

# 2014

# Annual Research Report

VA NEW ENGLAND HEALTHCARE SYSTEM



**VA**



U.S. Department  
of Veterans Affairs

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***The mission of the Veterans Health Administration (VHA) is to “Honor America’s Veterans by providing exceptional health care that improves their health and well-being.”***

## A Message From the Network Director



In the VA New England Healthcare System (VISN 1), the research relationships we have established with our community, medical, and academic partners enable us to offer state-of-the-art care. We also believe our most important research partners are the Veterans we serve.

On page 4, for example, see how they are making a difference in the Million Veteran Program. The CONFIRM study on colorectal cancer screening methods (page 6) is another instance where Veteran participation is helping us—and helping fellow Veterans.

The segment on page 8 explains how the study of Veterans' chronic pain (PRIME) is providing pain sufferers hope for a better future.

The Center for Healthcare Organization and Implementation Research (CHOIR) focuses on the way we deliver care (page 10); and we cannot forget our women Veterans, some of whom seek maternity care outside our facilities (page 12).

About half of all patients who have foot amputations die within five years. On page 14, meet the podiatric team that is heading up important wound healing research.

Another crucial area of research is the genetic link between post-traumatic stress disorder and the tendency to abuse drugs or alcohol (page 16). The Mental Illness Research, Education, and Clinical Center (MIRECC) is also making great strides helping Veterans with mental health conditions, as explained on page 18.

On page 20, learn how the Translational Research Center for TBI and Stress Disorders (TRACTS) is developing innovative treatments for treating the “whole” Veteran. Finally, read how our research efforts affect Veterans, thanks to the VISN 1 Clinical Trials Network (CTN) (see page 22).

I am proud of the VISN 1 research efforts, and I look forward to many new and exciting discoveries that will help us help America's heroes live healthy, happy lives.

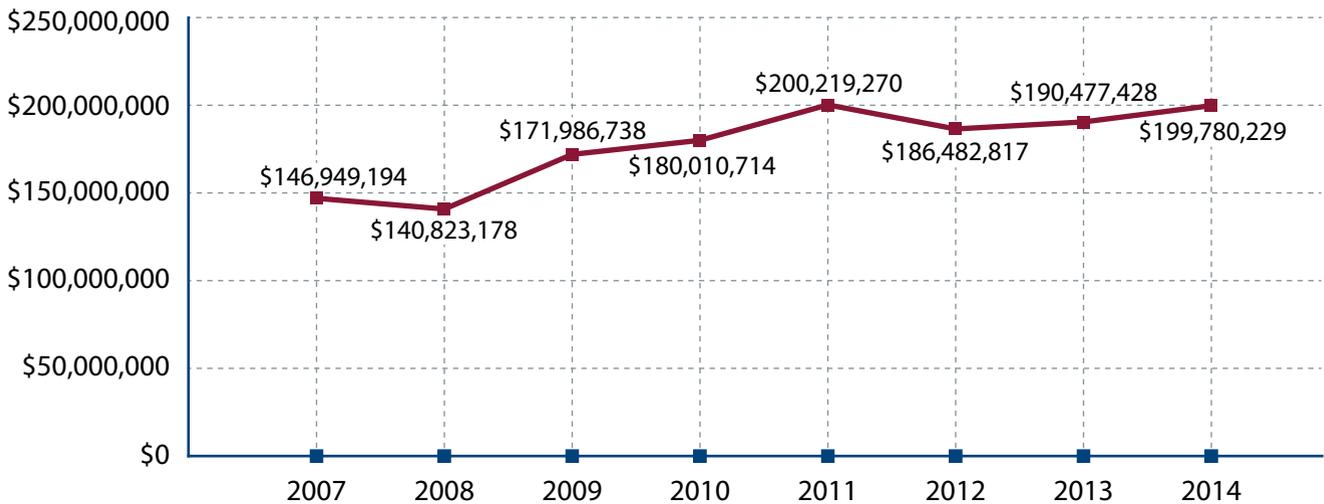
Sincerely,  
Michael F. Mayo-Smith, M.D., M.P.H.  
Network Director



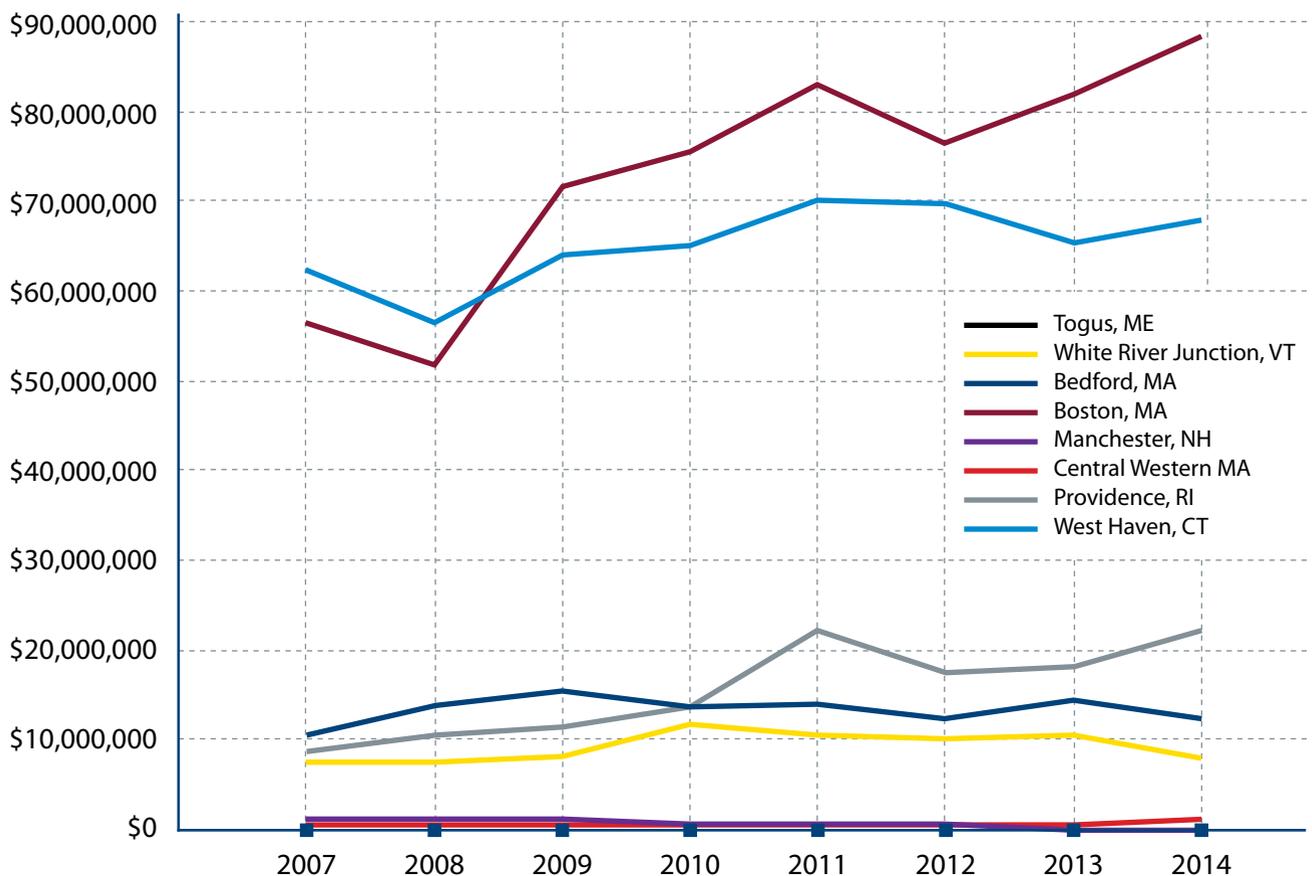
**THE VA NEW ENGLAND HEALTHCARE SYSTEM** is one of 21 Veterans Integrated Service Networks (VISNs) within the U.S. Department of Veterans Affairs (VA). Services are provided through primary care supported by eight Joint Commission accredited medical centers. We are located throughout the six New England states – Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, and Connecticut. VISN 1 has over 35 Community-Based Outpatient Clinics (CBOCs), six nursing homes, and two domiciliaries.

# Funding 2007–2014

## VISN 1 Research Financial Report VERA + Expenditures in VISN 1 2007 – 2014



## VISN 1 Research Financial Report VERA + Expenditures VISN 1 Facilities 2007 – 2014



# Academic Partners and Affiliations

## ACADEMIC AFFILIATES

- Boston University School of Medicine
- Brown Medical School
- Dartmouth Medical School
- Harvard Medical School
- Tufts University School of Medicine
- University of Connecticut School of Medicine
- University of Massachusetts School of Medicine
- University of New England School of Osteopathic Medicine
- University of Vermont School of Medicine
- Yale University School of Medicine
- Tufts University, Lesley College, Worcester State University, Salem State University, Endicott College, UMASS Boston, UMASS Lowell, Massachusetts College of Pharmacy, Massachusetts College of Optometry, and Boston College
- Harvard Medical School and Boston University School of Medicine, as well as with Brigham and Women's Hospital, Boston Medical Center, Beth Israel Deaconess Medical Center, Massachusetts General Hospital, Massachusetts Eye and Ear Infirmary, and Spaulding Rehabilitation Center

## NATIONAL ACCREDITATION ORGANIZATIONS:

- The Joint Commission
- Commission on Accreditation of Rehabilitation Facilities (CARF)
- National Committee for Quality Assurance (NCQA)
- College of American Pathologists (CAP)
- American Psychological Association
- American Dental Association for Advanced Dental Education
- Association for the Accreditation of Human Research Protection Programs (AAHRPP)
- Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)
- American Association of Blood Banks (AABB)





**STACEY WHITBOURNE, Ph.D.**, has been conducting research for VA for nine years. She earned her Ph.D. in Social/Developmental Psychology from Brandeis University and did her postdoctoral training in assessment of cognitive and sensory aging in the VA Normative Aging Study. She is Principal Investigator for the Veteran Genetics Health Referent Cohort and Program Director for the Million Veteran Program.



**JENNIFER DEEN** earned her B.S. in Rehabilitation and Human Services from Boston University Sargent College of Health and Rehabilitation Sciences. During her 10 years with VA, she served as Research Coordinator working with Veterans from the Normative Aging Study (focused on assessing physical, cognitive, and sensory aging) prior to accepting her current position as Program Manager for the Million Veteran Program.

## Million Veteran Program – Building a Legacy

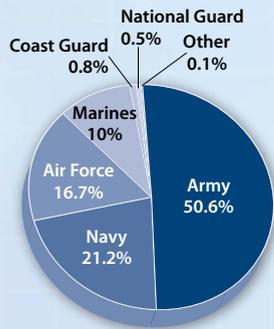
By now, most people in the VISN 1 network have heard of the Million Veteran Program (MVP) and its goal of enrolling one million Veterans to help researchers better understand the role of genes in disease risk and response to treatment. Unlike typical scientific work conducted with a specific hypothesis, the project will establish a characteristic or longitudinal cohort of Veterans in which further types of research is conducted.

“This new model—the genetic information, health and lifestyle information, and continuous updating through VA’s electronic health records system—will allow researchers to access the information for studies on almost anything,” explained Dr. Stacey Whitbourne, MVP Program Director. “For example, many diseases in the Veteran population pertain to post-traumatic stress disorder (PTSD) and other mental health disorders. This data will help us understand from a genetic, biological, or epidemiological standpoint what factors are associated with these disorders. The same is true for heart disease, cancer, and other diseases. As we move into the age of genetic research and the personalized medicine approach, this large number of folks will show any changes in numbers in the genomes, for example.”

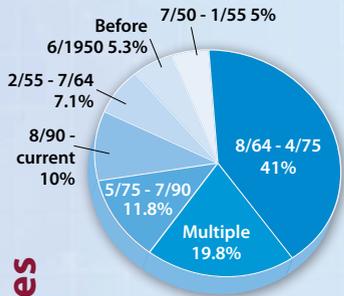
Researchers can also put information into the database. “The benefit of that,” Dr. Whitbourne continued, “combined with new participants’ information

constantly added and existing participants’ information constantly updated, creates a nicely characterized cohort that will continue to grow, evolve, and change. We hope this type of cohort—and the ability to contact Veterans to see if they want to participate in other research—will also decrease the cost of getting new studies up and running. In the near future, we will be reaching out to researchers to let them know that data is being sequenced and that they can start applying to use this resource.”

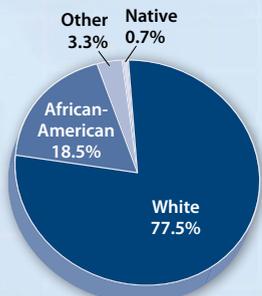
Jennifer Deen, MVP Program Manager, said the number of participants continues to rise, with 300,000 Veterans now enrolled at more than 50 sites across the country. “VISN 1 conducts enrollments at the VA Boston and VA Connecticut Healthcare Systems and added Maine, Manchester, White River Junction, Bedford, and Northampton/ Worcester in fall 2014. By expanding MVP to all areas of New England and by participating in outreach events, we are now able to offer this unique opportunity to Veterans who reside in rural or underserved areas of the Northeast. Many Veterans don’t expect to benefit from the research but have expressed that they feel participating is a way to help other Veterans. They are making this program successful and leaving a legacy for future generations, as are MVP staff in the field, many of whom are Veterans who feel strongly about the potential MVP has for helping others.”



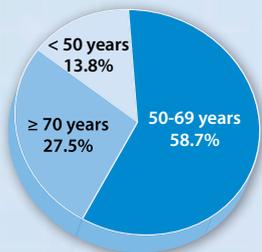
**BRANCH**



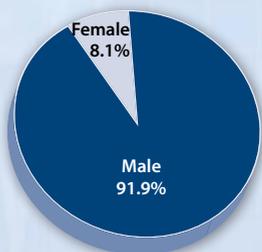
**ERA**



**RACE**



**AGE**



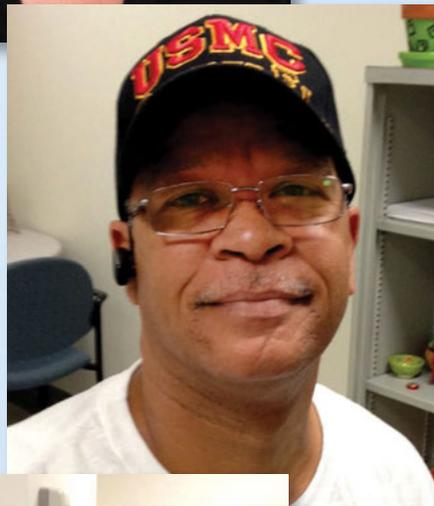
**SEX**

**Characteristics of MVP Enrollees**



"I am proud to be a part of a program that will be able to help Veterans' healthcare."

Elizabeth Jobes  
U.S. Army  
Cold War Era



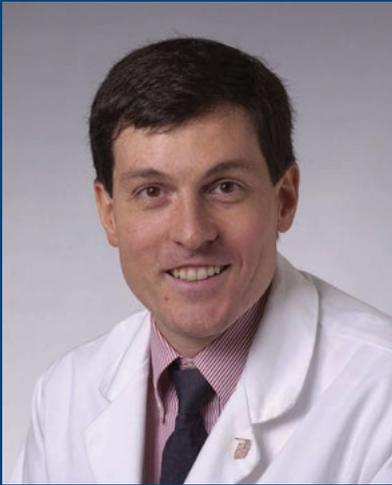
"I just want to help other Veterans."

Donald Wright  
U.S. Marine Corps  
1976 - 1980



"I enrolled in The MVP because I thought it would help Veterans get even better healthcare in the future."

Gennaro F. Carbone  
U.S. Marine Corps  
Gulf War Era



**DOUGLAS J. ROBERTSON, MD, MPH**, earned his MD and completed his residency in Internal Medicine at the University of Connecticut. He completed his GI fellowship training at the University of North Carolina at Chapel Hill, earned an MPH in Epidemiology from the UNC School of Public Health, and now serves as Chief of Gastroenterology at the White River Junction VA. Dr. Robertson's research interests are in the epidemiology of colorectal cancer and the utility of screening and surveillance for this disease. He is a past recipient of a VA HSR&D Career Development Award and has served as Clinical Director of the Polyp Prevention Study Group. Currently, he is the National Co-Chair of the CONFIRM trial. He is a member of the US Multi-Society Task Force on Colorectal Cancer, serves as associate editor for *Gastroenterology*, and is on the editorial board of *Clinical Gastroenterology and Hepatology*.

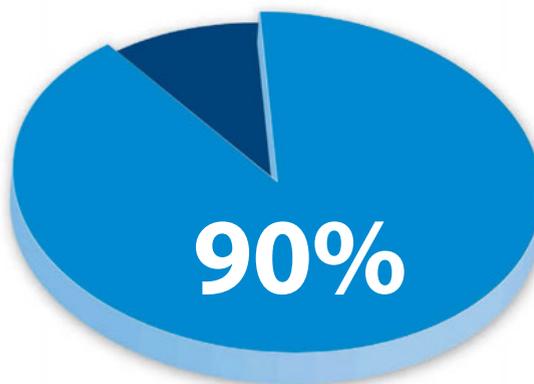
## CONFIRM Evaluates Screening Methods for Colorectal Cancer

Colorectal cancer, the second most common cause of cancer death in the United States, is also one of the most preventable cancers. Douglas Robertson, MD, MPH, of the White River Junction VA, explains how the CONFIRM (Colonoscopy versus Fecal Immunochemical Testing in Reducing Mortality from Colorectal Cancer) study is designed to determine if one of two successful screening methods prevents more cancer deaths than the other.

"We have known for a long time that colorectal cancer screening works," he said, "whether it is the fecal immunochemical test (FIT) or a colonoscopy, both save lives. The difference is that stool cards provide a simple, convenient test for patients at home, whereas a colonoscopy is invasive, requires prep time and usually sedation, and there is always the risk for complications."

CONFIRM is a randomized, comparative effectiveness study that will track colorectal cancer mortality between two large sample groups for approximately 10 years—in this case, 50,000 Veterans, with half getting a colonoscopy and half getting an annual FIT. So far, about 20,000 Veterans are enrolled nationwide. VISN 1 participating sites are White River Junction, Providence, Boston, West Haven, and Manchester.

"VA has long recognized the importance of colorectal cancer screenings," Dr. Robertson added. "The Computerized Patient Record System (CPRS) reminds patients about screenings, and it's been one of the External Peer Review Program (EPRP) measures. Learning how these tests function may well influence future VA policy about how we should screen for colon cancer across the VA."

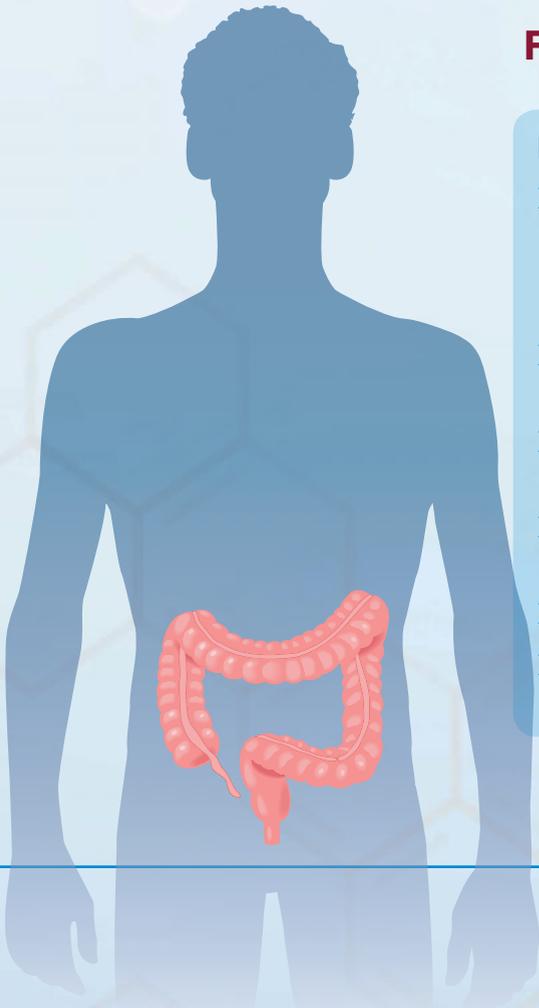


About 90 percent of people live five or more years when their colorectal cancer is found early through testing.



Left to right: Amy V. Rose, National Study Coordinator; Maegan Berry, National Research Assistant; Amy Ridley, National Research Assistant; and Doug Robertson, M.D.

## FOBT/FIT or Colonoscopy? Key Considerations



### FOBT/FIT

- › Proven to reduce death from colorectal cancer
- › Done on your own at home and returned
- › Safe, available, and easy to complete
- › Finds most cancers early when done yearly
- › Need to perform annually
- › If positive, follow-up colonoscopy required



### Colonoscopy

- › Proven to reduce death from colorectal cancer
- › Examines the entire colon
- › Opportunity to remove abnormal growths (i.e. polyps) in the colon
- › If normal, only repeated every 10 years
- › Requires a bowel prep
- › Invasive with some small risk for significant complications





**ROBERT D. KERNS, Ph.D.**, is Special Advisor for Pain Research for the Veterans Health Administration (VHA), Director of the Pain Research, Informatics, Multi-morbidities, and Education (PRIME) Center at the VA Connecticut Healthcare System; he is also Professor of Psychiatry, Neurology, and Psychology at Yale University. He received his doctorate in Bioclinical Psychology from Southern Illinois University in 1980. Dr. Kerns has published over 250 articles and two books on behavioral medicine and pain management, including research on psychological and complementary approaches to pain management. He recently learned of the intent to fund a project pertaining to identifying complementary health approaches in VHA's electronic health record. Dr. Kerns has received numerous honors and awards; was a member of the Institute of Medicine Committee on Advancing Pain Research, Care, and Education; and is a member of the Health and Human Services National Pain Strategy Oversight Panel that will establish an action plan to transform pain care in America.

## PRIME: Helping Veterans Relieve Pain

A significant proportion of Veterans experience chronic pain that inhibits their participation in everyday activities, including work related and social activities, and subsequently disrupts their overall sense of well-being. The PRIME (Pain Research, Informatics, Multi-morbidities, and Education) Center of Innovation in VISN 1 is using several models to change that, according to Dr. Robert Kerns, Director of the PRIME Center at VA Connecticut Healthcare System.

“One aspect we focus on is research related to high impact chronic pain—which is moderate to severe pain that persists over time and disrupts a person’s participation in activities. We want to better understand the contributors to high impact chronic pain and its broad and negative impacts.”

Dr. Kerns said researchers look at the differences among Veterans (e.g., age, gender, race, geography) and the differences in the prevalence of high impact chronic painful conditions. They are also interested in specific models of care and the effectiveness of non-pharmacological interventions, including some emerging complementary services like acupuncture, yoga, and chiropractic care.

“The value, cost effectiveness, and comparative value of these complementary treatments are important,” he explained, “because we want to identify approaches with the greatest likelihood of reducing or preventing the chronic

pain and the associated disability that can accompany it.”

In addition to researchers associated with the PRIME Center at both West Haven and Newington campuses, Dr. Kerns said the team relies on partners and investigators at other facilities around the country working on various PRIME initiatives. One current line of research involves smartphone technology that provides evidence-based psychological or behavioral interventions, such as teaching Veterans pain management coping skills and helping them set goals for exercise and activity.

“We are also developing solutions such as the use of high speed video conferencing that can provide one-on-one care to Veterans across the country—or potentially around the world—which is important because travel can be painful for some chronic pain patients.”

Dr. Kerns said learning about the interactions between pain and associated chronic conditions and behavioral health factors will help researchers develop other interventions that reduce pain and its negative impacts on Veterans’ emotional well-being. “We want to increase their health-related quality of life through safe, effective treatments for pain and pain-related disability. Providing improved access to care and interventions tailored to each Veteran’s experience empowers the patient—it can give that person his or her life back,” Kerns said.



The Donaghue Foundation and The Mayday Fund awarded Dr. Kerns a grant titled "Implementing a VA Stepped Care Model of Pain Management."

Grant Dates – 7/1/2010–6/30/2015

The project examines the implementation of the Stepped Care Model of Pain Management (SCM-PM) at VA Connecticut Healthcare System (VACHS) with goals of improving pain care services and aiding national implementation efforts. The study evaluates processes of implementation to determine best practice models for broader dissemination and implementation.

**Back (left to right)**

Fred Wright, MD: ACOS, Research – VACHS  
 Patricia Rosenberger, Ph.D. (deceased):  
 Research Psychologist – VACHS,  
 Co-Investigator  
 Linda Honan Pellico, Ph.D., APRN: Qualitative  
 Analyst, Yale University School of Nursing  
 Gerald Grass, MD: former Chief of Pain  
 Medicine, VACHS

**Front (left to right)**

Joseph Goulet, Ph.D.: Director, Biostatistics  
 and Methodology Core, The PRIME Center  
 Robert D. Kerns, Ph.D.: Director, The PRIME  
 Center, Principal Investigator  
 Lesley Lincoln, MD: former Pain Champion  
 of Primary Care, VACHS

**The PRIME Center's current research portfolio and priorities for future research are guided by four strategic objectives:**

- 1** Promote organizational change that can increase health-related quality of life and reduce symptom burden for Veterans with pain and associated chronic conditions.
- 2** Promote access, continuity, and sustainability of safe and effective interventions for pain and pain-related disability.
- 3** Increase respect for patient risks, preferences, and priorities.
- 4** Reduce ethnic/racial, geographic, gender- and age-related disparities in access and delivery of effective pain care.





**DR. DAN R. BERLOWITZ**, a 25-year employee of VA, earned his MD at Albert Einstein College of Medicine and his MPH at Boston University School of Public Health. He is board certified in Internal Medicine and has been involved in over 50 funded research projects devoted to assessing and improving VA healthcare. His history at VA includes many academic appointments—most recently as Co-Director of CHOIR at Bedford/Boston since 2013—as well as university, educational, and clinical appointments. Dr. Berlowitz's distinguished career includes numerous positions on editorial boards and national panels. He has served as an educator and mentor and has written a total of over 200 book chapters, monographs, articles, and grants.

## CHOIR: Identifying Ways to Improve Healthcare Delivery

To continue providing excellent healthcare for our nation's Veterans, VA must continually look for ways to improve both the product and the way we deliver our services. The Center for Healthcare Organization and Implementation Research (CHOIR), a Health Services Research and Development (HSR&D) Service Center of Innovation based at Bedford and Boston, is doing just that.

CHOIR's mission is to improve Veterans' health outcomes by developing, studying, and applying evidence-based practices that will be widely implemented and sustained. The team is accomplishing that through involvement in projects that focus on assessing and improving the quality of VA healthcare.

Dan R. Berlowitz, MD, MPH, explained that, "An ecological model (see graphic on next page) describes and explains the many influences on patients in specialty healthcare settings. In evaluating healthcare quality, the team—consisting of over 125 investigators and staff—adapted this conceptual framework to place the Veteran at the center of his/her environment, surrounded by his/her family, social support system, and the teams of providers caring for them (*micro-level*). Veterans, families, and providers are nested within a community that includes VA facilities and practice settings

where Veterans receive care (*meso-level*). State and Network policies governing VA facilities determine Veterans' care (*macro-level*), while VA and national policies represent the economic, social, educational, legal, and political systems (*exo-level*) in which all previous levels are embedded. Our goal is to understand these many influences on Veterans and their health."

Guiding CHOIR's partnered research is the understanding that each level has multiple, interacting, and bi-directional relationships on Veterans; their families; their providers; and VA local, regional, and national healthcare systems; and policies determining their care. In order to inform operational partners and improve Veterans' health, many of CHOIR's health services research and organizational/ implementation science studies will be multi-level. Simply put, the research intends to identify ways in which VA healthcare can be better delivered.

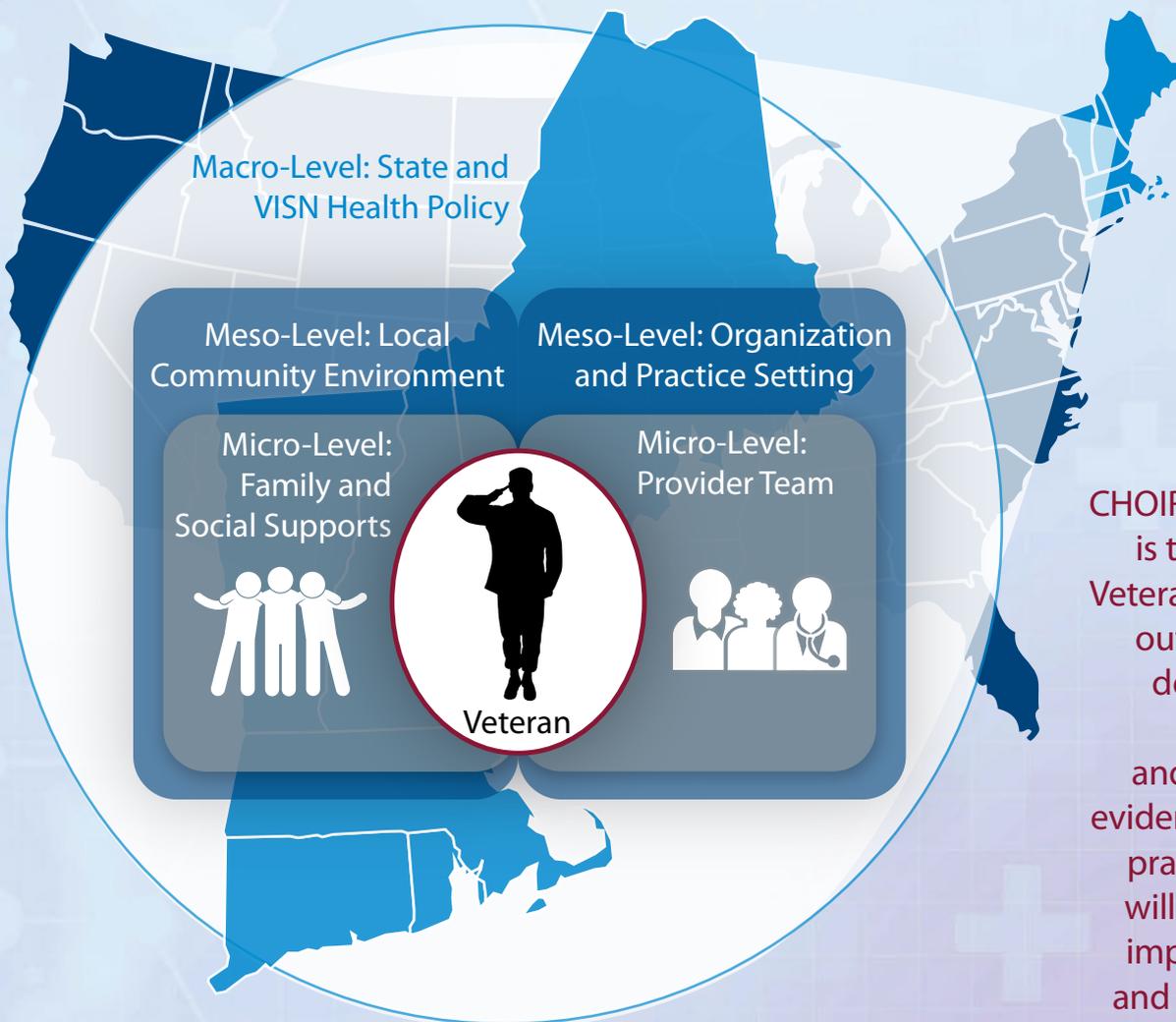
This project is intended to create an infrastructure that will support other research projects. Priority areas for the research include mental health recovery, public health communication, and medication optimization. The Center is co-located at Bedford and Boston VAMCs. However, CHOIR staff collaborate with investigators at over 20 different VAMCs across the country.



CHOIR staff and investigators.

## Ecological Model

Exo-Level: National and VA Health Policy



CHOIR's mission is to improve Veterans' health outcomes by developing, studying, and applying evidence-based practices that will be widely implemented and sustained.



**KRISTIN MATTOCKS Ph.D., MPH**, received her MPH and Ph.D. from Yale University School of Medicine. Among her academic appointments are Assistant Professor of Quantitative Health Sciences and Psychiatry, University of Massachusetts Medical School; and Adjunct Professor, Department of Epidemiology and Biostatistics. Her administrative appointments include VISN 1 Research Lead, Department of Veterans Affairs; and her present positions as Associate Chief of Staff for Research and Education, VA Central Western Massachusetts Healthcare System. Dr. Mattocks has served on numerous advisory and review committees and in various VA leadership positions. She has conducted VA studies—many involving women’s care issues—and has been published in dozens of manuscripts, book chapters, reports, and white papers. She is also a speaker and presenter at scientific conferences and meetings.

## Maternity Care for Women Veterans

Over two million Veterans are female, and many are of childbearing age, so caring for their maternity needs is critical. Because women Veterans remain a numeric minority in the VA, nearly all maternity care takes place outside the VA from community-based obstetrical providers.

Dr. Kristin Mattocks, Associate Chief of Staff for Research and Education for VA Central Western Massachusetts Healthcare System (VACWM), describes how VISN 1 facilities are ensuring pregnant Veterans get the care they need, both inside and outside the VA.

“We are focused on providing female Veterans coordinated VA care beginning before their babies are born,” she said. “All VA facilities have a Women Veterans Program Manager (WVPM) to advise women Veterans and some also have a Maternity Care Coordinator (MCC). Through a grant with the Office of Rural Health, we hired Judy Kuzdeba (RN) as our VISN 1 Maternity Care Coordinator to work with other VISN 1 facilities to ensure pregnant Veterans have access to all the information and services they need during their pregnancies. We’re evaluating what care coordination here looks like now and how we can improve it.”

“In the past five years,” Dr. Mattocks continued, “the number of women Veterans using VA maternity care has increased by about 40 percent. We need to know what is happening with these women during their

pregnancy. Across VISN 1, Judy works closely with facility-level Women Veterans Program Managers, and they stay in contact with those Veterans to make sure they have the community-based resources and support they need before and after they deliver.”

Kim Adams, RN, VA Central Western Massachusetts’ WVPM, explained further: “Before, when women Veterans left our facilities to get maternity care from outside providers, their care became fragmented. We didn’t know the quality of care they got; if they had problems, they weren’t sure who to call at VA. Now, women get a point of contact—a maternity care coordinator. I’m proud that Central Office has focused so intently on a group that represents only a small part of the Veteran population.”

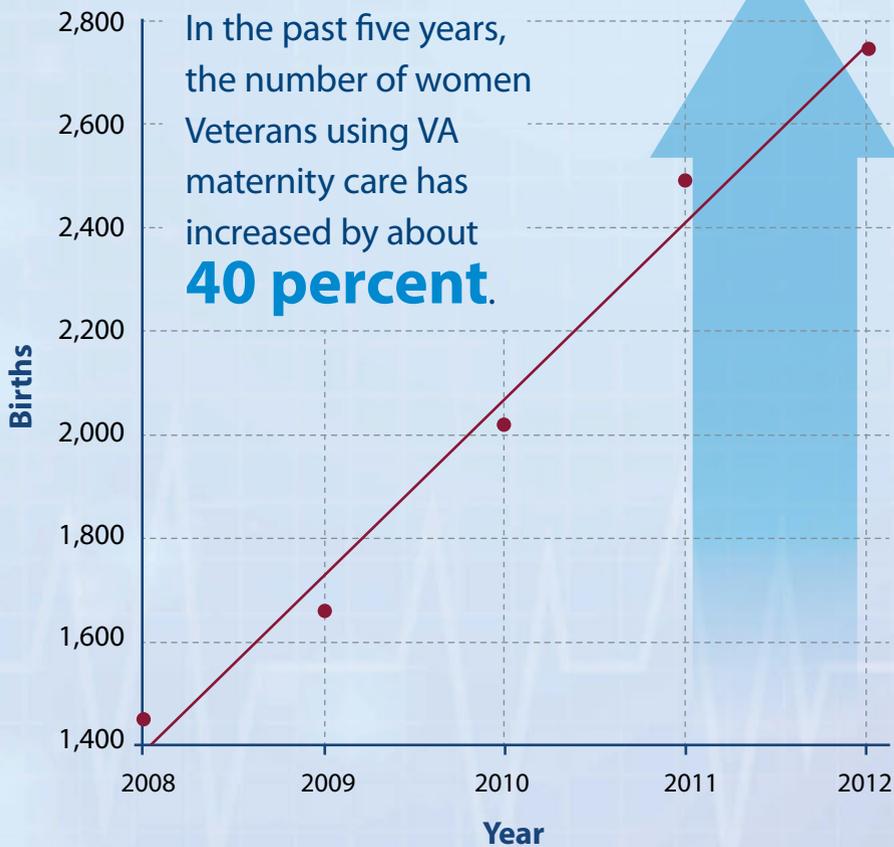
Dr. Mattocks said the project is an excellent example of the value of VA partnerships. “I’m a health services researcher, and Dr. Megan Gerber at VA Boston (co-PI of the study) is the VISN 1 Women’s Medical Director. But as a team with Judy and Kim, we have found that we can work together to evaluate pregnancy care that can be coordinated with ongoing VA care and examine better ways to do it. None of us can do it alone; we can accomplish much more by working together.”

Seven of the eight VISN 1 sites are participating in the research; White River Junction has its own maternity care coordinator and is part of a separate research study.



Left to right: Kristin Mattocks, Ph.D., MPH, Kimberly Adams, R.N., and Judith Kuzdeba, R.N.

### Births vs. Year





**DR. VICKIE R. DRIVER, MS, DPM, FACS**, is the Chief of Podiatric Surgery at the VA New England Health Care Division in Providence. She has an academic appointment as Professor of Orthopedic Surgery (clinical), Brown University School of Medicine, and has also assumed a leadership role in the Hyperbaric and Wound Healing Center at Rhode Island Hospital, an 850-bed Brown teaching institution. Her responsibilities include Director of Limb Preservation and Wound Healing Research. She is the President of the Association for the Advancement of Wound Care, which is the largest wound healing association in the world. Dr. Driver has served as an investigator for more than 60 important multi-center randomized clinical trials, developed and supervised multiple research fellowship training programs, co-authored over 100 publications and abstracts, and served in numerous university and hospital teaching roles. She is board-certified in foot surgery by the American Board of Podiatric Surgery and is a Fellow at the American College of Foot and Ankle Surgeons. She serves on multiple national and international government and private committees that focus on preventing limb loss and improving wound healing in the high-risk population.

## Making Strides in Podiatric Wound Care Research

The cost of care of chronic wounds is an enormous burden to society, both economically and socially. Ulcer care in the diabetic population alone adds \$9–13 billion annually to take care of diabetic patients in the United States. Current approved therapies are not sufficient in managing and preventing complications that can include amputations.

Dr. Vickie R. Driver, Chief of Podiatric Surgery in Providence, is currently leading a team that is researching wound care, tissue repair, and amputation prevention. The research can be divided into two types: clinical research and economic/outcomes research.

“Our clinical research focus is on bringing new therapies to market for the treatment of conditions our Veterans suffer greatly from, such as diabetic foot ulcers, critical limb ischemia, and venous and arterial ulcers—as well as understanding the mechanism of molecular action of advanced therapies,” Dr. Driver explained. Her team is interested in understanding how to predict responders to cellular therapies such as is developed and understood in oncology. Another important area of clinical

research is on a new category of antibiotic, as antibiotic resistance has risen dramatically.

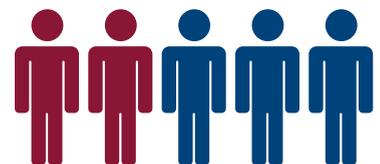
The economics/outcomes research investigates the use of currently approved therapies—specifically, her team examines effectiveness, cost, utilization, and quality of life. “Novel therapies in development and in trials offer the potential for faster healing, as well as reduced infections and other complications, such as amputations,” said Dr. Driver.

Her team’s research occurs at Providence VA Medical Center, although she is assisting with an effort to develop wound healing clinical trials at multiple VA sites.

Veteran volunteers that participate in the research trials can receive novel treatments not available yet to the public, and research grants that fund these studies aid the VA in its care of Veteran participants.

“Ultimately,” she added, “by examining current practices and current methods of care, we hope to identify the best pathways of care for Veterans, and economic analysis that can aid the VA in determining the best method of allocating resources to achieve the best possible outcomes for patients.”

Approximately **two** out of every **five** Americans will develop type 2 diabetes at some point during their adult lives, according to new U.S. government estimates.<sup>1</sup>





Left to right: Dr. Kirsti Diehl, Research Fellow; Dr. Vickie Driver, Chief of Podiatric Surgery; Michael Anne French, JD Research Associate; Dr. Laticia Allen, Attending and Co-Researcher



More than **60%** of non-traumatic lower-limb amputations occur in people with diabetes.<sup>2</sup>

About **50%** of patients who have foot amputations die within five years – a worse mortality rate than for most cancers.<sup>3</sup>

In 1998 only **16%** of the VA population was diabetic, but **over half** of all patient hospitalizations from lower extremity ulcerations were for diabetic ulcerations.

In 1998 **34%** of peripheral vascular disease procedures and **64%** of amputations were performed on patients with diabetes.

In 2011, VA hospitals had over **227,000** ulcer encounters in the inpatient setting, involving over **54,000** patients with nearly **77,000** new ulcers recorded.

Studies show that a focused multidisciplinary foot care program for patients with diabetes can significantly reduce amputations by as much as **84%**.<sup>4</sup>

<sup>1</sup>CDC Report published online Aug. 13 in The Lancet Diabetes & Endocrinology, <http://www.thelancet.com/journals/landia/onlinefirst>

<sup>2</sup>National Diabetes Fact Sheet, [http://www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2011.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf)

<sup>3</sup>[http://www.idsociety.org/2012\\_Diabetic\\_Foot\\_Infection\\_Guideline/#sthash.GP7zRT4j.dpuf](http://www.idsociety.org/2012_Diabetic_Foot_Infection_Guideline/#sthash.GP7zRT4j.dpuf)

<sup>4</sup>V. Driver, J. Madsen, R. Goodman, Reducing Amputation Rates in Patients with Diabetes at a Military Medical Center, Diabetes Care, February 2005 vol. 28 no. 2 248-253



**JOEL GELERNTER, MD**, came to West Haven VA in 1988. A board certified psychiatrist, he received his BS from Yale University, his MD from SUNY-Downstate, residency at Western Psychiatric Institute in Pittsburgh, PA, and fellowship at NIMH. Among his professional honors and recognitions are inclusion in “Best Doctors in America” (2010-present) and receiving the International Society for Biomedical Research on Alcoholism (ISBRA) James B. Isaacson Award (2014). Dr. Gelernter is a member of numerous professional and scientific societies; serves as a reviewer and editorial board member for multiple distinguished publications; has participated in grant review committees for VA, the National Institute on Drug Abuse (NIDA), and the National Institutes of Health (NIH); and is a member of several scientific advisory boards and committees. He has authored over 300 peer-reviewed articles, and he has spoken internationally to over 100 organizations, groups, government agencies, academic institutions, and hospitals.

## Genetic Studies’ Important Role

Figuring out which Veterans are most prone to suffer from post-traumatic stress disorder (PTSD) or are most at risk for dependence on alcohol or other drugs (e.g., nicotine, cocaine, opioids, cannabis) is becoming increasingly more scientific. In fact, genes that influence risk for these disorders have already been identified. Dr. Joel Gelernter of the West Haven VA explains how far science has evolved in his 26 years there.

“We have moved from identifying genes by genetic linkage, to genome-wide association studies, to sequencing exomes, to full-genome sequencing that includes the entire human genome. That then allows us to examine not just the coding regions but regulatory regions,” said Gelernter. This type of research helps explain the biology of disorders that cause important morbidity and mortality and may play an important role in drug discovery.

Researchers are closer all the time to figuring out the biology of certain disorders, sometimes in ways that surprise them. For example, Dr. Gelernter said they recently published a genome-wide association study for opioid dependence and found calcium signaling and potassium signaling are the most important pathways for influencing risk for this trait, at least in their particular sample. “That was not completely surprising because those were known important pathways in addictions and in brain cells

talking to each other,” he said. “But they wouldn’t have been on the top of our list as the most important systems.”

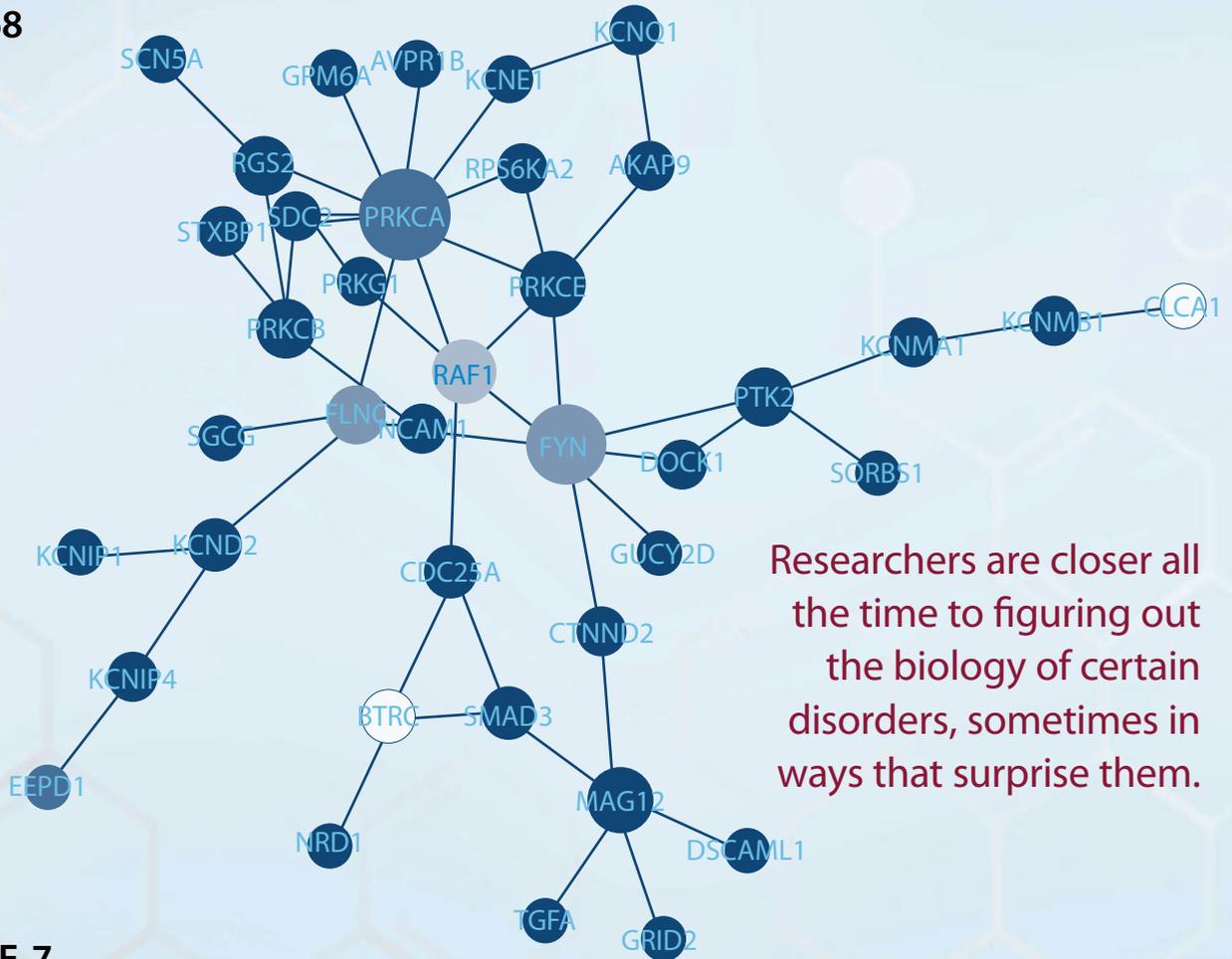
A similar genome-wide association study for alcohol dependence recently was equally significant. “Our results were strong ... for association with a variant in a gene called ADH1B, which is important in metabolizing alcohol—thus affecting risk for alcohol dependence.”

Dr. Gelernter also mentioned a genome-wide association study for PTSD, published about a year ago. “We identified novel genes involved in PTSD risk, and another research group replicated the results, which is an important validation for our findings.”

Currently, Dr. Gelernter’s team is working on a large cooperative study that will involve 20,000 subjects from the Million Veteran Program (MVP). He anticipates the results will be highly relevant to understanding PTSD in Veterans. “We know genes are important in influencing PTSD risk,” he explained, “but there is a level at which resilience and susceptibility make a big difference—those factors are influenced greatly by genetics.” Gelernter hopes findings might eventually help identify Veterans who are at high risk for PTSD. While Dr. Gelernter’s research program is at the VA and Yale, he is working with numerous other investigators involved in the MVP study program, as well as partners outside the VA.



$p = 0.068$



Researchers are closer all the time to figuring out the biology of certain disorders, sometimes in ways that surprise them.

$p = 2.78E-7$

Gene subnetwork constructed with the top 5 percent modules generated in EAs and replicated in AAs of the merged SAGE and COGA GWAS data sets. The blue-white color gradient of a node is proportional to its p values. The size of a node is proportional to its degree.



**CHARLES E. DREBING, Ph.D.**, received his Ph.D. in Clinical Psychology from Fuller Theological Seminary and completed a two-year research fellowship in neuropsychology at the UCLA School of Medicine. He is currently the Mental Health Service Line Manager at the Edith Nourse Rogers Memorial Veterans Hospital in Bedford, Massachusetts and the Associate Director of the MIRECC Bedford Division. Dr. Drebing has been conducting health services research for 25 years—and 22 of those were at Bedford. His work has contributed to a number of new service models and enhancements for Veterans with mental health disorders, including supported self-employment, contingency management for vocational rehabilitation, motivational interviewing interventions for employment, and peer-mediated supported education. He has published literature on a number of the key studies regarding the VA health care system's Compensated Work Therapy program, and his ongoing work seeks to support enhanced utilization and better outcomes for common mental health services.

## MIRECC in Bedford Restoring Lives

Emphasizing early screening and early intervention for Veterans with mental health issues is critical. The problem, however, is that many Veterans do not participate in mental health services for years because of the stigma some associate with it. In fact, many do not come to VA until significant damage has occurred in their lives: loss of family (e.g., separation or divorce), job problems or unemployment, and a tremendous reduction in confidence.

Charles E. Drebing, Ph.D., CPRP, of the New England Mental Illness Research, Education, and Clinical Center (MIRECC) Bedford Division, has been working for nearly two decades on psychosocial rehabilitation research, looking at interventions to help Veterans with mental health conditions recover their lives.

"We see many Veterans who've had serious life issues, and those circumstances ultimately put them at risk for homelessness," Drebing said. Most of his work focuses on helping Veterans regain employment, but he has worked on other rehabilitation services as well.

"Simply treating their mental health condition to reduce or eliminate their symptoms doesn't solve the issues of being homeless and unemployed, lacking family support, and the associated loss of confidence," he explained. "Services have to wrap around those larger

issues; finding interventions that are effective at helping people rebuild their lives is key."

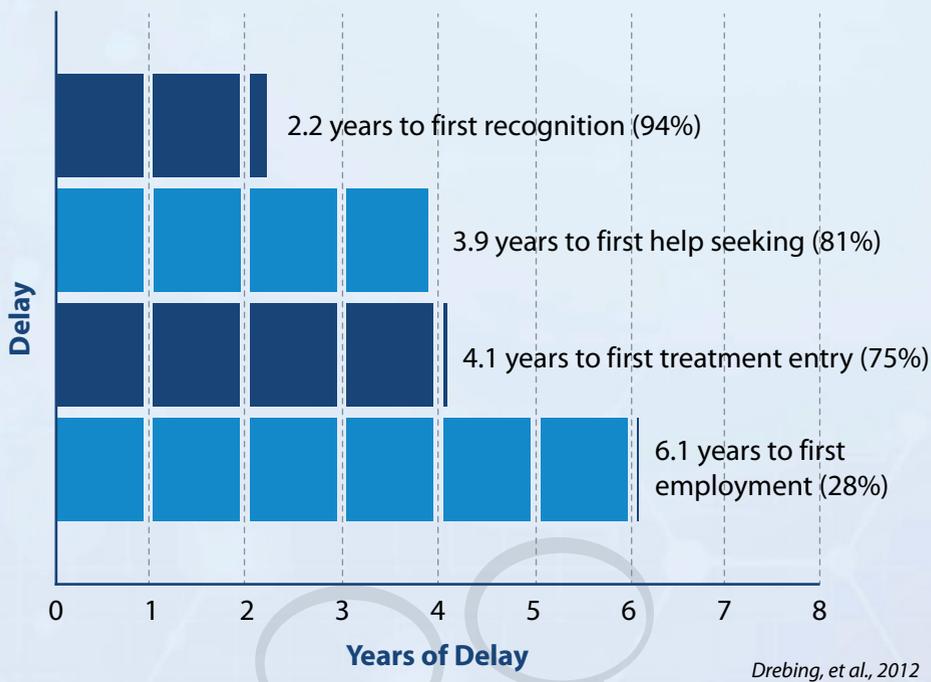
According to Dr. Drebing, research shows that people with mental health conditions do not just want freedom from symptoms. "They want their lives back, and our research in the VISN 1 MIRECC is designed entirely around how to help achieve that. If we treat their symptoms but don't help them get their life activities back—returning to work, reconnecting with their family—then they are much more likely to exit treatment, and they are likely to have continued problems. They do not have a life, which is often associated with continued symptoms. It is more expensive to rehabilitate someone like that than to aggressively help them enter treatment early in their illness and address functional issues then. When we do that, Veterans are more likely to successfully transition out of treatment, which is the goal, and it makes room for other Veterans. In that way, it improves access to care for others in need," Drebing said.

Most of the mental health research has taken place at Bedford and West Haven, but data has also been collected in studies at the Dallas VA and through non-VA partners such as New Hampshire Mental Health System with collaborators from the Dartmouth Medical School.



Left to right: Kendra Pugh, Dr. Megan Kelly, Dr. Patricia Sweeney, Dr. Charles Drebing, and Dr. Lisa Mueller.

## Median Delay Between Vocational Problem and Treatment Entry



## Costs of Delayed Entry to Needed Mental Health Care are Considerable

- › Prolonged suffering among Veterans
- › Losses in work
- › Disrupted family and other relationships
- › Risk of homelessness
- › Overall demoralization—“I am unemployable”
- › Increased cost to VHA and CWT Programs for rehabilitation
- › Lost revenue for VHA





**REGINA MCGLINCHEY, Ph.D.**, began working as a research assistant at the VA Outpatient Clinic in Boston in 1984. She earned her doctorate at Tufts University and has conducted neuropsychological research on cognitive and neural changes associated with aging, stroke, disease, and trauma for approximately 25 years. Dr. McGlinchey serves as Principal Investigator and Director of the TRACTS program and is Co-Director of the Geriatric Neuropsychology Laboratory in the Geriatric Research, Education, and Clinical Center, conducting research associated with aging and related diseases. She is an Associate Professor of Psychology at Harvard Medical School, as well as a regional, national, and international lecturer and presenter. Throughout her distinguished career, Dr. McGlinchey has held numerous administrative leadership positions; worked as investigator on dozens of projects; served in numerous teaching, supervisory, and training roles; and has been widely published in peer-reviewed literature, including abstracts, book chapters, and reviews.

## TRACTS: Treating the Whole Veteran

Blast-related traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) are major concerns for Veterans. Approximately 19 percent of returning service members report a probable mild TBI (mTBI) during deployment, and 11–18 percent with likely PTSD. Effective treatment of these co-occurring problems requires focusing on the whole person.

VA's Traumatic Brain Injury Center of Excellence at VA Boston Healthcare System (VABHS), founded in 2009, is called the Translational Research Center for TBI and Stress Disorders (TRACTS). The TRACTS program has grown tremendously, thanks to Veterans committed to the research and researchers committed to Veterans. Dr. Regina McGlinchey, Director of the TRACTS program, explained the “whole person” approach.

“TRACTS focuses on developing new and innovative treatments for the physical and psychological issues some Veterans struggle with from Operations Enduring Freedom, Iraqi Freedom, and New Dawn (OEF/OIF/OND),” she said. “They often have multiple diagnoses—combinations of mTBI, PTSD, depression, chronic pain, sleep disturbance, and substance abuse. These health problems are not isolated. They frequently affect the same physiological symptoms; symptoms associated with one can worsen the symptoms associated with another; and treatment approaches can interfere with

each other. TRACTS considers the whole of a patient's health problems—how each contributes to the overall presentation—which enables us to design treatments that address the entirety of a Veteran's health issues.”

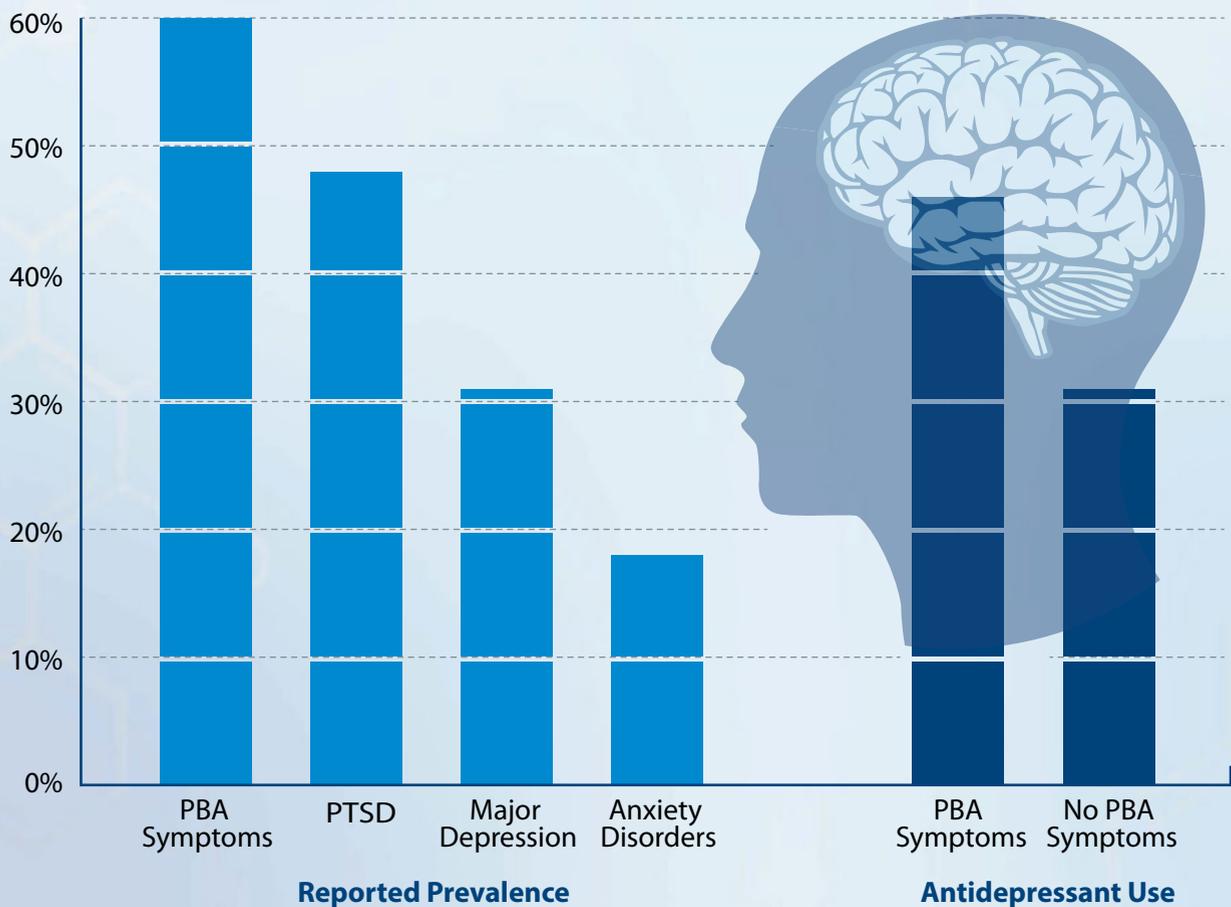
Dr. McGlinchey said TRACTS teams are conducting several lines of research.

“First, analytic studies will help us diagnose the clinical phenotypes presented by OEF/OIF/OND Veterans, which assist in developing a rehabilitation plan to maximize long-term outcomes. Second, clinical studies evaluate cognitive and physical rehabilitation and treatment strategies. For example, two preliminary studies focus on improving attention and concentration problems associated with deployment-related injuries; another study will help Veterans with reintegration issues. A third line of studies focuses on long-term consequences of mTBI. One study looks for a protein called tau in spinal fluid and the brain that is associated with cognitive decline in older adults; another looks for the same protein in older Veterans who had mild TBI while deployed.”

The TRACTS approach—professionals from many disciplines addressing Veterans' mental and physical health at many levels—can provide solutions that help thwart development of chronic illness so Veterans can go on to live happy, healthy lives.



## Pseudobulbar Palsy and Other Mental Health Challenges in Veterans with Mild TBI





### **MARY BROPHY, MD, MPH**

completed her residency and fellowship at the VA Medical Center in Boston and is Assistant Professor of Medicine at Boston University School of Medicine. Dr. Brophy serves as Director of Operations at MAVERIC, as well as Director of the VISN 1 Clinical Trials Network, an initiative to expand research and increase Veteran enrollment in clinical trials across the New England VA system. She continues to treat patients as a Hematologist/Oncologist for the VA Boston Healthcare System, as well as an attending physician on the Medical Inpatient Service. Dr. Brophy serves on numerous Executive Committees and Planning Committees for CSP studies. She is an Investigator on both the Million Veteran Program as well as the Point of Care Research Program.

Dr. Brophy also has an extensive background in the development of large-scale, national-level laboratory programs for the VA. She is the Director of the Genetic Tissue Core Laboratory, and is Director of the VA Central Biorepository.

## **Clinical Trials Network: Creating a VA Learning Health Care System**

In an effort to maintain the VA New England Healthcare System (VISN 1) as a fully integrated health care organization capable of providing state of the art care, Network Director, Michael F. Mayo-Smith, has initiated a VISN-wide effort to expand opportunities for Veterans to participate in clinical trials.

This new initiative, the Clinical Trials Network, will unify the eight medical centers in the VISN as one collaborative clinical trials network. VISN 1 has unique strengths to support research of importance to America's Veterans. To take advantage of these strengths, it has established a strategic objective to enhance its research activities. An important opportunity in the research arena is to significantly expand the number of clinical trials in VISN 1.

The VISN 1 Clinical Trials Network (CTN) provides logistical, administrative and operational support that frees researchers from burdensome tasks that get in the way of scientific discovery. Researchers will be able to leverage existing resources (e.g. Cooperative Studies Program Coordinating Center), infrastructure and expertise located in Boston.

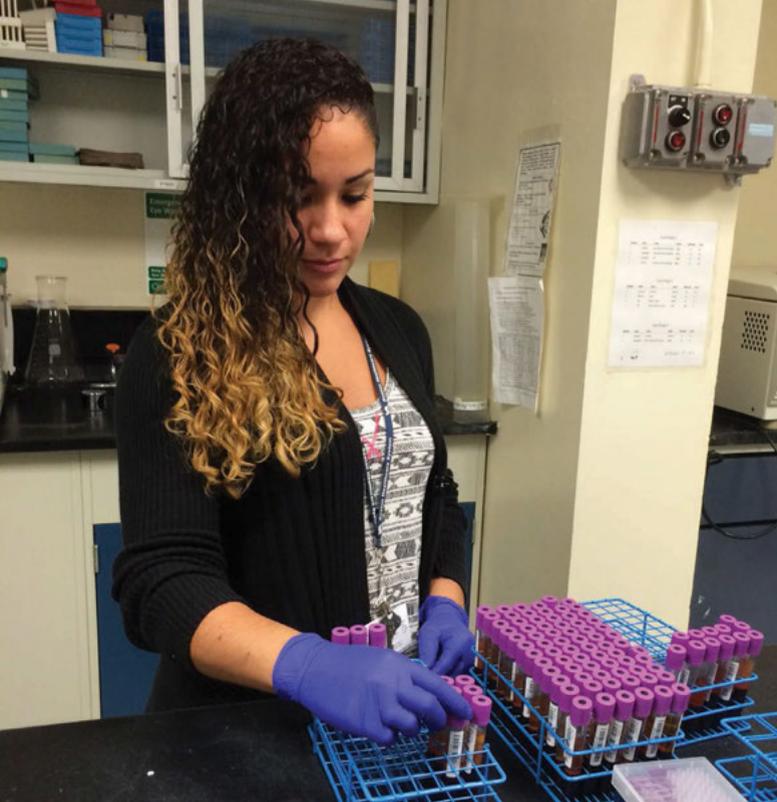
Expressing the importance of a learning health care system, Dr. Mary Brophy, MD, MPH, VISN 1 CTN Director, said, "Continuous discovery and improvement is

the bedrock of a top-notch health care system. Our leaders expect us to provide first-rate care, and our Veterans deserve it."

The CTN's goals are to provide New England Veterans broader access to emerging therapies through clinical investigation targeting diseases relevant to our population. In addition, increasing research opportunities in the VISN and implementing key findings from these trials into clinical practice will translate into better health care.

Nationally there is keen interest in expanding the availability of clinical trials and better integrating clinical research into medical practice by bringing health care providers and researchers together. Integrated clinical research with medical practice creates a patient-driven, science-driven learning health care enterprise. The VISN 1 Clinical Trials Network is well situated to do innovative and groundbreaking work along these lines.

Explaining why integration of research and clinical care is important, Brophy said, "By embedding research into clinical care through innovative research programs such as Point of Care Research and Precision Oncology, together as a VISN, we can deliver on the promise of providing the best and highest quality care to the Veterans we serve."



## VISN 1 Funded Research Studies

Funded Studies:

**926**

VA Studies:

**500**



### VISION

Transform VISN 1 into a learning healthcare system

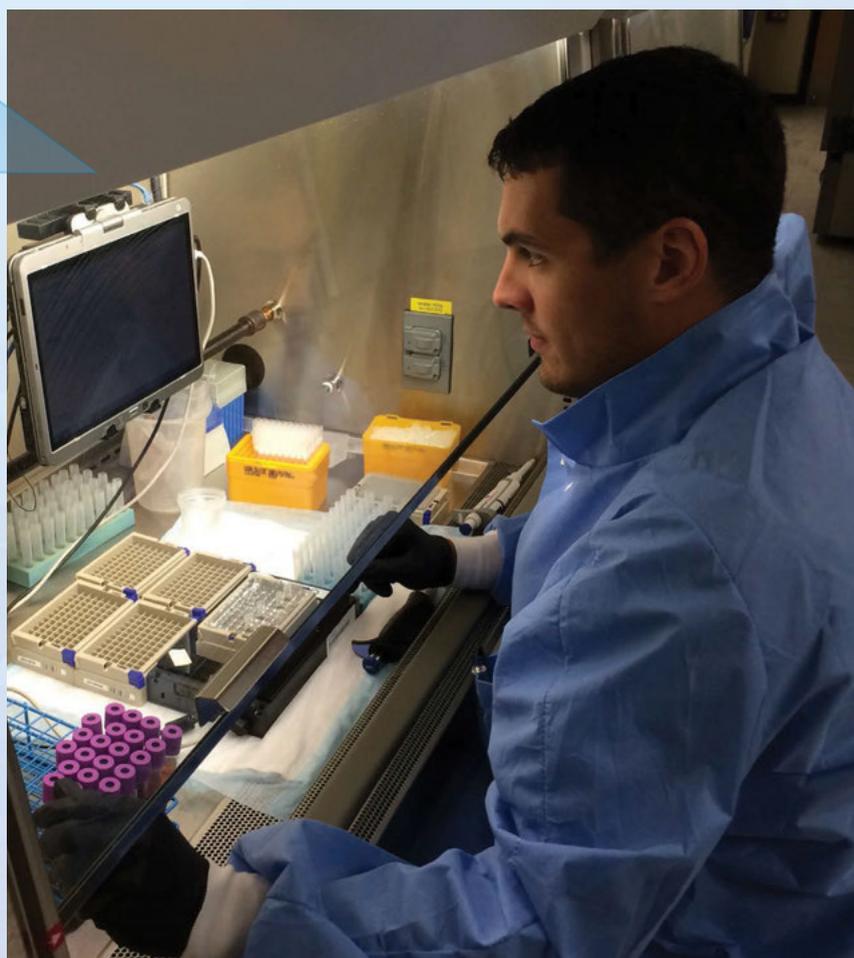


### MISSION

Contribute to traditional research activities, advance clinical care, and improve the quality of healthcare



Create infrastructure and process for clinical investigation within VISN 1





**COLLEEN SHANNON, MPH** earned a Master's degree in Public Health with a concentration in Epidemiology and Biostatistics in 1999. She has been working at the VA's Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC) since 1999. She has more than 15 years of experience in the design, conduct, management and analysis of both clinical trials and observational cohorts. She currently serves as the Deputy Director for the newly formed VISN 1 Clinical Trials Network.

**SARA TUREK, MPH** is a Program Manager for the Clinical Trials Network and provides overall support and organization for the Network's Operations Core, Field Component, and Scientific Core. She received her Master's in Public Health with a concentration in Environmental Health Sciences from Yale University in 2010. Ms. Turek comes to the Clinical Trials Network with broad experience in clinical research, including protocol design, study coordination, data management, and manuscript preparation.

## VALUABLE BENEFITS TO ALL OF VISN 1'S KEY STAKEHOLDERS

**Veterans and their Families** benefit by having greater opportunity to participate in trials of cutting edge treatments (such as cancer treatment trials) and to contribute to the accumulation of important medical knowledge. The quality of medical care would also benefit by the recruitment and retention of highly qualified clinicians.

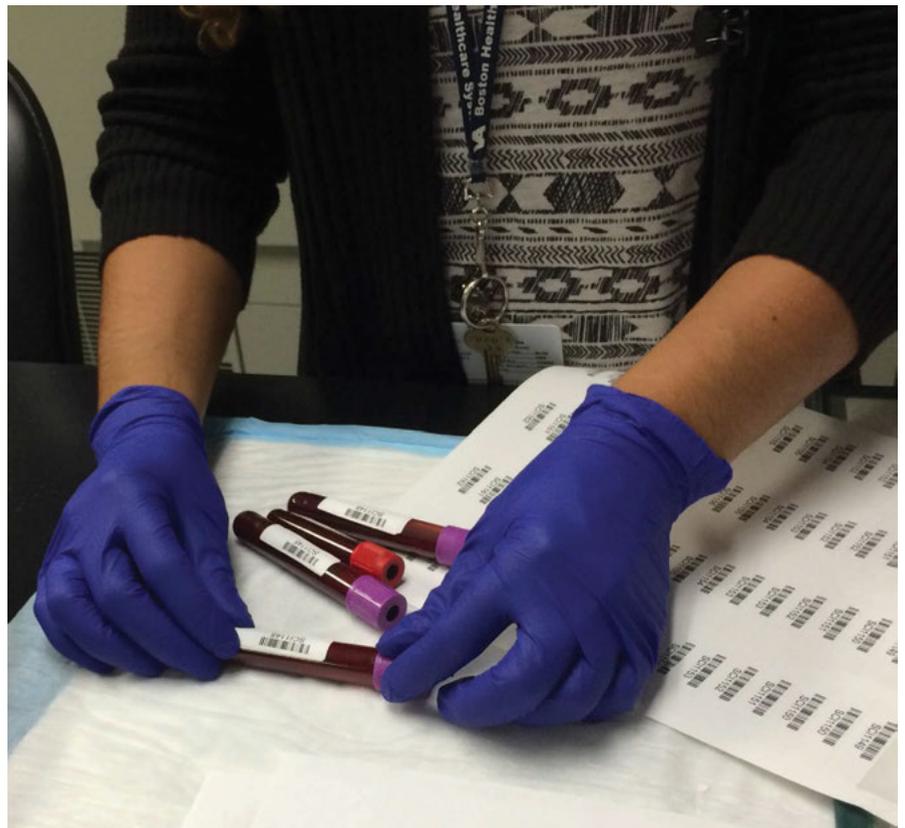
**Staff in VISN 1** can have an enriched professional environment through the opportunity to participate in world-class scientific research throughout the network.

**Academic Affiliates'** scientific and educational missions are greatly enhanced when supported by the VA.

**VA Central Office** strategic goals are supported for one of VHA's statutory missions: research that supports improvement of Veteran health care.

**Decrease Disparity** in care by providing state of the art care accessible through the region.

**New England Congressional Representatives** would see improved health care for Veterans and expanded regional economic activity, as medical research is an important part of the New England economy.



## ORGANIZATION

### Operations Core

- Serve as the operational system for the Scientific Core and Field Component

### Field Component

- Provide resources necessary to execute studies at each site
- One full-time site coordinator will be hired at each facility in the network to execute protocols initiated or expanded through the CTN
- Establish a network of sites to collaborate on research protocols
- Increase research opportunities in the VISN

### Scientific Core and Programs

- Assist in the development of disease specific consortia and facilitate investigator-initiated projects

### Investigator-Initiated Projects

The CTN encourages Investigators in the VISN to submit protocols that may be suitable for expansion across multiple sites. Through this effort, a wide variety of research can be promoted and effectively implemented by leveraging the experience of the CTN.

### Cardiology

The Cardiology Consortium includes representatives from across the VISN collaborating to implement studies of interest, expand new research, and open areas in their practice where clinical research could be applicable.

### Oncology

The Oncology Consortium establishes new Oncology trials in the VISN, and works together on established group studies from the National Cancer Institute and Southwest Oncology Group.

### Precision Oncology Program

The Precision Oncology Program offers targeted genomic analysis of tumor samples to Veterans with newly-diagnosed cancer. Through this program, detailed test results can be matched to relevant clinical trials to provide new treatment options. The program also bridges clinical care and research by allowing Veterans to share their test results in a research database with the goal of learning more about cancer.

## VISN 1 Clinical Trials Network

