AHRQ Quality Indicators
Recent validation efforts

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Overview

- Topics (focus on PSIs and PDIs)
  - Validation of prior tools
  - Extending face/consensual validity
  - Construct/predictive validity based on patient outcomes and resource utilization
  - Criterion validity based on present-of-admission (POA) data
  - Criterion validity based on data linkages
  - Criterion validity based on recoded/abstracted data
  - Criterion validity based on clinician case review
  - Other approaches
- Questions and answers

Validation of prior tools based on literature review (MEDLINE/EMBASE)

- Validation studies of Iezzoni et al.'s Complications Screening Program
  - At least one of three validation studies (coders, nurses, or physicians) confirmed PPV ≥75% among flagged cases
  - Nurse-identified process-of-care failures were more prevalent among flagged cases than among unflagged controls
- Other studies of coding validity
  - Very few in peer-reviewed journals, some in "gray literature"

Validation (%) of Complications Screening Program

Med Care 2000;38:785-806,868-76; *Int J Qual Health Care* 1999;11:107-18

CSP Indicator	PSI	Coder: % Complic Present	MD: % Complic present	RN: % Process problem	MD: % Quality problem
Postprocedural hemorrhage/ hematoma	#9 narrower: requires proc code + dx	83 (surg) 49 (med)	57 (surg) 55 (med)	66 vs 46 13 vs 5	37 vs 2 31 vs 2
Postoperative pulmonary compromise	#11 narrower: includes only resp failure	72	75	52 vs 46	20 vs 2
DVT/PE	#12 surgical only Slight changes	59 (surg) 32 (med)	70 (surg) 28 (med)	72 vs 46 69 vs 5	50 vs 2 20 vs 2
In-hosp hip frx and falls	#8 surgical only, no E codes	57 (surg) 11 (med)	71 (surg) 11 (med)	76 vs 46 54 vs 5	24 vs 2 5 vs 2

Percentage with process/quality problem among flagged cases vs. unflagged controls

Validation of prior tools:
Construct validity evidence in literature

Indicator	Explicit process	Implicit process	Staffing
Complications of anesthesia			
Death in low mortality DRGs		+	
Decubitus ulcer			±
Failure to rescue			++
Foreign body left during procedure			
Iatrogenic pneumothorax			
Selected infections due to medical care			
Postop hip fracture	+	+	
Postop hemorrhage or hematoma	±	+	
Postop physiologic/metabolic derangements			–
Postop respiratory failure	±	+	±
Postop thromboembolism	+	+	±
Postop sepsis			–
Accidental puncture or laceration			
Transfusion reaction			
Postop abdominopelvic wound dehiscence			

Extending consensual/face validity:
OECD Health Care Quality Indicators Project

- Includes 21 countries, WHO, European Commission, World Bank, ISQua, etc.
- Patient safety is one of five priority areas
- Indicator selection criteria:
  - Importance
    - Impact on health
    - Policy importance (concern for policymakers and consumers)
    - Susceptible to influence by the health care system
  - Scientific soundness
    - Face validity (clinical rationale and past usage)
    - Content validity
  - Feasibility
    - Data availability and reporting burden

Extending consensual/face validity: OECD Review Process

- Patient safety panel constituted with 5 members (Dr. John Millar, Chair)
- 50 indicators from 7 sources submitted for review (US, Canada, Australia)
- Modified RAND/UCLA Appropriateness Method
- Panelists rated each indicator on importance and scientific soundness (2 rounds with intervening discussion)
- Retained indicators with median score >7 (1-9 scale) on both domains; rejected indicators with median score 5 or below on either domain

International OECD panel ratings of PSIs

McLoughlin V, et al. *Int J Qual Health Care* 2006 Sep;18 Suppl 1:14-20

PSIs recommended	PSIs not recommended	Experimental or rejected PSIs recommended
Selected infections due to medical care	Death in low mortality DRG	Postop wound infection
Decubitus ulcer	Postop hemorhage/ hematoma	In-hospital hip fracture or fall
Complications of anesthesia	Iatrogenic pneumothorax	
Postop PE or DVT	Postop abdominopelvic wound dehiscence	
Postop sepsis	Failure to rescue	
Technical difficulty with procedure	Postop physiologic/ metabolic derangement	
Transfusion reaction	Postop respiratory failure	
Foreign body left in		
Postop hip fracture		
Birth trauma		
Obstetric trauma (all types)		

AHRQ panel ratings of PSI "preventability" very similar to OECD ratings

Acceptable	Acceptable (-)	Unclear	Unclear (-)
Decubitus ulcer	Complications of anesthesia	Death in low mortality DRG	Failure to rescue
Foreign body left in	Selected infections due to medical care	Postop hemorhage/ hematoma	Postop physioic/ metabolic derange
Iatrogenic pneumothorax[a]	Postop PE or DVT[b]	Postop respiratory failure	
Postop hip fracture[a]	Transfusion reaction	Postop abdominopelvic wound dehiscence	
Technical difficulty with procedure	Birth trauma	Postop sepsis	
Obstetric trauma (all delivery types)			

[a] Panel ratings were based on definitions different than final definitions. For "Iatrogenic pneumothorax," the rated denominator was restricted to patients receiving thoracentesis or central lines; the final definition expands the denominator to all patients (with same exclusions). For "In-hospital fracture" panelists rated the broader Experimental indicator, which was replaced in the Accepted set by "Postoperative hip fracture" due to operational concerns.

[b] Vascular complications were rated as Unclear (-) by surgical panel; multispecialty panel rating is shown here.

Approaches to assessing construct validity

- Is the outcome indicator associated with explicit processes of care (e.g., appropriate use of medications)? – YOUR STUDY
- Is the outcome indicator associated with implicit process of care (e.g., global ratings of quality)?
- Is the outcome indicator associated with nurse staffing or skill mix, physician skill mix, or other quality-related aspects of hospital structure?
- Is the outcome indicator associated with other meaningful outcomes of care (predictive validity)?

Validation Using Implicit Processes of Care: Regression of PSIs on JCAHO Overall Evaluation

Miller MR, et al., *Am J Med Qual* 2005;20:239-252

PSI	Regression coefficient	PSI	Regression coefficient
Complications of anesthesia	0.029	Postop sepsis	-0.209
Death in low-mortality DRG	0.012	Postop wound dehiscence	-0.098
Decubitus ulcer	0.004	Accidental puncture/laceration	-0.212 (p<.01)
Failure to rescue	0.112	Birth trauma	0.045
Foreign body left in	-0.102	Ob trauma, vaginal w/out instrum	-0.114
Iatrogenic pneumothorax	0.261 (p=.03)	Ob trauma, vaginal w instrum	0.165 (p=.04)
Selected infection 2° to care	-0.037	Ob trauma, cesarean	-0.027
Postop hip fracture	-0.112	PSI factor 1	-0.108 (p=.02)
Postop hemorrhage/hematoma	0.096	PSI factor 2	0.026
Postop respiratory failure	-0.284 (p<.01)	PSI factor 3	-0.010
Postop DVT/PE	-0.210 (p=.06)		

Validation Using Structural Measures: Regression of FTR on Skill Mix Measures

Silber J, et al., *Med Care* 2007;45(10):918-925

Indicator	FTR-Silber	FTR-Needleman	FTR-AHRQ
Teaching hospital (COTH member)	0.89	0.86	0.85
Medium-large hospital (>200 beds)	0.92	0.94	0.92
Bed-to-nurse (RN+LVN) ratio	1.04	1.04	1.04
Nursing skill mix RN/(RN+LPN)	0.92	0.87	0.87

Odds ratios from multivariable logistic regression, adjusted for all patient characteristics and all other specified hospital characteristics, based on 1999-2000 Medicare inpatient claims.

Odds ratios further from 1 indicate larger, more clinically important effects.

Yellow: $0.0001<p<0.01$

Red: $p<0.0001$

Predictive validity: Impact of preventing each PSI event on mortality, LOS, charges (ROI)

NIS 2000 analysis by Zhan & Miller, *JAMA* 2003;290:1868-74

Indicator	Δ Mort (%)	Δ LOS (d)	Δ Charge ($)
Postoperative septicemia	21.9	10.9	$57,700
Selected infections due to medical care	4.3	9.6	38,700
Postop abd/pelvic wound dehiscence	9.6	9.4	40,300
Postoperative respiratory failure	21.8	9.1	53,500
Postoperative physiologic or metabolic derangement	19.8	8.9	54,800
Postoperative thromboembolism	6.6	5.4	21,700
Postoperative hip fracture	4.5	5.2	13,400
Iatrogenic pneumothorax	7.0	4.4	17,300
Decubitus ulcer	7.2	4.0	10,800
Postoperative hemorrhage/hematoma	3.0	3.9	21,400
Accidental puncture or laceration	2.2	1.3	8,300

Excess mortality, LOS, and charges computed from mean values for PSI cases and matched controls.

Predictive validity: Impact of preventing each PSI event on mortality, LOS, VA expenditures (ROI)

VA PTF 2001 analysis by Rivard et al., *Med Care Res Rev*; in press

Indicator	Δ Mort (%)	Δ LOS (d)	Δ Cost ($)
Postoperative septicemia	30.2	18.8	$31,264
Selected infections due to medical care	2.7	9.5	13,816
Postop abd/pelvic wound dehiscence	11.7	11.7	18,905
Postoperative respiratory failure	24.2	8.6	39,745
Postoperative physiologic or metabolic derangement			
Postoperative thromboembolism	6.1	5.5	7,205
Postoperative hip fracture			
Iatrogenic pneumothorax	2.7	3.9	5,633
Decubitus ulcer	6.8	5.2	6,713
Postoperative hemorrhage/hematoma	5.1	3.9	7,863
Accidental puncture or laceration	3.2	1.4	3,359

Excess mortality, LOS, and charges computed from mean values for PSI cases and matched controls.

Predictive validity: Impact of preventing each PSI event on mortality, LOS, VA expenditures (ROI)

VA PTF 2001 analysis by Rivard et al., *Med Care Res Rev*; in press

Indicator	Δ LOS (d)	Δ Cost ($)
Postoperative septicemia	5.7	$13,395
Selected infections due to medical care	4.5	7,292
Postop abd/pelvic wound dehiscence	8.3	17,281
Postoperative respiratory failure	4.5	9,641
Postoperative physiologic or metabolic derangement		
Postoperative thromboembolism	4.5	9,064
Postoperative hip fracture		
Iatrogenic pneumothorax	3.4	5,476
Decubitus ulcer	3.7	5,552
Postoperative hemorrhage/hematoma	4.7	10,012
Accidental puncture or laceration	3.1	6,880

Excess mortality, LOS, and charges computed from GEE regression models (logged costs and LOS).

Predictive validity questionable based on NIS/VA

Zhan & Miller, *JAMA* 2003;290:1868-74
Rosen et al., *Med Care* 2005;43:873-84

Indicator	Δ Mort (%)	Δ LOS (d)	Δ Charge ($)
Birth trauma	-0.1 (NS)	-0.1 (NS)	300 (NS)
Obstetric trauma –cesarean	-0.0 (NS)	0.4	2,700
Obstetric trauma - vaginal w/out instrumentation	0.0 (NS)	0.05	-100 (NS)
Obstetric trauma - vaginal w instrumentation	0.0 (NS)	0.07	220
Complications of anesthesia*	0.2 (NS)	0.2 (NS)	1,600
Transfusion reaction*	-1.0 (NS)	3.4 (NS)	18,900 (NS)
Foreign body left during procedure†	2.1	2.1	13,300

*** All differences NS for transfusion reaction and complications of anesthesia in VA/PTF.**

† Mortality difference NS for foreign body in VA/PTF.

Criterion validity: POA coding in NY and CA

Houchens, Elixhauser, Romano. *Joint Comm J Qual Safety; in press*

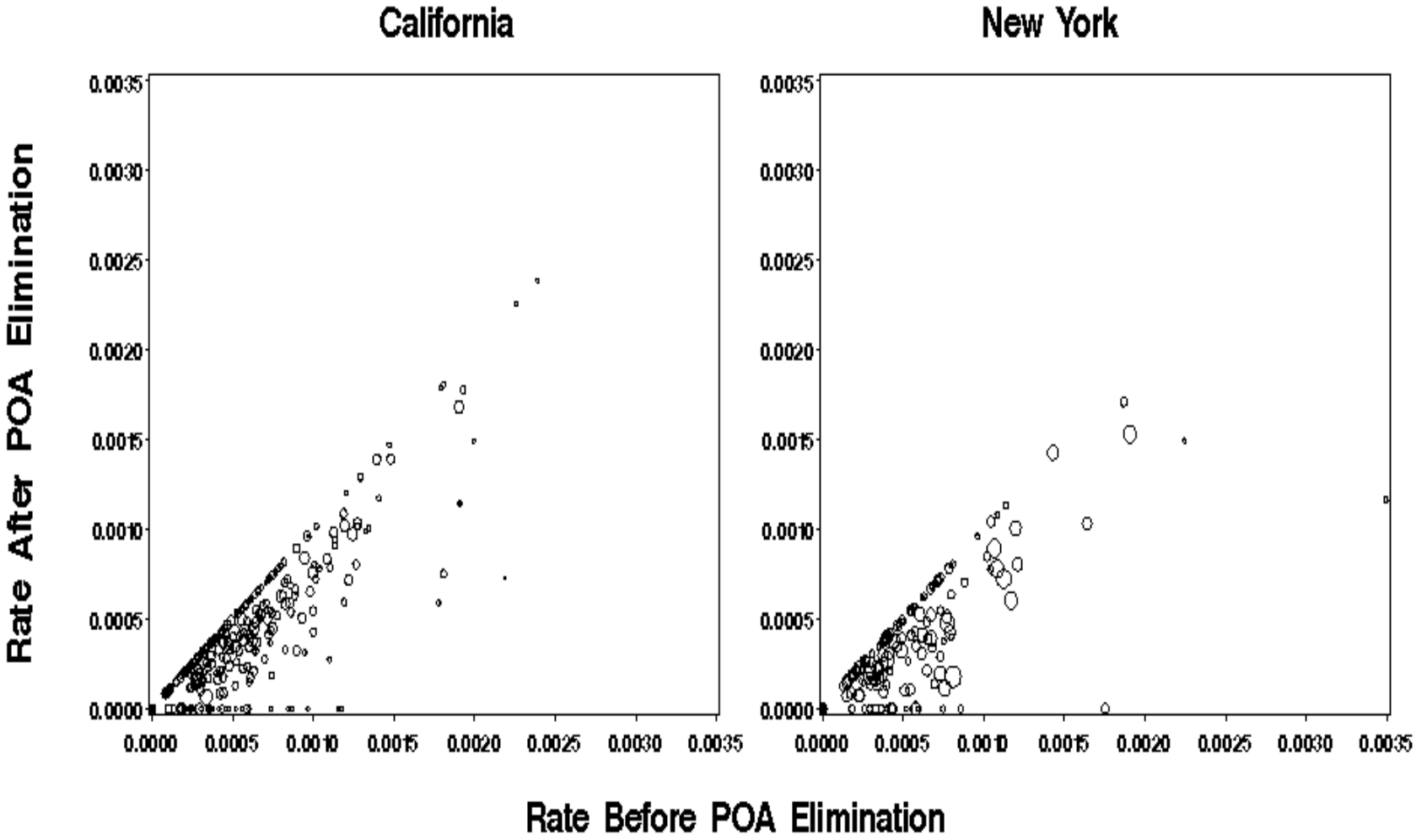
PSI	CA cases	%not POA	NY cases	%not POA
PSI 1: Complications of Anesthesia	934	100	284	100
PSI 3: Decubitus Ulcer	17,789	11	16,425	14
PSI 5: Foreign Body Left During Procedure	258	64	169	76
PSI 6: Iatrogenic Pneumothorax	1,256	73	782	65
PSI 7: Infection Due To Medical Care	4,286	65	2,406	65
PSI 8: Postop Hip Fracture	106	21	69	26
PSI 9: Postop Hemorrhage or Hematoma	1,800	79	859	71
PSI 10: Postop Physiologic and Metabolic Derangement	686	77	228	64
PSI 11: Postop Respiratory Failure	2,374	94	1,312	93
PSI 12: Postop PE or DVT	6,715	46	5,318	43
PSI 13: Postop Sepsis	865	73	453	70
PSI 15: Accidental Puncture/Laceration	9,107	87	3,743	87
PSI 16: Transfusion Reaction	12	58	9	78

Criterion validity: POA coding at Mayo hospitals

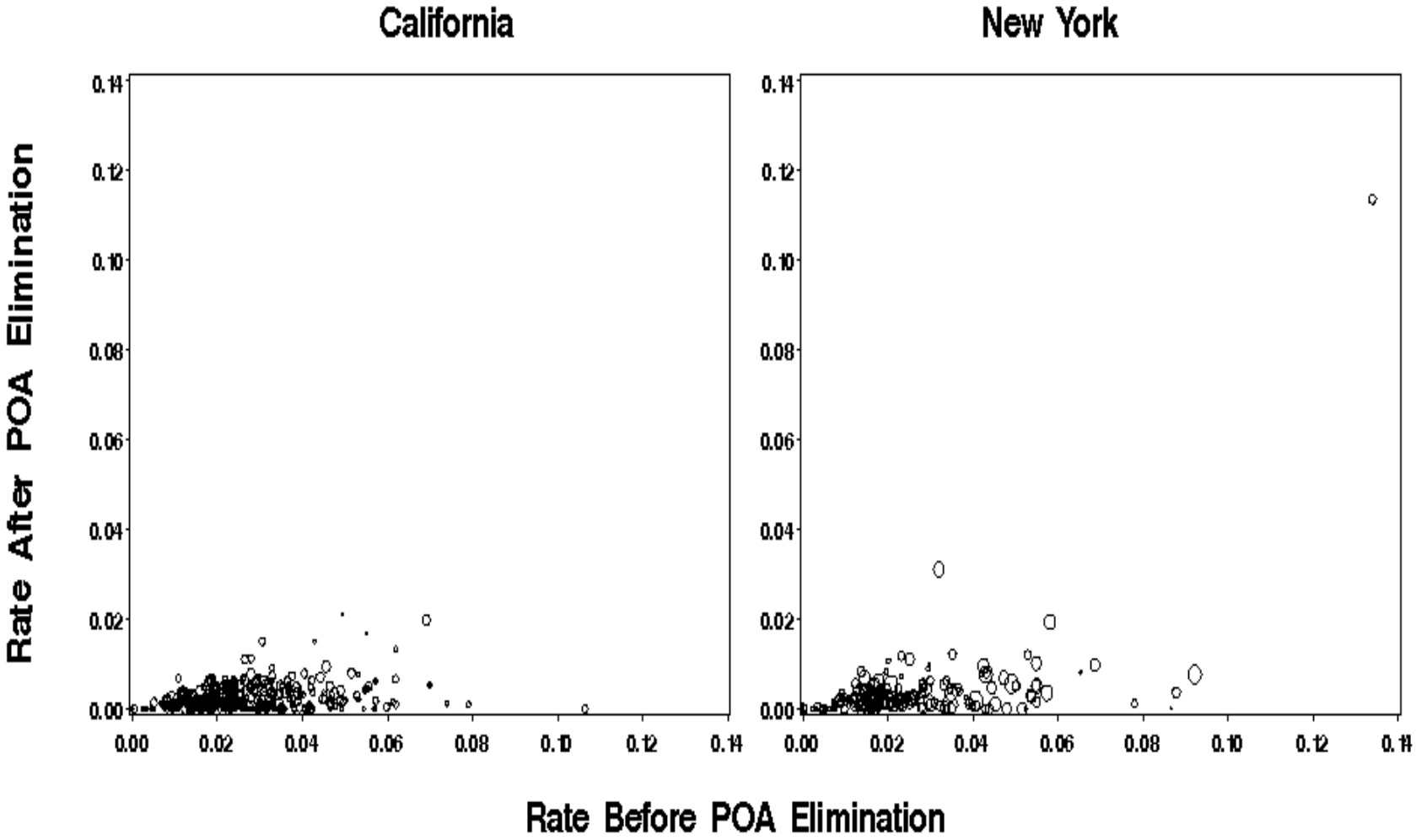
Naessens et al. *Med Care 2007;45:781-788* (ob/birth indicators excluded)

PSI	# cases	%not POA	AHRQ denomin	Corrected denomin
PSI 1: Complications of Anesthesia	16	6	29,681	29,681
PSI 3: Decubitus Ulcer	285	18	18,698	18,772
PSI 5: Foreign Body Left	13	54	58,206	58,206
PSI 6: Iatrogenic Pneumothorax	63	78	47,809	49,605
PSI 7: Infection Due To Medical Care	137	60	40,019	40,288
PSI 8: Postop Hip Fracture	9	22	16,770	16,788
PSI 9: Postop Hemorrhage or Hematoma	143	87	28,998	28,998
PSI 10: Postop Physiologic and Metabolic Derangement	48	46	23,654	23,669
PSI 11: Postop Respiratory Failure	123	74	18,270	18,270
PSI 12: Postop PE or DVT	492	40	28,876	28,949
PSI 13: Postop Sepsis	63	76	6,349	6,467
PSI 15: Accidental Puncture/Laceration	891	85	55,840	55,840
PSI 14: Postop Wound Dehiscence	34	100	7,637	7,637

Impact of POA coding in a hospital report card: postop hemorrhage



Impact of POA coding in a hospital report card: decubitus ulcer



Criterion validity: NY data linkage

Gallagher et al., *AHRQ Advances in Patient Safety*; Shufelt et al., *Am J Med Qual* 2005;20:210-8; Weller et al., *Joint Comm J Qual Safe* 2004;30:497-504

- Linking 30 day readmissions increased overall rate of PSIs:
  - Selected Infections from 2.02 to 2.52 per 1,000 eligible discharges (56% dialysis patients)
  - Postoperative DVT/PE from 9.3 to 11.3 per 1,000 (45% PE)
  - Postoperative Hemorrhage/Hematoma from 1.86 to 2.05 per 1,000
- Relaxing the dx-procedure linking criterion increased the rate of Postoperative Hemorrhage/Hematoma from 1.86 to 2.35 per 1,000
- Based on procedure codes for repair of iatrogenic injuries, the PSI for Accidental Punctures and Lacerations missed:
  - 27% of bladder injuries from hysterectomy
  - 21% of bowel injuries from cholecystectomy
  - 47% of abdominal injuries from lysis of adhesions
  - 54% of abdominal injuries from nephroureterectomy
  - 20% of spinal injuries from lumbar surgery

Criterion validity based on recoded data: CA Obstetric Validation Study

- Organized to assess validity of various potential measures of adverse events after delivery
- Cases sampled from OHSPD Patient Discharge Data Set (nonfederal acute care hospitals)
- Linked delivery, antepartum, postpartum records using SSN and DOB
- Stratified random cluster sample of 1,662 records from 52 hospitals (30% primary cesarean, 19% repeat cesarean, 51% vaginal)
- 97.1% of records received and reviewed by "expert" coder and obstetric nurse abstractor

Criterion validity in CA hospital discharge data

Romano PS, et al. *Obstet Gynecol* 2005;106(4):717-725

Indicator	Sensitivity		Pos Pred Value	
	Unweighted	Weighted	Unweighted	Weighted
FORMER AHRQ PSI: Obstetric trauma, Cesarean	11%	5%	67%	94%
HealthGrades: major comps, Vaginal	67%	58%	91%	91%
HealthGrades: major comps, Cesarean	55%	47%	64%	79%
AHRQ/JCAHO: 3rd or 4th degree laceration	90%	93%	90%	73%

Sensitivity = TP/(TP+FN) – are all the real cases captured?

PPV = TP/(TP+FP) – are all the flagged cases real?

Brubaker L, et al. *Obstet Gynecol* 2007;109(5):1141-5 reported sensitivity of 77%, specificity of 99.7%, based on a clinical research data set with 393 positive (3rd/4th degree tears) and 383 negative vaginal deliveries.

Criterion validity: Linking VA PTF and NSQIP abstraction

- NSQIP is a national project that collects and feeds back data on surgical outcomes from 123 VA facilities
- Trained surgical clinical nurse reviewers collect preoperative, intraoperative, and postoperative data.
- Patients are followed for 30 days after index procedure
- Sampling frame: veterans, FY 2001, mainland US acute care facilities
- VA's Patient Treatment File (similar to HCUP) was linked with NSQIP using SSN, dates of admission and discharge, facility number
- Final data file included 55,752 hospitalizations, representing 59,838 surgeries and 51,832 patients in 110 hospitals

Criterion validity of PSIs linked to NSQIP in VA hospitals

Romano PS, et al. *HSR* forthcoming?

Indicator	Sensitivity		PPV		Positive likelihood ratio	
	Current Inpatient	Better Inpatient	Current Inpatient	Better Inpatient		
Postoperative sepsis	32%	37%	44%	45%	123	131
Postoperative thromboembolism	56%	58%	22%	22%	65	64
Postoperative respiratory failure	19%	67%	74%	66%	194	134
Postop physiologic/ metabolic derangement	44%	48%	54%	63%	524	744
Postop abdominopelvic wound dehiscence	29%	61%	72%	57%	160	79

Sensitivity = TP/(TP+FN) – are all the real cases captured?

PPV = TP/(TP+FP) – are all the flagged cases real?

PLR = Sensitivity/(100-Specificity) – how many times more likely is the event?

NACHRI Pediatric Patient Safety Indicator (PSI) Collaborative

- Ran the AHRQ PSIs on NACHRI's Case Mix database, containing 3 million discharges from approximately 70 children's hospitals.
- Developed the NACHRI Pediatric PSI Collaborative, a self-selected group of 20 hospitals interested in further study
- Developed and released a PSI Toolkit with sample press release, op ed, Q&A, and background documents for hospitals to educate their communities on the relevance and utility of PSIs for pediatrics.
- Developed an online, secure chart review tool that allowed Collaborative participants to review the preventability of patients flagged as having any of 11 selected PSI events.
- Fostered a relationship with AHRQ and Stanford/UC Davis to update each other on NACHRI's findings and the PedQI development work.

NACHRI Pediatric Patient Safety Indicator (PSI) Collaborative

Collaborative Participants

- AL / Children's Hospital of Alabama / Dr. Crayton Farguson*
- CA / Lucile Packard CH at Stanford / Dr. Paul Sharek*
- CA / UC-Davis / Dr. James Marcin**
- DC / Children's National Medical Center / Dr. Tony Slonim*
- CA / Mattel Children's at UCLA / Ms. Mary Kimball**
- FL / All Children's / Dr. Jack Hutto*
- KY / Kosair Children's Hospital / Dr. Ben Yandell*
- LA / Children's Hospital New Orleans / Ms. Cindy Nuesslein*
- MD / Johns Hopkins Children's Center / Dr. Marlene Miller*
- MA / Children's Hospital Boston / Drs. Daniel Nigrin and Don Goldmann
- MI / C.S. Mott Children's Hospital – U Mich / Dr. Aileen Sedman*
- MO / Children's Mercy Kansas City / Dr. Cathy Carroll*
- OH / The Children's Medical Center Dayton / Dr. Thomas Murphy*
- OH / Cincinnati Children's Medical Center / Drs. Uma Kotagal, Joseph Luria*
- OH / Children's Hospital Columbus / Dr. Thomas Hansen*
- OH / Children's Hospital MC of Akron / Dr. Michael Bird
- PA / Children's Hospital of Philadelphia / Drs. James Stevens, Joel Portnoy
- TX / Texas Children's Hospital / Dr. Joan Shook*
- TX / Children's Medical Center of Dallas / Dr. Fiona Levy, Ms. Kathy Lauwers*
- WI / Children's Hospital of Wisconsin / Dr. Matthew Scanlon*

Criterion validity based on clinician review: AHRQ PSIs in Children's Hospitals

Sedman A, et al. *Pediatrics* 2005;115(1):135-145

PSI	No. reviewed (total events)	Preventable (PPV %)	Nonpreventable	Unclear
Complications of anesthesia	74 (503)	11 (15%)	37	25
Death in low-mortality DRG	121 (1282)	16 (13%)	89	16
Decubitus ulcer	130 (2300)	71 (55%)	47	10
Failure to rescue	187 (5271)	15 (8%)	148	11
Foreign body left in	49 (235)	25 (51%)	14	10
Postop hemorrhage or hematoma	114 (1571)	40 (35%)	51	23
Iatrogenic pneumothorax	114 (1113)	51 (45%)	42	21
Selected infection 2° to med care	152 (7291)	63 (41%)	45	39
Postop DVT/PE	126 (1956)	36 (29%)	61	29
Postop wound dehiscence	41 (232)	19 (46%)	16	6
Accidental puncture or laceration	133 (4020)	86 (65%)	19	26

Key findings from NACHRI's PSI physician case reviews

"…while 40% to 50% may seem low for positive predictive value, in terms of real patients, this means that 4 or 5 out of 10 children had a preventable event for this indicator. This is worth looking at and the things we are finding in some instances, will allow for immediate changes that may impact outcomes for future patients." [Collaborative physician reviewer]

Examples from NACHRI's PSI physician case reviews

- During removal of non functioning port cath the end of the catheter was noted to be "irregular and not smoooth cut". It appeared the tip had been embolized for an unknown duration…
- During replacement of pacemaker lead, a fragment of the lead broke off, embolized and ended up lodged (puncture) in the anterolateral papillary muscle.
- No notation in original operative note or nursing record that sponge/needle counts were done and correct.
- Count was reported as correct. Sponge discovered on xray due to complaints of abdominal pain by patient.
- Child with bone tumor who had mandible removed with subsequent bone graft and much packing in wound. This was supposedly removed before extubation, but at the time of extubation a remaining pack blocked her airway causing reintubation with pack removal.

Romano's Conclusions

- Several studies addressing PSI/PDI validity have been published, and several more are on the way.
- Most PSIs have domestic and international consensual (face) validity.
- Most PSIs have strong evidence of predictive (construct) validity in both VA and non-VA data.
- 3 PSIs have significant "POA problems": postoperative DVT/PE, postoperative hip fracture, decubitus ulcer.
- Linked readmissions data may be helpful in ruling in/out early discharge as a cause of low PSI rates.
- "Complications of Anesthesia" may be problematic.
- Coding validity looks strong for obstetric PSIs, and mixed for postoperative PSIs, but very limited data.
- Case review suggests 33-67% of most PSIs are potentially preventable (in children), except lower for death-based PSIs, DVT/PE, and complications of anesthesia.

Questions?