



VA Comparative Effectiveness Research

VA Mission

- **VA Mission**

“...to care for him who shall have borne the battle and for his widow, and his orphan”

A. Lincoln, 2nd Inaugural

- **VA Research Mission:**

“To discover knowledge and create innovations that advance the health and care of veterans and the nation.”

- **Veterans first and always in all we do**

Attributes for Comparative Effectiveness Research

- **VA attributes for Comparative Effectiveness Research for the benefit of veterans**
 - Large healthcare system
 - Outstanding research program embedded in healthcare system - “Intramural”
 - Infrastructure for clinical trials
 - Vehicles for translation and implementation of research into the health care system

Large Healthcare System

- **Large system**
 - 5.5 million patients/yr, 7.8 million enrollees
 - >1200 Sites of Care
 - 153 Medical Centers
 - 737 Community-based Outpatient Clinics
 - 225 Readjustment Counseling Centers
- **Intramural research system - a unique strength**
- **Electronic Health Record**
- **117 VAMCs have Federal Wide Assurances for research**
- **Community of ≈3000 VA researchers**
 - Published 46,149 articles in past 7 years in the best journals
- **≈2100 VA funded projects**

Rich 60 Year History

- **3 Nobel Laureates, 6 Lasker Award Winners**
- **Many important discoveries and inventions**
 - Cardiac Pacemaker, First liver transplant, Radioimmunoassay, CT Scanner
- ***Clinical Trials***
 - First large scale clinical trial – TB
 - Cooperative Studies Program
 - Trials strongly influence medical practice



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VA Programs in Comparative Effectiveness Research

Comparative Effectiveness Research

- **Definition**

- CBO: “...a rigorous evaluation of the impact of different options that are available for treating a given medical treatment for a given set of patients.”

- **Speaker’s previous interest in the topic**

- Kupersmith et al, Journal of Investigative Medicine, 2005

VA Comparative Effectiveness Research

- **Research**

- Cooperative Studies Program
 - Clinical trials
- Health Services Research – health system oriented research
- Rehabilitation

- **Implementation**

- Quality Enhancement Research Initiative program
- Evidence Synthesis program

VA Cooperative Studies Program

- **Large VA clinical trials program**
 - **Major vehicle for Comparative Effectiveness Research**
- **Method of funding projects**
 - Letter of intent submitted
 - Ideas based on clinical practice observations, gaps in literature, etc
 - *Project review by experts who collaborate with the proposer*
 - Include clinicians, clinical researchers, trialists, biostatisticians, pharmacists, others

VA Cooperative Studies Program

- **Review considerations include clinical and policy considerations**
 - Clinical relevance and importance to VHA population, methodology, feasibility (testable hypothesis, sample size), ethics, resources needed, investigator qualifications, possible new technology or findings that may impact study
- **After approval, steps in a procedure to**
 - *Central IRB approval*
 - Form study Committees, Coordinating Center, etc
 - Local Medical Center approvals
 - Other
- **Collaboration with NIH and others in many trials**

VA Cooperative Studies Program -- Examples

- **Computerized Tomography vs Positron Emission Tomography in solitary pulmonary nodule (PET better)**
 - Journal of Nuclear Medicine, 2008
- **Sotalol vs Amiodarone in atrial fibrillation (similar)**
 - New England Journal of Medicine, May 5, 2005
- **Standard care with & without Phlebotomy in stable peripheral artery disease (no sign difference)**
 - Journal of the American Medical Association, February 14, 2007
- **Medical therapy vs Coronary revascularization prophylaxis prior to elective vascular surgery (no sign difference)**
 - New England Journal of Medicine, December 30, 2004

VA Cooperative Studies Program -- Examples

- **Percutaneous coronary intervention/optimal medical therapy vs Optimal medical therapy alone (COURAGE) (no sign difference)**
 - New England Journal of Medicine, March 27, 2007
- **Open mesh vs Laparoscopic mesh repair for inguinal hernia (open mesh better)**
 - New England Journal of Medicine, April 29, 2004
- **Care model (patient's self-management, continuity of care, information via nurse care coordinator) vs Standard care in Bipolar Disorder (care model better for most end points)**
 - Psychiatric Services, July 2006
- **Intensive vs Less Intensive Renal Support in Critically Ill Patients with Acute Kidney Injury (no sign difference)**
 - New England Journal of Medicine, July 8, 2008
- **Prolonged Exposure Therapy vs Patient-Centered therapy in PTSD (PET better)**
 - Journal of the American Medical Association, Feb 28, 2007

VA Cooperative Studies Program - Ongoing

- **Radical Prostatectomy vs Palliative Expectant Management for localized Prostate Cancer**
- **Intensive vs Standard glycemic control in diabetes**
- **Home monitoring vs “High quality” anti-coagulation clinic in atrial fibrillation and/or mechanical heart valve**
- **CABG vs Percutaneous coronary intervention with stents in diabetes**
- **Robotic assisted training in upper extremity movement vs Intensive stretching and range of motion exercise via trained therapist vs Usual care in stroke**
- **Self-management (education, action plan & case management) vs Standardized care in severe Chronic Obstructive Lung Disease**

Health Services Research - Ongoing

- **Health systems oriented projects**
- **Laboratory based vs Home evaluation of sleep apnea**
- **Examples of studies vs “usual care” control**
 - Collaborative care model for depression
 - Site randomization of Outpatient Clinics (CBOCs)
 - Plain language decision aid for patient decision making in prostate cancer
 - Collaborative care using primary care physician, RN and PharmD for hypertension/diabetes to implement stroke risk management
 - Patient preference tailored information concerning colon cancer screening
 - Training caregivers with a Home Safety Toolkit in Alzheimer’s Disease

Analysis of Electronic Health Record

- **Besides clinical trials, analysis of EHR represents an approach to Comparative Effectiveness Research**
 - Compare treatments and approaches to care in *clinically rich* data in EHR
- **Using EHR data provides**
 - Immediacy of results
 - Less costly studies
 - However, there are methodologic issues
 - E.g. are groups comparable?
 - Text recognition

Analysis of Electronic Health Record

- **VA examples**

- EHR diabetes cohort database shows no difference in mortality among oral antidiabetic drugs
 - Diabetes Care, July 2007
- Blood transfusion in surgical cases
 - NSQIP database in VA Patients (National Surgery Quality Improvement Program)
- Comparison of obesity care practices
- NSAID prescription strategies
- Carvedilol **vs** Controlled-release Metoprolol in heart failure



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Implementation/Translation

Quality Enhancement Research Initiative

Evidence Synthesis Program



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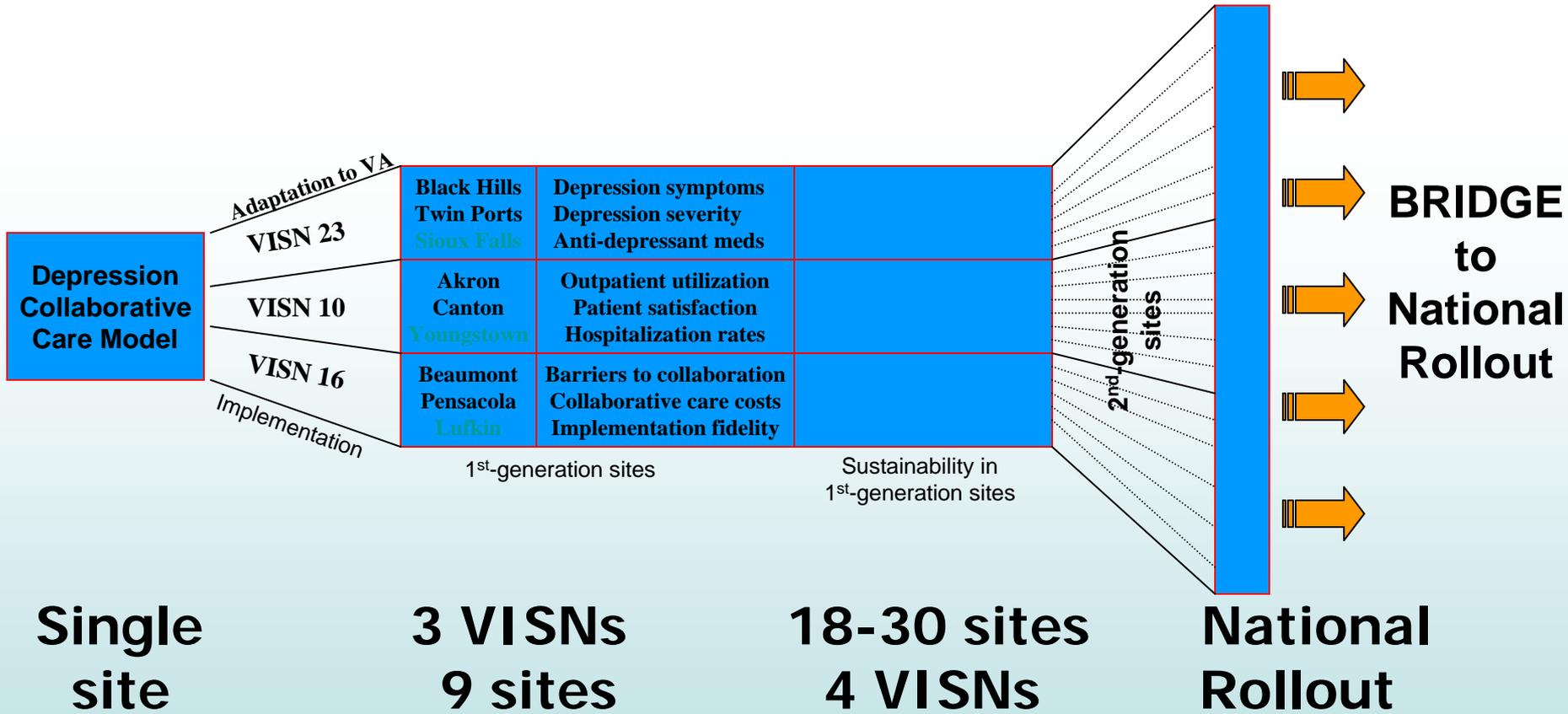
Quality Enhancement Research Initiative

QUERI Program

QUERI Program

- **Mission** - Systematically implement/ translate evidence-based clinical practices & research findings into routine clinical practice
- **Steps in QUERI process**
 - Identify gap in Evidence Based Practice
 - Develop and implement a strategy for change
 - Test strategy
 - Single site pilot
 - Small scale implementation pilot
 - Large scale, multi-region implementation trial
 - System-wide roll-out
 - Document system improvements
 - Document outcomes & QOL improvements

Implementation of System Change Collaborative Care of Depression



Spinal Cord Injury National Vaccination Project

	VA performance measures: SCI		Veterans w/SCI Survey	
	Flu	PPV	Flu	PPV
1997	25%	20%	NA	NA
1998	26%	25%	NA	NA
2000	28%	40%	NA	NA
2001	33%	50%	57%	NA
2002	62%	78%	62%	60%
2003	61%	79%	68%	75%
2004	68%	88%	79%	82%
2005	65%	82%	72%	NA



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VA Evidence Synthesis Program

VA Evidence Synthesis Program

- **Reviewing the evidence on a topic**
- ***Policy oriented synthesis of evidence to inform medical practice and health systems planning***
 - *Informed by policy considerations with input by Patient Care Services*
- **Recent topics**
 - Drug management of BPH – Led to Formulary change
 - Osteoporosis – Incorporated into Guideline on screening male veterans
 - Pain in Polytrauma – Need more research



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Fundamental Questions Re Comparative Effectiveness Research

Questions Re Comparative Effectiveness Research

- **What are the criteria for choosing studies?**
- **Who should choose?**
- **Which type of methodologies should be used?**
- **How should the results of studies be**
 - **Used?**
 - **Communicated?**
 - **Implemented?**

By its experience and expertise, VA has responses to these questions



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VA's Operational Readiness in Comparative Effectiveness Research

VA's Operational Readiness in CER

- **VA has an ongoing program and many attributes to undertake and implement Comparative Effectiveness Research**
 - Intramural research program in a large healthcare system
 - Infrastructure for clinical studies
- **VA has in place the structure and talent pool and is “shovel-ready” (in line with ARRA) for a variety of projects and collaborations such as**
 - Specific research projects via CSP or HSR
 - Trials management and execution via CSP
 - EHR analysis and studies
 - Expertise in methodology
 - Translation and implementation
 - Evidence synthesis

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The VA Cooperative Studies Program: A Legacy of Landmark Studies That Have Improved the Healthcare of Veterans

Peter Peduzzi, Ph.D.

VA Cooperative Studies Program Coordinating Center
West Haven, CT

The VA Cooperative Studies Program



- **The VA Cooperative Studies Program is a national clinical research program within the VA Office of Research and Development.**
- **Its mission is to advance the health and care of Veterans and the nation through collaborative research studies that produce innovative and effective solutions to national healthcare problems.**

What is a cooperative study?



- **A cooperative study is a research study to determine the best way to treat patients with a particular disease or to prevent a disease.**
- **Studies are conducted under the highest ethical standards.**
- **Studies involve many volunteers from many hospitals.**
- **Treatments to be tested or compared often include drugs, surgical procedures and vaccines.**

History of the VA Cooperative Studies Program



- **The Program dates to the 1940s when VA was concerned with how to care for thousands of WWII Veterans with tuberculosis (TB).**
- **In 1946, VA launched the first successful study to test an antibiotic (streptomycin) for treatment of TB.**
- **Since the TB study, the VA Cooperative Studies Program has completed 175 research studies in virtually all disease areas.**
- **Many have been landmark studies that have improved the healthcare of Veterans and changed clinical practice.**

Landmark VA Cooperative Studies



First studies in the world to show:

- Heart bypass surgery helps people with very bad hearts live longer.
- Warfarin (coumadin) prevents stroke.
- Aspirin prevents heart attacks and death.
- Anti-hypertensive drugs are effective in controlling high blood pressure. Led to a Nobel Prize nomination.
- Insulin pump improves the quality of life in diabetics.
- A vaccine prevents shingles.

Recent VA Cooperative Studies



- 1. Heart angioplasty**
- 2. Acute kidney failure**
- 3. Stroke rehabilitation**

Study of Heart Angioplasty



Purpose: To determine the best way to treat people with chest pain because the heart does not get enough blood because of blocked arteries (acute coronary syndrome):

1. Angioplasty (medical procedure to open blocked heart arteries)
2. Heart drugs and lifestyle changes (exercise, proper diet, quitting smoking).

Collaborators: Canadian Institutes of Health Research and 15 drug companies.

Need for a Study of Heart Angioplasty



- **Coronary artery disease is the leading cause of death in the U.S.**
- **Acute coronary syndrome (ACS) is a common and life-threatening form of coronary artery disease.**
- **ACS occurs when the arteries that supply oxygen-rich blood to the heart muscle are blocked. Thus, the heart does not get enough oxygen leading to chest pain or a heart attack.**
- **1.2 million people have ACS in the U.S. each year and nearly half a million die from it.**

Study of Heart Angioplasty

Study timeline: 1999 – 2006.

Study participants: 2287 heart patients from 50 U.S. and Canadian hospitals.

- **968 (41%) were Veterans from 15 VA hospitals.**

Study of Heart Angioplasty



Major study finding:

- Angioplasty does not reduce the chance of dying or of having a heart attack more than giving heart drugs and lifestyle changes.

Study significance:

- Patients with chest pain from blocked heart arteries can be first treated safely with heart drugs and lifestyle changes and later given angioplasty if necessary.

Study of Acute Kidney Failure



Purpose:

To determine the best way to treat critically ill hospitalized patients with acute kidney failure:

1. Usual treatment: dialysis every other day
2. Intensive treatment: dialysis every day.

Collaborators: National Institutes of Health (NIH)

Need for a Study of Acute Kidney Failure



- **Acute kidney failure is the rapid loss in the ability of the kidneys to function. It results in the retention of fluid and waste products normally removed by the kidneys.**
- **It is a life-threatening condition in which more than half of hospitalized patients die.**
- **It is most often a complication of surgery, trauma or severe infection.**

Need for a Study of Acute Kidney Failure



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There are no medications to treat people with acute kidney failure.

It can only be treated by using methods that do the work of the kidneys such as dialysis, which removes wastes and extra fluid from the body.

Study of Acute Kidney Failure



Study timeline

2003 – 2007

Study participants

1124 patients enrolled from 27 hospitals; 281 (25%) were Veterans from 18 VA hospitals

Major study findings

Giving more dialysis does not:

1. Reduce the chances of dying
2. Allow the kidneys to recover their ability to function any faster

Study of Acute Kidney Failure



Study significance

Giving dialysis every other day:

1. Remains the best medical practice for treating acute kidney failure.
2. Doesn't overburden the patient and is less costly compared with giving dialysis every day.

Study of Stroke Rehabilitation



Purpose:

To determine the best way to treat people who suffered a stroke and have lasting arm impairment:

1. Robot-assisted therapy
2. Conventional therapy given by a physical therapist
3. Usual stroke care – drugs (aspirin) and lifestyle changes (exercise, proper diet, quitting smoking) to prevent a second stroke.

Collaborators:

- VA Rehabilitation Research & Development Service
- Robot developed by MIT researchers

Need for a Study of Stroke Rehabilitation



- **Stroke is the leading cause of long-term disability in U.S.**
- **780,000 strokes annually; 500,000 people have lasting impairment of the arm and hand.**
- **No proven rehabilitative therapies for patients 6 months after a stroke (known as chronic stroke period).**
- **Rehabilitation rarely given to treat chronic stroke because it is believed most recovery occurs in first 6 months after the stroke.**

Robot-assisted Therapy



Study of Stroke Rehabilitation



Study timeline:

- 2006-2009

Study participants:

- 127 Veterans from 4 VA hospitals

Major study findings:

- Due early 2010

Potential significance:

1. Robots have the potential to improve the function of the impaired arm and the quality of life in Veterans who have suffered a stroke.
2. Robots offer a less costly way to treat a large number of Veterans.

New Initiatives for the VA Cooperative Studies Program



- **Research studies to help understand the genetic basis of disease to better individualize treatment care.**
- **Development of advanced computer technology to handle an explosion of genetic data and data from electronic health records.**

Thanks to Our Veterans



- **Our sincerest thanks to the many thousands of Veterans who have participated in VA Cooperative Studies over the decades.**
- **These Veterans have served their country twice – first in military service and second by participating in studies to help improve the healthcare of others.**



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Best Medical Therapy vs. Deep Brain Stimulation for Parkinson's Disease:

Results from a Multi-Site Randomized Trial

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University Study Co-Chairperson, CSP 468 Study Group

Funding by: VA Cooperative Studies Program/ Office of Research and Development
National Institute of Neurological Disorders and Stroke (NINDS) Medtronic Neurologic

Some Facts about Parkinson's Disease (PD)



PD is a progressive neurological disorder that worsens over time.

Symptoms:

- Tremor/shaking
- Slowed movements
- Rigidity or stiffness
- Shuffling gait and balance problems.

Many other problems also occur over time:

- Speech, swallowing
- Depression, anxiety, compulsive behaviors (like gambling)
- Dementia, hallucinations
- Low blood pressure
- Sleep problems.

Some Facts about Parkinson's Disease (PD)



PD is a common cause of disability:

- Around 60,000 new cases are diagnosed each year in U.S.
- In the VA population – we estimate over 45,000 patients have PD.

Background

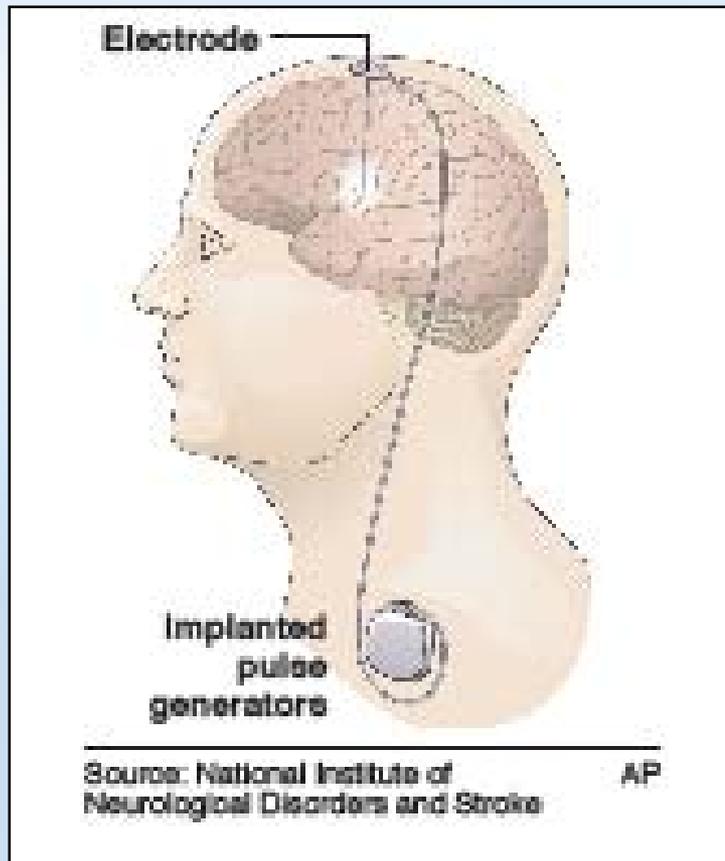
- **Deep Brain Stimulation - is an accepted surgical treatment for individuals with Parkinson's disease (PD) who have motor complications when taking medication.**
- **Many questions remain, including:**
 - **Is Surgery better than Best Medical Therapy for PD?**

What is Best Medical Therapy?



- Patients are cared for by experts in PD.
- PD medications are adjusted as needed.
- It includes use of therapies (physical, occupational, speech) as needed.
- The goal is for patient to have the best control over symptoms and best functioning possible.

What is Deep Brain Stimulation Surgery?



- **Electrodes are inserted in the brain on both right and left sides.**
- **Pulse generator (battery) is inserted in chest.**
- **Wires connect the electrodes and battery.**
- **Amount of stimulation can be adjusted.**
- **Stimulation is continuous, like a pacemaker for the brain.**

Study Patients/Sites

- **This study included veterans and non-veterans who had PD, took medications but still had problems with control of their movements or motor function.**
- **They could not have dementia or other serious mental health problems.**
- **They must be able to tolerate undergoing surgery.**
- **Study sites included: 7 VA Parkinson's Disease Research, Education, and Clinical Care Centers, and 6 University Medical Centers.**

Study Plan

- **Patients provided signed informed consent and were randomized (50/50 chance) to receive Surgery or Best Medical Therapy for six months.**
- **At six months, Surgery and Best Medical Therapy patients were compared on their:**
 - Movements/motor function
 - Quality of life
 - Psychological/cognitive functioning
 - Complications of treatment.

Findings

Before Surgery:

Patients averaged 6.4 hours/day when they were able to move and do their daily activities.

After Surgery:

Good movement time increased to almost 11 hours/day.

Medical therapy patients:

No changes, remained at 7 hours/day.

Findings

- **Quality of life improved after Surgery.**
- **Patients who received surgery were able to reduce the amount of medication they took for PD.**
- **More patients experienced serious complications after Surgery than after best medical therapy (such as: infections, falls, depression/confusion).**

Conclusions

- **Surgery was superior to Best Medical Therapy in improving motor function/movement and quality of life.**
- **Older patients did almost as well as younger patients following Surgery on motor function and quality of life.**
- **Physicians and patients should carefully weigh the risks vs. benefits when making decisions about Surgery for PD.**

Improving Veterans' Lives



- **VA has a network of facilities that have expertise in treating veterans with PD and other movement disorders including:**
 - The 6 Parkinson's Disease Research & Clinical Care Centers
 - 41 specialized clinics connected with PADRECCs
 - Neurology clinics at the remaining VAs.
- **Surgery is an effective treatment for PD and is available to veterans.**
- **We have more information about the risks and the benefits so that patients and their doctors are better prepared to make well-informed decisions.**

Acknowledgements

Thank you to:

- Our site study teams: neurologists, neurosurgeons, neuropsychologists, nurse coordinators;
- And a very special thank you to our study patients – our Veterans and others with PD who agreed to participate to benefit others.



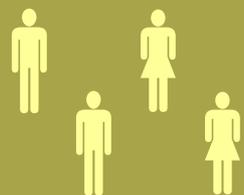
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VA Primary Care - Mental Health

**JoAnn E. Kirchner, MD,
Associate Director, VA South Central MIRECC**

Primary Care – Mental Health Interface



**Some
veterans are
in excellent
mental health**

**They have limited need
for mental health services**

**Some
veterans have
severe
mental illness**



**They are served
by specialty mental health**

**Many veterans have mild-to-
moderate mental health problems**



**Primary Care - Mental
Health Interface**

Primary Care - Mental Health Development



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Early
Research

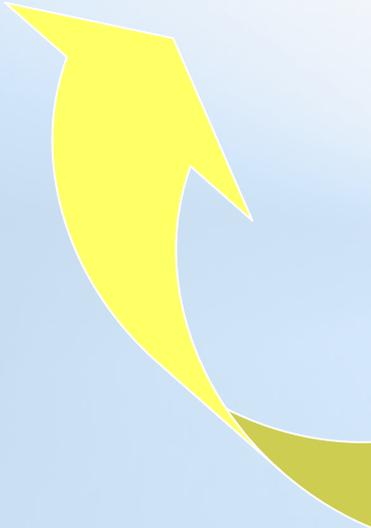
Primary Care - Mental Health Development



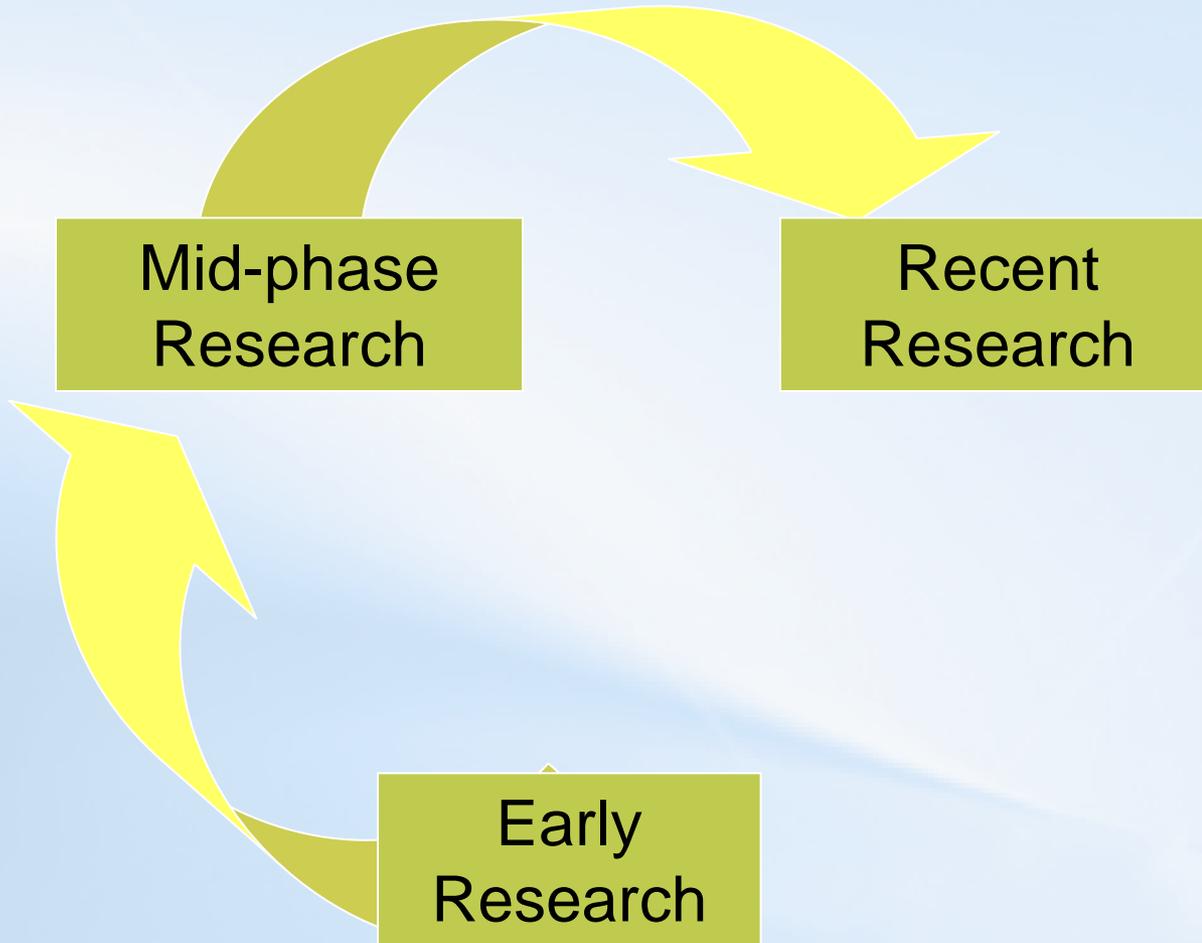
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Mid-phase
Research

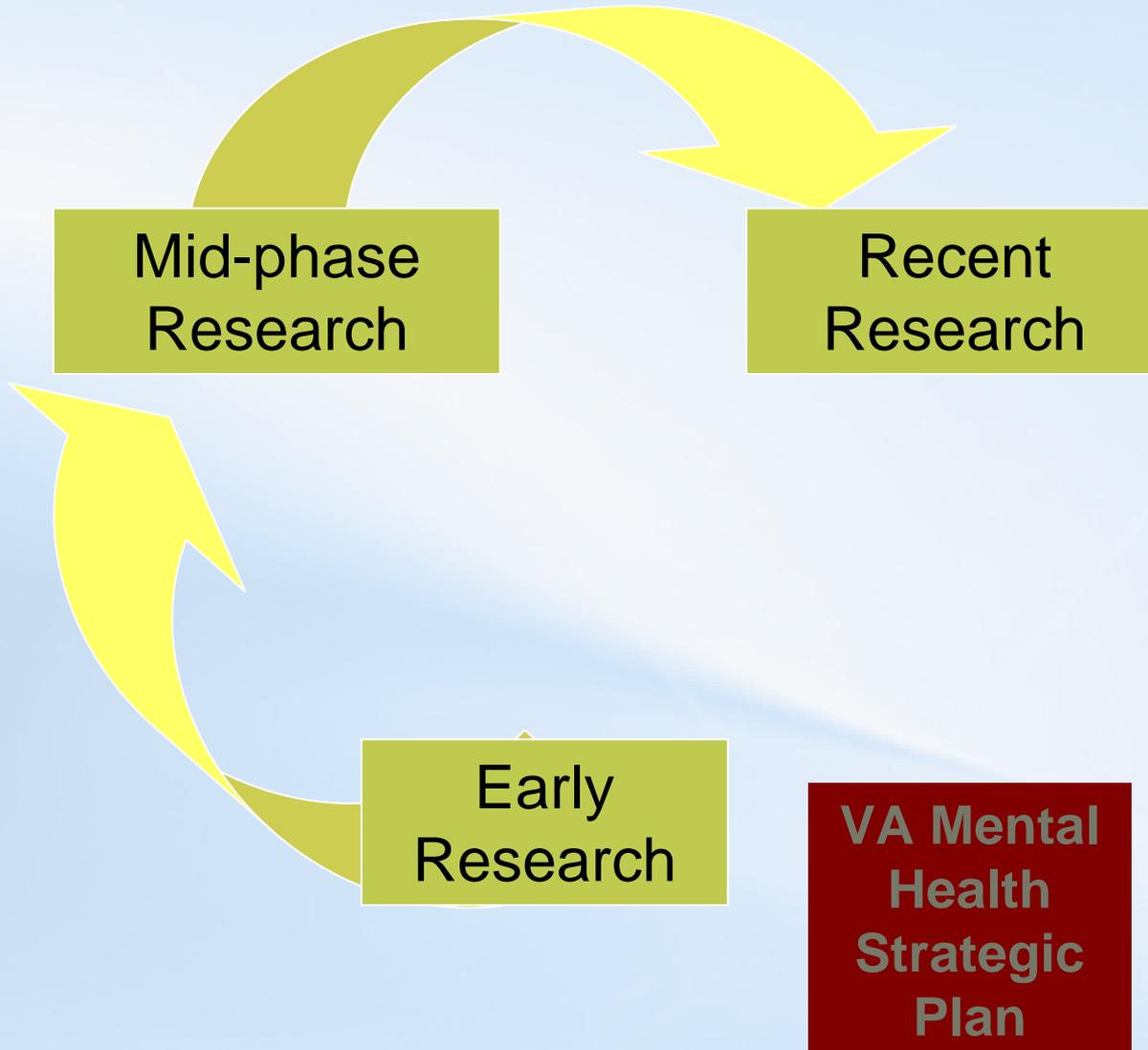
Early
Research



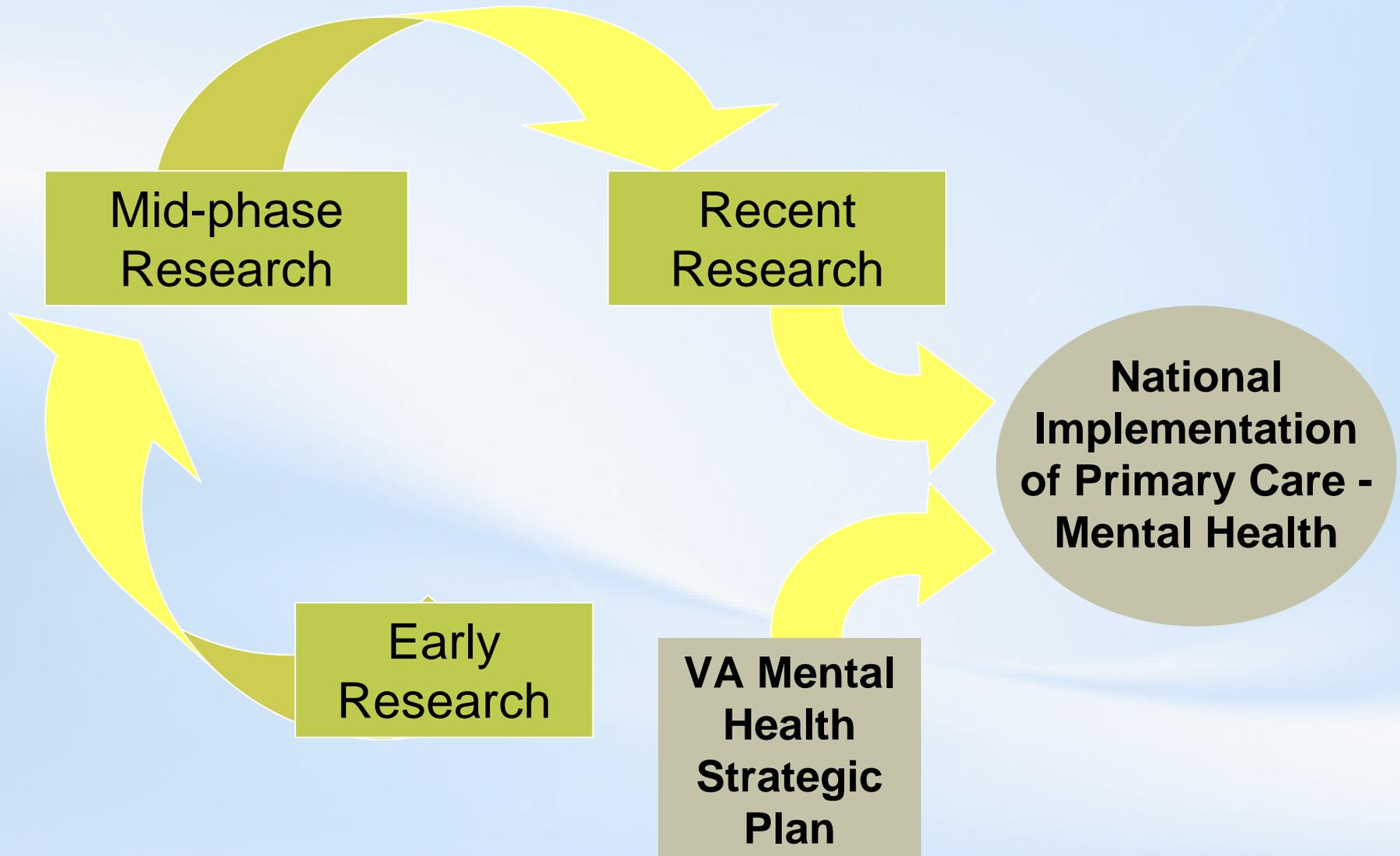
Primary Care - Mental Health Development



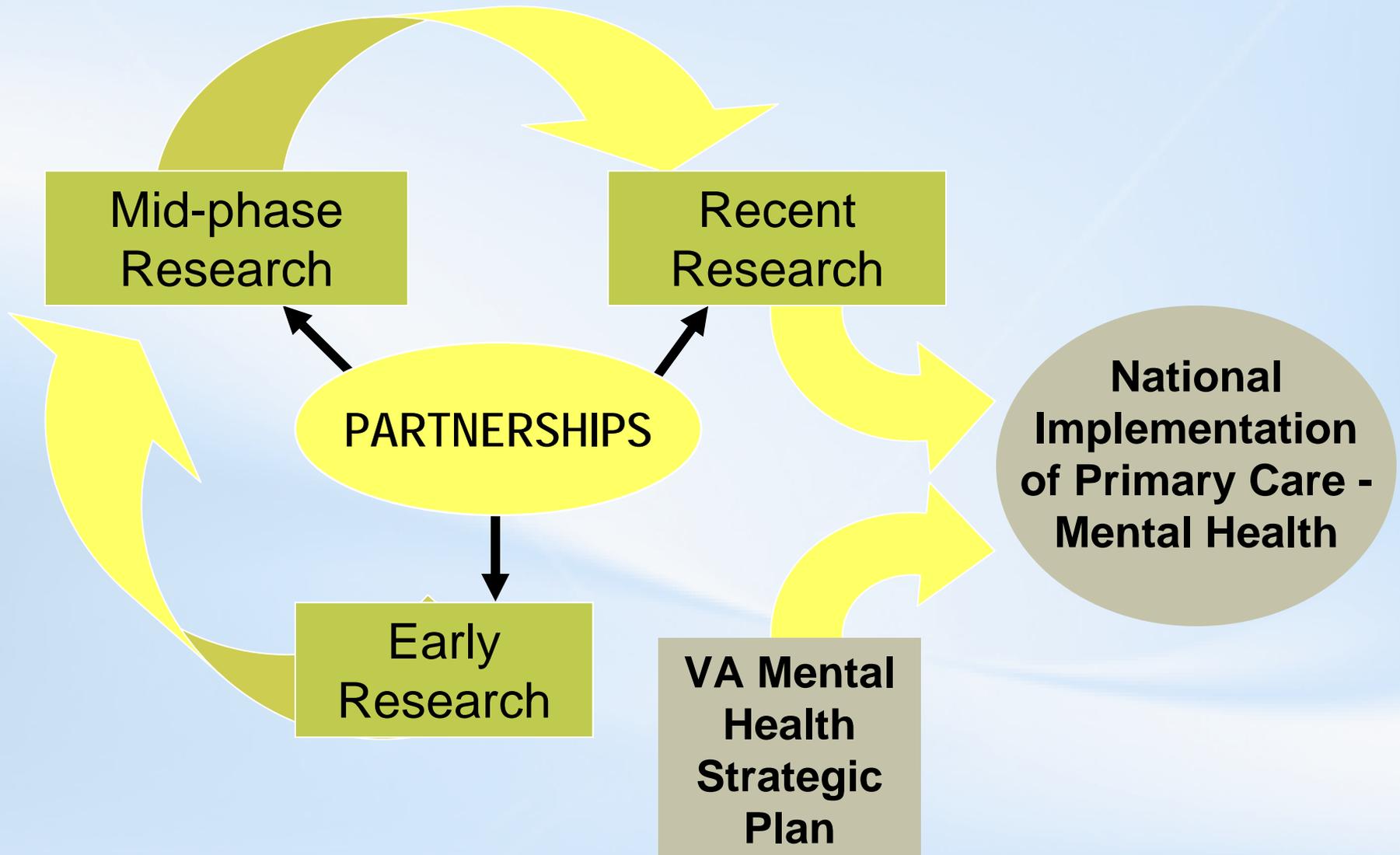
Primary Care - Mental Health Development



Primary Care - Mental Health Development



Primary Care - Mental health Development



Partnerships



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Understanding and Addressing Disparities in Veterans' Health Care

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VAMC

Disparities in Care - defined

“Differences”

- Variations in care, but not evaluated in terms of clinical appropriateness and patient factors, with no evidence of differential outcomes of treatment

“Disparities”

- Difference in appropriate treatment use, not attributable to patient factors
- Associated with poorer outcomes

Why Study Disparities in Care?



- **Disparities observed in care in every healthcare setting and system in US; what about VA?**
- **Numerous studies found disparate cardiac care in and outside of VA for white and black patients**
- **National data on hypertension showed disparities between black and white patients**
- **Dental care – veterans using VA dental care report worse oral health than other adults and tooth loss is common amongst users of VA care**
- **Women's health – women reported special concerns about obtaining care in VA**

VA is an ideal place to study disparities



- So often, cause of disparities thought to be differential access to care
- In VA, where patients are already determined to be eligible for care, this potential cause of disparities is eliminated
- Unparalleled availability of data to study care
- Veterans are willing to help with research – to help their fellow veterans
- Any solutions we identify can help veterans all over the nation, throughout the nation's largest healthcare system
- VA's value on providing high quality, equitable care to all veterans, and constant striving for improvement throughout the healthcare system

Cardiac Care

- **Why are there disparities in receipt of invasive cardiac procedures, e.g. cardiac catheterization?**
- **Is it patient beliefs or distrust?**
- **We interviewed over 1,000 white and black patients with cardiac disease at five different VAMCs (Houston, St. Louis, Durham, Atlanta, Pittsburgh)**
- **Black patients less likely to receive cardiac catheterization (33% vs. 47%), BUT**

Cardiac Care (Cont.)

- **Not because of patients' beliefs about their heart disease, their doctors, or the VA**
- **Black patients' doctors thought they weren't as sick – and this was true**
- **Black patients didn't have as severe coronary artery disease (fewer blockages) as white patients**
- **Over the next year, black patients had more favorable functional status outcomes (fewer limitations)**
- **What initially looked like *disparities* in care proved to be *different but appropriate* care**

Hypertension Care

- **Black patients more likely to have hypertension, less likely to take blood pressure (BP) medications, and less likely to have well-controlled blood pressure (nationally and in VA)**
- **Is this due to patients' beliefs about BP and medications? Doctor-patient communication?**
- **Can we improve care, medication adherence and ultimately, blood pressure outcomes?**
- **Our intervention: Electronic medical record reminder and training clinicians in patient-centered counseling**

Hypertension Care (Cont.)



- **Interviewed 800 white and black veterans with hypertension at three VAMCs (Chicago, St. Louis, and Philadelphia), and administrative data on ~10,000 additional veterans**
- **Black patients had stronger beliefs about the seriousness of their hypertension; their doctors counseled them more than they did white patients**
- **Placing a reminder in the medical record led to greater improvements for white, but not black, patients**
- **Providing training to improve clinician-patient communication plus medical record reminder led to the greatest improvements in blood pressure outcomes and greatest reductions in disparities**
- **BP outcomes improved for thousands of veterans**

Strengthening ties between research and patient care services



- **Through VA Health Services Research & Development Service's QUERI program, reviewed and synthesized the evidence from VA studies to improve BP medication adherence and physician adherence to guidelines for care (comparative effectiveness of different approaches)**
- **Working with VHA's Office of Patient Care Services to use our findings to inform new initiatives to improve chronic disease care**

Dental Care

- **Veterans' oral health is worse than non-veteran populations of older adults (more tooth loss, worse oral health-related functional status)**
- **Black veterans more likely to have their teeth extracted than white veterans (even among patients with full eligibility for dental care)**
- **Now, we will study why this happens and try to address disparate rates of tooth extraction by fostering improved treatment decision making**

JGIM

Journal of General Internal Medicine

Volume 21 Supplement 3
March 2006

VA Research on Women's Health
Guest Editors: Donna L. Washington, Elizabeth M. Yano, Ronnie D. Horner

- **>180 studies on women Veterans**
- **Women use VA less than men**
- **Gender-specific care increases women's use of VA**
- **Virtually all VAMC's have basic women's health services**
- **Many studies on PTSD and association of sexual trauma with PTSD**

Summary

- **VA is a national leader in examining, understanding, and intervening upon disparities in care**
- **Through VA disparities research, our collective national understanding of disparities has increased and our ability to intervene has been enhanced**
- **Most importantly, thousands of veterans have received improved care, based on research findings**
- **Our heartfelt thanks to the thousands of veterans who have participated in these studies**



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