



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, last and always in all we do

Attributes for Comparative Effectiveness Research

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- 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
 - \$36.3 Billion budget (FY2007)
 - 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
- Electronic Health Record

Intramural Research Program

- Intramural research system - a unique strength
 - Researchers must be employed by VA
 - >70% of VA investigators are clinicians
 - Links researchers directly veterans' needs
 - Facilitates implementation of research results
- Unique research resources also include
 - *Electronic Health Record*
 - Cooperative Studies Program – Clinical Trials
 - Health Services Research
 - Rehabilitation

Intramural Research Program

- 117 VAMCs have Federal Wide Assurances for research
- Community of ≈ 3000 VA researchers
 - Published 46,149 articles in past 7 years
 - Publish in the best journals
- ≈ 2000 VA funded projects
- Best buy in government

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*
 - TB – First large scale clinical trial
 - Cooperative Studies Program
 - Trials strongly influence medical practice



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VA Programs in Comparative Effectiveness Research

Comparative Effectiveness Research

- Definition
 - Research evaluating the clinical effectiveness, risks and benefits of 2 or more medical treatments and/or services
- Speaker's previous interest in the topic
 - Kupersmith et al, Journal of Investigative Medicine, 2005

VA Comparative Effectiveness Research

- Research
 - Clinical trials
 - Cooperative Studies Program
 - Health Services Research – health system oriented research
 - Rehabilitation
- Implementation
 - Quality Enhancement Research Initiative program
 - Evidence Based Synthesis program

VA Cooperative Studies Program

- Large VA clinical trials program
- Major vehicle for Comparative Effectiveness Research
- Organization
 - Headquarters – Central Office, under Office of R & D
 - 5 Data and Statistical Coordinating Centers
 - 4 Epidemiology Research Centers
 - Pharmacy Coordinating Center
 - Health Economics Resource Center
 - Pharmacogenomics Analysis Laboratory

VA Cooperative Studies Program

- Method of funding projects
 - Letter of intent submitted
 - Project review by experts who collaborate with the proposer
- Review includes policy considerations
 - Participation of Patient Care Services
 - Economic review of issue in VA healthcare system
- 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
- 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

- Colonoscopy at 2-3 and 5 years **vs** 5 years only in asymptomatic subjects with small colorectal polyps
- 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
 - 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

Interrogation of Electronic Health Record

- Besides clinical trials, interrogation 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 still methodologic issues
 - E.g. are groups comparable?
 - Text recognition

Interrogation of Electronic Health Record

- VA examples
 - EHR diabetes cohort database shows no difference in mortality among oral antidiabetic drugs
 - Diabetes Care, July 2007
 - 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-Based Synthesis' Program*



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Quality Enhancement Research Initiative

QUERI Program

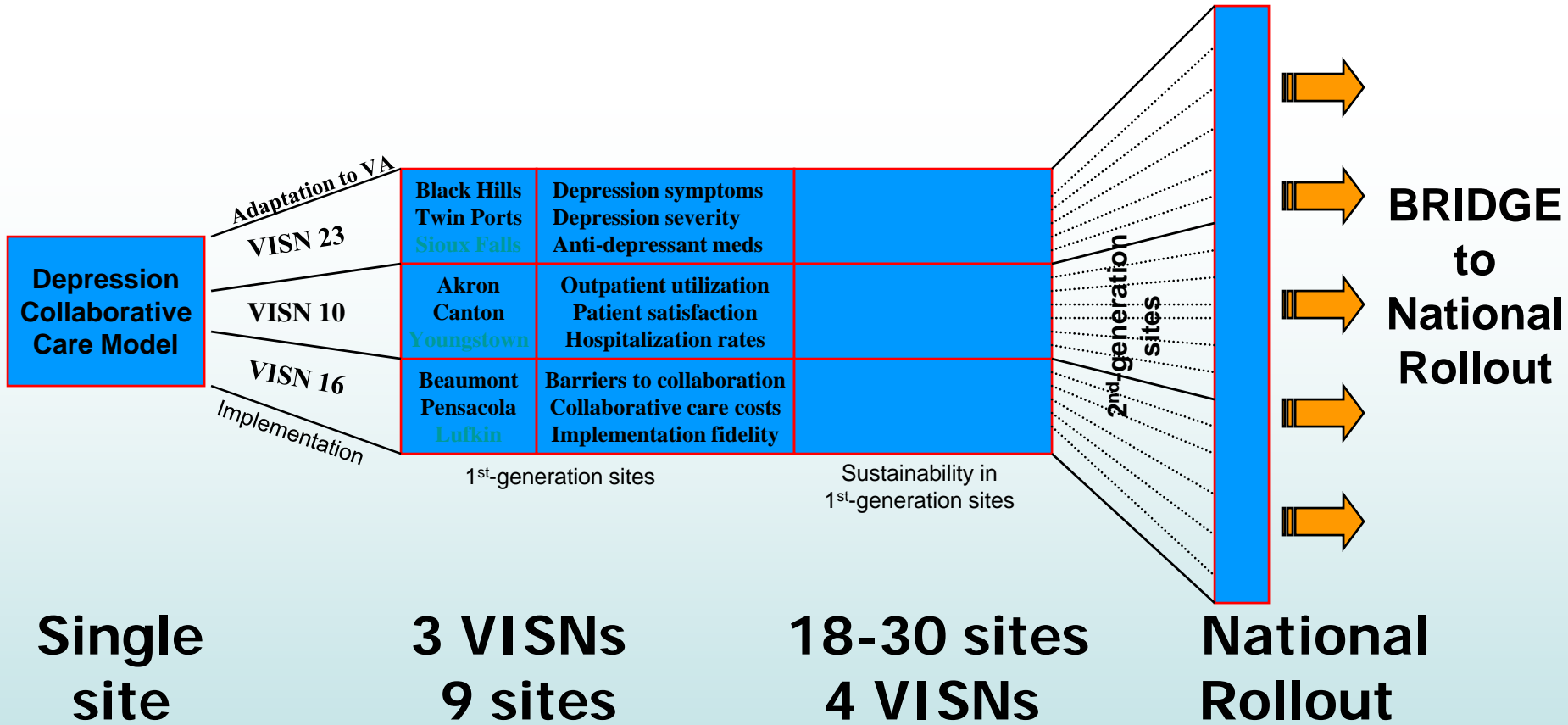
QUERI Program

- *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

Spinal Court 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

Implementation of System Change Collaborative Care of Depression





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Evidence Based Synthesis Program

Evidence Based 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

Syntheses of the Evidence on Two Aspects of Pain Finds Little to Guide Clinicians

The HSR&D [Evidence-Based Synthesis Program \(ESP\)](#) was established to provide timely and accurate syntheses of targeted health care topics of particular importance to VA managers and policymakers – and to disseminate these reports throughout VA. Recently, investigators at the Portland VA Medical Center conducted two systematic and comprehensive literature reviews focusing on pain.

Pain in Patients with Polytrauma

In a review of the literature (published 1950 – July 2008), and a survey of active research, investigators sought to: address the assessment and management of pain in patients with polytraumatic injuries, identify...

Conclusions

- VA has many attributes to *undertake* and *implement* Comparative Effectiveness Research
 - Intramural research program in a large healthcare system
 - Infrastructure for clinical studies
- VA has a strong ongoing program and many accomplishments *in the service of veterans* in Comparative Effectiveness Research
- Besides clinical trials, interrogation of the Electronic Health Record will also be an approach to Comparative Effectiveness Research