USING VASQIP AND SQDUG AS A RESEARCH RESOURCE

Faisal Bakaeen, M.D. FACS
Association of VA Surgeons
April 10-12, 2016
Unique

- Rich resource
- Clinical database
- Surgical Clinical Nurse Reviewer
- Compulsory-uniform and non-biased
- Longitudinal outcomes
- Link and merge with other VA databases
WHY SQDUG?

• Projects with no IRB
• Data flow outside of VA
• No data security
• Data mining without clear objectives
• Projects rarely closed
• Misinterpretation with resultant misrepresentation of VA practices
21% of the boys and 30% of the girls support me; therefore I'll get 51% of the vote.
Goals

• Preserve information safety
• Projects are feasible and data available
• Ensure proper interpretation of data
• Quality abstracts and manuscripts
National Surgery Office Data Use Agreement

Procedure for Obtaining Surgical Outcomes Data for Research Purposes

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

Policy
August 2015

NATIONAL SURGERY OFFICE (NSO) DATA USE AGREEMENT (DUA)
PROCEDURE FOR OBTAINING SURGICAL OUTCOMES DATA FOR RESEARCH PURPOSES

1. BACKGROUND. In accordance with VHA Handbook 1200.12. Use of Data and Data Repositories in Research, the National Surgery Office (NSO) is the data steward of data contained in the VistA Surgery Package and surgical outcomes data, including solid organ and bone marrow transplantation. VHA Handbook 1200.12 requires the data steward to establish policies and procedures to make this data available to VA researchers while ensuring the safe handling and accurate representation of patient data. This policy has also been developed in accordance with R&D policies (1200 series), Privacy policies (1605 series) as well as VHA Handbook 1102.01, National Surgery Office. As such, this document delineates the policy of the NSO regarding requests for the use of data for VA research through review and evaluation by the Surgical Quality Data Use Group (SQDUG). Final approval resides with the NSO data steward: the National Director of Surgery or his/her designee.

2. AUDIENCE. This document is to be used as a guide and reference for VA researchers requesting surgery data derived from Surgical Package data, inclusive of VA Surgical Quality Improvement Program (VASQIP), ophthalmology, and transplant data. It delineates the responsibilities of the research team: Principal Investigator (PI),
National Surgical Databases

- VASQIP
- Ophthalmology Data
- Transplant Data
Composition

• Chair
• VASQIP Medical Director
• NSO Chief Biostatistician
• NSO Biostatistician
• Four Members-at-large
SQDUG-Schedule

• Bi-Weekly conference calls to review:
  • Publication requests
  • Data transfer agreements

• Published calendar of meeting dates and lead time for submissions to receive approval
  • 10 days for abstracts and manuscripts
  • 30 days for data transfer agreements
Life Cycle of a Research Proposal
PI Submits Proposal & DUA → SQDUG Administrative Review → Assigned to Reviewers → SQDUG Board Meeting → SQDUG Board Recommendation to Data Steward → Study Closure; Data Disposition

If approved: Data Released to PI

SQDUG review of abstracts, manuscripts

Decision by Data Steward
Data Access Request Tracker

- All proposal-related forms located in DART
- Primary Investigators will submit proposals and Data Use Agreement amendments in DART
Data Access

- VA Informatics and Computing Infrastructure (VINCI) Workspace
- Secure National Surgery Office SharePoint site
SQDUG – Research Studies

41 Active Projects

FY13: 11 abstracts and 15 manuscripts

FY14: 16 abstracts and 13 manuscripts

FY 15: 17 abstracts and 20 manuscripts
Examples of High Impact Projects Categorized
Clinical vs. Administrative Databases
Objective: Validate the administrative database PSIs using VASQIP as the gold standard

– Five PSIs align with 7 VASQIP post-op complications
Use chart review to explore reasons for disagreement

<table>
<thead>
<tr>
<th>AHRQ PSI</th>
<th>VASQIP Surgical AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 Post-op Physiologic and Metabolic Derangement</td>
<td>Actual Renal Failure</td>
</tr>
<tr>
<td>11 Post-op Respiratory Failure</td>
<td>- Failure to Wean</td>
</tr>
<tr>
<td></td>
<td>- Reintubation</td>
</tr>
<tr>
<td>12 Post-op Pulmonary Embolism (PE)/ Deep Vein Thrombosis (DVT)</td>
<td>- PE</td>
</tr>
<tr>
<td></td>
<td>- DVT</td>
</tr>
<tr>
<td>13 Post-op Sepsis</td>
<td>Systemic Sepsis</td>
</tr>
<tr>
<td>14 Post-op Wound Dehiscence</td>
<td>Dehiscence</td>
</tr>
</tbody>
</table>

Methods – Record Matching

- All DRGs in PTF FY03-07: 2,813,169 hospitalizations flagged by PSI v4.0
- FY03-07 VASQIP Records: 290,542 surgeries (all inpatient and assessed)
- PTF Only: 2,544,327 hospitalizations
- VASQIP Only: 7,145 surgeries
- Matched (by SCRSSN and dates of care):
  - 283,397 surgeries
  - 268,771 hospitalizations
  - 117 VA hospitals
## Results – PSI Validity

<table>
<thead>
<tr>
<th>Comparison Group</th>
<th>Results for PSI version 4.1a, FY03-07 Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cases eligible for PSI (%)*</td>
</tr>
<tr>
<td>PSI</td>
<td></td>
</tr>
<tr>
<td>#10 PMD</td>
<td>ARF</td>
</tr>
<tr>
<td>#11 RF</td>
<td>FW</td>
</tr>
<tr>
<td></td>
<td>R/UI</td>
</tr>
<tr>
<td>#12 PE/DVT</td>
<td>PE</td>
</tr>
<tr>
<td></td>
<td>DVT</td>
</tr>
<tr>
<td>#13 Sepsis</td>
<td>SS</td>
</tr>
<tr>
<td>#14 WD</td>
<td>Dehiscence</td>
</tr>
</tbody>
</table>

These results suggest that the PSIs have moderate criterion validity.
Trends in Therapy
Trends Over Time in the Relative Use and Associated Mortality of On-Pump and Off-Pump Coronary Artery Bypass Grafting in the Veterans Affairs System

Faisal G. Balaeen, MD; Rosemary F. Kelly, MD; Danny Chu, MD; Michael E. Jessen, MD; Herbert B. Ward, MD; William L. Holman, MD

**IMPORTANCE** Numerous studies have compared the results of on-pump and off-pump coronary artery bypass grafting (CABG), but little is known about how either the relative use of these procedures or their associated perioperative mortality have changed with time.

**OBJECTIVE** To examine trends in off- and on-pump CABG use and outcomes over time.

**DESIGN** Retrospective analysis of data from the Veterans Affairs Surgical Quality Improvement Program (VASQIP).

**SETTING** Data were collected from 42 Veterans Affairs cardiac surgery centers.

**PARTICIPANTS** All Veterans Affairs patients ($n = 65,097$) who underwent isolated primary CABG from October 1997 to April 2011.

**INTERVENTIONS** Patients underwent either on-pump (ON) or off-pump (OFF) CABG.

**MAIN OUTCOMES AND MEASURES** The percentages of ON vs OFF cases as a function of time. We also evaluated trends over time in rates of conversion from OFF to ON CABG, perioperative mortality (30-day or in-hospital), and VASQIP predicted risk of mortality.

**RESULTS** The relative use of OFF CABG peaked at 24% in 2003, followed by a slow and mostly consistent decline to stabilize at about 19%. The conversion rate decreased with time and has stayed less than 3.5% since 2007 ($P < .001$). Perioperative mortality rates decreased over time for both ON and OFF CABG ($P < .001$) and have stayed less than 3% for the entire period.
Comparative Effectiveness
Performing Coronary Artery Bypass Grafting Off-Pump May Compromise Long-Term Survival in a Veteran Population

Faisal G. Bakaen, MD, Danny Chu, MD, Rosemary F. Kelly, MD, Herbert B. Ward, MD, Michael E. Jessen, MD, G. John Chen, PhD, Nancy J. Petersen, PhD, and William L. Holman, MD

Division of Cardiothoracic Surgery, Michael E. DeBakey Department of Surgery, University of Texas Medical School at Houston, Houston, TX; Division of Cardiothoracic Surgery, University of Minnesota, Minneapolis, MN; Division of Cardiothoracic Surgery, University of Texas Southwestern Medical Center, Dallas, TX; Houston Veterans Affairs Health Services Research and Development Center of Excellence, Houston, TX; and Department of Cardiothoracic Surgery, University of Alabama at Birmingham and The Birmingham Veterans Affairs Medical Center, Birmingham, Alabama

Background. There are ample data regarding the short-term outcomes of on-pump and off-pump coronary artery bypass grafting (CABG), but little is known about the long-term survival associated with these approaches.

Methods. Using the Veterans Affairs (VA) Continuous Improvement in Cardiac Surgery Program, we identified all VA patients (n = 65,057) who underwent primary isolated CABG from October 1997 to April 2011. The primary outcome measure was all-cause mortality. Age, 17 preoperative risk factors, and year of operation were used to calculate propensity scores for each patient. A greedy-match algorithm using the propensity scores of 4,911 off-pump with 24,738 on-pump patients. Survival fractions were estimated by the Kaplan-Meier method and compared by using the log-rank test.

Results. In the complete cohort, off-pump was used in 11,289 of 65,057 (17.4%) operations. For the matched cohort, the median follow-up was 6.7 years (interquartile range, 3.7 to 9.35 years). Risk-adjusted mortality did not differ significantly between the off-pump and on-pump groups at 1 year (4.8% vs 4.7%), risk ratio (RR) 0.98; 95% confidence interval [CI] 0.88 to 1.09) or 3 years (9.2% vs 8.9%; RR, 1.04; 95% CI, 0.96 to 1.12). However, risk-adjusted mortality was higher in the off-pump group at 5 years (14.7% vs 13.4%; RR, 1.00; 95% CI, 1.02 to 1.13) and 10 years (23.8% vs 23.7%; RR, 1.07; 95% CI, 1.02 to 1.12). Overall, the hazard ratio for off-pump vs on-pump was 1.06 (95% CI, 1.03 to 1.13); p = 0.04.

Conclusions. Off-pump CABG may be associated with increased long-term survival. Further studies are needed to identify the reasons behind this finding.
Significantly lower mortality after 1 to 5 years (HR, 0.45 [95% CI, 0.36-0.56]) and 5 to 14 years (HR, 0.47 [95% CI, 0.39-0.58]).
Validating Guidelines
Major Adverse Cardiac Events following Noncardiac Surgery in Patients with Coronary Stents

Published in JAMA
October 2013

Mary Hawn MD, Laura Graham MPH, Joshua Richman MD PhD, Kamal Itani MD, Thomas Maddox MD
Unadjusted MACE Rate Across Time by Stent Type

- Unadjusted MACE rates were non-significantly higher among DES patients for surgeries within 6 weeks of stent placement but significantly lower beyond 6 weeks and up to 6 months following stent placement.
Complications and Outcomes
Effect of Post-operative Complications on Colorectal Cancer Outcomes

David Berger MD
Michael E. DeBakey VAMC
Methods

• VASQIP and VACCR databases (1999-2009) merged using scrambled SSNs

****Unique to VA, this cannot be done with NSQIP and NCDB because they do not collect patient identifiers like scrambled SSN)
Results

- Any postoperative complication associated with worse long-term survival
- Infectious complications associated with worse survival compared to non-infectious or no complications

Evaluation of the Surgical Care Improvement Project in VA
Surgical Care Improvement Project (SCIP)

• Implemented in 2006 by Centers for Medicare and Medicaid Services

• 3 Focus Areas:
  – Surgical site infections
  – Adverse cardiac events
  – Venous thromboembolism (VTE)

Reduce Surgical Complications by 25% in 2010

Evaluation of SCIP Effectiveness

- Stulberg et al, 2010
  - *ICD9 code*

- Hawn et al, 2008
  - *SCIP-1 only*
  - Hawn et al, 2010

- Nicholas et al, 2010
  - *Hospital Compare*
  - ?*ICD9 code*

- Ingraham et al, 2010
  - *Hospital Compare*

- Claims Data

- NSQIP

Stulberg JJ *JAMA*. 2010;303(24):2479-2485
Nicholas LA *Arch Surg*. 2010;145(10):999-1004
Adherence and Adjusted SSI Over Time

Adherence to SCIP measures improved whereas risk-adjusted SSI rates remained stable. Policies regarding continued SCIP measurement and reporting should be reassessed.

The Business Case for Reducing Surgical Complications
Merged data from the VASQIP to cost information from the VA Decision Support System (DSS).

Costs of surgical complications were estimated using regression models to control for differences in severity of patients who do and do not develop complications, as well as differences in costs across hospitals.
Unadjusted Costs associated with complications in general surgery patients

Overall, the presence of any complication increases unadjusted costs nearly 3-fold...
Costs associated with complications after adjusting for differences in patient severity

Type of complication

- Respiratory
- Urinary Tract
- Central Nervous System
- Cardiac
- Wound
- No Complication

Dollars per complication

$0 $20,000 $40,000 $60,000

Vaughan Sarrazin et al, Surgery, 2009
Surgical Site Infections (SSI)

50,348 VA inpatient surgery patients in VASQIP in FY2010

2,101 (4.2%) experienced a Surgical Site Infection (SSI)
  - 1.1% had a deep SSI
  - 3.1% had a superficial SSI

Costs for SSI after risk adjustment

<table>
<thead>
<tr>
<th></th>
<th>Cost relative to patient with no SSI</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial SSIs</td>
<td>1.22 times greater</td>
<td>$ 4,531</td>
</tr>
<tr>
<td>Deep SSIs</td>
<td>1.61 times greater</td>
<td>$12,927</td>
</tr>
</tbody>
</table>
Education
The July Effect: Impact of the Beginning of the Academic Cycle on Cardiac Surgical Outcomes in a Cohort of 70,616 Patients

Faisal G. Bakaeen, MD, Joseph Huh, MD, Scott A. LeMaire, MD, Joseph S. Coselli, MD, Shubhada Sansgiry, PhD, Prasad V. Atluri, MD, and Danny Chu, MD

Division of Cardiothoracic Surgery, Michael E. DeBakey Department of Surgery, Baylor College of Medicine, The Michael E. DeBakey Veterans Affairs Medical Center, and The Texas Heart Institute at St. Luke’s Episcopal Hospital, Houston, Texas

Background. Because surgical residents’ level of experience may be at its nadir early in the academic year, academic seasonality—or the “July effect”—could affect cardiac surgical outcomes.

Methods. Prospectively collected data from the Department of Veterans Affairs Continuous Improvement in Cardiac Surgery Program were used to identify 70,616 consecutive cardiac surgical procedures performed between October 1997 and October 2007. Morbidity and mortality rates were compared between early (July 1 to August 31, n = 11,975) and late (September 1 to June 30, n = 58,641) periods in the academic year. A predictive model was constructed by using stepwise logistic regression modeling.

Results. The two patient groups had similar demographic and risk variables. Isolated coronary artery bypass grafting accounted for 76.7% of early-period procedures and 75.8% of later-period procedures (p = 0.03). Morbidity rates did not differ significantly between the early (14.0%) and later periods (14.2%; odds ratio [OR], 1.01; 95% confidence interval [CI], 0.96 to 1.07; p = 0.67) and operative mortality was similar, 3.7% vs 3.9% (OR, 0.99; 95% CI, 0.89 to 1.11; p = 0.90). The early portion of the year was associated with longer cardiac ischemia times (84 ± 40 vs 83 ± 42 minutes), cardiopulmonary bypass times (126 ± 52 vs 124 ± 56 minutes), and total surgical times (295 ± 90 vs 288 ± 90 minutes; p < 0.05 for all). Conclusions. The early part of the academic year was associated with slightly longer operative times; however, risk-adjusted outcomes were similar in both periods. This finding should lessen concerns about the quality of cardiac surgical care at the beginning of the academic year.

(Ann Thorac Surg 2009;88:70–5)
© 2009 by The Society of Thoracic Surgeons
SQDUG & VASQIP & More

• Allows for highly reliable observational study design
  – Unbiased assessors

• VA HSRD Centers of Excellence
  – Have the data management infrastructure
  – Programmer and analytic expertise
  – Staff to assist with regulatory requirements

• Funding Opportunities
  – AHRQ
  – VISN Career Development Awards
SQDUG – User Friendly

- Electronic packet submission—online submission process
- Published timelines and meeting times
- Single email address that can be accessed by SQDUG administrative staff
  
  VHASQDUGadmin@va.gov
SQDUG – Future Goal

Increase volume of SQDUG protocols and publications
Thank You!

SQDUG Members and Administrative Staff

Sandy Cupples
Peter Nelson
Christina Hammond
Tracy Smith
Mark Wilson
Rosemary Torres
Doug Bronson
Marco Zenati

Mark Wilson
Soonhee Han
Matthew Maciejewski
Benjamin Brooks
Robert Krouse
Xinli Li
Deeply Indebted

VASQIP nurses

All those who care for the Veteran

And most importantly the Veterans who served our country and entrust us with their care
Resources

• Single email address for all SQDUG inquiries:
  VHASQDUGadmin@va.gov
DART Tutorial

DART ACCESS Site