VIReC Database and Methods Cyber Seminar Series

VIReC
RESEARCHERS' GUIDE TO VA DATA

VIReC Database and Methods Cyber Seminar Series

Measuring Outpatient Pharmacy Use in the VA Using VA Pharmacy Data

October 4, 2010

Presented by:
Todd A. Lee, PharmD, PhD

VIReC
RESEARCHERS' GUIDE TO VA DATA

Audience Poll

- **Have you ever used VA Pharmacy Data?**
  - Yes
  - No

Audience Poll

- **How would you rate your overall knowledge of VA Pharmacy Data?**
  - 1 (Never Used)
  - 2
  - 3
  - 4
  - 5 (Used Frequently, Very familiar)

Session Objectives

- How has outpatient pharmacy utilization been measured in VA studies?
- Overview of VA Pharmacy databases
- Finding information in the VA Pharmacy databases
- Examples of VA studies that have used the VA Pharmacy databases
- Where to go for more help

VIReC
RESEARCHERS' GUIDE TO VA DATA

Session Objectives

- **How has outpatient pharmacy utilization been measured in VA studies?**
- **Overview of VA Pharmacy databases**
- **Finding information in the VA Pharmacy databases**
- **Examples of VA studies that have used the VA Pharmacy databases**
- **Where to go for more help**

How has outpatient pharmacy utilization been measured in VA studies?: Chronic Medication Use

- **Stroupe KT, Smith BM, et al. Effect of Increased Copayments on Pharmacy Use in the Department of Veterans Affairs. *Med Care* 2007; 45:1090-1097**
- How was pharmacy data utilized?

ORIGINAL ARTICLE

Effect of Increased Copayments on Pharmacy Use in the Department of Veterans Affairs

Kevin T. Stroupe, PhD,†‡ Bridget M. Smith, PhD,*‡ Todd A. Lee, PharmD, PhD,*‡ Elizabeth Tarlov, PhD,§ Ramon Durazo-Arvizu, PhD,¶ Zhiping Huo, MS,‡ Tammy Barnett, MA,*† Lishan Cao, MS,‡ Muriel Burk, PharmD,‖ Francesca Cunningham, PharmD,‖ Denise M. Hynes, PhD,*§¶ and Kevin B. Weiss, MD*‡*

Objectives: In February 2002, the Department of Veterans Affairs (VA) raised medication copayments from $2 to $7 per 30-day supply of medication for certain veteran groups. We examined the impact of the copayment increase on medication acquisition from VA.

Methods: This was a retrospective cohort study using data from national VA databases from February 2001 through February 2003. We took a random sample of over 5% of male VA users in 2001. Of 149,107 veterans sampled, 19,504 (13%) had copayments for no drugs, 101,410 (68%) had copayments for some drugs, and 28,193 (19%) had copayments for all drugs. We used multivariable count models to examine changes in the number of 30-day medication supplies after the increase.

Results: After the copayment increase, veterans subject to copayments for all drugs received 8% fewer 30-day supplies of medication annually relative to veterans with no copayments ($P < 0.001$). The effect of the copayment increased as the number of different medications veterans received increased. Among veterans subject to copayments for all drugs, acquisition of lower-cost drugs fell by 36%, higher-cost medications fell by 6%, over-the-counter medications fell by 40%, and prescription-only medications fell by 4% relative to veterans with no drug copayments.

Conclusions: The number of medications veterans obtained from VA decreased after the copayment increase. There were relatively larger impacts on veterans with higher medication use and on lower-cost and over-the-counter medications.

Key Words: veterans, copayments, drugs

(*Med Care* 2007;45: 1090–1097)

Healthcare payers in both the public and private sectors face ever-increasing medication costs. They have sought to control their medication costs using a variety of strategies including increased cost sharing with patients[1] by raising copayments or coinsurance rates, increasing deductibles, removing drugs from formularies, moving to multitier copayments,[2] or a combination of these measures.[3] The Department of Veterans Affairs (VA), which operates the largest healthcare organization in the United States, spent over $3 billion in fiscal year 2001 for outpatient medications, accounting for 14% of its medical care budget.[4] As in the private sector, the VA has increased cost sharing by patients. In February 2002, the VA increased medication copayments from $2 to $7 per 30-day medication supply for veterans required to pay copayments,[4] and in January 2006 copayments were increased again to $8 per 30-day supply. Moreover, recent proposals have been made to increase copayments further for certain veteran groups.[5]

Several studies outside VA have found that copayment increases have decreased overall prescription-drug utilization.[1,2,6–9] The impact of cost sharing may depend on drug class and copayment amount.[10] A study of elderly patients found that drug use decreased by 9% for more essential and 15% for less essential medications as cost sharing increased.[1] This reduction in essential medication use was associated with an increase in emergency department visits and adverse event rates.[1] If increased copayments lead to reductions in medication use with resulting adverse effects on health, pharmaceutical cost savings by healthcare payers may be lost due to increases in other healthcare costs.

Because VA patients tend to be older and have more chronic diseases than the general population,[11] previous estimates of the impact of copayment changes may not be relevant to the current VA healthcare system. Whether veterans are subject to copayments for no, some, or all drugs

From the *Center for Management of Complex Chronic Care, Hines, Illinois; †Cooperative Studies Program Coordinating Center, Hines, Illinois; ‡Feinberg School of Medicine, Northwestern University, Chicago, Illinois; §VA Information Resource Center, Hines, Illinois; ¶Department of Preventive Medicine and Epidemiology, Stritch School of Medicine and Niehoff School of Nursing, Loyola University Chicago, Maywood, Illinois; and ‖VA Pharmacy Benefit Management/Strategic Health Group, Hines, Illinois.

Supported in part by VA Health Services Research & Development (ECI 02-220).

Presented at the VA HSR&D 2005 Annual Meeting (February 16–18, 2005) in Washington, DC, and at the Academy Health 2005 Annual Research Meeting (June 26–28, 2005) in Boston, MA.

The views expressed are solely the authors'.

Reprints: Kevin T. Stroupe, PhD, Center for Management of Complex Chronic Care (CMC3), Hines VA Hospital, PO Box 5000 (151H); 5000 South 5th Ave Bldg 1B260, Hines, IL 60141-5151. E-mail: kevin.stroupe@va.gov.

ISSN: 0025-7079/07/4511-1090

VIReC
RESEARCHERS' GUIDE TO VA DATA

How has outpatient pharmacy utilization been measured in VA studies?: Quality of Care

- **Tiwari A, Rajan M, Miller D, Pogach L, Olfson M, Sambamoorthi U. Guideline-consistent antidepressant treatment patterns among veterans with diabetes and major depressive disorder. *Psych Serv* 2008; 59: 1139-1147.**
- How was pharmacy data utilized?

Guideline-Consistent Antidepressant Treatment Patterns Among Veterans With Diabetes and Major Depressive Disorder

Anjali Tiwari, M.B.B.S., M.S.
Mangala Rajan, M.B.A.
Donald Miller, Sc.D.
Leonard Pogach, M.D.
Mark Olfson, M.D., M.P.H.
Usha Sambamoorthi, Ph.D.

Objective: **This study estimated guideline-consistent antidepressant treatment of depression among veterans with diabetes and examined its variation by patient-level demographic characteristics, socioeconomic characteristics, access to care, and health status.** ***Methods:*** **Data were retrospectively analyzed from Veterans Health Administration (VHA) and Medicare claims of VHA clinic users with diabetes and major depressive disorder (N=3,953). Major depression was identified by using *ICD-9-CM* codes 296.2 and 296.3. Incident episode was identified by using 120-day negative diagnosis and medication history on or before the first depression diagnosis date in fiscal year 1999. Guideline-consistent depression treatment was defined as the receipt of antidepressants for at least 90 days within a period of six months after the onset of depression. Chi square tests and logistic regressions were used to analyze patterns of guideline-consistent antidepressant treatment.** ***Results:*** **Overall, 51% received any antidepressant treatment for diagnosed major depression; among patients using any antidepressants, 62% received guideline-consistent antidepressant treatment. VHA users who received care from a mental health specialist were more likely to have guideline-consistent treatment than those who were not receiving care from a mental health specialist. African Americans, older veterans, and those with substance use disorders were less likely to have guideline-consistent antidepressant treatment.** ***Conclusions:*** **Guideline-consistent depression care was lower for certain subgroups of individuals. Further research is necessary to evaluate the reasons for this finding, so that targeted care coordination strategies could be developed to improve antidepressant treatment. Increased contact with mental health specialty staff, which is now being implemented in the VHA, may increase antidepressant treatment among VHA users with diabetes and major depression. (*Psychiatric Services* 59:1139–1147, 2008)**

Dr. Tiwari, Ms. Rajan, Dr. Pogach, and Dr. Sambamoorthi are affiliated with the Health Services Research and Development Center for Health Care Knowledge and Management, New Jersey Health Care System, Department of Veteran Affairs (VA), East Orange, New Jersey. Dr. Sambamoorthi is also with the Department of Psychiatry, University of Massachusetts Medical School, Worcester. Dr. Miller is with the Center for Health Quality, Outcomes, and Economic Research, VA, Bedford, Massachusetts. Dr. Olfson is with the Department of Psychiatry, Columbia University, New York City. Send correspondence to Dr. Sambamoorthi at the Health Services Research and Development Center for Health Care Knowledge and Management, New Jersey Health Care System, VA, 385 Tremont Ave., Mail Stop 129, East Orange, NJ 07018 (e-mail: usha.sambamoorthi@umassmed.edu).

The prevalence of depression among persons with diabetes is very high and ranges from as low as 11%, when standardized diagnostic interviews are used, to as high as 31%, when assessed by questionnaires (1). Comorbid depression complicates diabetes care and adversely affects health care expenditures and clinical outcomes. Specifically, co-occurring depression as measured by using symptom scales or diagnostic criteria is associated with hyperglycemia (2), has been shown to lower adherence to oral hypoglycemic and lipid-lowering medications (3), and is associated with functional disability (4). Total health care expenditures of individuals with self-reported depression and diabetes are 4.5 times higher than those of individuals with diabetes without depression (5).

However, clinical trials have shown that pharmacologic treatments, specifically the new-generation antidepressants, and nonpharmacologic treatments for major depression tend to improve glycemic control (6,7). In a randomized double-blind placebo-controlled trial of patients with comorbid diabetes and depression, fluoxetine, as compared with a placebo, was associated with better glycemic control and reduced depressive symptoms (7).

Recent studies have documented cost advantages of treating depression among individuals with diabetes. A one-year cross-sectional observation-

VIReC
RESEARCHERS' GUIDE TO VA DATA

How has outpatient healthcare utilization been measured in VA studies?: Medication Adherence

ORIGINAL ARTICLE

A Refill Adherence Algorithm for Multiple Short Intervals to Estimate Refill Compliance (ReComp)

Chris L. Bryson, MD, MS,† David H. Au, MD, MS,*† Bessie Young, MD, MS,†‡ Mary B. McDonell, MS,* and Stephan D. Fihn, MD, MPH*†*

Background: There are many measures of refill adherence available, but few have been designed or validated for use with repeated measures designs and short observation periods.
Objective: To design a refill-based adherence algorithm suitable for short observation periods, and compare it to 2 reference measures.
Methods: A single composite algorithm incorporating information on both medication gaps and oversupply was created. Electronic Veterans Affairs pharmacy data, clinical data, and laboratory data from routine clinical care were used to compare the new measure, ReComp, with standard reference measures of medication gaps (MEDOUT) and adherence or oversupply (MEDSUM) in 3 different repeated measures medication adherence-response analyses. These analyses examined the change in low density lipoprotein (LDL) with simvastatin use, blood pressure with antihypertensive use, and heart rate with β-blocker use for 30- and 90-day intervals. Measures were compared by regression based correlations (R^2 values) and graphical comparisons of average medication adherence-response curves.
Results: In each analysis, ReComp yielded a significantly higher R^2 value and more expected adherence-response curve regardless of the length of the observation interval. For the 30-day intervals, the highest correlations were observed in the LDL-simvastatin analysis (ReComp R^2 = 0.231; [95% CI, 0.222–0.239]; MEDSUM R^2 = 0.054; [95% CI, 0.049–0.059]; MEDOUT R^2 = 0.053; [95% CI, 0.048–0.058]).
Conclusions: ReComp is better suited to shorter observation intervals with repeated measures than previously used measures.

Key Words: drug, compliance, adherence, validity, methods, pharmacy

(*Med Care* 2007;45: 497–504)

From the *Health Services Research and Development Northwest Center of Excellence and the ‡Epidemiologic Research and Information Center, Veterans Affairs Puget Sound Health Care System, Seattle, Washington; and †Department of Medicine, University of Washington, Seattle.
Supported by a VA Career Development Award (RCD03-177 and RCD00-018). The Veterans Affairs (VA) Ambulatory Care Quality Improvement Project (ACQUIP) was funded by VA HSR&D Grants no. SDR96-002 and IIR99-376.
Views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs, or the University of Washington.
Reprints: Chris L. Bryson, MD, MS, Department of Veterans Affairs, Health Services Research and Development Northwest Center of Excellence, VA Puget Sound Health Care System, 1100 Olive Way, Suite 1400, Seattle, WA 98101. E-mail: cbryson@u.washington.edu.

ISSN: 0025-7079/07/4506-0497

Electronic pharmacy databases are growing in number and availability, providing epidemiology and health services researchers with unprecedented opportunities to examine important questions including drug safety, treatment effectiveness, and variation in prescribing practices. There are a number of relatively accessible electronically stored databases with detailed prescription information, including those from the Department of Veterans Affairs,[1] Group Health Cooperative,[2] and Kaiser Permenente.[3] Questions about the effectiveness and safety of pharmaceutical therapy accompanied by the availability of this information have reinvigorated an interest in assessing pharmacy information as both a source of information for drug exposure in epidemiologic studies and as a rich source of data illuminating the behavior of adherence to prescription medication. Objections have been raised that pharmacy-based refill assessment is not as accurate as electronic monitoring caps or devices due to modest correlation between these measures.[4] It has also been recognized that pharmacy-based refill adherence provides different information than patient self-report does,[4,5] and is not necessarily just a surrogate for medication taking behavior, but is a behavior in itself[6] that has been widely studied and linked to a variety of clinical outcomes.[7,8]

Methods have been developed to address pharmacy-based refill adherence in diverse situations. These methods often involve different formulas to measure different aspects of adherence, such as defining periods of medication gaps between prescriptions where no drug is observed to be available, or obtaining oversupply where more medications are obtained than are required for a specified period of time.[8] Many of these measures are simple equations patterned after measurements described initially by Steiner,[9] and these equations can generally be categorized by 2 summary measures we will call MEDSUM and MEDOUT. MEDSUM, defined as the number of daily doses dispensed during a period divided by the number of days in the period, can take into account oversupply, but without modification does not accurately reflect the number of days a patient may not have medication in certain refill patterns. When applied continuously over time, it is a measure of continuous medication acquisition or adherence.[8] MEDOUT, defined as the percent of days a subject does not have drug available, ranges from 0 to 1 and accurately reflects the number of days a patient does not have medication available, but does not account for

- **Bryson CL, Au DH, Young B, McDonnell MB, Fihn SD. A Refill Adherence Algorithm for Multiple Short Intervals to Estimate Refill Compliance (ReComp). *Med Care 2007; 45: 497-504.***
- How was pharmacy data utilized?

VIReC RESEARCHERS' GUIDE TO VA DATA

How has outpatient pharmacy utilization been measured in VA studies?: Medication Use / Exposure

- **Lee TA, Pickard AS, Au DH, Bartle B, Weiss KB. (2008). Risk for death associated with medications for recently diagnosed chronic obstructive pulmonary disease. *Ann Intern Med., 149,* 380-390.**

- How was pharmacy data utilized?

ARTICLE | Annals of Internal Medicine

Risk for Death Associated with Medications for Recently Diagnosed Chronic Obstructive Pulmonary Disease

Todd A. Lee, PharmD, PhD; A. Simon Pickard, PhD; David H. Au, MD, MS; Brian Bartle, MPH; and Kevin B. Weiss, MD, MPH, MS

Background: Concerns exist regarding increased risk for mortality associated with some chronic obstructive pulmonary disease (COPD) medications.

Objective: To examine the association between various respiratory medications and risk for death in veterans with newly diagnosed COPD.

Design: Nested case–control study in a cohort identified between 1 October 1999 and 30 September 2003 and followed through 30 September 2004 by using National Veterans Affairs inpatient, outpatient, pharmacy, and mortality databases; Centers for Medicare & Medicaid Services databases; and National Death Index Plus data. Cause of death was ascertained for a random sample of 40% of those who died during follow-up. Case patients were categorized on the basis of all-cause, respiratory, or cardiovascular death. Mortality risk associated with medications was assessed by using conditional logistic regression adjusted for comorbid conditions, health care use, and markers of COPD severity.

Setting: U.S. Veterans Health Administration health care system.

Participants: 32 130 case patients and 320 501 control participants in the all-cause mortality analysis. Of 11 897 patients with cause-of-death data, 2405 case patients had respiratory deaths and 3159 case patients had cardiovascular deaths.

Measurements: All-cause mortality; respiratory and cardiovascular deaths; and exposure to COPD medications, inhaled corticosteroids, ipratropium, long-acting β-agonists, and theophylline in the 6 months preceding death.

Results: Adjusted odds ratios (ORs) for all-cause mortality were 0.80 (95% CI, 0.78 to 0.83) for inhaled corticosteroids, 1.11 (CI, 1.08 to 1.15) for ipratropium, 0.92 (CI, 0.88 to 0.96) for long-acting β-agonists, and 1.05 (CI, 0.99 to 1.10) for theophylline. Ipratropium was associated with increased cardiovascular deaths (OR, 1.34 [CI, 1.22 to 1.47]), whereas inhaled corticosteroids were associated with reduced risk for cardiovascular death (OR, 0.80 [CI, 0.72 to 0.88]). Results were consistent across sensitivity analyses.

Limitations: Current smoking status and lung function were not measured. Misclassification of cause-specific mortality is unknown.

Conclusion: The possible association between ipratropium and elevated risk for all-cause and cardiovascular death needs further study.

Ann Intern Med 2008;149:380-390. www.annals.org
For author affiliations, see end of text.

Chronic obstructive pulmonary disease (COPD) is associated with substantial burden in terms of prevalence of disease (1), death and disability risk (2, 3), and health care costs (4). Despite recent interest in examining long-term outcomes associated with medications in patients with COPD (5, 6), some issues are not easily addressed by using randomized clinical trials. From a pharmacovigilance perspective, relatively rare adverse events—such as death associated with medication use—may not be detected in the short term. The patients who receive a medication may not be similar to those participating in clinical trials (7, 8) and may be more vulnerable to such events. Thus, evidence of longer-term benefits and harms associated with medications—particularly in patients with COPD, who tend to be elderly and have multiple comorbid conditions (9)—can be informed by research that relies on observational data.

Potential safety concerns with medications used to manage COPD may be substantial. A recent meta-analysis (10) showed a nearly 2.5-fold increase in respiratory deaths among patients receiving long-acting β-agonists compared with those receiving placebo. In the Lung Health Study (11), the group randomly assigned to ipratropium bromide had more than twice as many cardiovascular deaths as those receiving placebo. In addition, the U.S. Food and Drug Administration recently issued a notice regarding the potential for an increased risk for stroke associated with tiotropium use in patients with COPD (12). The extent to which these safety concerns exist and can be generalized to patients with COPD outside the context of clinical trials is unclear. Therefore, we sought to examine the association between medication use and risk for death, including respiratory and cardiovascular deaths, in a large population of patients with recently diagnosed COPD.

See also:
Print
Editors' Notes 381
Web-Only
Conversion of graphics into slides

Methods

We conducted this nested case–control study in patients with recently diagnosed COPD by using national Veterans Affairs inpatient, outpatient, pharmacy, and mortality databases, supplemented with data from the Centers for Medicare & Medicaid Services. Our sample comprised U.S. veterans who used the U.S. Veterans Health Admin-

VIReC
RESEARCHERS' GUIDE TO VA DATA

How has outpatient healthcare utilization been measured in VA studies?: Risk Adjustment

MEDICAL CARE
Volume 41, Number 6, pp 753–760

Predicting Costs of Care Using a Pharmacy-Based Measure Risk Adjustment in a Veteran Population

ANNE E. SALES, PHD,*† CHUAN-FEN LIU, PHD,*† KEVIN L. SLOAN, MD,*‡ JESSE MALKIN, PHD,‖ PAUL A. FISHMAN, PHD,†§ AMY K. ROSEN, PHD, ¶** SUSAN LOVELAND, MA,¶ W. PAUL NICHOL, MD, *†† NORMAN T. SUZUKI, PHARMD, *‡‡ EDWARD PERRIN, PHD,* NANCY D. SHARP, PHD,*† AND JEFFREY TODD-STENBERG*

BACKGROUND. Although most widely used risk adjustment systems use diagnosis data to classify patients, there is growing interest in risk adjustment based on computerized pharmacy data. The Veterans Health Administration (VHA) is an ideal environment in which to test the efficacy of a pharmacy-based approach.

OBJECTIVE. To examine the ability of RxRisk-V to predict concurrent and prospective costs of care in VHA and compare the performance of RxRisk-V to a simple age/gender model, the original RxRisk, and two leading diagnosis-based risk adjustment approaches: Adjusted Clinical Groups and Diagnostic Cost Groups/Hierarchical Condition Categories.

METHODS. The study population consisted of 161,202 users of VHA services in Washington, Oregon, Idaho, and Alaska during fiscal years (FY) 1996 to 1998. We examined both concurrent and predictive model fit for two sequential 12-month periods (FY 98 and FY 99) with the patient-year as the unit of analysis, using split-half validation.

RESULTS. Our results show that the Diagnostic Cost Group /Hierarchical Condition Categories model performs best ($R^2 = 0.45$) among concurrent cost models, followed by ADG (0.31), RxRisk-V (0.20), and age/sex model (0.01). However, prospective cost models other than age/sex showed comparable R^2: Diagnostic Cost Group /Hierarchical Condition Categories $R^2 = 0.15$, followed by ADG (0.12), RxRisk-V (0.12), and age/sex (0.01).

CONCLUSIONS. RxRisk-V is a clinically relevant, open source risk adjustment system that is easily tailored to fit specific questions, populations, or needs. Although it does not perform better than diagnosis-based measures available on the market, it may provide a reasonable alternative to proprietary systems where accurate computerized pharmacy data are available.

Key words: Case-mix; pharmacy; veterans; risk adjustment. (Med Care 2003;41:753–760)

From the *VA Puget Sound Health Care System, Seattle, Washington.

From the †Department of Health Services, the ‡Department of Psychiatry, the ††Department of Medicine, and ‡‡the School of Pharmacy, University of Washington, Seattle, Washington.

From the ‖the RAND Corporation, Arlington, Virginia.

From the §the Center for Health Studies, Group Health Cooperative, Seattle, Washington.

From the ¶Center for Health Quality, Outcomes and Economics, Bedford VA Medical Center, Bedford, Massachusetts.

From the **Boston University School of Public Health, Boston, Massachusetts.

This research was supported by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development Service Project IIR 99001-1. The views expressed in this report are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs or the Health Services Research and Development Service.

Address correspondence and reprint requests to: Anne E. Sales, PhD, VA Puget Sound Health Care System (152 HSRD), 1660 S. Columbian Way, Seattle, WA 98108. E-mail: Ann.Sales@med.va.gov

- **Sales AE, Liu CH, Sloan KL, et al. Predicting costs of care using a pharmacy-based measure risk adjustment in a veteran population. Med Care. 2003; 41: 753-760.**
- How was pharmacy data utilized?

VIReC
RESEARCHERS' GUIDE TO VA DATA

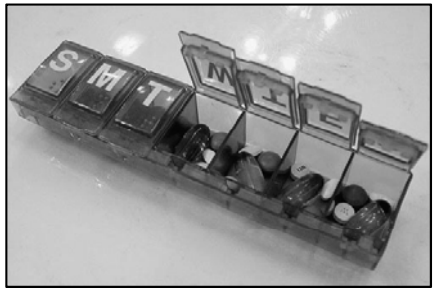
Session Objectives

- How has outpatient pharmacy utilization been measured in VA studies?
- Overview of VA Pharmacy databases
- Finding information in the VA Pharmacy databases
- Examples of VA studies that have used the VA Pharmacy databases
- Where to go for more help

VIReC
RESEARCHERS' GUIDE TO VA DATA

Pharmacy Data Sources

- **Local Databases**
  - VistA
  - VISN Warehouses



- **National Data Sources**
  - PBM
  - DSS NDE Pharmacy SAS® Datasets

- **Other Key Pharmacy Data Sources**
  - DSS Product Table
  - National Drug File

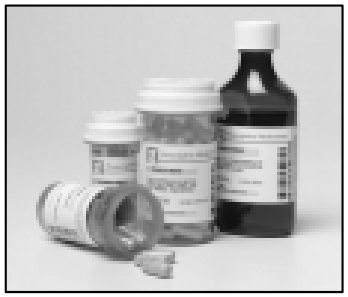
VIReC
RESEARCHERS' GUIDE TO VA DATA

Audience Poll

- **Which national sources of VA pharmacy data have you used in the past?**
  - DSS NDE Pharmacy Data
  - PBM Pharmacy Data
  - Both
  - Neither

VA Pharmacy Data Sources

- **VA Decision Support System (DSS) National Data Extract (NDE) Pharmacy SAS Datasets**



  - Became available in 2003
  - Data from FY2002 to present
  - Primary source of data is VistA
  - All inpatient and outpatient prescriptions dispensed by a VAMC or VA Consolidated Mail Outpatient Pharmacy (CMOP)
  - Housed at Austin Information Technology Center (AITC) and directly accessible

VA Pharmacy Data Sources

- **VA Pharmacy Benefits Management (PBM) Database**
  - Available since 2000
  - Data from FY1999 to present
  - Primary source of data is VistA
  - Contains both inpatient and outpatient prescriptions

VIReC
RESEARCHERS' GUIDE TO VA DATA

PBM vs. DSS

	PBM	DSS
Cost	Drug supply cost	Actual cost (ACT_COST) Dispensing cost (DISPCOST) Supply cost (VS_COST)
Access	Researcher requested extract	Direct access
Data availability	FY1998 (Outpatient) FY2006 (Inpatient)	FY2002 (Outpatient & Inpatient)
Directions for use	SIG available	

How Similar are PBM and DSS Data?

- **CSP 456 Hernia Study**
- **Population**
  - 1,591 Patients
- **Prescriptions**
  - Outpatient
  - FY2002
  - Fills and refills
  - 42,469 prescriptions
- **Results**
  - High match rate between data sources
  - Discrepancy in only 1.7% of prescriptions
- **Report Available at:**
  - http://www.virec.research.va.gov/References/TechnicalReports/VIReCTechnicalReport1.pdf

VIReC
RESEARCHERS' GUIDE TO VA DATA

How Similar are PBM and DSS Data?

- **Limitations**
  - Outpatient only
  - Cohort not representative of whole population
- **Conclusions**
  - DSS and PBM Pharmacy extracts capture same prescriptions
  - DSS or PBM?
- **Future Comparisons**
  - Inpatient data?
  - Representative Cohort
- **Anecdotal evidence of other examples where match is not as good**

VIReC
RESEARCHERS' GUIDE TO VA DATA

Other Pharmacy Data Sources

- **DSS Product Table**
  - Key Variables
    - IPNum, Feeder Key, Description (short and long), Drug Class
    - Feeder Key => 1st 5 characters are VA product file IEN; last 12 characters are NDC
  - Available on DSS website
- **National Drug File**
  - Key Variables
    - VA_PRODUCT, FEEDER, NDF_NDC, VA_CLASS

Session Objectives

- How has outpatient pharmacy utilization been measured in VA studies?
- Overview of VA Pharmacy databases
- Finding information in the VA Pharmacy databases
- Examples of VA studies that have used the VA Pharmacy databases
- Where to go for more help

VIReC
RESEARCHERS' GUIDE TO VA DATA

Key Pharmacy Variables

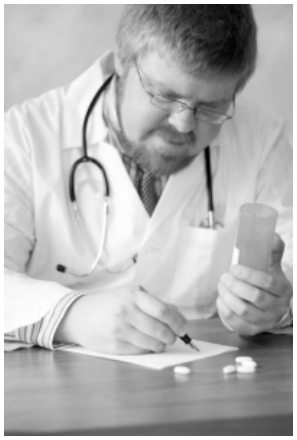
Variable	DSS	PBM
Days Supply	X	X
Drug Description	X	X
Quantity	X	X
NDC	X	X
Medication class	X	X

VIReC
RESEARCHERS' GUIDE TO VA DATA

Assessing Outpatient Pharmacy Use:
Finding info in VA Pharmacy Datasets

- **Where can I find cost variables?**

- **DSS and PBM contain different cost variables**
  - PBM: cost of the drug product from the supplier
  - DSS:



1) Dispensing Cost (DISPCOST): direct pharmacist labor for dispensing the prescription and the mailing costs
2) Supply Cost (VS_COST): Drug product cost and cost of supplies used in preparing the prescription, such as bottles and labels
3) Actual Cost (ACT_COST): Drug product cost, cost of supplies such as bottles and labels to prepare the prescription, indirect costs, and overhead

VIReC
RESEARCHERS' GUIDE TO VA DATA

Assessing Outpatient Pharmacy Use:
Finding info in VA Pharmacy Datasets

- **Why is the NDC for the same prescription different on the PBM record than on the DSS record?**

- The NDC's are obtained from different sources
- Differences can result if Local Drug File has not been updated to reflect supply that was stocked when medication was dispensed
- Different NDC's will refer to the same drug, dosage, and strength, but may indicate a different manufacturer and/or package size

VIReC
RESEARCHERS' GUIDE TO VA DATA

Assessing Outpatient Pharmacy Use:
Examples of Types of Questions Addressed with Pharmacy Data

- **Cohort identification**
  - *Can pharmacy data be used to identify specific groups of patients?*
- **Medication utilization**
  - *Recent year? Longer historical view? Does policy change impact medication use?*
- **Healthcare Quality**
  - *Are patients being prescribed medications in accordance with quality measures?*
- **Medication adherence**
  - *How much of a prescribed medication are patients using?*
- **Exposure to specific medications or medication classes**
  - *Are specific drugs associated with better/worse outcomes?*
- **Combining outpatient and pharmacy data to identify events**
  - *Can we identify acute exacerbations of COPD with outpatient and prescription data?*
- **Assessing comorbidity or case-mix with medication data**

VIReC
RESEARCHERS' GUIDE TO VA DATA

Session Objectives

- How has outpatient pharmacy utilization been measured in VA studies?
- Overview of VA Pharmacy databases
- Finding information in the VA Pharmacy databases
- Examples of VA studies that have used the VA Pharmacy databases
- Where to go for more help

VIReC
RESEARCHERS' GUIDE TO VA DATA

How has outpatient pharmacy utilization been measured in VA studies?: Chronic Medication Use

- **Stroupe KT, Smith BM, et al. Effect of Increased Copayments on Pharmacy Use in the Department of Veterans Affairs. *Med Care* 2007; 45:1090-1097**
- **Objective: Evaluate the impact of copayment change for prescription drugs on medication use**

ORIGINAL ARTICLE

Effect of Increased Copayments on Pharmacy Use in the Department of Veterans Affairs

Kevin T. Stroupe, PhD,†‡ Bridget M. Smith, PhD,*‡ Todd A. Lee, PharmD, PhD,*‡ Elizabeth Tarlov, PhD,§ Ramon Durazo-Arvizu, PhD,¶ Zhiping Huo, MS,‡ Tammy Barnett, MA,*† Lishan Cao, MS,‡ Muriel Burk, PharmD,‖ Francesca Cunningham, PharmD,‖ Denise M. Hynes, PhD,*§¶ and Kevin B. Weiss, MD*‡*

Objectives: In February 2002, the Department of Veterans Affairs (VA) raised medication copayments from $2 to $7 per 30-day supply of medication for certain veteran groups. We examined the impact of the copayment increase on medication acquisition from VA.

Methods: This was a retrospective cohort study using data from national VA databases from February 2001 through February 2003. We took a random sample of over 5% of male VA users in 2001. Of 149,107 veterans sampled, 19,504 (13%) had copayments for no drugs, 101,410 (68%) had copayments for some drugs, and 28,193 (19%) had copayments for all drugs. We used multivariable count models to examine changes in the number of 30-day medication supplies after the increase.

Results: After the copayment increase, veterans subject to copayments for all drugs received 8% fewer 30-day supplies of medication annually relative to veterans with no copayments ($P < 0.001$). The effect of the copayment increased as the number of different medications veterans received increased. Among veterans subject to copayments for all drugs, acquisition of lower-cost drugs fell by 36%, higher-cost medications fell by 6%, over-the-counter medications fell by 40%, and prescription-only medications fell by 4% relative to veterans with no drug copayments.

Conclusions: The number of medications veterans obtained from VA decreased after the copayment increase. There were relatively larger impacts on veterans with higher medication use and on lower-cost and over-the-counter medications.

Key Words: veterans, copayments, drugs

(*Med Care* 2007;45: 1090–1097)

Healthcare payers in both the public and private sectors face ever-increasing medication costs. They have sought to control their medication costs using a variety of strategies including increased cost sharing with patients[1] by raising copayments or coinsurance rates, increasing deductibles, removing drugs from formularies, moving to multitier copayments,[2] or a combination of these measures.[3] The Department of Veterans Affairs (VA), which operates the largest healthcare organization in the United States, spent over $3 billion in fiscal year 2001 for outpatient medications, accounting for 14% of its medical care budget.[4] As in the private sector, the VA has increased cost sharing by patients. In February 2002, the VA increased medication copayments from $2 to $7 per 30-day medication supply for veterans required to pay copayments,[4] and in January 2006 copayments were increased again to $8 per 30-day supply. Moreover, recent proposals have been made to increase copayments further for certain veteran groups.[5]

Several studies outside VA have found that copayment increases have decreased overall prescription-drug utilization.[1,2,6–9] The impact of cost sharing may depend on drug class and copayment amount.[10] A study of elderly patients found that drug use decreased by 9% for more essential and 15% for less essential medications as cost sharing increased.[1] This reduction in essential medication use was associated with an increase in emergency department visits and adverse event rates.[1] If increased copayments lead to reductions in medication use with resulting adverse effects on health, pharmaceutical cost savings by healthcare payers may be lost due to increases in other healthcare costs.

Because VA patients tend to be older and have more chronic diseases than the general population,[11] previous estimates of the impact of copayment changes may not be relevant to the current VA healthcare system. Whether veterans are subject to copayments for no, some, or all drugs

From the *Center for Management of Complex Chronic Care, Hines, Illinois; †Cooperative Studies Program Coordinating Center, Hines, Illinois; ‡Feinberg School of Medicine, Northwestern University, Chicago, Illinois; §VA Information Resource Center, Hines, Illinois; ¶Department of Preventive Medicine and Epidemiology, Stritch School of Medicine and Niehoff School of Nursing, Loyola University Chicago, Maywood, Illinois; and ‖VA Pharmacy Benefit Management/Strategic Health Group, Hines, Illinois.

Supported in part by VA Health Services Research & Development (ECI 02-220).

Presented at the VA HSR&D 2005 Annual Meeting (February 16–18, 2005) in Washington, DC, and at the Academy Health 2005 Annual Research Meeting (June 26–28, 2005) in Boston, MA.

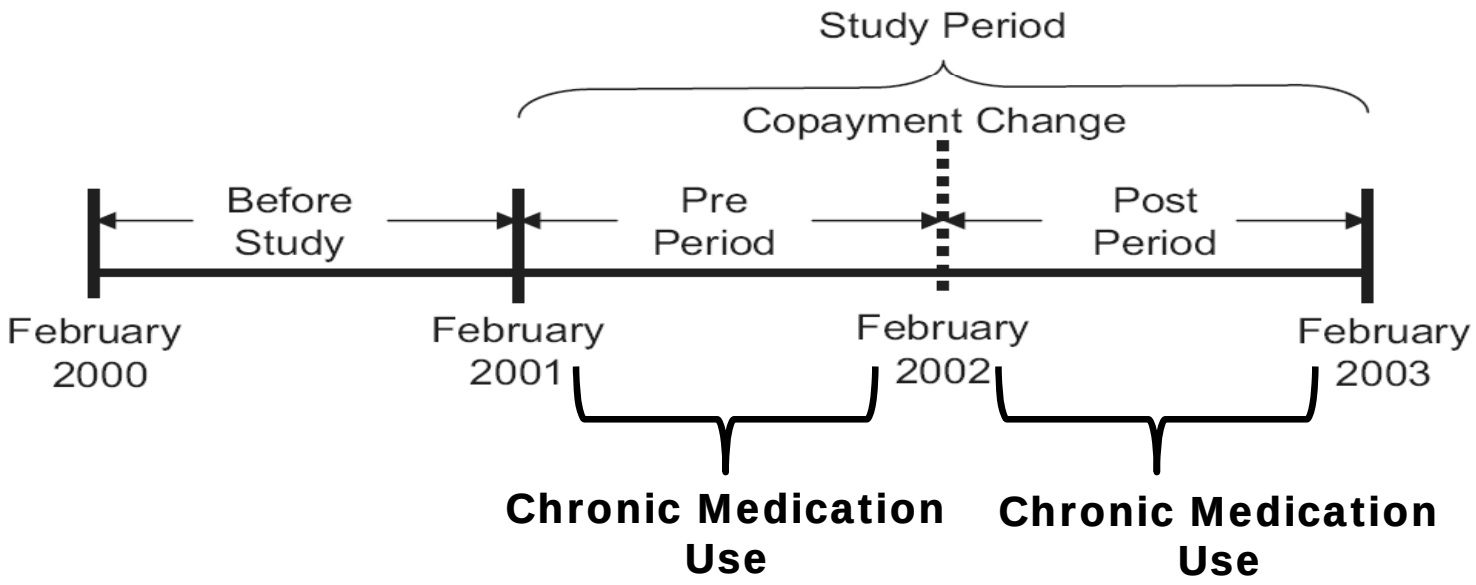
The views expressed are solely the authors'.

Reprints: Kevin T. Stroupe, PhD, Center for Management of Complex Chronic Care (CMC3), Hines VA Hospital, PO Box 5000 (151H); 5000 South 5th Ave Bldg 1B260, Hines, IL 60141-5151. E-mail: kevin.stroupe@va.gov.

ISSN: 0025-7079/07/4511-1090

VIReC
RESEARCHERS' GUIDE TO VA DATA

Chronic Medication Use: Stroupe et al. Med Care 2007



- Number of 30-day equivalents dispensed over 12 month period
- Days supply variable is key to analysis
- Focused on “chronic” medications, excluded medications for which patient did not receive any 30-day supply
- Dispensing with less than 30-day supply was counted as 1 30-day equivalent

VIReC
RESEARCHERS' GUIDE TO VA DATA

Chronic Medication Use: Stroupe et al. Med Care 2007

Copayments for No Drugs*
n = 19,504

	Before	After	Difference
All chronic drugs	55.44	57.95	2.51

Copayments for Some Drugs*
n = 101,410

Before	After	Difference	Difference In Differences
41.28	41.29	0.01	−2.50†

Copayments for All Drugs*
n = 28,193

Before	After	Difference	Difference In Differences
34.05	33.69	−0.36	−2.87†

†$P < 0.05$

Adapted from Stroupe et al. Med Care 2007 Table 3

How has outpatient pharmacy utilization been measured in VA studies?: Quality of Care

- **Tiwari A, Rajan M, Miller D, Pogach L, Olfson M, Sambamoorthi U. Guideline-consistent antidepressant treatment patterns among veterans with diabetes and major depressive disorder. *Psych Serv* 2008; 59: 1139-1147.**

- **Objective: Estimate guideline-consistent antidepressant treatment of new episodes of depression in veterans with diabetes**

Guideline-Consistent Antidepressant Treatment Patterns Among Veterans With Diabetes and Major Depressive Disorder

Anjali Tiwari, M.B.B.S., M.S.
Mangala Rajan, M.B.A.
Donald Miller, Sc.D.
Leonard Pogach, M.D.
Mark Olfson, M.D., M.P.H.
Usha Sambamoorthi, Ph.D.

Objective: **This study estimated guideline-consistent antidepressant treatment of depression among veterans with diabetes and examined its variation by patient-level demographic characteristics, socioeconomic characteristics, access to care, and health status.** ***Methods:*** **Data were retrospectively analyzed from Veterans Health Administration (VHA) and Medicare claims of VHA clinic users with diabetes and major depressive disorder (N=3,953). Major depression was identified by using *ICD-9-CM* codes 296.2 and 296.3. Incident episode was identified by using 120-day negative diagnosis and medication history on or before the first depression diagnosis date in fiscal year 1999. Guideline-consistent depression treatment was defined as the receipt of antidepressants for at least 90 days within a period of six months after the onset of depression. Chi square tests and logistic regressions were used to analyze patterns of guideline-consistent antidepressant treatment.** ***Results:*** **Overall, 51% received any antidepressant treatment for diagnosed major depression; among patients using any antidepressants, 62% received guideline-consistent antidepressant treatment. VHA users who received care from a mental health specialist were more likely to have guideline-consistent treatment than those who were not receiving care from a mental health specialist. African Americans, older veterans, and those with substance use disorders were less likely to have guideline-consistent antidepressant treatment.** ***Conclusions:*** **Guideline-consistent depression care was lower for certain subgroups of individuals. Further research is necessary to evaluate the reasons for this finding, so that targeted care coordination strategies could be developed to improve antidepressant treatment. Increased contact with mental health specialty staff, which is now being implemented in the VHA, may increase antidepressant treatment among VHA users with diabetes and major depression. (*Psychiatric Services* 59:1139–1147, 2008)**

Dr. Tiwari, Ms. Rajan, Dr. Pogach, and Dr. Sambamoorthi are affiliated with the Health Services Research and Development Center for Health Care Knowledge and Management, New Jersey Health Care System, Department of Veteran Affairs (VA), East Orange, New Jersey. Dr. Sambamoorthi is also with the Department of Psychiatry, University of Massachusetts Medical School, Worcester. Dr. Miller is with the Center for Health Quality, Outcomes, and Economic Research, VA, Bedford, Massachusetts. Dr. Olfson is with the Department of Psychiatry, Columbia University, New York City. Send correspondence to Dr. Sambamoorthi at the Health Services Research and Development Center for Health Care Knowledge and Management, New Jersey Health Care System, VA, 385 Tremont Ave., Mail Stop 129, East Orange, NJ 07018 (e-mail: usha.sambamoorthi@umassmed.edu).

The prevalence of depression among persons with diabetes is very high and ranges from as low as 11%, when standardized diagnostic interviews are used, to as high as 31%, when assessed by questionnaires (1). Comorbid depression complicates diabetes care and adversely affects health care expenditures and clinical outcomes. Specifically, co-occurring depression as measured by using symptom scales or diagnostic criteria is associated with hyperglycemia (2), has been shown to lower adherence to oral hypoglycemic and lipid-lowering medications (3), and is associated with functional disability (4). Total health care expenditures of individuals with self-reported depression and diabetes are 4.5 times higher than those of individuals with diabetes without depression (5).

However, clinical trials have shown that pharmacologic treatments, specifically the new-generation antidepressants, and nonpharmacologic treatments for major depression tend to improve glycemic control (6,7). In a randomized double-blind placebo-controlled trial of patients with comorbid diabetes and depression, fluoxetine, as compared with a placebo, was associated with better glycemic control and reduced depressive symptoms (7).

Recent studies have documented cost advantages of treating depression among individuals with diabetes. A one-year cross-sectional observation-

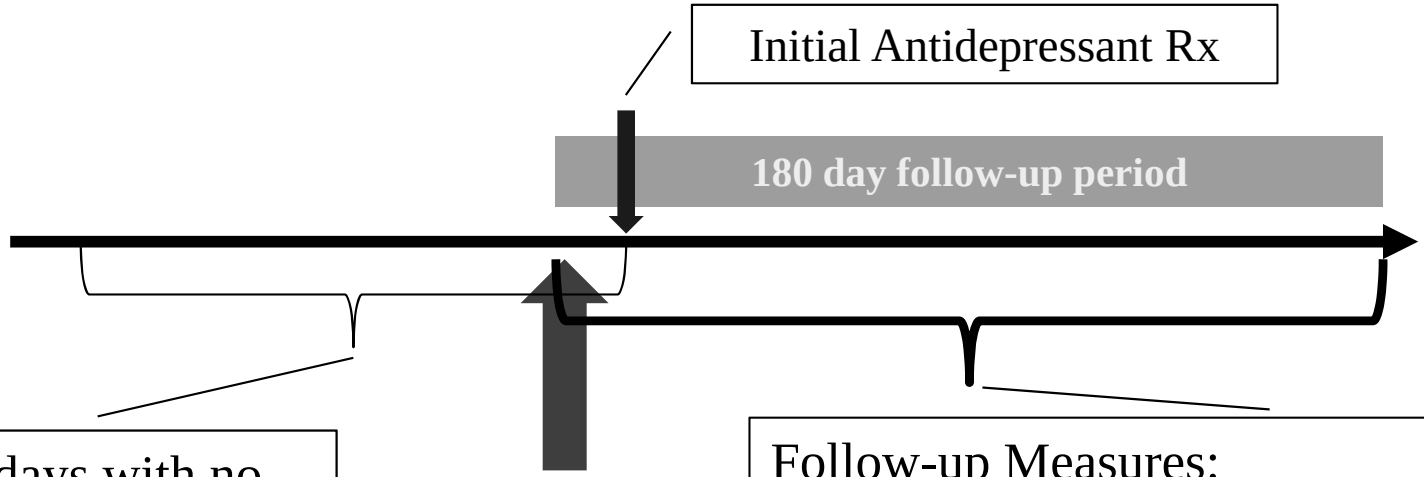
VIReC
RESEARCHERS' GUIDE TO VA DATA

Quality of Care: Tiwari et al. Psych Services 2008

- **Cohort of patients with diabetes and new episode of major depressive episode**
- **Guideline-consistent depression treatment**
  - Antidepressant medication for at least 3 months within 6 months of initial diagnosis
- **Evaluated two outcomes**
  - Received antidepressant
  - Guideline-consistent antidepressant use

Quality of Care: Tiwari et al. Psych Services 2008

- **How was pharmacy data used?**



VIReC
RESEARCHERS' GUIDE TO VA DATA

Quality of Care: Tiwari et al. Psych Services 2008

Received Antidepressant during follow-up:

51%

Guideline-consistent depression:

31.4%

(62% of those with any antidepressant)

Adapted from Tiwari et al
Psych Serv 2008

VIReC
RESEARCHERS' GUIDE TO VA DATA

Quality of Care: Tiwari et al. Psych Services 2008

Table 2

Receipt of any antidepressant treatment among persons with diabetes and incident depression who used the Veterans Health Administration (VHA) for health care, fiscal year 1999[a]

	Any antidepressant treatment (N=2,001)			Logistic regression		
Variable	N	%	p	AOR	95% CI	p
Age			<.001			
<50	383	59.2				
50–64	856	58.5		.89	.72–1.09	
65–74	467	46.3		.58	.46–.74	<.001
≥75	295	35.3		.38	.29–.50	<.001
Mental health specialty visit			<.001			
Yes	1,482	56.9		2.19	1.89–2.53	<.001
No	519	38.4				

Adapted from Tiwari et al Psych Serv 2008

VIReC RESEARCHERS' GUIDE TO VA DATA

Quality of Care: Tiwari et al. Psych Services 2008

Table 3

Receipt of guideline-consistent antidepressant treatment among persons with diabetes and incident depression who used the Veterans Health Administration (VHA) for health care, fiscal year 1999[a]

Age			<.01			
<50	226	59.0				
50–64	568	66.4		1.17	.90–1.53	
65–74	283	60.6		.80	.58–1.11	
≥75	166	56.3		.65	.45–.96	<.05
Mental health specialty visit			<.001			
Yes	956	64.5		1.62	1.30–2.01	<.001
No	287	55.3				

Adapted from Tiwari et al
Psych Serv 2008

VIReC
RESEARCHERS' GUIDE TO VA DATA

How has outpatient healthcare utilization been measured in VA studies?: Medication Adherence

ORIGINAL ARTICLE

A Refill Adherence Algorithm for Multiple Short Intervals to Estimate Refill Compliance (ReComp)

Chris L. Bryson, MD, MS,† David H. Au, MD, MS,*† Bessie Young, MD, MS,†‡ Mary B. McDonell, MS,* and Stephan D. Fihn, MD, MPH*†*

Background: There are many measures of refill adherence available, but few have been designed or validated for use with repeated measures designs and short observation periods.
Objective: To design a refill-based adherence algorithm suitable for short observation periods, and compare it to 2 reference measures.
Methods: A single composite algorithm incorporating information on both medication gaps and oversupply was created. Electronic Veterans Affairs pharmacy data, clinical data, and laboratory data from routine clinical care were used to compare the new measure, ReComp, with standard reference measures of medication gaps (MEDOUT) and adherence or oversupply (MEDSUM) in 3 different repeated measures medication adherence-response analyses. These analyses examined the change in low density lipoprotein (LDL) with simvastatin use, blood pressure with antihypertensive use, and heart rate with β-blocker use for 30- and 90-day intervals. Measures were compared by regression based correlations (R^2 values) and graphical comparisons of average medication adherence-response curves.
Results: In each analysis, ReComp yielded a significantly higher R^2 value and more expected adherence-response curve regardless of the length of the observation interval. For the 30-day intervals, the highest correlations were observed in the LDL-simvastatin analysis (ReComp R^2 = 0.231; [95% CI, 0.222–0.239]; MEDSUM R^2 = 0.054; [95% CI, 0.049–0.059]; MEDOUT R^2 = 0.053; [95% CI, 0.048–0.058]).
Conclusions: ReComp is better suited to shorter observation intervals with repeated measures than previously used measures.

Key Words: drug, compliance, adherence, validity, methods, pharmacy

(*Med Care* 2007;45: 497–504)

From the *Health Services Research and Development Northwest Center of Excellence and the ‡Epidemiologic Research and Information Center, Veterans Affairs Puget Sound Health Care System, Seattle, Washington; and †Department of Medicine, University of Washington, Seattle.
Supported by a VA Career Development Award (RCD03-177 and RCD00-018). The Veterans Affairs (VA) Ambulatory Care Quality Improvement Project (ACQUIP) was funded by VA HSR&D Grants no. SDR96-002 and IIR99-376.
Views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs, or the University of Washington.
Reprints: Chris L. Bryson, MD, MS, Department of Veterans Affairs, Health Services Research and Development Northwest Center of Excellence, VA Puget Sound Health Care System, 1100 Olive Way, Suite 1400, Seattle, WA 98101. E-mail: cbryson@u.washington.edu.

ISSN: 0025-7079/07/4506-0497

Electronic pharmacy databases are growing in number and availability, providing epidemiology and health services researchers with unprecedented opportunities to examine important questions including drug safety, treatment effectiveness, and variation in prescribing practices. There are a number of relatively accessible electronically stored databases with detailed prescription information, including those from the Department of Veterans Affairs,[1] Group Health Cooperative,[2] and Kaiser Permenente.[3] Questions about the effectiveness and safety of pharmaceutical therapy accompanied by the availability of this information have reinvigorated an interest in assessing pharmacy information as both a source of information for drug exposure in epidemiologic studies and as a rich source of data illuminating the behavior of adherence to prescription medication. Objections have been raised that pharmacy-based refill assessment is not as accurate as electronic monitoring caps or devices due to modest correlation between these measures.[4] It has also been recognized that pharmacy-based refill adherence provides different information than patient self-report does,[4,5] and is not necessarily just a surrogate for medication taking behavior, but is a behavior in itself[6] that has been widely studied and linked to a variety of clinical outcomes.[7,8]

Methods have been developed to address pharmacy-based refill adherence in diverse situations. These methods often involve different formulas to measure different aspects of adherence, such as defining periods of medication gaps between prescriptions where no drug is observed to be available, or obtaining oversupply where more medications are obtained than are required for a specified period of time.[8] Many of these measures are simple equations patterned after measurements described initially by Steiner,[9] and these equations can generally be categorized by 2 summary measures we will call MEDSUM and MEDOUT. MEDSUM, defined as the number of daily doses dispensed during a period divided by the number of days in the period, can take into account oversupply, but without modification does not accurately reflect the number of days a patient may not have medication in certain refill patterns. When applied continuously over time, it is a measure of continuous medication acquisition or adherence.[8] MEDOUT, defined as the percent of days a subject does not have drug available, ranges from 0 to 1 and accurately reflects the number of days a patient does not have medication available, but does not account for

- **Bryson CL, Au DH, Young B, McDonnell MB, Fihn SD. A Refill Adherence Algorithm for Multiple Short Intervals to Estimate Refill Compliance (ReComp). *Med Care 2007; 45: 497-504.***

- Objective: Design a refill based algorithm of medication use that can be used for short observation periods

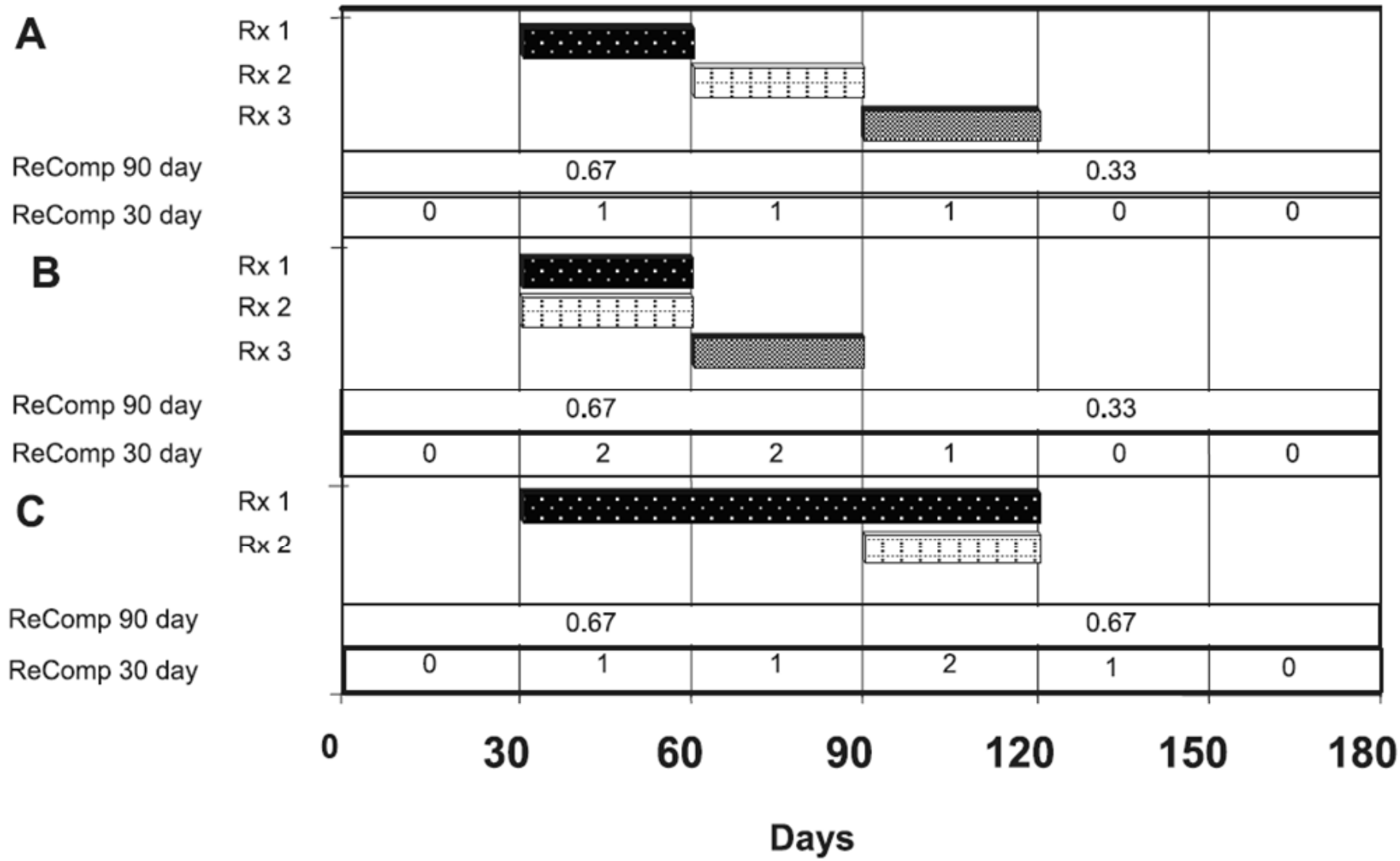
VIReC
RESEARCHERS' GUIDE TO VA DATA

Medication Adherence: Bryson et al. Med Care 2007

- **Use data from ACQUIP to compare 3 methods of determining medication use**
  - MEDSUM – Daily doses divided by days in period
  - MEDOUT – Number of medication gaps
  - ReComp – Algorithm for describing medication use / adherence
- **Evaluated the association between medication adherence using the measures and outcomes for select medications**
  - Simvastatin and LDL
  - Antihypertensives and BP
  - Beta-blockers and heart rate

VIReC
RESEARCHERS' GUIDE TO VA DATA

Medication Adherence: Bryson et al. Med Care 2007



From Bryson et al Med Care 2007

VIReC
RESEARCHERS' GUIDE TO VA DATA

Medication Adherence: Bryson et al. Med Care 2007

TABLE 1. Characteristics of the 3 Validation Cohorts, Outcome Measures, and Recomp Scores

	LDL Cohort	BP Cohort	HR Cohort
Mean number of fills (SD)	8 (6)	10 (10)	4 (4)
Recomp mean (SD)	0.47 (0.73)	1.41 (1.32)	0.51 (1.01)
Recomp range	0–21.6	0–22	0–42.8
MEDSUM mean (SD)	0.45 (0.58)	2.91 (1.81)	0.51 (1.03)
MEDSUM range	0–4.33	0–17	0–9
1-MEDOUT mean (SD)	0.75 (0.33)	0.59 (0.29)	0.14 (0.28)
1-MEDOUT range	0–1	0–1	0–1

From Bryson et al Med Care 2007

Medication Adherence: Bryson et al. Med Care 2007

Regression	Measure	30-day R^2	90-day R^2
LDL-Simvastatin	ReComp	0.231	0.213
	MEDSUM	0.054	0.142
	MEDOUT	0.053	0.133
BP	ReComp	0.090	0.083
	MEDSUM	0.007	0.050
	MEDOUT	0.007	0.046
HR β-Blocker	ReComp	0.104	0.134
	MEDSUM	0.041	0.102
	MEDOUT	0.042	0.101

Adapted from Bryson et al Med Care 2007

How has outpatient pharmacy utilization been measured in VA studies?: Medication Use / Exposure

- **Lee TA, Pickard AS, Au DH, Bartle B, Weiss KB. (2008). Risk for death associated with medications for recently diagnosed chronic obstructive pulmonary disease. *Ann Intern Med., 149,* 380-390.**

- Objective: Examine association between COPD-related medication use and risk of death

ARTICLE | Annals of Internal Medicine

Risk for Death Associated with Medications for Recently Diagnosed Chronic Obstructive Pulmonary Disease

Todd A. Lee, PharmD, PhD; A. Simon Pickard, PhD; David H. Au, MD, MS; Brian Bartle, MPH; and Kevin B. Weiss, MD, MPH, MS

Background: Concerns exist regarding increased risk for mortality associated with some chronic obstructive pulmonary disease (COPD) medications.

Objective: To examine the association between various respiratory medications and risk for death in veterans with newly diagnosed COPD.

Design: Nested case–control study in a cohort identified between 1 October 1999 and 30 September 2003 and followed through 30 September 2004 by using National Veterans Affairs inpatient, outpatient, pharmacy, and mortality databases; Centers for Medicare & Medicaid Services databases; and National Death Index Plus data. Cause of death was ascertained for a random sample of 40% of those who died during follow-up. Case patients were categorized on the basis of all-cause, respiratory, or cardiovascular death. Mortality risk associated with medications was assessed by using conditional logistic regression adjusted for comorbid conditions, health care use, and markers of COPD severity.

Setting: U.S. Veterans Health Administration health care system.

Participants: 32 130 case patients and 320 501 control participants in the all-cause mortality analysis. Of 11 897 patients with cause-of-death data, 2405 case patients had respiratory deaths and 3159 case patients had cardiovascular deaths.

Measurements: All-cause mortality; respiratory and cardiovascular deaths; and exposure to COPD medications, inhaled corticosteroids, ipratropium, long-acting β-agonists, and theophylline in the 6 months preceding death.

Results: Adjusted odds ratios (ORs) for all-cause mortality were 0.80 (95% CI, 0.78 to 0.83) for inhaled corticosteroids, 1.11 (CI, 1.08 to 1.15) for ipratropium, 0.92 (CI, 0.88 to 0.96) for long-acting β-agonists, and 1.05 (CI, 0.99 to 1.10) for theophylline. Ipratropium was associated with increased cardiovascular deaths (OR, 1.34 [CI, 1.22 to 1.47]), whereas inhaled corticosteroids were associated with reduced risk for cardiovascular death (OR, 0.80 [CI, 0.72 to 0.88]). Results were consistent across sensitivity analyses.

Limitations: Current smoking status and lung function were not measured. Misclassification of cause-specific mortality is unknown.

Conclusion: The possible association between ipratropium and elevated risk for all-cause and cardiovascular death needs further study.

Ann Intern Med 2008;149:380-390. www.annals.org
For author affiliations, see end of text.

Chronic obstructive pulmonary disease (COPD) is associated with substantial burden in terms of prevalence of disease (1), death and disability risk (2, 3), and health care costs (4). Despite recent interest in examining long-term outcomes associated with medications in patients with COPD (5, 6), some issues are not easily addressed by using randomized clinical trials. From a pharmacovigilance perspective, relatively rare adverse events—such as death associated with medication use—may not be detected in the short term. The patients who receive a medication may not be similar to those participating in clinical trials (7, 8) and may be more vulnerable to such events. Thus, evidence of longer-term benefits and harms associated with medications—particularly in patients with COPD, who tend to be elderly and have multiple comorbid conditions (9)—can be informed by research that relies on observational data.

Potential safety concerns with medications used to manage COPD may be substantial. A recent meta-analysis (10) showed a nearly 2.5-fold increase in respiratory deaths among patients receiving long-acting β-agonists compared with those receiving placebo. In the Lung Health Study (11), the group randomly assigned to ipratropium bromide had more than twice as many cardiovascular deaths as those receiving placebo. In addition, the U.S. Food and Drug Administration recently issued a notice regarding the potential for an increased risk for stroke associated with tiotropium use in patients with COPD (12). The extent to which these safety concerns exist and can be generalized to patients with COPD outside the context of clinical trials is unclear. Therefore, we sought to examine the association between medication use and risk for death, including respiratory and cardiovascular deaths, in a large population of patients with recently diagnosed COPD.

See also:
Print
Editors' Notes 381
Web-Only
Conversion of graphics into slides

Methods

We conducted this nested case–control study in patients with recently diagnosed COPD by using national Veterans Affairs inpatient, outpatient, pharmacy, and mortality databases, supplemented with data from the Centers for Medicare & Medicaid Services. Our sample comprised U.S. veterans who used the U.S. Veterans Health Admin-

VIReC RESEARCHERS' GUIDE TO VA DATA

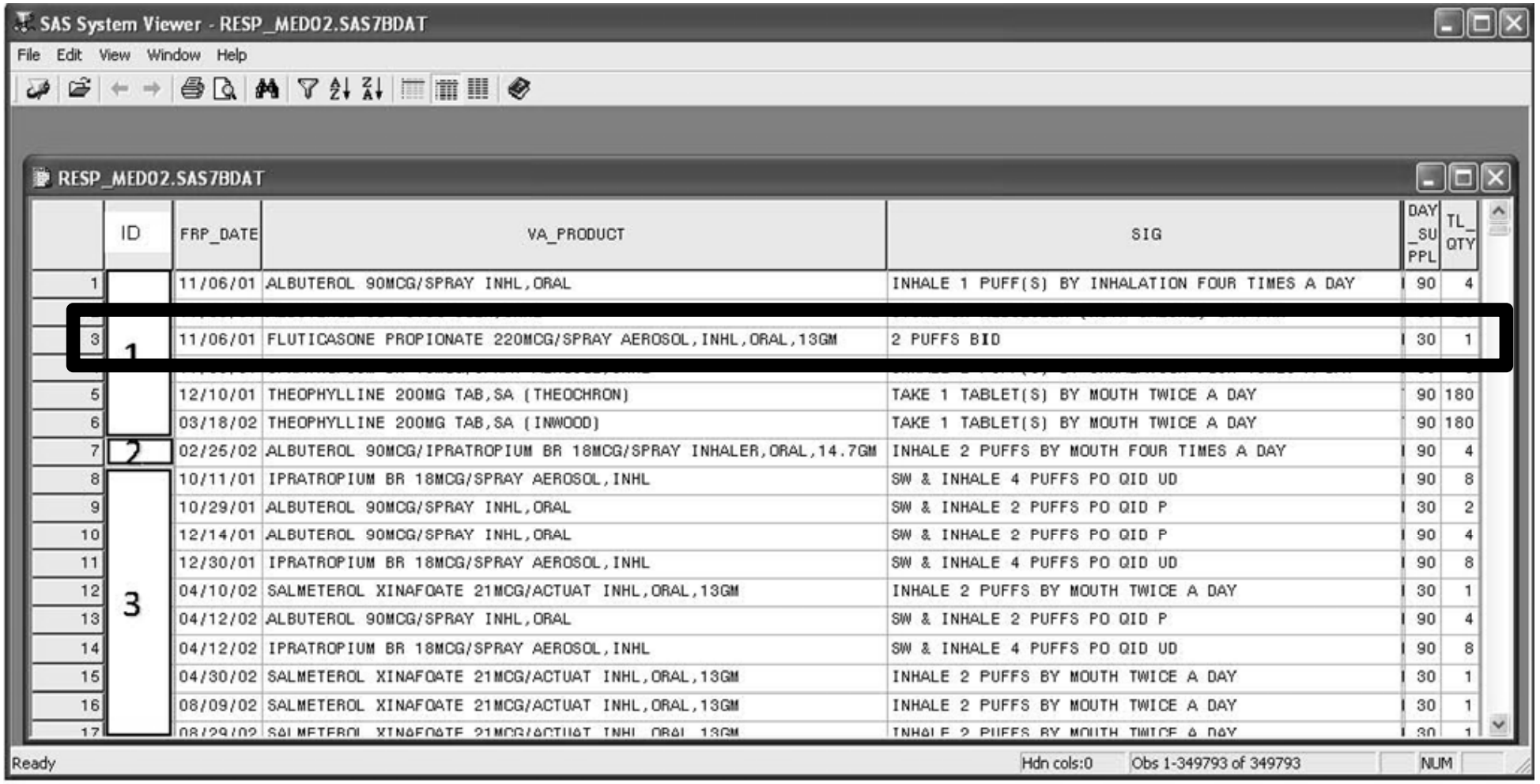
Medication Use / Exposure: Lee et al. Ann Intern Med 2008

- Nested case-control study of patients with newly diagnosed COPD
- Identified all-cause and respiratory-related and cardiovascular-related deaths
- Examined the association between respiratory medications and risk for events

Medication Use / Exposure: Lee et al. Ann Intern Med 2008

- **How was pharmacy data used?**
- **Pharmacy data was used to define medication exposure in 6 months preceding an index date**
  - Medication use (yes / no)
  - Medication regimens
  - Actively treated patients / current users
  - Amount of medication / dose
    - Needed to quantify amount of use of inhaled medications
    - Pharmacy data not always easy to work with – particularly true with regard to inhaled products
      - More straightforward to calculate cumulative exposure when dealing with tablets/capsules than with inhalers

Medication Use / Exposure: Lee et al. Ann Intern Med 2008


SAS System Viewer - RESP_MED02.SAS7BDAT

File Edit View Window Help

RESP_MED02.SAS7BDAT

	ID	FRP_DATE	VA_PRODUCT	SIG	DAY_SUPPL	TL_QTY
1		11/06/01	ALBUTEROL 90MCG/SPRAY INHL,ORAL	INHALE 1 PUFF(S) BY INHALATION FOUR TIMES A DAY	90	4
3	1	11/06/01	FLUTICASONE PROPIONATE 220MCG/SPRAY AEROSOL,INHL,ORAL,13GM	2 PUFFS BID	30	1
5		12/10/01	THEOPHYLLINE 200MG TAB,SA (THEOCHRON)	TAKE 1 TABLET(S) BY MOUTH TWICE A DAY	90	180
6		03/18/02	THEOPHYLLINE 200MG TAB,SA (INWOOD)	TAKE 1 TABLET(S) BY MOUTH TWICE A DAY	90	180
7	2	02/25/02	ALBUTEROL 90MCG/IPRATROPIUM BR 18MCG/SPRAY INHALER,ORAL,14.7GM	INHALE 2 PUFFS BY MOUTH FOUR TIMES A DAY	90	4
8		10/11/01	IPRATROPIUM BR 18MCG/SPRAY AEROSOL,INHL	SW & INHALE 4 PUFFS PO QID UD	90	8
9		10/29/01	ALBUTEROL 90MCG/SPRAY INHL,ORAL	SW & INHALE 2 PUFFS PO QID P	30	2
10		12/14/01	ALBUTEROL 90MCG/SPRAY INHL,ORAL	SW & INHALE 2 PUFFS PO QID P	90	4
11		12/30/01	IPRATROPIUM BR 18MCG/SPRAY AEROSOL,INHL	SW & INHALE 4 PUFFS PO QID UD	90	8
12	3	04/10/02	SALMETEROL XINAFOATE 21MCG/ACTUAT INHL,ORAL,13GM	INHALE 2 PUFFS BY MOUTH TWICE A DAY	30	1
13		04/12/02	ALBUTEROL 90MCG/SPRAY INHL,ORAL	SW & INHALE 2 PUFFS PO QID P	90	4
14		04/12/02	IPRATROPIUM BR 18MCG/SPRAY AEROSOL,INHL	SW & INHALE 4 PUFFS PO QID UD	90	8
15		04/30/02	SALMETEROL XINAFOATE 21MCG/ACTUAT INHL,ORAL,13GM	INHALE 2 PUFFS BY MOUTH TWICE A DAY	30	1
16		08/09/02	SALMETEROL XINAFOATE 21MCG/ACTUAT INHL,ORAL,13GM	INHALE 2 PUFFS BY MOUTH TWICE A DAY	30	1
17		08/29/02	SALMETEROL XINAFOATE 21MCG/ACTUAT INHL,ORAL,13GM	INHALE 2 PUFFS BY MOUTH TWICE A DAY	30	1

Ready Hdn cols:0 Obs 1-349793 of 349793 NUM

VIReC
RESEARCHERS' GUIDE TO VA DATA

Medication Use / Exposure: Lee et al. Ann Intern Med 2008

- **VA_PRODUCT**
  - Used to determine specific product
  - Used to determine dose strength
  - Used to determine number of actuations
- **SIG**
  - Used to determine dosing frequency
  - Used to determine number of doses per day

Medication Use / Exposure: Lee et al. Ann Intern Med 2008

1	ALBUTEROL SOL 0.5% SOLN,INHL	0.5ML IN NEBULIZER (WITH SALINE) QID PRN	30	20
1	FLUTICASONE PROPIONATE 220MCG/SPRAY AEROSOL,INHL,ORAL,13GM	2 PUFFS BID	30	1
1	IPRATROPIUM BR 18MCG/SPRAY AEROSOL,INHL	INHALE 2 PUFF(S) BY INHALATION FOUR TIMES A DAY	90	6

- **Calculation of cumulative ICS exposure**
  - Determine strength for each prescription
    - Fluticasone 220μg
  - Convert strength to beclomethasone equivalents
    - BDP_Equiv => 220*0.5 = 110μg per dose
  - Determine number of doses per prescription
    - quantity dispensed * doses per product
    - 1 canister * 120 actuations/canister = 120 doses
  - Calculate beclomethasone equivalents for each prescription and sum for cumulative exposure

VIReC
RESEARCHERS' GUIDE TO VA DATA

How has outpatient healthcare utilization been measured in VA studies?: Risk Adjustment

MEDICAL CARE
Volume 41, Number 6, pp 753–760

Predicting Costs of Care Using a Pharmacy-Based Measure Risk Adjustment in a Veteran Population

ANNE E. SALES, PHD,*† CHUAN-FEN LIU, PHD,*† KEVIN L. SLOAN, MD,*‡ JESSE MALKIN, PHD,‖ PAUL A. FISHMAN, PHD,†§ AMY K. ROSEN, PHD, ¶** SUSAN LOVELAND, MA,¶ W. PAUL NICHOL, MD, *†† NORMAN T. SUZUKI, PHARMD, *‡‡ EDWARD PERRIN, PHD,* NANCY D. SHARP, PHD,*† AND JEFFREY TODD-STENBERG*

BACKGROUND. Although most widely used risk adjustment systems use diagnosis data to classify patients, there is growing interest in risk adjustment based on computerized pharmacy data. The Veterans Health Administration (VHA) is an ideal environment in which to test the efficacy of a pharmacy-based approach.

OBJECTIVE. To examine the ability of RxRisk-V to predict concurrent and prospective costs of care in VHA and compare the performance of RxRisk-V to a simple age/gender model, the original RxRisk, and two leading diagnosis-based risk adjustment approaches: Adjusted Clinical Groups and Diagnostic Cost Groups/Hierarchical Condition Categories.

METHODS. The study population consisted of 161,202 users of VHA services in Washington, Oregon, Idaho, and Alaska during fiscal years (FY) 1996 to 1998. We examined both concurrent and predictive model fit for two sequential 12-month periods (FY 98 and FY 99) with the patient-year as the unit of analysis, using split-half validation.

RESULTS. Our results show that the Diagnostic Cost Group /Hierarchical Condition Categories model performs best ($R^2 = 0.45$) among concurrent cost models, followed by ADG (0.31), RxRisk-V (0.20), and age/sex model (0.01). However, prospective cost models other than age/sex showed comparable R^2: Diagnostic Cost Group /Hierarchical Condition Categories $R^2 = 0.15$, followed by ADG (0.12), RxRisk-V (0.12), and age/sex (0.01).

CONCLUSIONS. RxRisk-V is a clinically relevant, open source risk adjustment system that is easily tailored to fit specific questions, populations, or needs. Although it does not perform better than diagnosis-based measures available on the market, it may provide a reasonable alternative to proprietary systems where accurate computerized pharmacy data are available.

Key words: Case-mix; pharmacy; veterans; risk adjustment. (Med Care 2003;41:753–760)

From the *VA Puget Sound Health Care System, Seattle, Washington.

From the †Department of Health Services, the ‡Department of Psychiatry, the ††Department of Medicine, and ‡‡the School of Pharmacy, University of Washington, Seattle, Washington.

From the ‖the RAND Corporation, Arlington, Virginia.

From the §the Center for Health Studies, Group Health Cooperative, Seattle, Washington.

From the ¶Center for Health Quality, Outcomes and Economics, Bedford VA Medical Center, Bedford, Massachusetts.

From the **Boston University School of Public Health, Boston, Massachusetts.

This research was supported by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development Service Project IIR 99001-1. The views expressed in this report are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs or the Health Services Research and Development Service.

Address correspondence and reprint requests to: Anne E. Sales, PhD, VA Puget Sound Health Care System (152 HSRD), 1660 S. Columbian Way, Seattle, WA 98108. E-mail: Ann.Sales@med.va.gov

- **Sales AE, Liu CH, Sloan KL, et al. Predicting costs of care using a pharmacy-based measure risk adjustment in a veteran population. Med Care. 2003; 41: 753-760.**
- Objective: Compare pharmacy based risk adjustment methods to other methods in VA data

VIReC
RESEARCHERS' GUIDE TO VA DATA

Risk Adjustment: Sales et al. Med Care 2003

- **Comparison of VA-specific pharmacy-based risk adjustment model to other risk adjustment models (ACG, HCC, RxRisk)**
- **Development of a VA-based version of RxRisk (Chronic Disease Score)**
  - Sloan KL, et al. Construction and characteristics of RxRisk-V: a VA-adapted pharmacy-based case-mix instrument. *Med Care* 2003; 41(6): 761-74
  - Includes 45 chronic disease categories identified through Rx data
- **Potential value in using pharmacy-based measures versus ICD-based measures**

VIReC
RESEARCHERS' GUIDE TO VA DATA

Risk Adjustment: Sales et al. Med Care 2003

TABLE 3. Comparing Model Performance for Prospective Costs

Models	Number of Parameters	R-Squared	Adjusted R-Squared
Age/Sex	21	0.011	0.011
HCC	127	0.154	0.153
ADG	53	0.126	0.125
RxRisk	50	0.111	0.111
RxRisk-V	64	0.123	0.122

Adapted from Sales et al Med Care 2003

Session Objectives

- How has outpatient pharmacy utilization been measured in VA studies?
- Overview of VA Pharmacy databases
- Finding information in the VA Pharmacy databases
- Examples of VA studies that have used the VA Pharmacy databases
- Where to go for more help

VIReC
RESEARCHERS' GUIDE TO VA DATA

VIReC Help

- **VIReC Webpage**
  http://www.virec.research.va.gov
  - Information on VA data sources and how to access data
  - Resource users guide for pharmacy data
    - http://www.virec.research.va.gov/References/RUG/RUG-Pharmacy-2nd-Ed-er.pdf

VIReC Help (cont'd)

- **HSRData Listserv**
  - Join at the VIReC Web site
  - Discussion among >400 data stewards, managers, and users
  - Past messages in archive (on intranet)

- **VIReC Help Desk**
  - VIReC staff will answer your question and/or direct you to available resources on topics
  - VIReC@va.gov
  - (708) 202-2413

VIReC
RESEARCHERS' GUIDE TO VA DATA

Questions?

Selected Recent References on VA Outpatient Pharmacy Use

- Lee, T. A., Pickard, A. S., Au, D. H., Bartle, B., & Weiss, K. B. (2008). Risk for death associated with medications for recently diagnosed chronic obstructive pulmonary disease. *Ann Intern Med., 149,* 380-390.
- Sernyak, M. J. & Rosenheck, R. A. (2008). Antipsychotic use in the treatment of outpatients with schizophrenia in the VA from fiscal years 1999 to 2006. *Psychiatr Serv., 59,* 567-569.
- Walbrown, M. A., Aspinall, S. L., Bayliss, N. K., Stone, R. A., Cunningham, F., Squier, C. L. et al. (2008). Evaluation of Clostridium difficile-associated diarrhea with a drug formulary change in preferred fluoroquinolones. *J Manag Care Pharm., 14,* 34-40.
- Mortensen, E. M., Restrepo, M. I., Copeland, L. A., Pugh, J. A., Anzueto, A., Cornell, J. E. et al. (2007). Impact of previous statin and angiotensin II receptor blocker use on mortality in patients hospitalized with sepsis. *Pharmacotherapy., 27,* 1619-1626.
- Iqbal, S. U., Cunningham, F., Lee, A., Wang, S., Hamed, A., Miller, D. R. et al. (2007). Divalproex sodium vs. valproic acid: drug utilization patterns, persistence rates and predictors of hospitalization among VA patients diagnosed with bipolar disorder. *J Clin Pharm Ther., 32,* 625-632.
- Damush, T. M., Jia, H., Ried, L. D., Qin, H., Cameon, R., Plue, L. et al. (2008). Case-finding algorithm for post-stroke depression in the veterans health administration. *Int J Geriatr Psychiatry., 23,* 517-522..
- Frayne, S. M., Yu, W., Yano, E. M., Ananth, L., Iqbal, S., Thrailkill, A. et al. (2007). Gender and use of care: planning for tomorrow's Veterans Health Administration. *J Womens Health (Larchmt.)., 16,* 1188-1199.

VIReC
RESEARCHERS' GUIDE TO VA DATA

Selected Recent References on VA Outpatient Pharmacy Use (cont)

- Mahmood, M., Malone, D. C., Skrepnek, G. H., Abarca, J., Armstrong, E. P., Murphy, J. E. et al. (2007). Potential drug-drug interactions within Veterans Affairs medical centers. *Am J Health Syst Pharm., 64,* 1500-1505.
- Davis, R. G., Hepfinger, C. A., Sauer, K. A., & Wilhardt, M. S. (2007). Retrospective evaluation of medication appropriateness and clinical pharmacist drug therapy recommendations for home-based primary care veterans. *Am J Geriatr Pharmacother., 5,* 40-47.
- Berlowitz, D. R. & Pugh, M. J. (2007). Pharmacoepidemiology in community-dwelling elderly taking antiepileptic drugs. *Int Rev Neurobiol., 81:153-63.,* 153-163.
- Poon, I. O., Lal, L., Brown, E. N., & Braun, U. K. (2007). The impact of pharmacist-managed oral anticoagulation therapy in older veterans. *J Clin Pharm Ther., 32,* 21-29.
- Jia, H., Damush, T. M., Qin, H., Ried, L. D., Wang, X., Young, L. J. et al. (2006). The impact of poststroke depression on healthcare use by veterans with acute stroke. *Stroke., 37,* 2796-2801.
- Fultz, S. L., Skanderson, M., Mole, L. A., Gandhi, N., Bryant, K., Crystal, S. et al. (2006). Development and verification of a "virtual" cohortusing the National VA Health Information System. *Med Care., 44,* S25-S30.
- VIReC Technical Report: Comparison of VA Outpatient Prescriptions in the DSS Datasets and the PBM Database http://vaww.virec.research.va.gov/References/TechnicalReports/VIReCTechnicalReport1.pdf

VIReC
RESEARCHERS' GUIDE TO VA DATA