

# Development of an Adverse Event Surveillance Tool for Outpatient Surgery

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# Overview

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- Surgery in Veterans Health Administration
- Surgical outcomes measurement
- Outpatient surgery research

# Poll Question #1

- What is your primary role in VA?
  - Student, trainee, or fellow
  - Clinician – surgeon
  - Clinician – other
  - Researcher
  - Other

# Poll Question #2

- Which best describes your experience with the CDA program?
  - Considering a CDA
  - CDA awardee
  - CDA mentor
  - Other

# VA Surgical Care

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- Approx 400,000 surgical procedures a year.
  
- Surgical care available in
  - 111 inpatient hospitals with standard, intermediate or complex ratings;
  - 20 ambulatory surgery centers.
  
- Facility requirements (“CPT Matrix”) for the level of infrastructure needed to perform surgery.

# VA Surgical Care: VASQIP

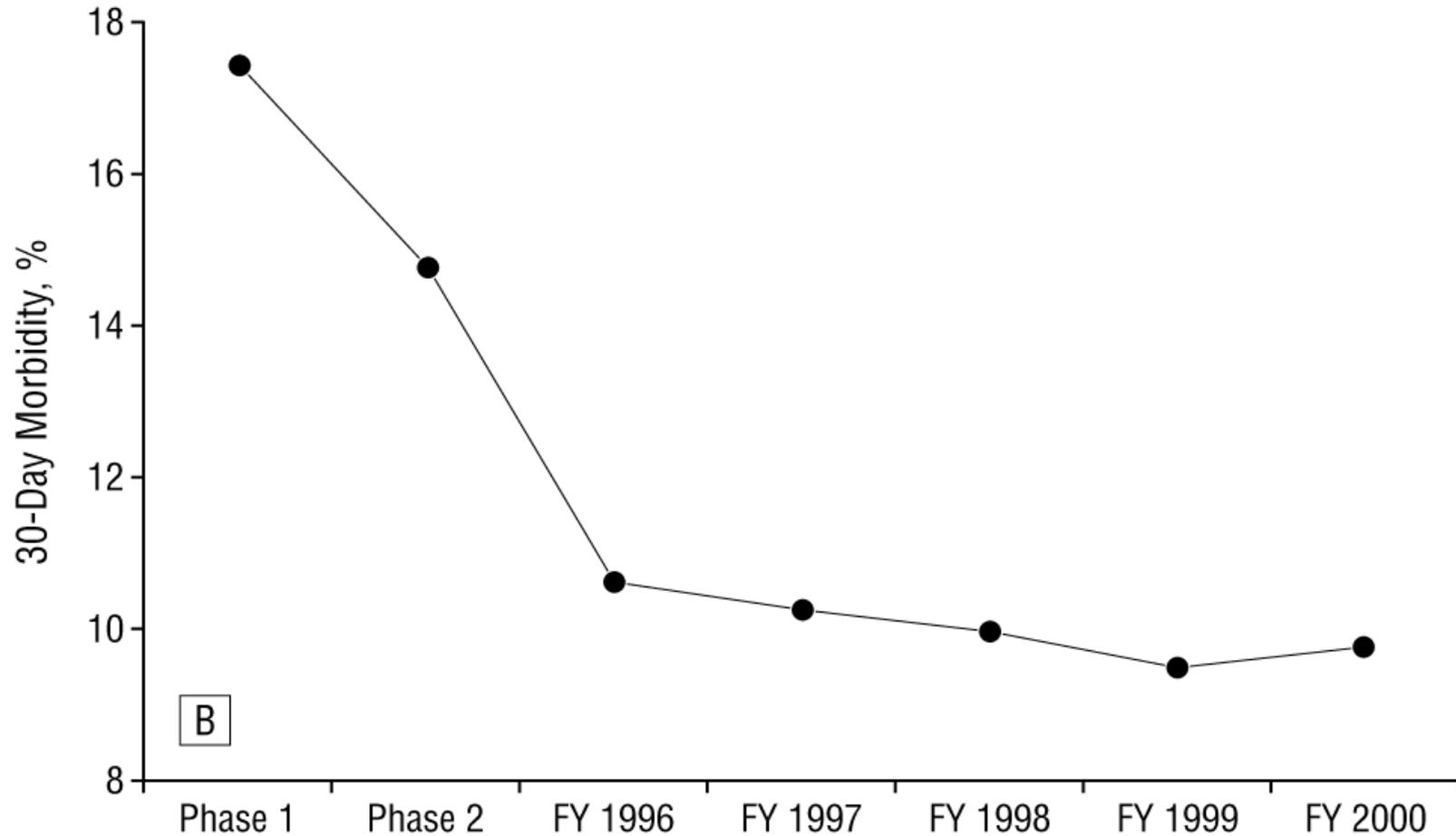
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- VA Surgical Quality Improvement Program (VASQIP) measures surgical outcomes.



# VASQIP Benefits

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*Arch Surg.* 2002;137(1):20-27

HJ Mull 1/10/17

# VASQIP limitations

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- VASQIP is insufficient for outpatient surgery.



- Using the CPT matrix only a selection of high-volume surgeries (e.g., hernia and lumpectomy) are reviewed;
- Most outpatient surgeries are never reviewed.

# VASQIP limitations

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- VASQIP is insufficient for outpatient surgery.



- Chart review tool is a poor fit for outpatient surgical complications (e.g., heart attacks and coma).
  - Chart review process is time consuming and may generate more data than is necessary for reporting and quality improvement.
- 
- Can we adapt VASQIP for outpatient surgery?

# Outpatient surgery research

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- We developed an adverse event surveillance tool for outpatient surgery.
- Follows the general model of VASQIP



1. Identify surgeries likely to have adverse events
2. Review cases to confirm and describe these events
3. Report results back to surgical programs to improve quality of care.

# Methods – Study Sample

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- 2012-2014 VA outpatient encounters from 111 hospitals and 20 ambulatory surgery centers (ASCs)
  - For each outpatient encounter in the VA's Corporate Data Warehouse (CDW) created a “principal CPT” using the highest Medicare RVU calculation;
  - Applied the Healthcare Cost and Utilization Program's (HCUP)'s Surgery Flag software to the principal CPT;
  - Excluded selected procedures from outpatient surgery dataset -
    - eye surgeries
    - likely miscoded inpatient cases;
    - care performed in the emergency room (ER);
    - procedures with a RVU=0;
    - missing relevant patient or procedure data.

# Methods – Developing triggers

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Trigger	CDA Trigger Definition
Emergency Department	Outpatient surgery and 1+ visits to an emergency department or urgent care clinic within 14 days
Same Day Admission	Outpatient surgery and same day admission with length of stay > 48 hours
Admission	Outpatient surgery and subsequent admission with length of stay > 24 hours 1- 14 days after surgery
Surgery Clinic	Outpatient surgery and 3+ clinic visit to a surgical specialty within 30 days
Urology	Outpatient surgery and 2+ clinic visits to urology clinic within 30 days
Telephone	Outpatient surgery and 1+ call to telephone triage within 7 days

# Methods – Building Dataset

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- Sampled  $\approx 1,900$  FY12-14 cases for chart review given project resources.
- 80% were trigger-flagged so we could estimate a false negative rate.
- Reviewed the literature and worked with experts on surgical AEs to revise our previously developed chart abstraction form.
- Used an InfoPath form and a SharePoint website to capture chart-reviewed data electronically.

# Methods – Chart Review Form

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Category	Specific AE
<b>Wound Occurrences</b>	<ul style="list-style-type: none"><li>– Superficial Incisional Surgical Site Infection (SSI)</li><li>– Deep Incisional SSI</li><li>– Organ/Space SSI</li><li>– Wound <i>Dehiscence</i>/Disruption</li><li>– <i>Hematoma</i></li></ul>
<b>Respiratory Occurrences</b>	<ul style="list-style-type: none"><li>– Pneumonia</li><li>– Unplanned Intubation for Resp/Cardiac Arrest</li><li>– <i>Unplanned Intubation - other</i></li><li>– Pulmonary Embolism</li><li>– On Ventilator &gt; 48 hours</li></ul>
<b>Urinary Tract Occurrences</b>	<ul style="list-style-type: none"><li>– Progressive Renal Insufficiency</li><li>– Acute Renal Failure</li><li>– Urinary Tract Infection</li><li>– <i>Urinary Retention</i></li></ul>

# Methods – Chart Review Form

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Category	Specific AEs		
<b>Central Nervous System Occurrences</b>	<ul style="list-style-type: none"> <li>– CVA/Stroke</li> <li>– Coma &gt; 24 hours</li> <li>– Peripheral Nerve Injury</li> </ul>		
<b>Cardiac Occurrences</b>	<ul style="list-style-type: none"> <li>– Cardiac Arrest req. CPR</li> <li>– Myocardial Infarction</li> </ul>		
<b>Other Occurrences</b>	<table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top; width: 50%;"> <ul style="list-style-type: none"> <li>– Graft/Prosthesis/Flap Failure</li> <li>– Deep Vein Thrombosis/Thrombophlebitis</li> <li>– Sepsis</li> <li>– Septic Shock</li> <li>– Clostridium difficile Colitis</li> <li>– Postoperative Ileus</li> <li>– Iatrogenic Pneumothorax</li> <li>– Death</li> </ul> </td> <td style="vertical-align: top; width: 50%;"> <ul style="list-style-type: none"> <li>– <i>Bleeding Req Any Units PRBC's or Transfusions &lt;72 hours after Surgery</i></li> <li>– <i>Intraoperative Iatrogenic Injuries</i></li> <li>– <i>Persistent Nausea/Vomiting</i></li> <li>– <i>Dental Occurrences</i></li> <li>– <i>Burn</i></li> <li>– <i>Allergic Reaction</i></li> <li>– <i>Adverse Drug Event</i></li> <li>– <i>Corneal Abrasion</i></li> </ul> </td> </tr> </table>	<ul style="list-style-type: none"> <li>– Graft/Prosthesis/Flap Failure</li> <li>– Deep Vein Thrombosis/Thrombophlebitis</li> <li>– Sepsis</li> <li>– Septic Shock</li> <li>– Clostridium difficile Colitis</li> <li>– Postoperative Ileus</li> <li>– Iatrogenic Pneumothorax</li> <li>– Death</li> </ul>	<ul style="list-style-type: none"> <li>– <i>Bleeding Req Any Units PRBC's or Transfusions &lt;72 hours after Surgery</i></li> <li>– <i>Intraoperative Iatrogenic Injuries</i></li> <li>– <i>Persistent Nausea/Vomiting</i></li> <li>– <i>Dental Occurrences</i></li> <li>– <i>Burn</i></li> <li>– <i>Allergic Reaction</i></li> <li>– <i>Adverse Drug Event</i></li> <li>– <i>Corneal Abrasion</i></li> </ul>
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# Methods – Chart Review Process

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## Nurse Review Process

- Recommended chart review order
  1. Operative record
  2. H&P
  3. Coding summary
  4. Consultation notes
  5. Laboratory results
  6. Orders
- Did the patient have post-op care  $\leq 30$  days outside the VA? If yes, briefly describe.
- Is an AE present?
  - Yes**
    - Document the following
      - AE date
      - Narrative description
      - Location of AE in EMR
      - Location of AE in facility/home
      - AE severity – Dindo scale
      - Harm score – IHI scale
  - No**
    - Document “no AE”
    - Move to next record

# Poll Question #3

- Which best describes your experience using multilevel models in research?
  - No experience
  - Some collaboration with experts
  - Estimated these models myself
  - Significant experience
  - Other

# Methods – Predictive model

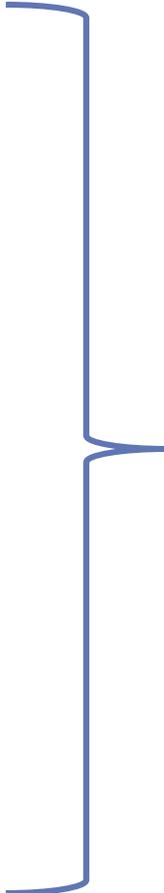
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- Cleaned chart review data to remove miscoded inpatient cases and created code for ‘any AE.’
- Merged chart review findings with descriptive data on FY12-14 outpatient surgeries.
- Used SAS Proc Glimmix to fit multilevel logistic regression model to the chart review data
  - ▣ Gauss-Hermite Quadrature estimation method;
  - ▣ Iteratively tested variables to optimize c-statistic.

# Methods – Model variables

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<b>TRIGGERS</b>	<ul style="list-style-type: none"><li>• ER, admit, same day, uro, surg vist, phone</li></ul>
<b>PATIENT</b>	<ul style="list-style-type: none"><li>• Comorbidities</li><li>• Marital status</li><li>• Age, sex, race</li><li>• Service connected disability</li><li>• Anesthesia risk score (ASA)</li><li>• <del>Income</del></li></ul>
<b>PROCEDURE</b>	<ul style="list-style-type: none"><li>• Organ system (e.g., digestive)</li><li>• RVU for surgery</li><li>• Duration of operation</li><li>• <del>Provider type</del></li><li>• Month/year of operation (nuisance variables)</li></ul>
<b>FACILITY</b>	<ul style="list-style-type: none"><li>• <del>Facility surgical volume</del></li><li>• Complexity of facility's surgical program</li><li>• Geographic region</li><li>• Group mean centered patient/procedure variables (e.g., average patient age in facility)</li></ul>



Probability of  
any AE  
YES or NO

# Results - Predictive model

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Type of Predictor	Significant Predictors in Final Model	Odds Ratio (95%CI)
Triggers	Admission Trigger	2.3 (1.27-4.18)
	ED Trigger	4.67 (3.35-6.51)
	Surg Visit Trigger	3.33 (2.28-4.86)
	Uro Clinic Trigger	1.62 (0.85-3.09)
Comorbidities	Deficiency Anemias	1.69 (1.11-2.58)
	Depression	1.42 (1.01-2.01)
	Renal failure	0.48 (0.28-0.82)
Procedure Characteristics	0.1 – 2.34 RVUs	ref
	2.35 - 4.97 RVUs	1.11 (0.64-1.92)
	4.99 - 7.13 RVUs	2.15 (1.25-3.69)
	7.14 - 10.47 RVUs	2.26 (1.3-3.94)
	10.49 - 27.41 RVUs	3.37 (2.01-5.65)
	Digestive system	2.94 (1.73-4.99)
	Nervous system	2.09 (1.02-4.26)
	Urinary system	2.22 (1.27-3.87)

Final model includes all comorbidities, organ systems, mean proportion of organ system at the facility and temporal effects.

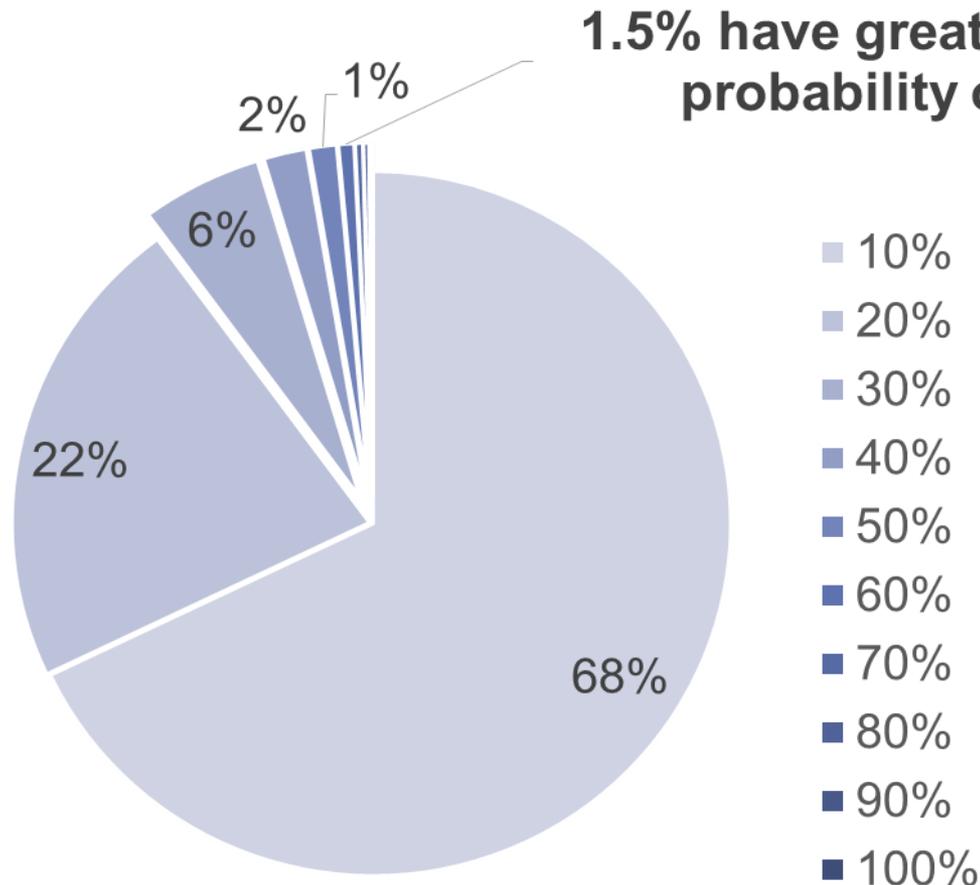
# Validation of Model in FY15 Data

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- Sample: 2015 VA outpatient surgeries
- Process:
  - Obtained outpatient encounters and followed the same steps to identify surgeries, merge patient and procedure characteristics and run triggers.
  - Applied coefficients from predictive model to FY15 dataset to get probability of an AE.
  - Used  $p \geq 80\%$  as the threshold for a true AE; in FY12-14 data, 95% of patients with  $p \geq 80\%$  had an AE.
  - Reviewed high probability and mid-probability cases.

# Results – FY15 validation data

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Model predicted 9% of outpatient surgeries had an adverse event.

# Results – FY15 chart review

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- Reviewed cases with a predicted probability >80% (n=405, 0.15% of all outpatient surgeries)
  - 85% of these cases had at least one AE;
  - Most false positives were patients returning to the ER for various complaints unrelated to the surgery.
- Reviewed a random sample of the surgeries with 40-50% predicted probability (n=3,186, 1%)
  - 38% had an AE.

# Results – Types of AEs

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- Reviewed 2,257 outpatient surgeries between FY12-15 and identified 1,010 AEs in 774 cases.
- 254 AEs (25%) did not fit any AE definitions in our review tool
- Most common AEs were
  - ▣ urinary problems (n=371, 37%)
    - infections (12%)
    - retention (23%)
  - ▣ wound issues (n=313, 31%)
    - dehiscence (8%)
    - hematoma (8%)

# Results – Severity of AEs

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- More than 50% of all AEs were temporary harm to the patient that required intervention.
- 28% were temporary harms requiring hospitalizations.
- 22% of AEs detected required at minimum a repeat surgery to fix (Dindo Grades IIIa or higher).
- There were 8 AEs requiring intervention to sustain life and 2 deaths within 30 days.

# Results – VASQIP events detected

Adverse Event	Total AEs (n=1,010 in 774 surgeries)	IHI Global Trigger Tool Harm Scale				
		Temp harm required intervention	Temp harm req initial/longer hospital stay	Permanent patient harm	Intervention to sustain life	Death
Urinary Tract Infection	120 (12%)	94	26	0	0	0
Superficial SSI	31 (3%)	28	3	0	0	0
Postoperative Ileus	28 (3%)	1	27	0	0	0
Sepsis	22 (2%)	0	21	0	1	0
Deep Incisional SSI	20 (2%)	3	16	1	0	0
Organ/Space SSI	13 (1%)	2	10	0	1	0
Pneumonia	13 (1%)	3	10	0	0	0
DVT	12 (1%)	7	5	0	0	0
Progressive Renal Insuffi	11 (1%)	1	10	0	0	0
Graft/Prosthesis/Flap Failure	6 (1%)	4	2	0	0	0
Pulmonary Embolism	5 (0%)	0	5	0	0	0
Myocardial Infarction	5 (0%)	0	3	0	2	0
Acute Renal Failure	3 (0%)	0	3	0	0	0
CVA/Stroke	3 (0%)	0	2	1	0	0
Clostridium difficile Colitis	3 (0%)	1	2	0	0	0
Septic Shock	2 (0%)	0	1	0	1	0
Death 30 days post-op	2 (0%)	0	0	0	0	2
Unplanned Intubation (arrest)	1 (0%)	0	0	0	1	0
<b>TOTAL:</b>	<b>303 (30%)</b>	<b>144</b>	<b>148</b>	<b>2</b>	<b>7</b>	<b>2</b>

# Results – New events detected

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Adverse Event	Total AEs (n=1,010 in 774 surgeries)	IHI Global Trigger Tool Harm Scale			
		Temp harm	Temp harm - hospital stay	Permanent harm	Intervention to sustain life
Urinary Retention	234 (23%)	196	38	0	0
Other	123 (12%)	65	58	0	0
Hematoma	87 (9%)	60	27	0	0
Wound Disruption/Dehiscence	81 (8%)	74	7	0	0
Other Wound Occurrence	81 (8%)	56	25	0	0
Persistent Nausea/Vomiting	25 (2%)	11	14	0	0
Bleeding req any units red blood cells <72hrs postop	20 (2%)	0	19	0	1
Intraoperative Iatrogenic Injuries	17 (2%)	8	9	0	0
Allergy	13 (1%)	12	1	0	0
Other Cardiac Occurrence	9 (1%)	3	6	0	0
Adverse Drug Event	6 (1%)	6	0	0	0
Other Respiratory Occurrence	5 (0%)	0	5	0	0
Other Urinary Occurrence	3 (0%)	1	2	0	0
Other CNS Occurrence	1 (0%)	0	1	0	0
Dental Occurrences	1 (0%)	1	0	0	0
Unplanned Intubation	1 (0%)	0	1	0	0
<b>New Events TOTAL</b>	<b>707 (70%)</b>	<b>493</b>	<b>213</b>	<b>0</b>	<b>1</b>

# Conclusions

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- In FY12-14 chart review data,  $\approx 11\%$  of surgeries had at least one AE.
  - Required review of 1,730 trigger-flagged cases to find 350 AEs (PPV=20%)
- In FY15 data using predictive model,  $\approx 9\%$  of surgeries had at least one AE.
  - Reviewed only the highest probability cases (n=405) and identified 344 AEs (PPV=85%)

***Surveillance system efficiently identified true postoperative AEs in outpatient surgery.***

# Next steps

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- How can we report our results to promote quality improvement?
  - ▣ Pilot testing the surveillance system in 2 facilities;
  - ▣ Evaluating implementation efforts.
  
- Will our system lead to changes in care and improvements in quality?

# Study Team

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- Mentors/Co-Investigators:
  - ▣ Amy Rosen, PhD, Senior Investigator, CHOIR
  - ▣ Kamal Itani, MD, Chief of Surgery, VA Boston
  - ▣ Mary Hawn, MD, MPH, Chief of Surgery, Stanford University
  - ▣ Martin Charns, DBA, Co-Director, CHOIR
  - ▣ Steven Pizer, PhD, Director, HCFE
  - ▣ Peter Rivard, PhD, Professor, Suffolk University
- Chart Reviewer:
  - ▣ Sally MacDonald, RN

# Questions/Comments?

## Contact Information

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Or [hjmull@bu.edu](mailto:hjmull@bu.edu)

# Back-up/Extra Slides

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# Dindo Classification

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<b>Grade I</b>	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions; Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at bedside
<b>Grade II</b>	Requiring pharmacological treatment with drugs other than such allowed for grade I complications; Blood transfusions and total parenteral nutrition (TPN) are also included
<b>Grade III</b>	Requiring surgical, endoscopic, or radiological intervention
<b>III a</b>	Intervention NOT under general anesthesia
<b>III b</b>	Intervention under general anesthesia
<b>Grade IV</b>	Life-threatening complication (including CNS complications) requiring IC/ICU management
<b>IV A</b>	Single organ dysfunction
<b>IV b</b>	Multi-organ dysfunction
<b>Grade V</b>	Death of a patient

\* Brain hemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks

CNS, central nervous system

IC, intermediate care

ICU, intensive care unit

# IHI Harm Scale

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- Considering the patient 30 days after the AE, please select first applicable category. Only rate harms associated with the AE:

Temporary harm to the patient and required intervention

Temporary harm to the patient and required initial or prolonged hospitalization

Permanent patient harm

Intervention required to sustain life

Patient death

# Results: Predictive Model Results

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Variables in Final Model	Likelihood Estimate (95%CI)
Triggers	
Admission Trigger	0.83 (0.24, 1.43) **
ED Trigger	1.54 (1.21, 1.87) ***
Surg Visit Trigger	1.2 (0.82, 1.58) ***
Uro Clinic Trigger	0.48 (-0.17, 1.13) p = 0.1458
Procedure Characteristics	
0.1 – 2.34 RVUs	control
2.35 - 4.97 RVUs	0.1 (-0.45, 0.65)
4.99 - 7.13 RVUs	0.77 (0.22, 1.31) **
7.14 - 10.47 RVUs	0.82 (0.26, 1.37) *
10.49 - 27.41 RVUs	1.21 (0.7, 1.73) ***
Cardiovascular system	0.57 (-0.11, 1.24) p = 0.1011
Digestive	1.08 (0.55, 1.61) ***
Female genital	0.8 (-0.48, 2.07)
Hemic	0.99 (-0.33, 2.3) p = 0.1418
Male genital	0.36 (-0.47, 1.19)
Musculoskeletal	-0.26 (-0.78, 0.27)
Nervous	0.74 (0.02, 1.45) *
Respiratory	-0.47 (-1.58, 0.64)
Urinary	0.8 (0.24, 1.35) *

Comorbidities in Final Model	Likelihood Estimate (95%CI)
Alcohol abuse	0.71 (0.41-1.25)
Deficiency Anemias	1.69 (1.11-2.58)
Rheumatoid arthritis/collagen vas	1.55 (0.7-3.42)
Chronic blood loss anemia	0.49 (0.08-3.09)
CHF	1.32 (0.76-2.28)
COPD	0.91 (0.64-1.3)
Coagulopathy	0.57 (0.21-1.6)
Depression	1.42 (1.01-2.01)
Diabetes w/o chronic complications	1 (0.68-1.46)
Diabetes w/ chronic complications	1.41 (0.89-2.23)
Drug abuse	0.7 (0.38-1.29)
Hypertension	0.89 (0.65-1.22)
Hypothyroidism	0.59 (0.33-1.09)
Liver disease	1.38 (0.72-2.63)
Lymphoma	0.25 (0.03-1.96)
Fluid and electrolyte disorders	1.12 (0.67-1.86)
Metastatic cancer	0.51 (0.15-1.76)
Other neurological disorders	1.27 (0.75-2.13)
Obesity	0.84 (0.59-1.21)
Paralysis	0.93 (0.28-3.09)
Peripheral vascular disease	0.92 (0.57-1.48)
Psychoses	0.89 (0.59-1.34)
Pulmonary circulation disease	0.68 (0.25-1.85)
Renal failure	0.48 (0.28-0.82)
Solid tumor w/out metastasis	0.9 (0.61-1.33)
Valvular disease	1.15 (0.57-2.33)
Weight loss	1.92 (0.95-3.87)