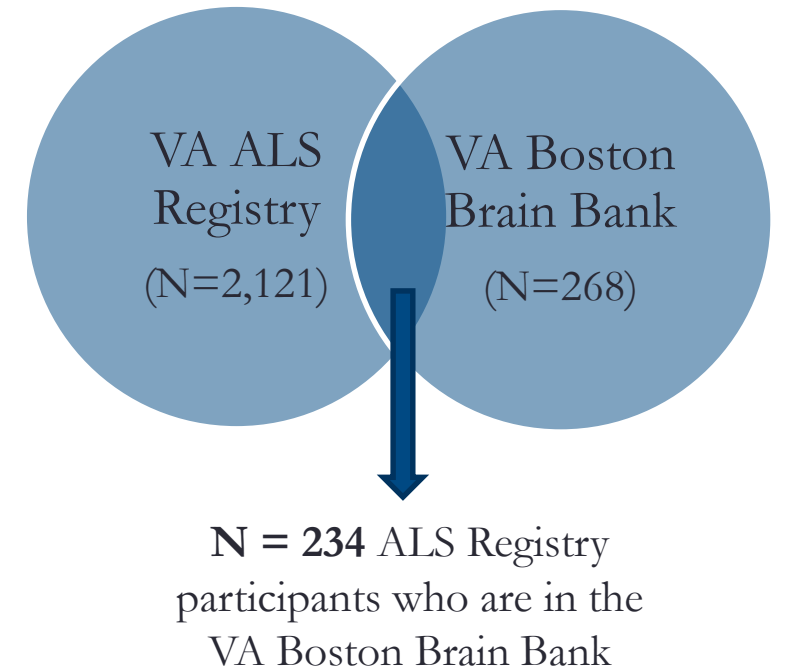
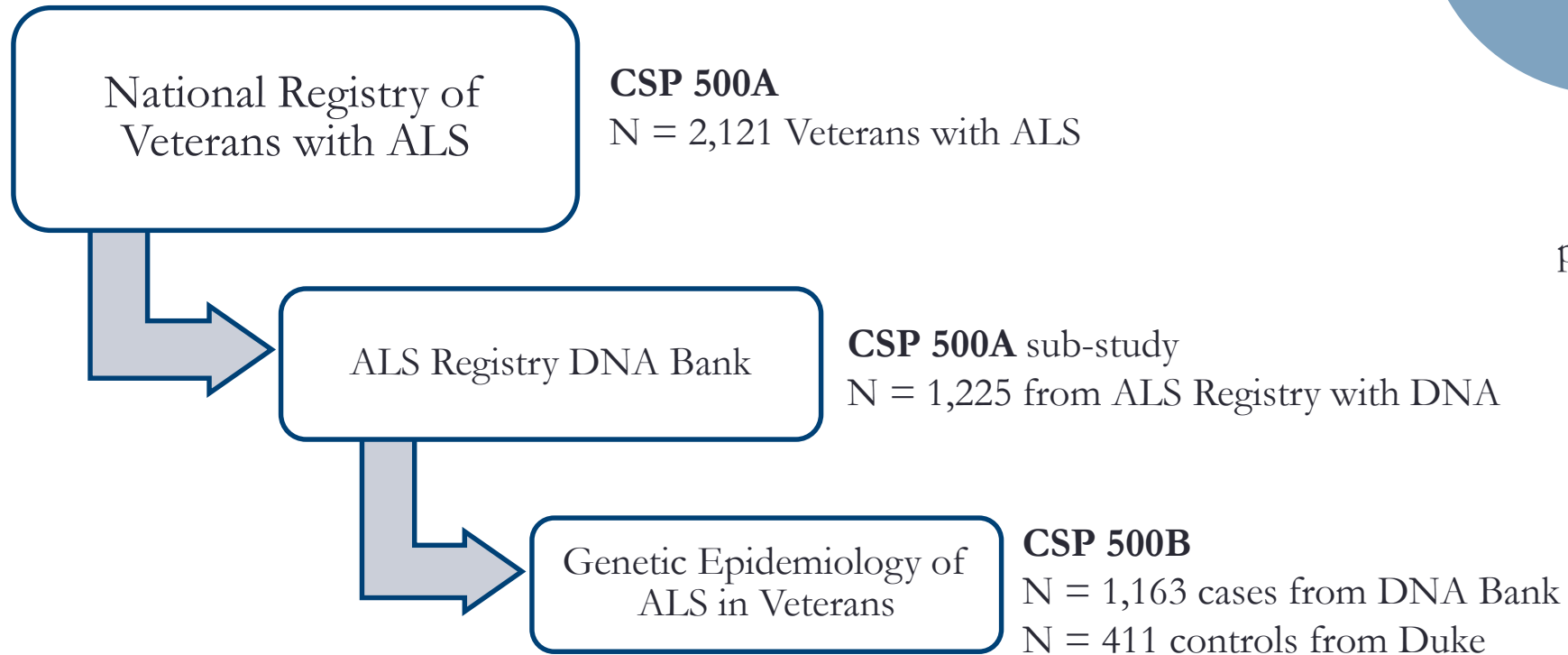
Veterans Health Administration
Research & Development

Improving Veterans' Lives  www.research.va.gov

Overview

1. **ALS Registry – background, types of data and specimens collected**
2. CSPEC-Durham Data and Specimen Repository – background, request process
3. Future of matched requests

ALS-Related Studies



National Registry of Veterans with ALS (CSP 500A)

Objectives

- To identify all living Veterans with ALS
- To track their health status
- To collect clinical information and DNA samples for studies on the causes and treatment of ALS
- To engage Veterans in other ALS-related research

Recruitment methods

- VA electronic health records
- Nationwide publicity efforts – ALS Association, ALS clinics, etc.

Enrollment for ALS Registry (CSP 500A)

Veterans enrolled from April 2003 – September 2007

One of the largest ALS patient collections coordinated by a single site (Durham VA)

- 4,600+ Veterans screened by phone
- 2,600+ Veterans eligible to participate
- 2,121 Veterans enrolled
- All 50 states represented

Records were reviewed by neurologists to confirm diagnosis

ALS Registry DNA Bank (CSP 500A sub-study)

All Registry participants asked to provide DNA samples

- 1,611 Veterans consented to participate
- 1,225 Veterans provided samples

85% blood samples and 15% saliva samples

Samples stored at MAVERIC in Boston, MA

Participants consented to use of DNA samples for future studies on ALS

Genetic Epidemiology of ALS in Veterans (CSP 500B)

Genome-wide association study (GWAS) to identify genetic factors that may contribute to ALS in Veterans

- 1,163 cases from the DNA Bank
- 411 controls from Duke

Collaboration starting in 2009 between:

- Duke Center for Human Genetics (CHG)/Duke Molecular Physiology Institute (DMPI)
- VA Pharmacogenomics Analysis Laboratory (PAL)
- Durham VA

ALS Registry Data and Specimens

ALS diagnosis and symptoms: date/site of onset, diagnosis date, types and severity of symptoms, ALS Functional Rating Scores (collected every 6 months for up to 60 months)

Health and healthcare utilization: family history, smoking status, labs, medications, comorbidities, imaging, trauma history, surgical history, VA healthcare utilization

Demographics: age, sex, race, ethnicity, marital status

Military history: branch, length of service, deployments

Specimens: plasma, DNA

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CSPEC-Durham Data and Specimen Repository

Established in August 2016

Purpose:

- To compile data and specimens across multiple IRB-approved, CSPEC-Durham affiliated studies for the purpose of facilitating the conduct of multiple research protocols, including future protocols not yet envisioned
- To store subject contact information for the purpose of serving as a central source for recruiting subjects into additional research studies

Unique within VA

- Includes studies that address a variety of topic areas
- Manages both data and specimens

Integration of CSPEC Repository and ALS Registry

Included ALS Registry, DNA Bank and GWAS as CSPEC Repository feeder studies

- Permits future use of data and samples for ALS-related studies
- Provides mechanism for newly generated data to be returned

Created an ALS Registry SQL database

- Combined and cleaned earlier Access databases used during enrollment
- Used to develop an HTML data dictionary (coming soon!)

Transferred governance of ALS Registry samples from the VA Palo Alto CSP Coordinating Center to CSPEC-Durham

- CSPEC Repository now maintains the crosswalk to link the data and samples

ALS Registry Data/Specimen Sharing

Data have been shared with at least 13 investigators to-date, examples include:

- “Veterans with ALS and Lead Exposure” (VALE)
- “The Genetic Characterization of Movement Disorders”
- “Biomarkers for ALS Among Active Duty Military”

Request for ALS data and plasma recently approved for sharing:

- “Brain-Derived Extracellular Vesicles as a Novel Source of Biomarkers for Disease Progression and Environmental Exposure in ALS”

Request Process for Repository

1. Researcher submits application:
 - Request form
 - Protocol
 - Documentation of IRB/R&D approval from each site
 - Documentation of funding approval
 - CVs or biosketches for all investigators, collaborators, and biostatisticians
2. Scientific and Ethical Oversight Committee (SEOC) reviews request
3. Data Use Agreement (DUA) and/or Material Transfer Agreement (MTA) approved
4. Repository request scripts create data set/data transferred
5. Annual reports/data returned to repository

Scientific and Ethical Oversight Committee (SEOC)

Content reviewers

- Scientific and ethical merit
- Potential of the project to generate long-term, significant support for future study
- Availability of specimens

Statistical reviewers

- Alignment of hypotheses, study design, and statistical analysis plan
- Sample size calculations, alpha levels, power

Veteran representatives

- Extent to which Veterans have been consulted/engaged
- Relevance of the research question to Veterans
- Alignment of intended use and Veterans' informed consent

CSPEC-Durham Repository Team

CSPEC Leadership

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Christina Williams

Investigator & Data Steward

Kellie Sims

Coordinators

Meghan O'Leary

Ashlyn Press

Quality Research Specialist

Jasmine Bullard

Computational Sciences/Statisticians

Blair Chesnut

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Beth Hauser

Rodney Jones

Ivey Redding

Research Staff

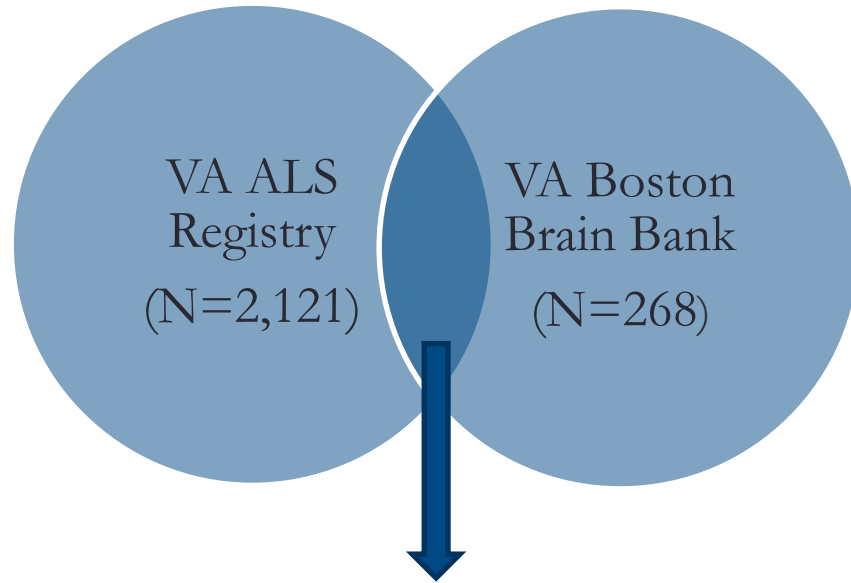
Teresa Day

Carrie May

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Future of Matched Requests



N = 234 ALS Registry participants
who are in the Brain Bank

Exciting opportunity to link the ALS Registry data/samples with the VA Boston Brain Bank samples

Potential to create a streamlined and joint repository and request process

Contact us

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Thank you!