Outcomes Studies & Clinical Practice

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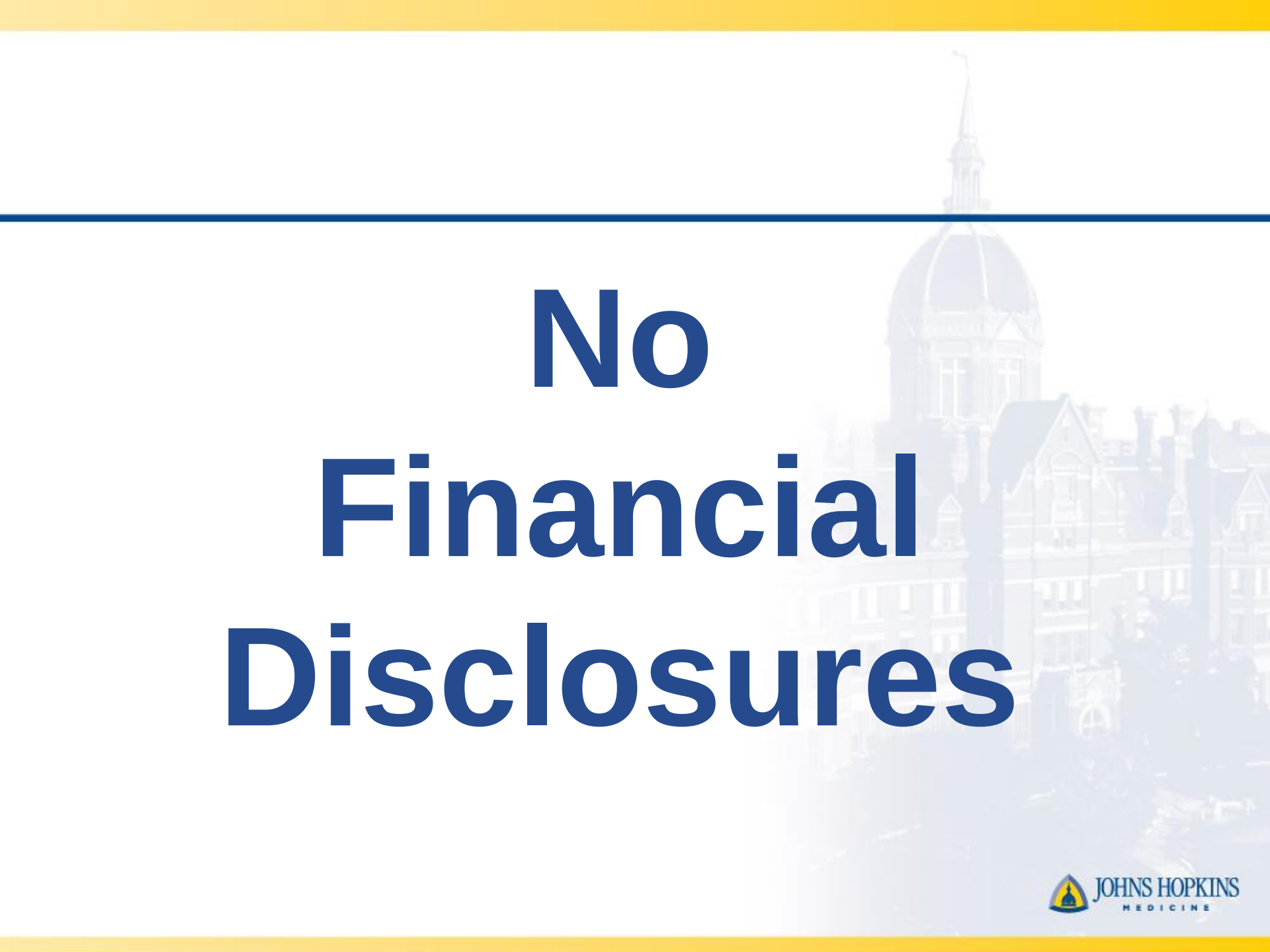
No Financial Disclosures



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McKinsey Quarterly

MCKINSEY GLOBAL INSTITUTE

Are you ready for the era of 'big data'?

Brad Brown, Michael Chui, and James Manyika

Radical customization, constant experimentation, and novel business models will be new hallmarks of competition as companies capture and analyze huge volumes of data. Here's what you should know.

The top marketing executive at a sizable US retailer recently found herself perplexed by the sales reports she was getting. A major competitor was steadily gaining market share across a range of profitable segments. Despite a counterpunch that combined online promotions with merchandizing improvements, her company kept losing ground.

Hospital Compare

Where do you want to find a hospital?

Search Information

Location - ZIP Code or City, State

e.g. 10009 or New York, NY

Search type [?]

- (•) General
- ( ) Medical Conditions
- ( ) Surgical Procedures

Hospital Spotlight

Click on the new Patient Safety Tab during your hospital search to see new information **Hospital Acquired Conditions** and **Serious Complications and Deaths.**

In January, Medicare will report new measures for heart attack care and surgical care. Also, for the first time, we will be reporting information on central line infections from the **Centers for Disease Control's National Healthcare Safety Network.**

You can now visit **Medicare's Hospital Value Based**

Hospital Compare

« Back to Results

Search Type [?]

- ○ General
- ○ Medical Conditions
  - Select a Condition
- ◉ Surgical Procedures
  - Abdominal
  - Hernia

Modify Results

View All Measures »

- Process of Care Measures
- Outcome of Care Measures
- Use of Medical Imaging

Survey of Patients' Hospital Experiences

HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) is a national survey that asks patients about their experiences during a recent hospital stay. Use the results shown here to compare hospitals based on ten important hospital quality topics. **Read more information about the survey of patients' hospital experiences.**

View Graphs » View Tables »

	JOHNS HOPKINS HOSPITAL, THE	MARYLAND GENERAL HOSPITAL	UNIVERSITY OF MARYLAND MEDICAL CENTER
	600 NORTH WOLFE STREET BALTIMORE,MD 21287 (410) 955-9540	827 LINDEN AVE BALTIMORE,MD 21201 (410) 225-8996	22 S GREENE ST BALTIMORE,MD 21201 (410) 328-0313
	Add To My Favorites	Add To My Favorites	Add To My Favorites
Patients who reported that their nurses "Always" communicated well.	78%	74%	75%

Process of Care Measures
Outcome of Care Measures
Use of Medical Imaging
Survey of Patients' Hospital Experiences
Patient Safety Measures
Medicare Payment and Volume

	Add To My Favorites	Add To My Favorites	Add To My Favorites
Patients who reported that their nurses "Always" communicated well.	**78%**	**74%**	**75%**
Patients who reported that their doctors "Always" communicated well.	**79%**	**80%**	**79%**
Patients who reported that they "Always" received help as soon as they wanted.	**62%**	**55%**	**60%**
Patients who reported that their pain was "Always" well controlled.	**71%**	**63%**	**68%**
Patients who reported that staff "Always" explained about medicines before giving it to them.	**62%**	**55%**	**64%**
Patients who reported that their room and bathroom were "Always" clean.	**67%**	**63%**	**62%**
Patients who reported that the area around their room was "Always" quiet at night.	**56%**	**63%**	**53%**
Patients at each hospital who reported that YES, they were			

Objectives

- Able to contrast differences between randomized clinical trails & outcomes research
- Review examples of how outcomes research is impacting our understandings of pediatric surgical disease & clinical practice

Outcomes Research in Pediatric Surgery

Definition

Analysis of pediatric surgical outcomes and their predictors at different levels in the healthcare delivery system

Outcomes research defined

- Relatively New Field
- Outcomes Research vs. Clinical Trials
- Clinical Trials → “Efficacy”

  Patient Outcome in Controlled Setting
- Outcomes Research → “Effectiveness”

  Patient Outcome in Natural Setting

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Clinical Trials vs Outcomes Research

Clinical Trials

- Utilize patient subsets
  - Inclusion criteria
- Homogenous patient populations
- Control patient differences by randomization
- Not critically important to track patient factors

Outcomes Research

- All patients
  - Databases
- Heterogeneous patient populations
- Control patient differences in analysis
- Important to track patient factors for analysis

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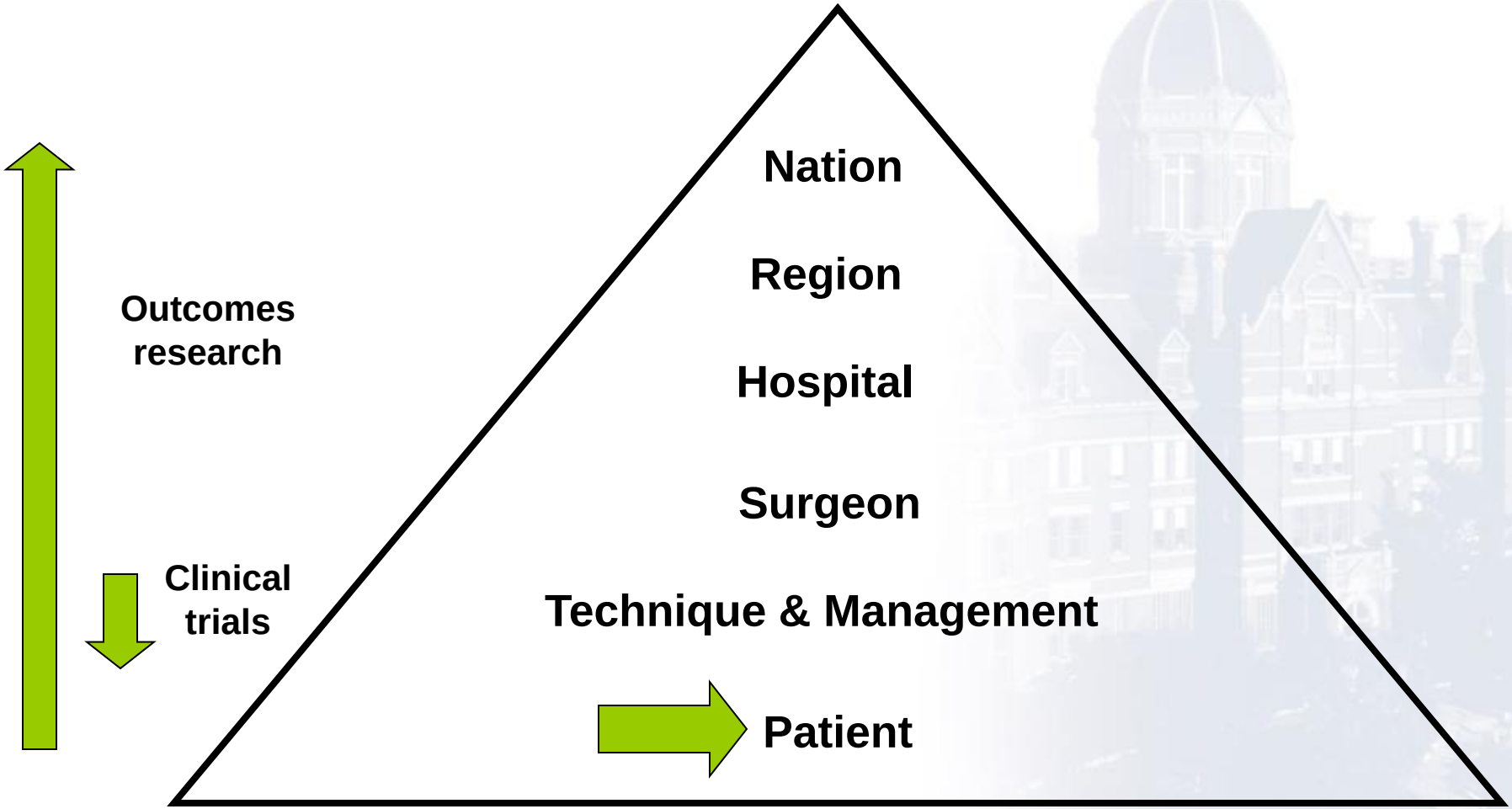
Outcomes research further defined

- Factors beyond the patient level

Hierarchy of Influence of Pediatric Surgery Outcomes



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Objectives

- Able to contrast differences between randomized clinical trails & outcomes research
- Review examples of how outcomes research might change our understanding of pediatric surgical disease and impact clinical practice

How does Outcomes Research Affect Clinical Practice? Two Examples

- Assessment of Operative Risk
- Disease management: Intussusception

Operative Mortality Risk: Primer

- Ex-24 week, 750 g infant on high frequency oscillator, three vasopressors with free air on DOL #3

- Ex- 36 week infant left CDH hernia with mild pulmonary hypertension and s/p CT for left pneumothorax now DOL #7

Pediatric Surgery Outcomes: Assessing Operative Risk

Patient + Operation = Operative Risk

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Objective

Develop a clinical risk index to assess operative risk in children that would be valid across multiple specialties

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Methods

- Inclusion criteria: Patients under 18 years of age with inpatient operative procedure from 1988-2005 nationwide state inpatient data
- Evaluated 285 co-morbidity categories as defined by Clinical Classification Software for independent predictive values for mortality.
- 69 co-morbidities plus age and gender selected as independent variables in final model for multivariate analysis
- Point values from the multivariate logistic regression model generated an 11-category scale which was applied to all patients

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Methods

- Model characteristics were evaluated with receiver operating characteristics (ROC) on development and validation datasets
- Validation sets included:
  - Kids Inpatient Database (KID) from 2006
  - California patient discharge data (OSHPD) from 2005-2007 (contains present on admission variable)
- The Charlson comorbidity index was compared to our index in the 1st validation dataset

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Results

Receiver Operating Characteristics (ROC) of Models	
Model	C-Statistic
Training dataset (NIS & KID 1988-2005)	
Original model	0.955
11-category point scale	0.949 (0.947-0.950)
Validation dataset (KID 2006)	
11-category point scale	0.960 (0.952-0.967)
Charlson index	0.596 (0.575-0.616)
Validation dataset (OSHPD 2005-2007)	
11-category point scale	0.901 (0.885-0.917)

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REVIEW OF SYSTEMS

Check the boxes where current or recent disease is present and add the points to grade severity.

Age		
age <24 months	☐	+ 1
subtotal		
Perinatal		
Hypoxia, asphyxia or aspiration during birth	☐	+ 2
Birth trauma	☐	**+ 1**
Short gestation; low birth weight; or fetal growth retardation	☐	0
Perinatal jaundice	☐	**0**
Other:	☐	0
subtotal		
Cardiovascular		
Cardiac arrest or ventricular fibrillation or flutter	☐	+ 3
Acute myocardial infarction	☐	**+ 1**
Coronary atherosclerosis or other ischemic heart disease	☐	+ 1
Pulmonary vascular disease (e.g. PE, pulmonary HTN)	☐	**+ 1**
Aortic; peripheral; or visceral artery aneurysms/dissection	☐	+ 1
Congenital cardiovascular anomalies	☐	**+ 1**
Peri-;endo-; or myocarditis; cardiomyopathy or tamponade (except caused by TB or STD)	☐	+ 1
Aortic or peripheral arterial embolism or thrombosis	☐	**+ 1**
Ventricular tachycardia or other cardiac dysrhythmias	☐	0
Congestive heart failure	☐	**0**
Other:	☐	0
subtotal		
Pulmonary		
COPD or bronchiectasis	☐	+ 1
Respiratory failure; insufficiency; arrest (adult)	☐	**+ 1**
Cystic fibrosis	☐	+ 1
Respiratory distress syndrome	☐	**+ 1**
Pneumonia (except that caused by TB or STD)	☐	0
Influenza	☐	**0**
Asthma	☐	0
Aspiration pneumonitis	☐	**0**
Other:	☐	0
subtotal		
Renal/Genitourinary		
Acute or renal failure	☐	+ 2
Chronic renal failure	☐	**+ 1**
Urinary tract infections or unspecified cystitis	☐	0
Other:	☐	**0**
subtotal		
Endocrine		
Thyroid disorders or other endocrine disorders	☐	+ 1
Diabetes mellitus or complications	☐	**+ 1**
Other:	☐	0
subtotal		

Gastrointestinal		
Peritoneal or intestinal abscess (except appendiceal); Peritonitis (except caused by TB or STD)	☐	+ 1
Liver disease (e.g. Cirrhosis, increased LFTs)	☐	**+ 1**
Gastrointestinal hemorrhage	☐	+ 1
Gastroduodenal ulcer, gastritis or duodenitis (non bleeding)	☐	**0**
Intestinal obstruction	☐	0
Biliary tract disease	☐	**0**
Pancreatic disorders (not diabetes)	☐	0
Other:	☐	**0**
Heme/Onc		
Leukemia	☐	+ 2
Lymphomas or reticuloendothelial neoplasms	☐	**+ 2**
Primary malignant tumor of adrenals or paraganglia	☐	+ 1
Hepatic tumors	☐	**+ 1**
CNS or miscellaneous intracranial or intraspinal neoplasms	☐	+ 2
Primary malignant bone or articular cartilage tumors	☐	**+ 1**
Soft tissue sarcomas	☐	+ 1
Immunity disorders (except AIDS)	☐	**+ 1**
Coagulation or hemorrhagic disorders	☐	+ 1
Renal tumors	☐	**0**
Disease of white blood cells (e.g. Lympocytosis, -penia)	☐	0
Other:	☐	**0**
Musculoskeletal and soft tissue		
SLE or connective tissue disorders	☐	+ 1
Chronic ulcer of skin	☐	**0**
Spondylosis; intervertebral disc disorders; other back problems	☐	0
Other:	☐	**0**
Trauma		
Intracranial Injury	☐	+ 3
Crushing injury or internal injury	☐	**+ 2**
Firearm	☐	+ 2
Poisoning by nonmedicinal substances	☐	**+ 2**
Suicide or intentional self-inflicted injury	☐	+ 2
Shock	☐	**+ 1**
Drowning/submersion	☐	+ 1
Motor vehicle traffic (MVT)	☐	**+ 1**
Suffocation	☐	+ 1
Pedal cyclist; not MVT (fall from bicycle)	☐	**0**
Skull or face fractures	☐	0
Fracture of long bone or spine	☐	**0**
Open wounds of head; neck; or trunk	☐	0
Superficial soft tissue injury; contusion	☐	**0**
Other:	☐	0

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Lymphomas or reticulo		
Primary malignant tum		
Hepatic tumors		
CNS or miscellaneous i		
intraspinal neoplasms		
Primary malignant bon		
Soft tissue sarcomas		
Immunity disorders (ex		
Coagulation or hemorrh		
Renal tumors		
Disease of white blood		
Other:		
Musculoskeletal and so		
SLE or connective tissue		
Chronic ulcer of skin		

Training Dataset			Validation Dataset	
Score	Total	Death (%)	Total	Death (%)
0	1,421,741	428 (0.0)	53,809	7 (0.0)
1	394,833	980 (0.2)	15,164	19 (0.1)
2	143,142	2722 (1.9)	6,225	57 (0.9)
3	61,822	3006 (4.9)	2,919	90 (3.1)
4	27,961	2726 (9.7)	1,040	80 (7.7)
5	13,964	2876 (20.6)	683	88 (12.9)
6	8,412	2186 (26.0)	373	76 (20.4)
7	3,521	1273 (36.2)	158	59 (37.3)
8	1,638	773 (47.2)	66	26 (39.4)
9	756	415 (54.9)	27	9 (33.3)
>=10	492	311 (63.2)	40	18 (45.0)

Limitations

- Risk index focused on mortality
- The index was developed utilizing a dataset that did not have present on admission variable although validated successfully in the OSHPD discharge database
- Comparison index being utilized was Charlson index
- Clinical utility still remains to be tested

Objectives

- Able to contrast differences between randomized clinical trails & outcomes research

- Review examples of how outcomes research might impact clinical practice
    - Risk Assessment
    - Intussusception

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Adult Intussusception (AI)

- Prior to era of outcomes research, data were lacking as AI was rare occurred at a rate 1 to 20,000-45,000 admissions
- Treatment: ‘Always operative’ as risk of malignancy 50-80% seen in small case series or institutional reviews

Adult Intussusception (AI): Impact of Outcomes Studies

- Large Databases of deidentified data as well as CT Scan data revealed:

  Enteric Intussusception – 0 to 1.8% Malignant
  Colonic Intussusception – 5-40% Malignant

- Changed Current Management: Increased role for expectant management and laparoscopy, reduction with limited resection vs. en bloc resection

- Previously reported high rates may have been due to selection and reporting bias

Conventional Wisdom

- **Intussusception**: 5 to 8 months of age; seldom after age 2

Case Selection

Inclusion Criteria:

- age < 18 years
- ICD-9 Diagnosis Codes Intussusception (INT) & Surgical or Radiologic Procedure

Excluded:

- Patients admitted on day of life zero
- Length of stay > 95th percentile (11 days)

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Results

512,519 Total Cases Screened

5,193 Cases of Intussusception

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Results – Age at Presentation

Intussusception

“5 to 8 months of age, seldom after age two”

Median age: 15 months

Mean age: 36 months

Pediatric Intusseception

Procedure	n	%
Radiologic Reduction	2,338	45.02
Exploration	392	7.55
Operative Reduction	615	11.84
Smal Bowel Resection	933	17.97
Large Bowel Resection	875	16.85
Lg/Sm Bowel Resection	40	0.77
Total	5,193	100

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Conclusions I

- Differing Role of Outcomes Research vs. Clinical Trials
- Outcomes Research can guide clinical decision making in a more structured way: novel risk score which reliably predicts inpatient mortality
- First step in development of systems-based assessment of operative risk
- Other endpoints beyond mortality: complication vs. PDIs, SSIs, Quality of Life Measures
- Better data – deidentified databases moving to NSQIP and other better aggregate data sources

Conclusions II

- Outcomes research is changing our understanding of rare diseases: Intussusception
- Much more to be learned about gathering and analyzing data in pediatric surgery i.e. ‘big data’ is coming - we need to be prepared

Thank You