QUALITY IN THE PEDIATRIC CATH LAB

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DISCLOSURE STATEMENT

Speakers:

Ralf Holzer, MD, MSc, FSCAI

- Have no relevant financial relationships to disclose

- Will discuss some off-label or investigational use of products

HOW HAS QUALITY IN MEDICINE BEEN DEFINED IN THE PAST ?

1933

"GOOD MEDICAL CARE IS THE KIND OF MEDICINE PRACTICED AND TAUGHT BY THE RECOGNIZED LEADERS OF THE MEDICAL PROFESSION"

Lee and Jones, The Fundamentals of Good Medical Care. Chicago, University of Chicago Press, 1933

1933: "8 ARTICLES OF FAITH"

- Good Medical Care:
  - Is limited to the practice of rational medical care based on the medical sciences
  - Emphasizes prevention
  - Requires intelligent cooperation between the lay public and practitioners of scientific medicine
  - Treats the individual as a whole

Lee and Jones, The Fundamentals of Good Medical Care. Chicago, University of Chicago Press, 1933

1933: "8 ARTICLES OF FAITH"

- Good Medical Care
  - Maintains a close and continuing personal relationship between physician and patient
  - Coordinates with social welfare work
  - Coordinates all types of medical services
  - Applies the application of all the necessary services of modern scientific medicine to the needs of all the people.

Lee and Jones, The Fundamentals of Good Medical Care. Chicago, University of Chicago Press, 1933

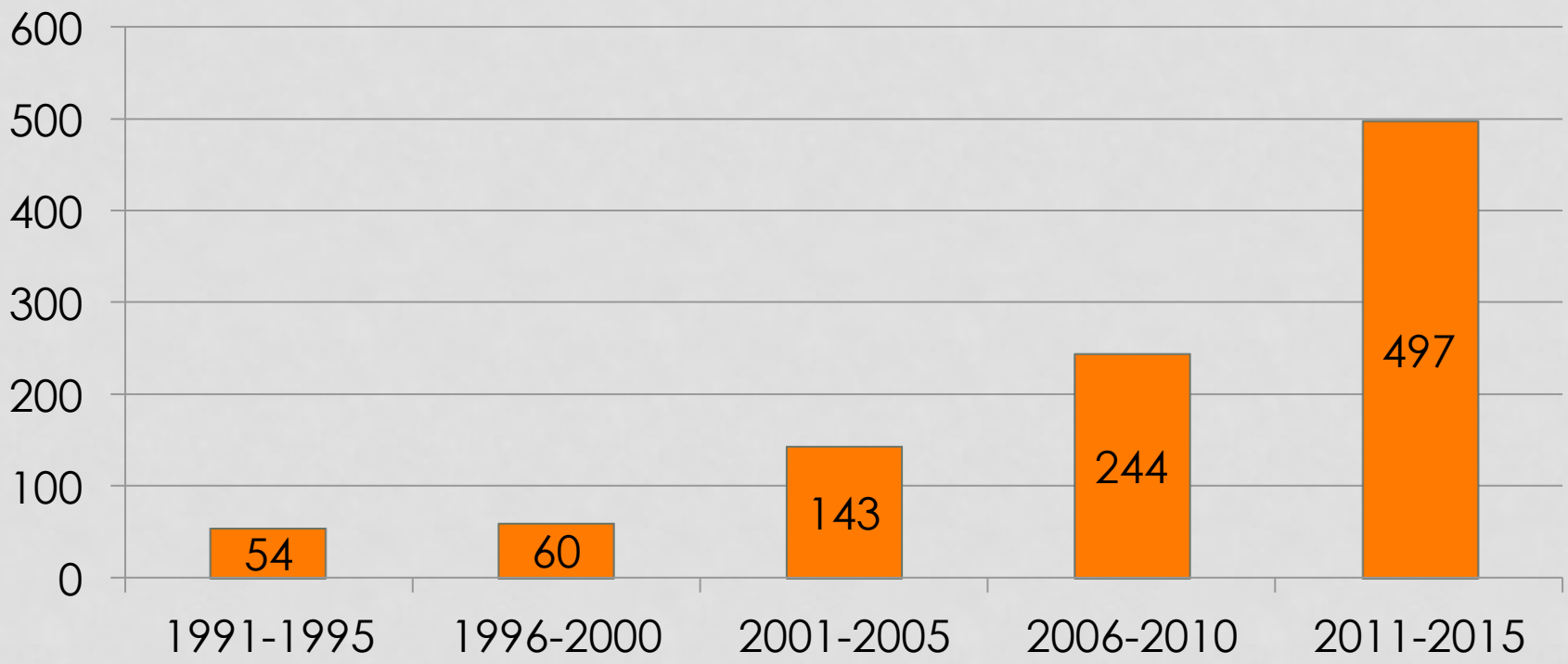
COMMITTEE ON QUALITY HEALTH CARE IN AMERICA 2003

- All health care organizations … should pursue six major aims; specifically, health care should be ….
  - Safe
  - Effective
  - patient-centered
  - Timely
  - Efficient
  - Equitable

QUALITY IN HEALTHCARE

- Different objectives (physician, patient, payer)
- Quality Assurance (QA)
  - Compliance with existing standard
- (Continuous) Quality Improvement (CQI)
  - Standard methodology (PDSA cycles)
- Measures of quality:
  - Structure (what is in place?)
  - Process (how do you do it?)
  - Outcome (what is the result?)

PUBMED: CONGENITAL HEART DISEASE AND QUALITY



INCREASING AWARENESS TO INCREASES QUALITY

Member of Qatar Foundation

Characterization of Radiation Exposure and Effect of a Radiation Monitoring Policy in a Large Volume Pediatric Cardiac Catheterization Lab

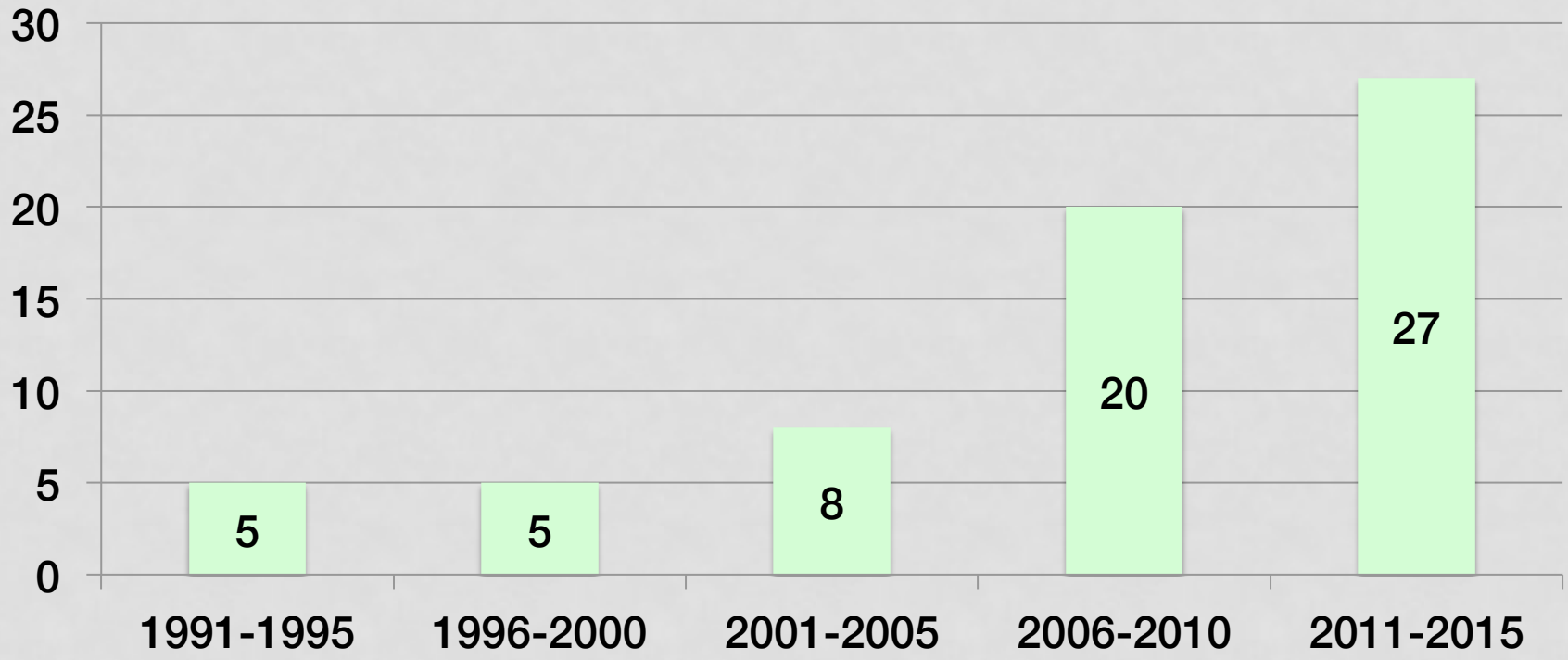
George R. Verghese,[1] MD, MBA, Doff B. McElhinney,[1] MD, Keith J. Strauss,[2] MSc, and Lisa Bergersen,[1*] MD, MPH

"… After the introduction of a radiation threshold monitoring and notification policy, there was a statistically significant decrease in radiation dose …"

Verghese et al. Catheter Cardiovasc Interv. 2012. 79(2):294-301

WHAT ABOUT QUALITY IN THE CONGENITAL CARDIAC CATHETERIZATION LABORATORY ?

PUBMED: CONGENITAL HEART DISEASE AND QUALITY AND CARDIAC CATHETERIZATION



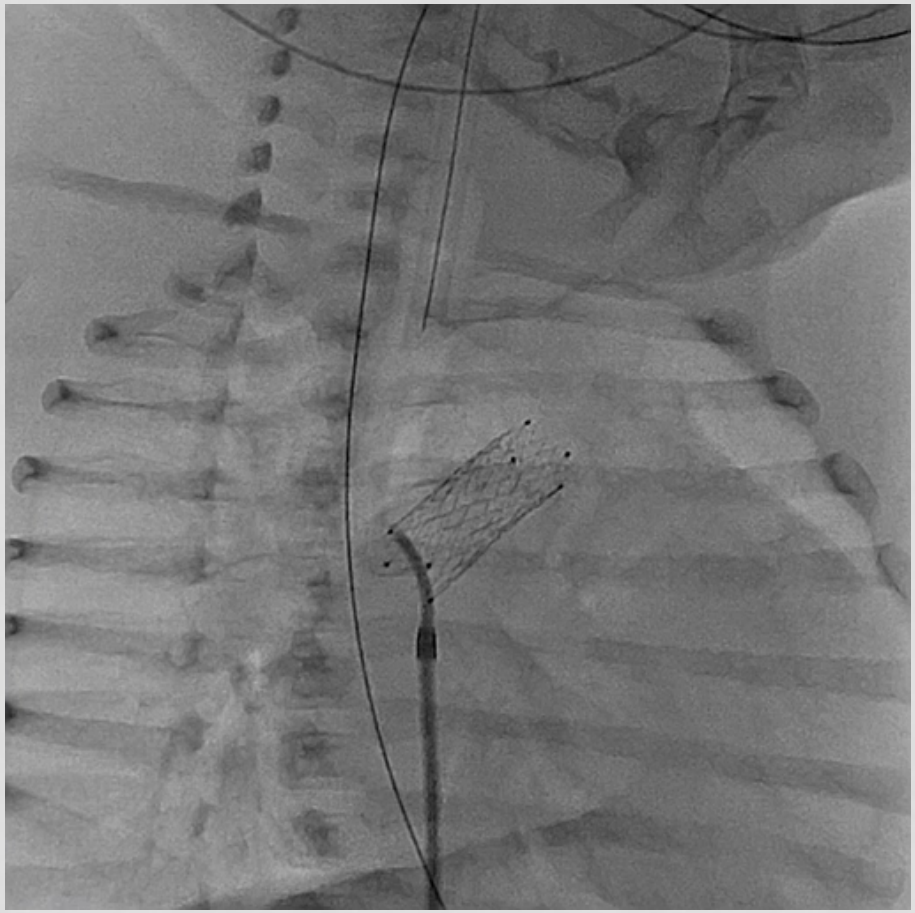
QUALITY IN THE CONGENITAL CATH LAB – PROBLEMS PRIOR TO 2003:

- No agreed nomenclature for procedures types
- No agreed definitions for complications or severity classification
- Outcomes:
  - single center
  - procedure/technology specific
- No active registries
- No adjustment methods for case mix complexity

CONGENITAL CATH LAB: OUTCOME REPORTING PRIOR TO 2003

Year	1974	1985	1992	1998	1999
Journal	Circulation	Ped Card	JACC	JACC	Card Yng
Name	Stanger	Cohn	Cassidy	Vitiello	Zeevi
Institution	San Franc	Boston	San Franc	Toronto	Tel-Aviv
Procedures/Year	580	312	366	825	94
Total Patients	1160	312 (<1yr)	1037	4952	425
Interventions	??	>12 %	15 %	29 %	100 %
Total complications	14.60 %	25.01 %	11.08 %	11.30 %	11.50 %
Major complications	2.93 %	9.61 %	1.44 %	2.05 %	1.40 %
Death	0.26 % (+x)	3.80 %	0.38 %	0.14 %	0.50 %
Arterial complications	3.10 %	5.12 %	3.76 %	3.53 %	3.80 %
Embolism (device/air)	0 %	1.28 %	0.09 %	0.46 %	1.40 %
Perforation/Rupture/ Major Bleed	0.17 %	0.96 %	0.29 %	0.30 %	0.20 %
Arrhythmia/ST changes	8.62 %	9.93 %	2.14 %	2.58 %	2.60 %

SOME ADVERSE EVENTS WILL ALWAYS BE REPORTED !



2 month old infant s/p Hybrid stage 1

REPORTING THE OBVIOUS ……

CATHETERIZATION OUTCOME REPORTING … MOVING ON

- Individual Center reports of new techniques
- VACA Registry in 1990's
- FDA sponsored device trials
- Investigator organized registries
  - CCISC
  - MAGIC
  - C3PO
- Larger societal registries
  - IMPACT

QUALITY IN THE CONGENITAL CATH LAB – CHALLENGES:

- Heterogeneity of patients
- Variation in case complexity
- Variation in case acuity
- Classical outcome parameters often not helpful
  - Low mortality
  - Low incidence of important adverse events (AE)
- Lack of evidence based markers of procedural efficacy

HOW TO MAKE EQUITABLE COMPARISONS OF OUTCOME ?

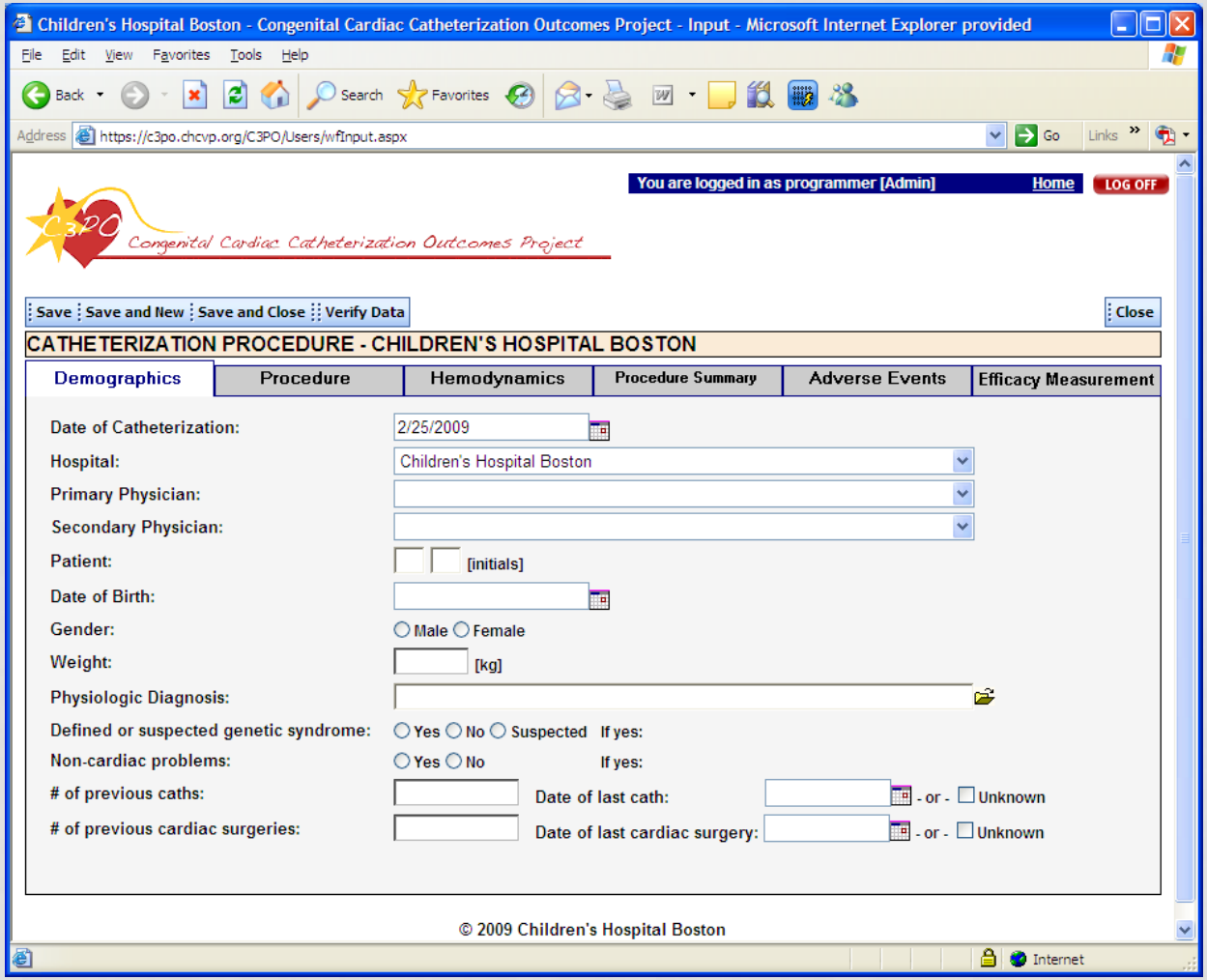
THE CONGENITAL CARDIAC CATHETERIZATION PROJECT ON OUTCOMES (C3PO)

- Started with local outcomes database at BCH
- Method for comparing outcomes at BCH
  - Is method generalizable?
- Multi-center registry (C3PO):
  - Assess and compare outcomes in pediatric and congenital cardiac catheterization

C3PO - DATA COLLECTION

- Data prospectively collected
- Web-based tool
- Stored on a secure server
- All catheterization cases (not EP)
- Data collection started February 2007
- All identification information encrypted

C3PO - INTERFACE



C3PO - ADVERSE EVENT SEVERITY

Severity Level 1 – None	**No harm, no change in condition, may have required monitoring to assess for potential change in condition with no intervention indicated.**
Severity Level 2 – Minor	**Transient change in condition, not life threatening, condition returns to baseline, required monitoring, required minor intervention such as holding a medication, obtaining lab test(s).**
Severity Level 3 – Moderate	**Transient change in condition may be life threatening if not treated, condition returns to baseline, required monitoring, required intervention such as reversal agent, additional medication, transfer to ICU for monitoring, or moderate transcatheter intervention to correct condition.**
Severity Level 4 – Major	**Change in condition, life threatening if not treated, change in condition may be permanent, may have required ICU admit or emergent readmit to hospital, may have required invasive monitoring, required interventions such as electrical cardioversion or unanticipated intubation or required major invasive procedures or trans-catheter interventions to correct condition.**
Severity Level 5 – Catastrophic	**Any death and emergent surgery or heart lung bypass support (ECMO) to prevent death with failure to wean from bypass support.**

ADVERSE EVENTS IN CONGENITAL CATHETERIZATION

THE C3PO REGISTRY

Catheterization and Cardiovascular Interventions 75:389–400 (2010)

PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Adverse Event Rates in Congenital Cardiac Catheterization – A Multi-Center Experience

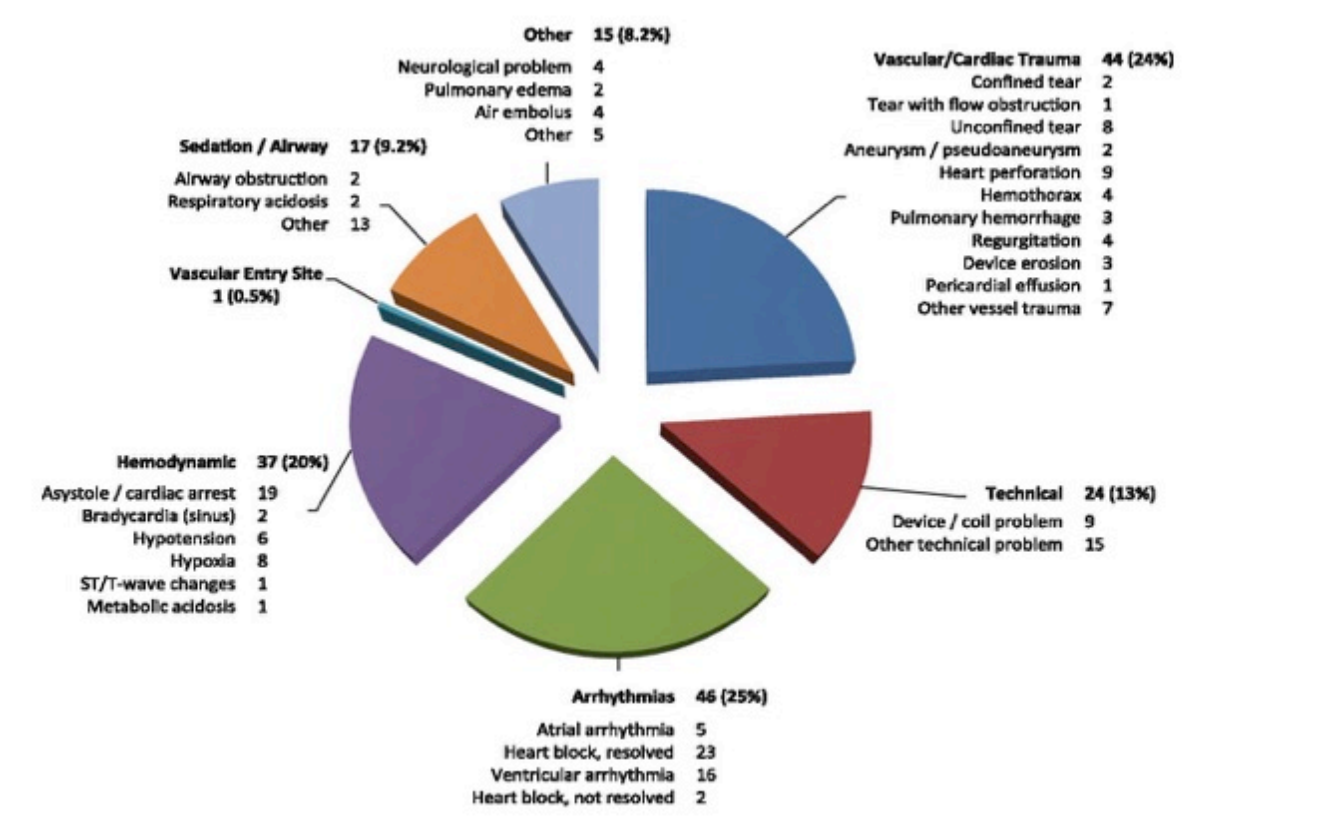
Lisa Bergersen,[1*] MD, Audrey Marshall,[1] MD, Kimberlee Gauvreau,[1] ScD, Robert Beekman,[2] MD, Russel Hirsch,[2] MD, Susan Foerster,[3] MD, David Balzer,[3] MD, Julie Vincent,[4] MD, William Hellenbrand,[4] MD, Ralf Holzer,[5] MD, John Cheatham,[5] MD, John Moore,[6] MD, James Lock,[1] MD, and Kathy Jenkins,[1] MD, MPH

Objectives: To describe case mix variation among institutions, and report adverse event rates in congenital cardiac catheterization by case type. Background: Reported adverse event rates for patients with congenital heart disease undergoing cardiac catheterization vary considerably, due to non-comparable standards of data inclusion, and highly variable case mix. Methods: The Congenital Cardiac Catheterization Outcomes Project (C3PO) has been capturing case characteristics and adverse events (AE) for all cardiac catheterizations performed at six pediatric institutions. Validity and completeness of data were independently audited. Results: Between 2/1/07 and 4/30/

ADVERSE EVENT RATES IN CONGENITAL CARDIAC CATHETERIZATION

- Incidence of any AE (level 1-5):
  - Interventional cases 19%
  - Diagnostic cases 10%
- Incidence of higher severity AE (level 3-5):
  - Interventional cases 9%
  - Diagnostic cases 5%
- Incidence of life threatening AE:
  - Level 4 1.4%
  - Level 5 (death) 0.2%

C3PO: TYPES OF LIFE THREATENING AE



Line et al. Pediatr Cardiol. 2014. 35:140-148

C3PO: PROCEDURE TYPE RISK GROUPS

Procedure-Type Risk Categories for Pediatric and Congenital Cardiac Catheterization

Lisa Bergersen, MD, MPH; Kimberlee Gauvreau, ScD; Audrey Marshall, MD; Jacqueline Kreutzer, MD; Robert Beekman, MD; Russel Hirsch, MD; Susan Foerster, MD; David Balzer, MD; Julie Vincent, MD; William Hellenbrand, MD; Ralf Holzer, MD; John Cheatham, MD; John Moore, MD; James Lock, MD; Kathy Jenkins, MD, MPH

Background—The Congenital Cardiac Catheterization Project on Outcomes (C3PO) was established to develop outcome assessment methods for pediatric catheterization.

Methods and Results—Six sites have been recording demographic, procedural and immediate outcome data on all cases, using a web-based system since February 2007. A sample of data was independently audited for validity and data completeness. In 2006, participants categorized 84 procedure types into 6 categories by anticipated risk of an adverse event (AE). Consensus and empirical methods were used to determine final procedure risk categories, based on the outcomes: any AE (level 1 to 5); AE level 3, 4, or 5; and death or life-threatening event (level 4 or 5). The final models were then evaluated for validity in a prospectively collected data set between May 2008 and December 31, 2009. Between February 2007 and April 2008, 3756 cases were recorded, 558 (14.9%) with any AE; 226 (6.0%) level 3, 4, or 5; and 73 (1.9%) level 4 or 5. General estimating equations models using 6 consensus-based risk categories were moderately predictive of AE occurrence (c-statistics: 0.644, 0.664, and 0.707). The participant panel made adjustments based on the collected empirical data supported by clinical judgment. These decisions yielded 4 procedure risk categories; the final models had improved discrimination, with c-statistics of 0.699, 0.725, and 0.765. Similar discrimination was observed in the performance data set (n=7043), with c-statistics of 0.672, 0.708, and 0.721.

Conclusions—Procedure-type risk categories are associated with different complication rates in our data set and could be an important variable in risk adjustment models for pediatric catheterization. (***Circ Cardiovasc Interv*. 2011;4:188-194.**)

Key Words: cardiac catheterization ■ cardiovascular interventions ■ complications ■ heart defects congenital ■ outcome

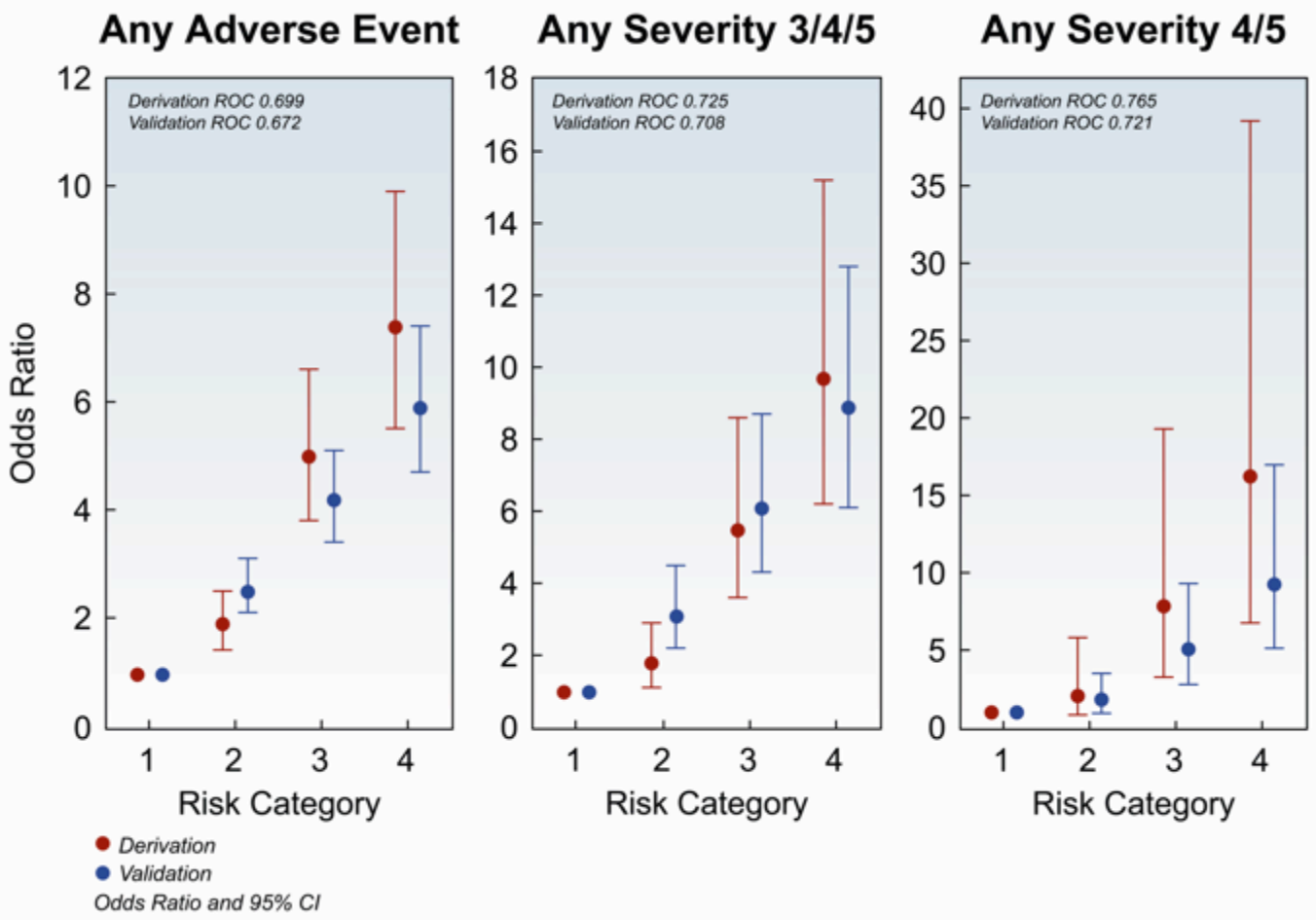
C3PO: PROCEDURE TYPE RISK GROUPS

- Many different types of procedure
- Type of procedure important determinant of outcome
- Categorize procedure types in groups with similar risk
- Methods:
  - Consensus and
  - Empiric

C3PO: PROCEDURE TYPE RISK GROUPS

	Risk Category 1	Risk Category 2	Risk Category 3	Risk Category 4
Diagnostic Case	Age ≥ 1 year	Age ≥ 1 month < 1year	Age < 1 month	
Valvuloplasty		Pulmonary Valve ≥1 month	Aortic valve ≥ 1 month Pulmonary valve < 1 month Tricuspid valve	Mitral Valve Aortic Valve < 1 month
Device or Coil Closure	Venous collateral LSVC	PDA ASD or PFO Fontan Fenestration Systemic to Pulmonary Artery collaterals	Systemic Surgical Shunt Baffle Leak Coronary Fistula	VSD Perivalvar leak
Balloon Angioplasty		RVOT Aorta dilation < 8 ATM	Pulmonary artery < 4 vessels Pulmonary artery ≥ 4 vessels all < 8 ATM Aorta > 8 ATM or CB Systemic Artery (not aorta) Systemic Surgical Shunt Systemic to Pulmonary Collaterals Systemic vein	Pulmonary Artery ≥ 4 vessels Pulmonary vein
Stent Placement		Systemic vein	RVOT Aorta Systemic artery (not aorta)	Ventricular septum Pulmonary artery Pulmonary vein Systemic Surgical Shunt Systemic pulmonary Collateral
Stent Redilation		RVOT Atrial Septum Aorta Systemic Artery (not Aorta) Systemic vein	Pulmonary Artery Pulmonary vein	Ventricular septum
Other	Myocardial Biopsy	Snare foreign body Trans-septal puncture	Atrial septostomy Recanalization of Jailed Vessel in Stent Recanalization of Occluded Vessel	Atrial Septum Dilation and Stent Any Catheterization < 4 days after Surgery Atretic valve perforation

C3PO: PROCEDURE TYPE RISK GROUPS

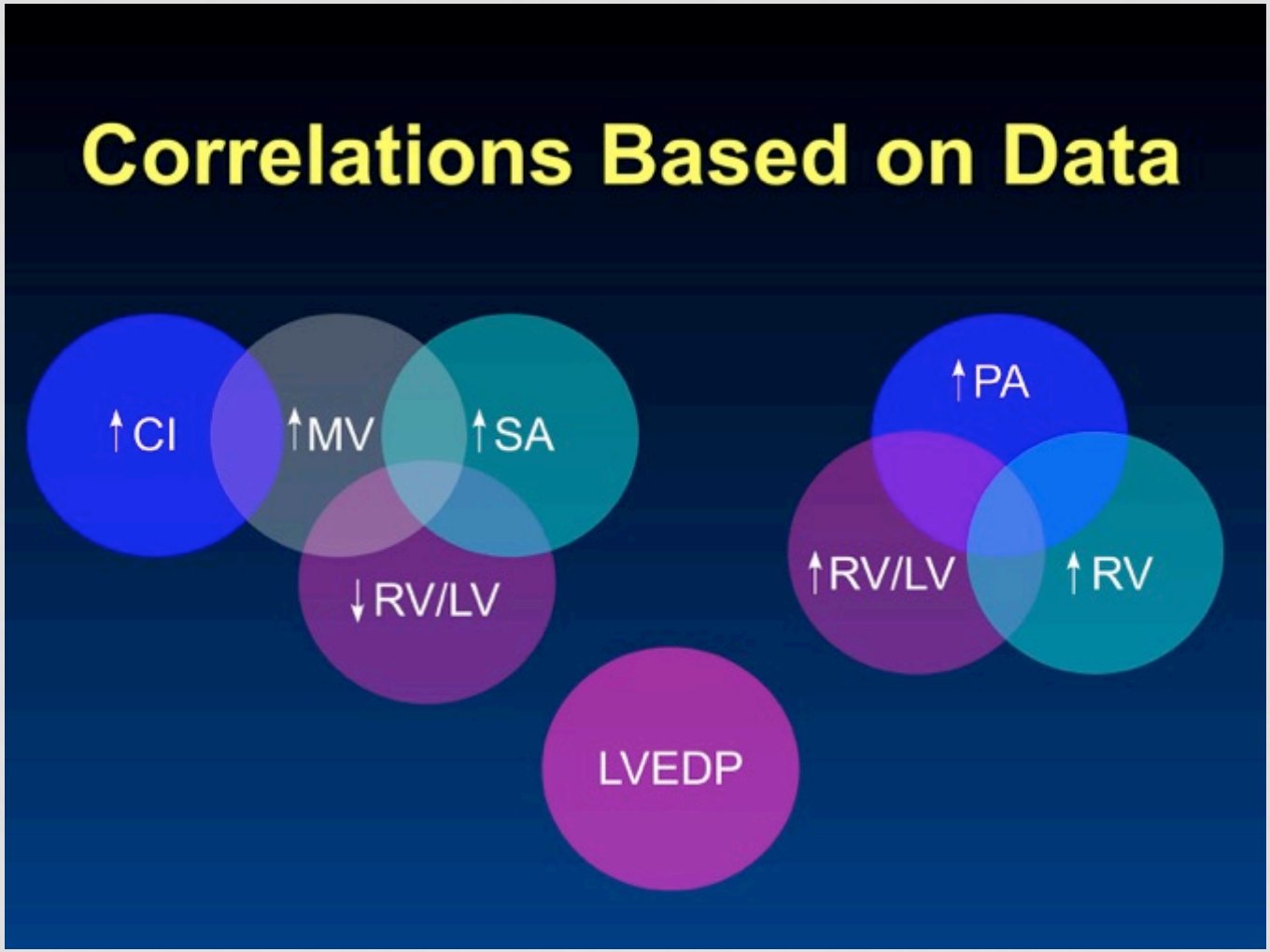


C3PO: HEMODYNAMIC VULNERABILITY

- Intrinsic patient risk factors can impact outcome
- Many physiologic variables describe patient status

- Goal:
  - Identify physiologic indicators associated with AE using empiric data
  - Create a composite measure for patient specific physiologic risk

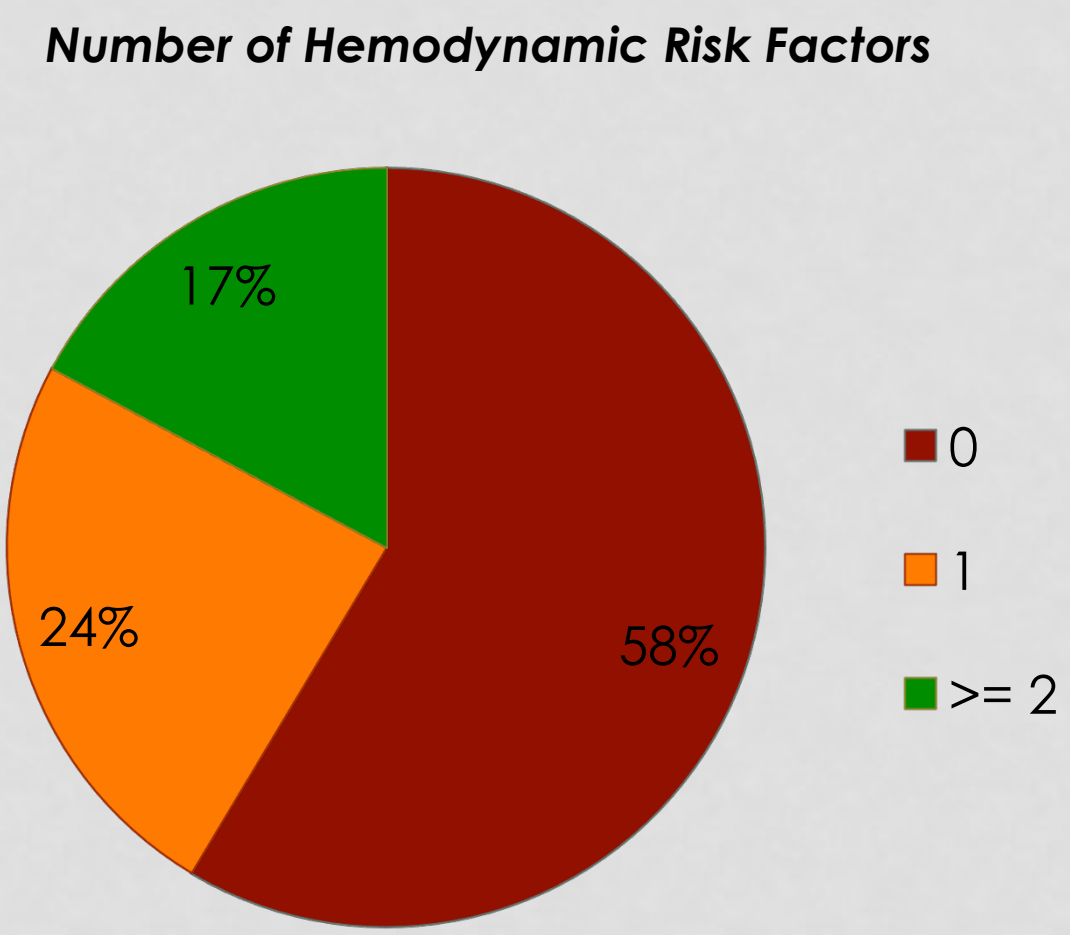
C3PO: HEMODYNAMIC VULNERABILITY



C3PO: HEMODYNAMIC VULNERABILITY

- LV end diastolic press
  - ≥ 18 mmHg
- Systemic arterial saturation
  - Single ventricle ≤ 72%
  - Two ventricles ≤ 95%
- MPA pressure
  - Single ventricle mean ≥17 mmHg
  - Two ventricles systolic ≥45 mmHg
- Cardiac Index
  - ≤ 2.8 L/Min/M^2

C3PO: HEMODYNAMIC VULNERABILITY



JACC: CARDIOVASCULAR INTERVENTIONS
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Catheterization for Congenital Heart Disease Adjustment for Risk Method (CHARM)

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Boston, Massachusetts; St. Louis, Missouri; Cincinnati and Columbus, Ohio; Pittsburgh, Pennsylvania; New York, New York; San Diego, California; and Portland, Oregon

Objectives This study sought to develop a method to adjust for case mix complexity in catheterization for congenital heart disease to allow equitable comparisons of adverse event (AE) rates.

Background The C3PO (Congenital Cardiac Catheterization Project on Outcomes) has been prospectively collecting data using a Web-based data entry tool on all catheterization cases at 8 pediatric institutions since 2007.

Methods A multivariable logistic regression model with high-severity AE outcome was built using a random sample of 75% of cases in the multicenter cohort; the models were assessed in the remaining 25%. Model discrimination was assessed by the C-statistic and calibration with Hosmer-Lemeshow test. The final models were used to calculate standardized AE ratios.

Results Between August 2007 and December 2009, 9,362 cases were recorded at 8 pediatric institutions of which high-severity events occurred in 454 cases (5%). Assessment of empirical data yielded 4 independent indicators of hemodynamic vulnerability. Final multivariable models included procedure type risk category (odds ratios [OR] for category: 2 = 2.4, 3 = 4.9, 4 = 7.6, all $p < 0.001$), number of hemodynamic indicators (OR for 1 indicator = 1.5, ≥2 = 1.8, $p = 0.005$ and $p < 0.001$), and age <1 year (OR: 1.3, $p = 0.04$), C-statistic 0.737, and Hosmer-Lemeshow test $p = 0.74$. Models performed well in the validation dataset, C-statistic 0.734. Institutional event rates ranged from 1.91% to 7.37% and standardized AE ratios ranged from 0.61 to 1.41.

Conclusions Using CHARM (Catheterization for Congenital Heart Disease Adjustment for Risk Method) to adjust for case mix complexity should allow comparisons of AE among institutions performing catheterization for congenital heart disease. (J Am Coll Cardiol Intv 2011;4:1037–46)

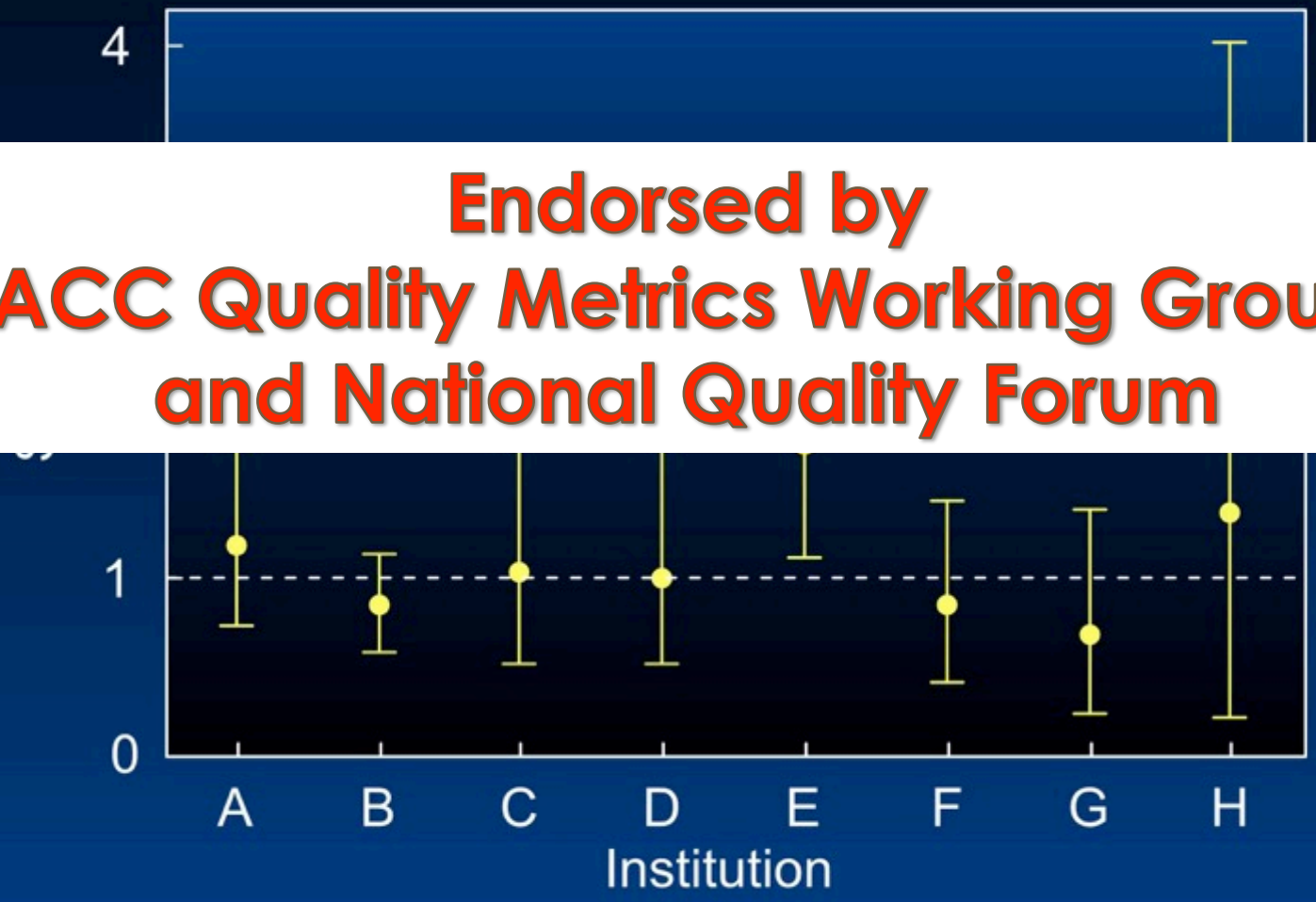
C3PO: THE CHARM MODEL

Table 6. Multivariable Models for Risk Adjusting High-Severity AE Rates

Outcome: Any Level 3/4/5 AE	Derivation Dataset			Validation Dataset		
All Ages*	OR	95% CI	p Value	OR	95% CI	p Value
Risk category						
2	2.4	1.6–3.6	<0.001	2.0	1.0–3.8	0.04
3	4.9	3.4–7.2	<0.001	4.9	2.7–9.0	<0.001
4	7.6	5.2–11.2	<0.001	4.8	2.5–9.2	<0.001
Hemodynamic variables, n (of 4)						
1	1.5	1.1–2.0	0.005	1.8	1.2–2.8	0.01
≥2	1.8	1.3–2.4	<0.001	2.0	1.2–3.3	0.008
Age <1 yr	1.3	1.1–1.6	0.04	1.5	1.0–2.2	0.05
Area under ROC curve	0.737			0.734		
Hosmer-Lemeshow test p value	0.74			0.20		

Standardized Adverse Event Ratios by Hospital

(Adjusted for Procedure Type Risk Group Case Mix)



Endorsed by
ACC Quality Metrics Working Group
and National Quality Forum

Original Article

Adjusting for Risk Associated With Pediatric and Congenital Cardiac Catheterization

A Report From the NCDR IMPACT Registry

Natalie Jayaram, MD, MSB; Robert H. Beekman III, MD; Lee Benson, MD; Ralf Holzer, MD; Kathy Jenkins, MD, MPH; Kevin F. Kennedy, MS; Gerard R. Martin, MD; John W. Moore, MD, MPH; Richard Ringel, MD; Jonathan Rome, MD; John A. Spertus, MD, MPH; Robert Vincent, MD; Lisa Bergersen, MD, MPH

Background—As US health care increasingly focuses on outcomes as a means for quantifying quality, there is a growing demand for risk models that can account for the variability of patients treated at different hospitals so that equitable comparisons between institutions can be made. We sought to apply aspects of prior risk-standardization methodology to begin development of a risk-standardization tool for the National Cardiovascular Data Registry (NCDR) IMPACT (Improving Pediatric and Adult Congenital Treatment) Registry.

Methods and Results—Using IMPACT, we identified all patients undergoing diagnostic or interventional cardiac catheterization between January 2011 and March 2013. Multivariable hierarchical logistic regression was used to identify patient and procedural characteristics predictive of experiencing a major adverse event after cardiac catheterization. A total of 19 608 cardiac catheterizations were performed between January 2011 and March 2013. Among all cases, a major adverse event occurred in 378 of all cases (1.9%). After multivariable adjustment, 8 variables were identified as critical for risk standardization: patient age, renal insufficiency, single-ventricle physiology, procedure-type risk group, low systemic saturation, low mixed venous saturation, elevated systemic ventricular end-diastolic pressure, and elevated main pulmonary artery pressures. The model had good discrimination (C statistic, 0.70), confirmed by bootstrap validation (validation C statistic, 0.69).

Conclusions—Using prior risk-standardization efforts as a foundation, we developed and internally validated a model to predict the occurrence of a major adverse event after cardiac catheterization for congenital heart disease. Future efforts should be directed toward further refinement of the model variables within this large, multicenter data set.

(*Circulation*. 2015;132:00-00. DOI: 10.1161/CIRCULATIONAHA.114.014694.)

Key Words: catheterization ■ heart defects, congenital ■ risk factors

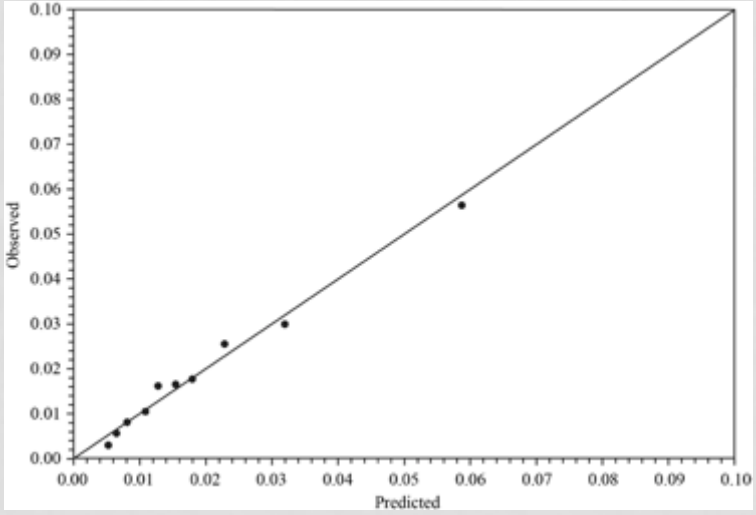


Table 5. Model Predictors of a Major Adverse Event (Including Death)

Predictor	Odds Ratio (95% CI)
Age	
Neonates (<30 d)	Reference
Infants (≥30 d–≤1 y)	0.46 (0.33–0.65)
Children (1–≤18 y)	0.30 (0.21–0.43)
Adults (>18 y)	0.28 (0.19–0.43)
SV	1.40 (1.13–1.74)
Renal insufficiency	4.89 (3.43–6.96)
Saturation <95% (non-SV) or <78% (SV)	
No	Reference
Yes	1.05 (0.84–1.32)
Missing	1.22 (0.85–1.74)
Mixed venous saturation <60% (non-SV) or <50% (SV)	
No	Reference
Yes	2.56 (1.99–3.30)
Missing	1.63 (1.18–2.26)
MPA systolic pressure ≥45 mm Hg (non-SV) or MPA mean pressure ≥17 mm Hg (SV)	
No	Reference
Yes	2.73 (2.15–3.46)
Missing	1.59 (1.21–2.09)
Systemic ventricular EDP ≥18 mm Hg	
No	Reference
Yes	1.65 (1.14–2.39)
Missing	1.31 (1.06–1.63)
Risk group	
1	Reference
2	2.18 (1.60–2.97)
3	1.97 (1.41–2.74)
4	3.01 (2.10–4.31)

CI indicates confidence interval; EDP, end diastolic pressure; MPA, main pulmonary artery; and SV, single ventricle.

C3PO: OPERATOR FACTORS

Catheterization and Cardiovascular Interventions 82:463–473 (2013)

Relationship Between Procedural Adverse Events Associated With Cardiac Catheterization for Congenital Heart Disease and Operator Factors: Results of a Multi-Institutional Registry (C3PO)

Ralf J. Holzer,[1*] MD, MSC, Kimberlee Gauvreau,[2] SCD, Jacqueline Kreutzer,[3] MD, John W. Moore,[4] MD, Doff B. McElhinney,[2] MD, and Lisa Bergersen,[2] MD, MPH

Background: Data examining the effect of operator years in practice and volume on adverse events (AE) after cardiac catheterization in patients with congenital heart disease is limited. Methods and Results: Data were prospectively collected using a multicenter registry (C3PO). 10,885 catheterizations performed between 02/07 and 06/10 at eight institutions were included. AE rates were risk-adjusted for hemodynamic vulnerability, procedure type risk group, and age and compared between operators with different years in practice (YIP) and volume. AE occurred in 13% of procedures. Operators with less than five YIP had higher adjusted odds of any AE (OR 1.42, 95% CI 1.14–1.77) or a high severity AE (OR 1.35, 95% CI 1.04–1.75), when compared with operators with 5 to less than 25 YIP ($5<25$), while operators with ≥ 25 YIP had higher odds of a high severity (but not any) AE (OR 1.39, 95% CI 1.08–1.80). Operators with <5 YIP had a higher percentage of preventable AE (out of all AE, 16% vs. 8%, $P<0.001$) as well as higher odds of vascular or cardiac trauma (OR 1.81, 95% CI 1.11–2.97), or technical AE (OR 1.98, 95% CI 1.31–2.99) when compared with operators with $5<25$ YIP. There was no consistent relationship between operator volume, and incidence of AE. Conclusions: Operators with less than 5 years in practice have higher risk-adjusted AE rates. While an important consideration in guiding and mentoring operators with fewer years in practice, it is important to emphasize that reporting adverse events does not take into account procedural efficacy.

Key words: congenital heart disease; operator years in practice; cardiac catheterization; adverse events

EFFECT OF OPERATOR EXPERIENCE

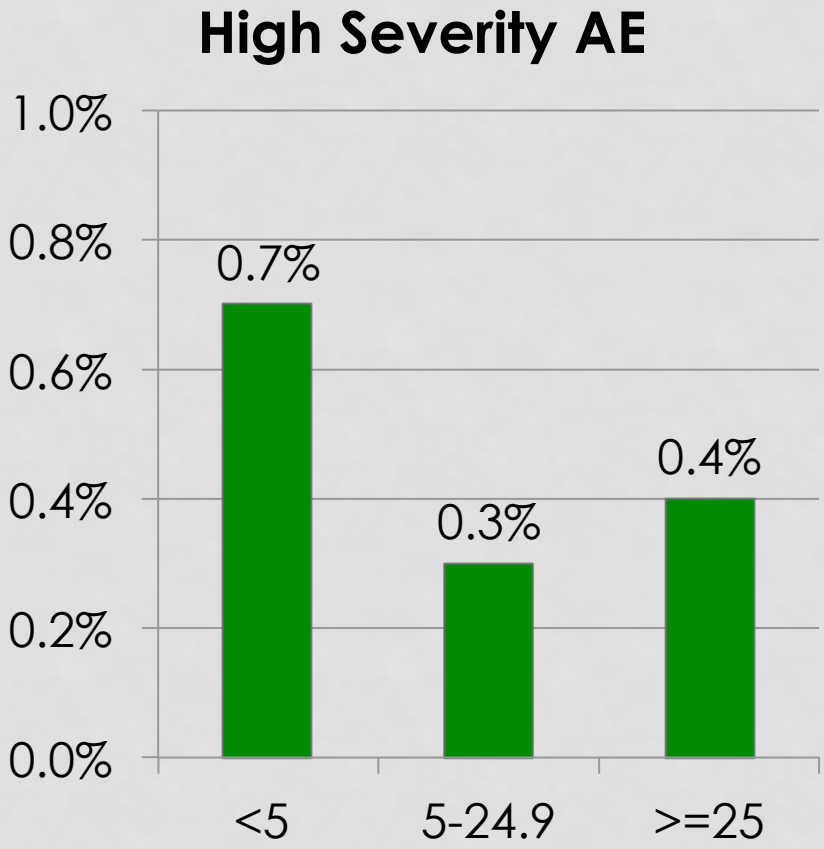
	Odds Ratio	*95% Confidence Interval*	*P Value*
Experience (yrs)			
<5	1.35	(1.04, 1.75)	0.03
5 to 24.9	1.00	--	--
≥25	1.39	(1.08, 1.80)	0.01

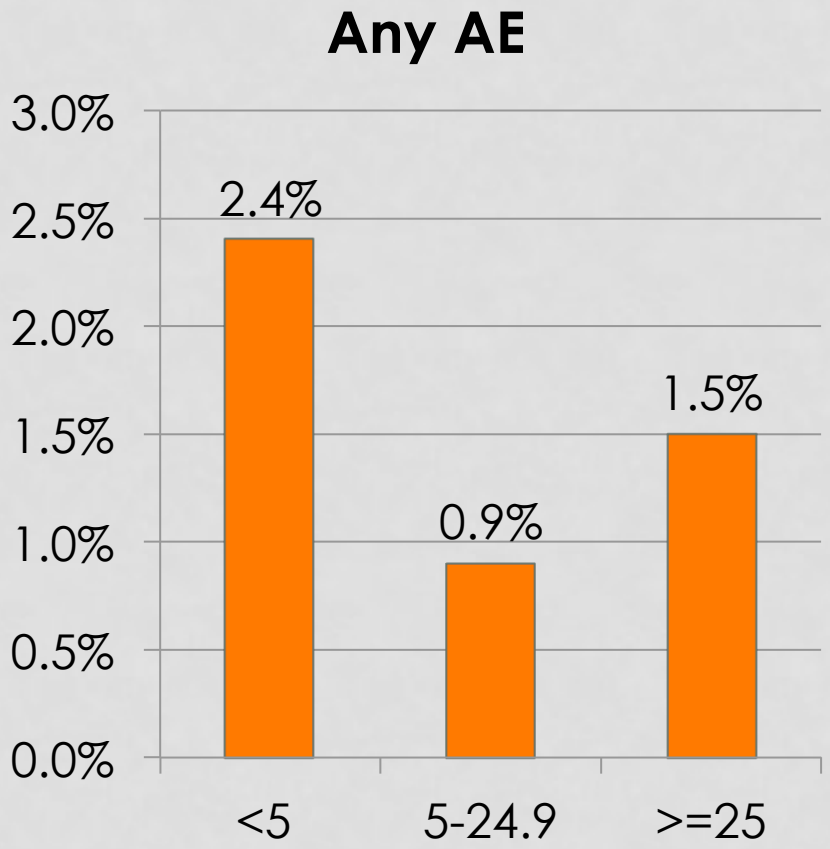
OR for Level 3-5 AE after adjustment with CHARM

MORE COMPLEX CASES IN SENIOR OPERATORS?

	< 5 Years	5-24 Years	>= 25 Years
Case Duration (min)	77 (47 to 117)	76 (47 to 113)	96 (65 to 137)
Fluoroscopy Time (min)	20 (11 to 37)	17 (9 to 30)	31 (17 to 49)
Contrast Dose (ml/kg)	2.7 (0.5 to 5.0)	2.3 (0.5 to 4.4)	3.3 (1.8 to 5.2)

PREVENTABLE AE BY OPERATOR EXPERIENCE

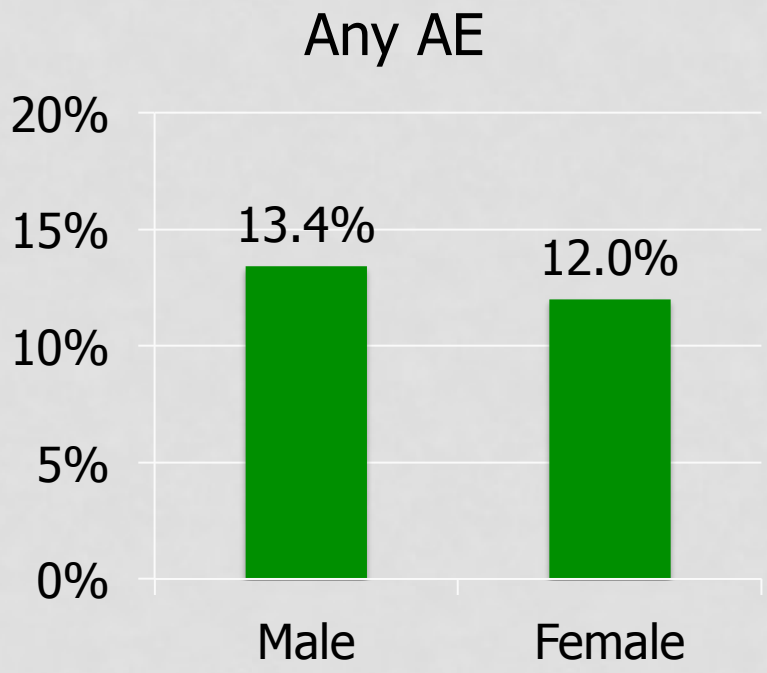


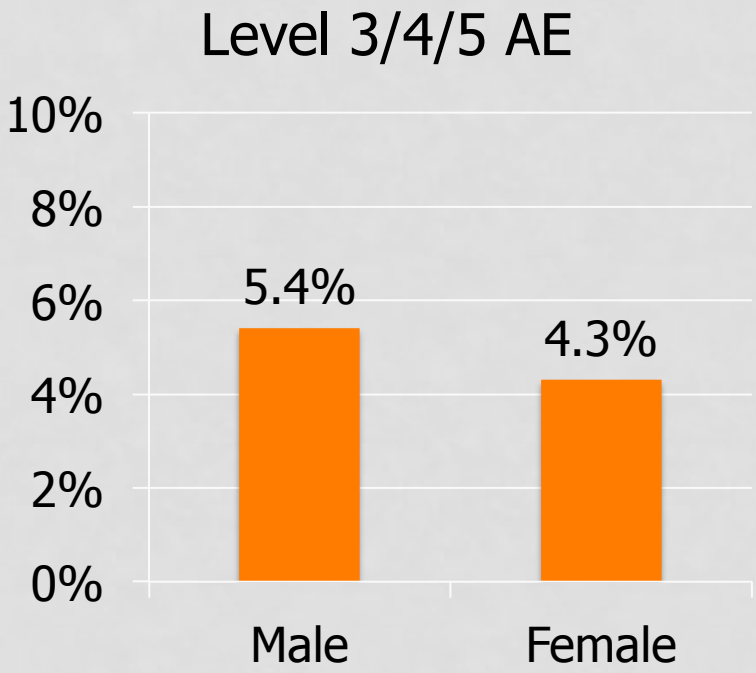


EFFECT OF OPERATOR VOLUME

	Odds Ratio	95% Confidence Interval	P Value
Total Operator Volume			
<75	0.78	(0.48, 1.25)	0.30
75 to 149	1.01	(0.76, 1.34)	0.97
150 to 199	1.34	(0.91, 1.96)	0.13
200 to 249	1.34	(1.05, 1.71)	0.02
≥250	1.00	--	--

ADVERSE EVENTS BY OPERATOR GENDER





	Any AE			Level 3/4/5 AE		
	Odds Ratio	95% CI	P-value	Odds Ratio	95% CI	P-value
Female Operator	0.95	(0.63, 1.44)	0.81	0.84	(0.64, 1.11)	0.22

C3PO:
(VERY) LOW WEIGHT

Catheterization and Cardiovascular Interventions 82:786–794 (2013)

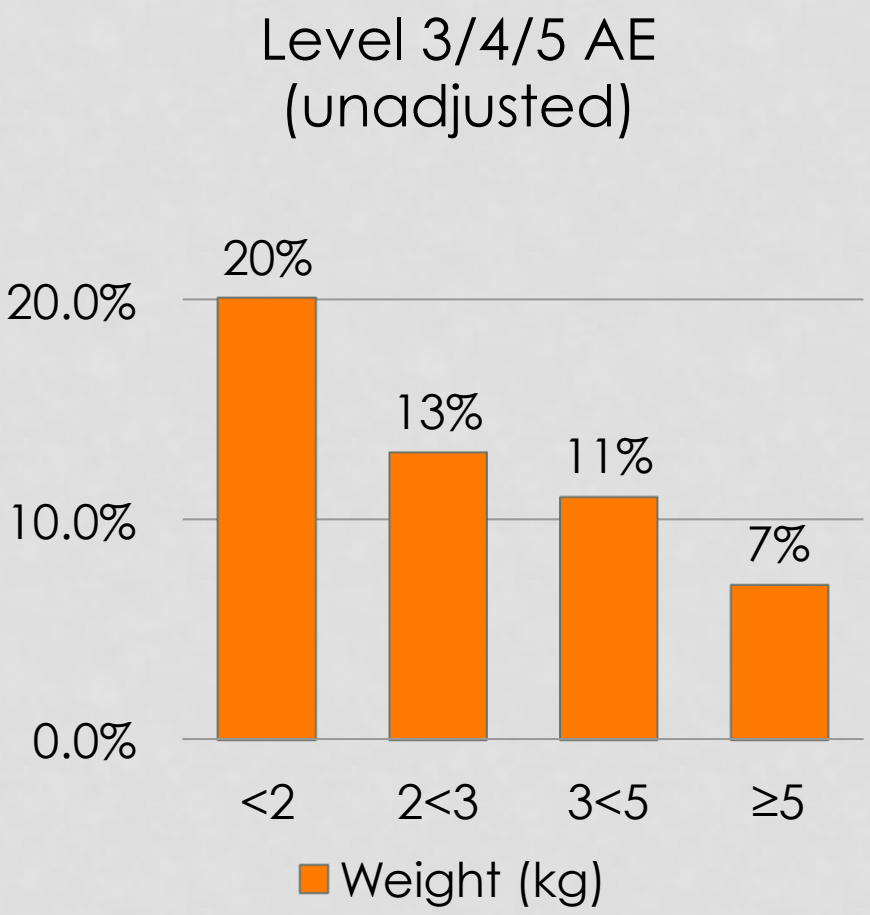
Low Weight as an Independent Risk Factor for Adverse Events During Cardiac Catheterization of Infants

Carl H. Backes,[1] M.D., Clifford Cua,[1] M.D., Jacqueline Kreutzer,[2] M.D., Laurie Armsby,[3] M.D., Howaida El-Said,[4] M.D., John W. Moore,[4] M.D., Kimberlee Gauvreau,[5] ScD, Lisa Bergersen,[5] M.D., M.P.H., and Ralf J. Holzer,[1*] M.D.

Background: Studies have documented the importance of procedure type and hemodynamic variables on the incidence of procedure related adverse events (AE) after cardiac catheterization. However, little is known about the impact of low weight on the incidence and severity of AE. Methods: Data were prospectively collected using a multicenter registry (C3PO). Infants <1 year were divided into four weight categories: <2 kg, 2–3 kg, 3–5 kg, ≥5 kg. AE severity was classified as level 1–5 (none, minor, moderate, major, death). Results: Eight centers submitted details on 3,679 cases (34% diagnostic) performed in infants <1 year from 2/07 to 6/10: <2 kg: 57 (1.5%), 2–3 kg: 403 (11%), 3–5 kg: 1,527 (41.5%), ≥5 kg: 1,692 (46%). AE occurred in 20% of cases (<2 kg: 28%, 2–3 kg: 25%, 3–5 kg: 23%, ≥5 kg: 16%) with 41% of all AE being level 3–5 AE. Death occurred more frequently in the <2 kg group (12%), 71% of which were interventional cases. The case-related mortality in all other weight groups was <1%. By multivariable analysis, weight <2 kg, 2–3 kg, and 3–5 kg were independent risk factors for high severity (level 3–5) AE (<2 kg: OR 2, 95%CI 1.1–3.6; 2–3 kg: OR 1.4, 95%CI 1–1.8; 3–5 kg: OR 1.3, 95%CI 1.1–1.5), with similar findings for all AE. Blood transfusions were more common in lower weight categories (<2 kg: 42%, 2–3 kg: 29%, 3–5 kg: 25%, ≥5 kg: 15%, p<0.001). Conclusions: The risk of AE during cardiac catheterization of infants increases with lower weight. Infants who weigh less than 2 kg have a significantly higher risk of adverse events (most notably death) even after correcting for hemodynamic vulnerability and procedure type risk group.

Key words: pCOMP; complications pediatric cath/intervention; PEDS; pediatric interventions; CATH; diagnostic cardiac catheterization

ADVERSE EVENTS IN LOW WEIGHT PATIENTS



	Multivariable Analysis	
	Odds Ratio (95% CI)	P Value
Weight		
≥ 5.0 kg	1.0	--
≥ 3.0, < 5.0 kg	1.35 (1.04, 1.77)	0.03
≥ 2.0, < 3.0 kg	1.47 (1.01, 2.14)	0.04
< 2.0 kg	3.03 (1.49, 6.14)	0.002

C3PO:
DATA ON SPECIFIC PROCEDURE TYPES

C3PO:
PULMONARY ARTERY REHABILITATION

Sidra
Sidra Medical and Research Center
Member of Qatar Foundation

Balloon Angioplasty and Stenting of Branch Pulmonary Arteries

Adverse Events and Procedural Characteristics: Results of a Multi-Institutional Registry

Ralf J. Holzer, MD, MSc; Kimberlee Gauvreau, ScD; Jacqueline Kreutzer, MD; Ryan Leahy, MD; Joshua Murphy, MD; James E. Lock, MD; John P. Cheatham, MD; Lisa Bergersen, MD, MPH

Background—Pulmonary artery (PA) balloon angioplasty and/or stenting (PA rehabilitation) is one of the most common procedures performed in the cardiac catheterization laboratory, but comprehensive and consistently reported data on procedure-related adverse events (AE) are scarce.

Methods and Results—Data were prospectively collected using a multicenter registry (Congenital Cardiac Catheterization Project on Outcomes). All cases that included balloon angioplasty and/or stent implantation in a proximal or lobar PA position were included. Multivariate analysis was used to evaluate for independent predictors of AE and need for early reintervention. Between February 2007 and December 2009, 8 institutions submitted details on 1315 procedures with a PA intervention. An AE was documented in 22% with a high severity (level 3 to 5) AE in 10% of cases. Types of AE included vascular/cardiac trauma (19%), technical AE (15%), arrhythmias (15%), hemodynamic AE (14%), bleeding via endotracheal tube/reperfusion injury (12%), and other AE (24%). AE were classified as not preventable in 50%, possibly preventable in 41%, and preventable in 9%. By multivariate analysis, independent risk factors for level 3 to 5 AE were presence of $\geq$2 indicators of hemodynamic vulnerability, age below 1 month, use of cutting balloons, and operator experience of $<$10 years. Reintervention during the study period occurred in 22% of patients undergoing PA rehabilitation.

Conclusions—PA rehabilitation is associated with a 10% incidence of high-level severity AE. Hemodynamic vulnerability, young age, use of cutting balloons, and lower operator experience were significant independent risk factors for procedure-related AE. (***Circ Cardiovasc Interv*. 2011;4:287-296.**)

Key Words: congenital heart disease ■ pulmonary artery stenosis ■ cardiac catheterization ■ adverse events

PA REHAB: TYPE OF ADVERSE EVENTS

Adverse Event Details	Total (n=324)	Proximal (n=174)	Lobar (n=61)	Mixed (n=89)	P-Value
Vascular / Cardiac Trauma	60 (19)	20 (11)	14 (23)	26 (29)	0.001
Technical AEs	50 (15)	40 (23)	2 (3)	8 (9)	<0.001
Arrhythmias	49 (15)	32 (18)	11 (18)	6 (7)	0.04
Hemodynamic AEs	45 (14)	24 (14)	10 (16)	11 (12)	ns
Reperfusion Injury / ETT bleed	40 (12)	9 (5)	12 (20)	19 (21)	<0.001
Vascular Entry Site AE	34 (10)	22 (13)	5 (8)	7 (8)	ns
Sedation / Anesth. / Airway	12 (4)	5 (3)	3 (5)	4 (4)	ns
Other	34 (10)	22 (13)	4 (7)	8 (9)	ns

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Other	34 (10)	22 (13)	4 (7)	8 (9)	ns

PA REHAB: RISK FACTORS FOR LEVEL 3-5 AE

	Incidence of all AE		Univariate	Multivariate Analysis	
	Predictor Present	Predictor Not Present	P Value	P-Value	Odds Ratio 95% CI
Emergent or non-elective cases	17/92 (18)	57/700 (8)	0.004	0.034	1.86 (1.05-3.3)
Use of inotropic support at start	7/44 (16)	67/748 (9)	0.175		
Age < 1 month	5/20 (25)	69/772 (9)	0.032	0.211	1.8 (0.72-4.52)
Weight < 5kg	8/58 (14)	66/734 (9)	0.238		
Date since last surgery < 30d	12/60 (20)	62/732 (8)	0.009	0.824	1.09 (0.52-2.26)
Date since last catheterization < 30d	5/40 (13)	69/752 (9)	0.411		
Number previous catheterizations >= 4	28/254 (11)	46/538 (9)	0.295		
Number of PA interventions >= 5	14/87 (16)	60/705 (9)	0.03	0.008	2.02 (1.2-3.4)
Single ventricle	8/92 (9)	66/700 (9)	>0.999		
Complex 2V and Suprasystemic RVp	8/67 (12)	66/725 (9)	0.508		
Lobar intervention	39/382 (10)	35/410 (9)	0.464		
Proximal Intervention	58/613 (9)	16/179 (9)	0.885		
Balloon angioplasty (<8atm)	10/171 (6)	64/621 (10)	0.101		
Balloon angioplasty (>8atm)	33/375 (9)	41/417 (10)	0.627		
Cutting balloon angioplasty	21/167 (13)	53/625 (8)	0.133		
Premounted stent	15/134 (11)	59/658 (9)	0.417		
None-premounted stent	21/178 (12)	53/614 (9)	0.241		

PA REHAB: RISK FACTORS FOR LEVEL 3-5 AE

	Incidence of all AE		Univariate	Multivariate Analysis	
	Predictor Present	Predictor Not Present	P Value	P-Value	Odds Ratio 95% CI
Emergent or non-elective cases	17/92 (18)	57/700 (8)	0.004	0.034	1.86 (1.05-3.3)
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None-premounted stent	21/178 (12)	53/614 (9)	0.241		

INDEPENDENT PREDICTORS OF NEED FOR REINTERVENTION

Predictor	High Severity Level 3-5 AE		Univariate	Multivariate Analysis	
	Number	Any 3-5 AE (%)	P-value	P-value	OR (95% CI)
Weight			<0.001		
• < 5kg	90	47 (52)		<0.001	26.9 (15.9, 49.1)
• 5 < 25kg	534	133 (25)		<0.001	5.95 (3.65, 9.75)
• 25 < 75kg	286	31 (11)		0.11	1.61 (0.90, 2.87)
• >= 75kg	59	4 (7)		---	1.00
Location of PA rehab			<0.001		
• Proximal	670	98 (15)		---	1.00
• Lobar	133	52 (39)		<0.001	5.59 (3.91, 8.00)
• Mixed	166	65 (39)		<0.001	4.26 (3.34, 5.42)
Bilateral Interventions	299	89 (30)	<0.001	0.03	1.39 (1.03, 1.88)

PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Device Therapy for Atrial Septal Defects in a Multicenter Cohort: Acute Outcomes and Adverse Events

Howaida El-Said,[1*] MD, P
William Hellenbrand,[3] MD
Ralf Holzer,[5] MD, Grant
Diego Porras,[9] MD, Lisa

Background: Secundum a
proval based on industry-
ies, demonstrating accept
report community practic
data was collected on ca
catheterization project on
2010. Eight centers contri
were independently review
(2/07–6/10), 653 of 688
AMPLATZER® Septal Occ
(HSO) in 33 (5%), and a
patients had an isolated A

PEDIATRIC AND CONGE

Original Studies

Safety and Efficacy of Balloon Pulmonary Valvuloplas
A Multicenter Experience

Ralf J. Holzer,[1*] MD, MSc, Kimberlee Gauvreau,[2] ScD, Jacqueline Kreutzer,[3] MD, Sara M. Trucco,[3] MD, Alejandro Torres,[4] MD, Shabana Shahanavaz,[4] MD, and Lisa Bergersen,[2] MD, MPH

Background: Balloon pulmonary valvuloplasty (BPV) is the treatment of choice for patients with pulmonary valve stenosis (PS); however, safety and efficacy outcomes are lacking in the current era. Methods: Demographic, procedural, and adverse event (AE) data were prospectively collected using a multicenter registry (C3PO) and cases performed between 02/07 and 06/10 at eight institutions. The registry was queried for cases of isolated BPV. Multivariable models were built to determine risk factors for procedure failure and adverse outcomes. Results: 211 cases were included (45%, <1 month). Procedural success was achieved in 91% procedures, being defined as one or more of the following: post-BPV peak systolic valvar gradient to < 25 mm Hg (68%), decrease in gradient by 50% (79%), or reduction of RV/systemic pressure ratio by 50% (45%). Procedural success was more common in neonates, when compared to older patients (96% vs. 87%, $P = 0.03$). Risk factors for procedural failure included moderate or severe pulmonary valve thickening (OR 2.9, CI 1–8.3), and presence of supravalve PS (OR 9.6, CI 2.7–33.8). Low severity AEs (levels 1–2) occurred in 9% of patients and higher severity AEs (levels 3–5) occurred in 3% of patient; there were no deaths. Risk factors for any AE (levels 1–5) were age below 1 month (OR 3.5, CI 1.3–9.9), as well as operator experience of less than 10 years (OR 3.8, CI 1.5–9.9). Conclusions: Procedural success is common and AEs, especially higher severity AEs, are rare for BPV in patients with isolated PS. Results have improved considerably when compared to historical data. © 2012 Wiley Periodicals Inc.

Key words: pCOMP; complications pediatric cath/intervention; PEDS, pediatric interventions; pulmonary valvuloplasty

Original Studies

Hybrid Procedures: Adverse Events and Procedural Characteristics—Results of a Multi-Institutional Registry

Ralf Holzer, MD,* Audrey Marshall, MD,† Jackie Kreutzer, MD,‡ Russel Hirsch, MD,§ Joanne Chisolm, RN,* Sharon Hill, ACNP,* Mark Galantowicz, MD,* Alistair Phillips, MD,† John Cheatham, MD,* and Lisa Bergerson, MD†

*Department of Cardiology, Nationwide Children's Hospital, Columbus, Ohio, †Department of Cardiology, Cincinnati Children's Hospital, Cincinnati, Ohio, ‡Department of Cardiology, Children's Hospital Boston, Boston, Mass, and §Department of Cardiology, Children's Hospital of Pittsburgh Pittsburgh, Pa, USA

ABSTRACT

Introduction. Procedural cooperation between cardiac surgeon and interventional cardiologist to facilitate interventions such as device delivery or angioplasty (hybrid procedure) has become increasingly common in the management of patients with congenital heart disease.

Design. Data were prospectively collected using a multicenter registry (C3PO). Between February 2007 and December 2008, seven institutions submitted data regarding 7019 cardiac catheterization procedures. Procedural data and adverse events (AEs) of 128 hybrid procedures were evaluated.

Results. There was significant variability in the number of hybrid procedures per center, ranging from one to 89 with a median of eight. A total of 60% of interventional (vs. strictly diagnostic) hybrid procedures were performed by one center. The median weight was 3.7 kg (0.7–86 kg). Single-ventricle circulation was present in 60% of the procedures. Hybrid procedures included: patent ductus arteriosus (PDA) stent placement (n = 55), vascular rehabilitation (n = 25), ventricular septal defect (VSD) device closure (n = 7), valvotomy (n = 3), and diagnostic hybrid procedures (n = 38). Sixteen AEs occurred in 15/128 (12%) procedures. These included minor or trivial AEs (n = 9), moderate AEs (n = 5), major AEs (n = 1), and catastrophic AEs (n = 1). The type of AE documented included arrhythmias (n = 6), hypoxia or hypotension (n = 3), vessel or cardiac trauma (n = 2), and other events (n = 5). Of documented AEs, 9/16 (56%) were classified as not preventable, 6/16 (38%) as possibly preventable, and 1/16 (6%) as preventable. The incidence of AE related to PDA stent placement with surgical exposure (5/50, 10%) was significantly lower when compared with PDA stent placement performed percutaneously (6/5, 80%, $P = .002$).

Conclusion. Hybrid procedures appear to have a low incidence of associated major AEs. PDA stent placement performed as a palliation of hypoplastic left heart syndrome (HLHS) or complex single/two ventricle patients may have a lower incidence of AEs if performed using a direct approach with surgical exposure rather than a percutaneous approach. Accurate definitions of these innovative procedures are required to facilitate prospective data collection.

Key Words. Hybrid Procedures; Cardiac Catheterization; Adverse Events

Original Studies

Balloon Valvuloplasty for Congenital Aortic Stenosis:
Multi-Center Safety and Efficacy Outcome Assessment

Alejandro Torres,[1] MD, Julie A. Vincent,[1] MD, Allen Everett,[2] MD, Scott Lim,[3] MD, Susan R. Foerster,[4] MD, Audrey C. Marshall,[5] MD, Robert H. Beekman III,[6] MD, Joshua Murphy,[7] MD, Sara M. Trucco,[8] MD, Kimberlee Gauvreau,[5] MD, Ralf Holzer,[9] MD, MSc,, Lisa Bergersen,[5] MD, MPH,, and Diego Porras,[5*] MD

ORIGINAL ARTICLE

Practice Variation in Single-Ventricle Patients Undergoing Elective Cardiac Catheterization: A Report from the Congenital Cardiac Catheterization Project on Outcomes (C3PO)

Bryan H. Goldstein, MD,* Ralf J. Holzer, MD, MSc,† Sara M. Trucco, MD,‡ Diego Porras, MD,§ Joshua Murphy, MD,¶ Susan R. Foerster, MD,** Howaida G. El-Said, MD,†† Robert H. Beekman III, MD,* and Lisa Bergersen, MD, MPH¶

*The Heart Institute, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, †The Heart Center, Nationwide Children's Hospital, Columbus, Ohio, ‡Heart Institute, Children's Hospital of Pittsburgh, Pittsburgh, Pa, §Department of diology, Washington University, St. Wis, ††Division of Cardiology, Rady

Catheterization and Cardiovascular Interventions 81:997–1005 (2013)

Rates and Risk Factors in Adults
rdiac Catheterization at Pediatric
Hospitals—Results From the C3PO

Christopher P. Learn,[1] MD, Ralf J. Holzer,[1] MD, Curt J. Daniels,[1] MD, Alejandro J. Torres,[2] MD, Julie A. Vincent,[2] MD, John W. Moore,[3] MD MPH, Laurie B. Armsby,[4] MD, Michael J. Landzberg,[5] MD, and Lisa Bergersen,[5*] MD MPH

Objective: Determine the frequency and risk fac
undergoing cardiac catheterization at pediatric
zation AE rates at pediatric hospitals are not w
Catheterization Project on Outcomes (C3PO)
eight pediatric institutions. Methods: Adult (≥1
were reviewed and compared with those of pe
classified into procedure risk categories from 1
intervention performed. AE were categorized by
model for high severity AE (HSAE), standardize
dividing the observed rates of HSAE by the exp
of total) were performed on adults and 11,422 ca
Adults less frequently underwent high-risk pro
(19% vs. 30%). AE occurred in 10% of adult c
0.001). HSAE occurred in 4% of adult and 5%
dure-type risk category (Category 2, 3, 4 OR
end diastolic pressure ≥ 18 mm Hg (OR 3.1)
0.751. There were no statistically significant di
Conclusions: Adults undergoing catheterization
less frequently than children did. The congeni
method for adults with congenital heart disease
risk in adult patients. © 2013 Wiley Periodicals, Inc.

Key words: heart defects; congenital; outcome a

surrounding elective cardiac catheter-

terization were collected prospectively
terization Project on Outcomes). We
ort in case type and timing. Cases were
stomosis [pre-BCPA], pre-Fontan and
de of airway management (assisted vs.

Safety of Percutaneous Patent Ductus Arteriosus Closure: An Unselected Multicenter Population Experience

Howaida G. El-Said, MD, PhD; Andras Bratincsak, MD, PhD; Susan R. Foerster, MD; Joshua J. Murphy, MD; Julie Vincent, MD; Ralf Holzer, MD; Diego Porras, MD; John Moore, MD, MPH; Lisa Bergersen, MD, MPH

Background—The technique and safety of transcatheter patent ductus arteriosus (PDA) closure have evolved during the past 20 years. We sought to report a multicenter experience of PDA closure with a focus on the rate of adverse events (AE) and a review of institutional practice differences.

Methods and Results—Outcome data on transcatheter PDA closure were collected at 8 centers prospectively using a multicenter registry (Congenital Cardiac Catheterization Project on Outcome Registry). Between February 2007 and June 2010, 496 PDA closures were recorded using a device in 338 (68%) or coils in 158 (32%). Most patients had an isolated PDA (90%). Fifty percent of patients were between 6 months and 3 years old, with only 40 patients (8%) <6 months old. Median minimum PDA diameter was 2.5 mm (range 1 to 12 mm; IQR 2 to 3 mm) for device closure and 1 mm (range 0.5 to 6 mm; IQR 1 to 2 mm) for coil closure ($P<0.001$). A device rather than coil was used in patients <3 years, weight <11 kg, and with a PDA minimum diameter >2 mm (all $P<0.001$). Three of 8 centers exclusively used a device for PDAs with a diameter >1.5 mm. In 9% of cases (n=46), an AE occurred; however, only 11 (2%) were classified as high severity. Younger age was associated with a higher AE rate. Coil-related AEs were more common than device-related AEs (10% versus 2%, $P<0.001$).

Conclusions—PDA closure in the present era has a very low rate of complications, although these are higher in younger children. Technical intervention-related events were more common in coil procedures compared with device procedures. For PDAs ≤2.5 mm in diameter, institutional differences in preference for device versus coil exist. (*J Am Heart Assoc.* 2013;2:e000424 doi: 10.1161/JAHA.113.000424)

Key Words: adverse events • complications • interventional catheterization • PDA • safety

WITH ALL THAT DATA: WHAT METHODS DO INDIVIDUAL CENTERS HAVE FOR QA AND QI ?

METHODS FOR QUALITY IMPROVEMENT AND QUALITY ASSURANCE

- Local quality assurance
- Local (continuous) quality improvement
- Medium-sized (research) registries / QI
- Large scale societal/government registries / QI

LOCAL QUALITY ASSURANCE

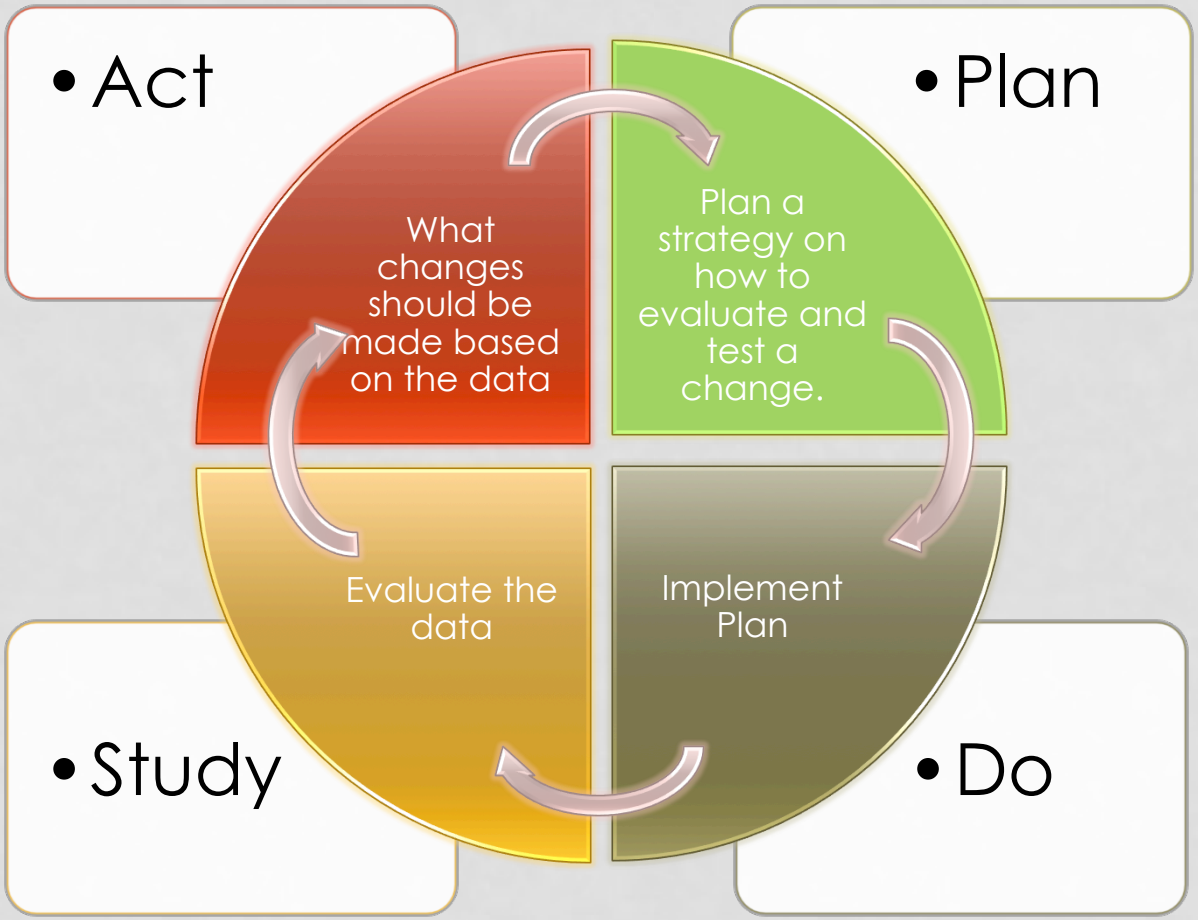
- Compliance with established standards
- Key performance measures
- Regular cath QI conferences
- Institutional event monitoring
- Regular QI presentations to department / leadership
- **Consistent data capture / data tracking is essential**

STRUCTURED CATHETERIZATION REPORT

- ACC/AHA/SCAI 2014 Health Policy Statement
- Elements of quality achieved:
  - Clarity and completeness
  - Consistency in the organization and presentation
  - Fulfillment of requirements for quality reporting, regulatory compliance, coding and billing
  - Reducing time for documentation and improving operator efficiency

Sanborn et al. JACC 2014. 63:2593-2623

CONTINUOUS QUALITY IMPROVEMENT IN THE CCCL: PDSA CYCLE



QUALITY IMPROVEMENT SHOULD BE NON PUNITIVE

- The goal of quality is not to find those who are underachieving and weed them out
- **The goal is to allow individuals and programs to identify areas for potential improvement and provide methods to achieve that improvement.**

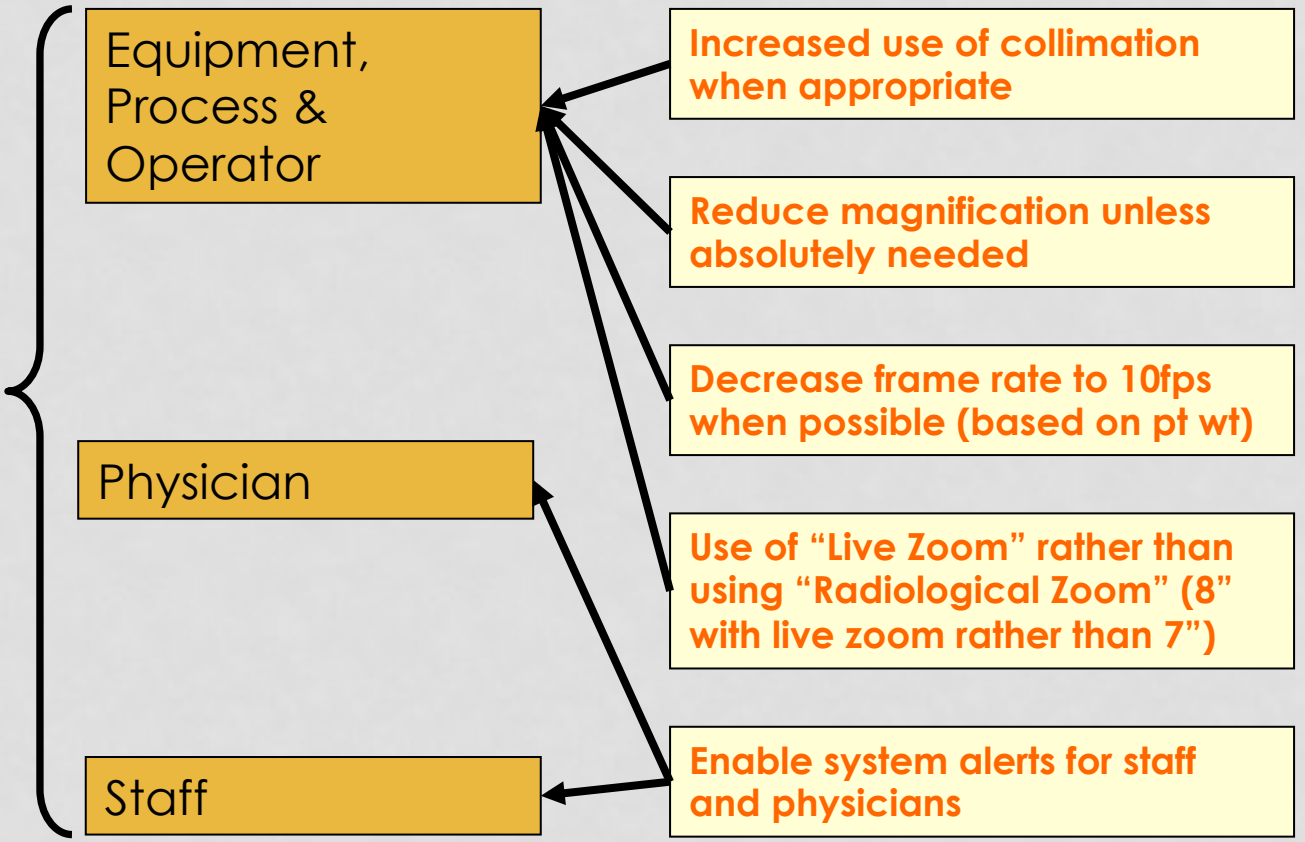
EXAMPLES OF POSSIBLE CATH LAB QI PROJECTS

1. Completeness of Handoffs
2. Reduction in Radiation Dose
3. Radiation Burn Prevention/Detection
4. Prevention of skin-related injuries

REDUCTION IN RADIATION DOSAGE (KEY DRIVER DIAGRAM)

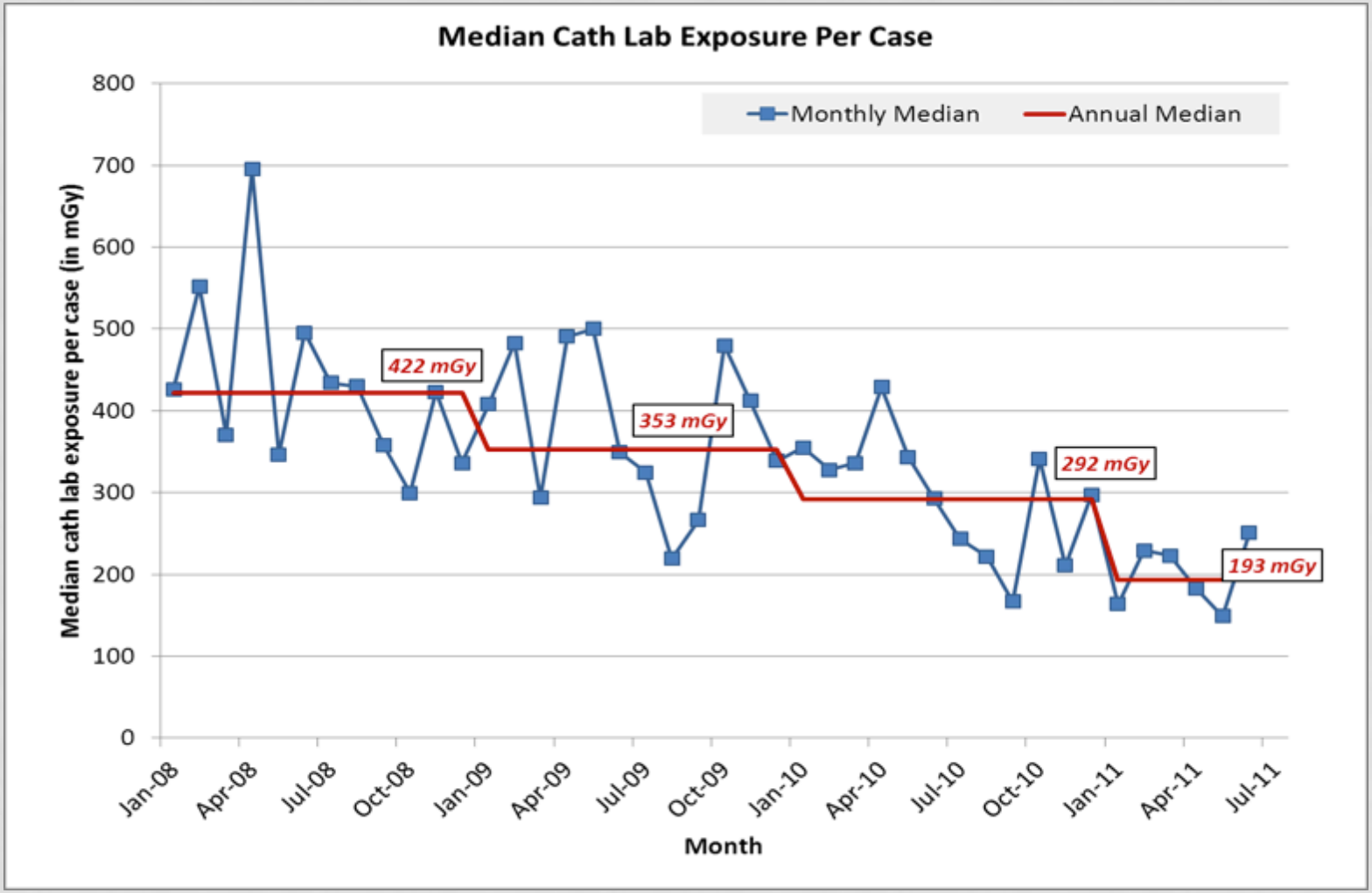
2011 Specific Aim

Median cath lab exposure per case in 2011 will be ≤ 95% of the median dose achieved during 2010.



Last revised: 9/28/11

REDUCTION IN RADIATION DOSE



CATH REGISTRIES

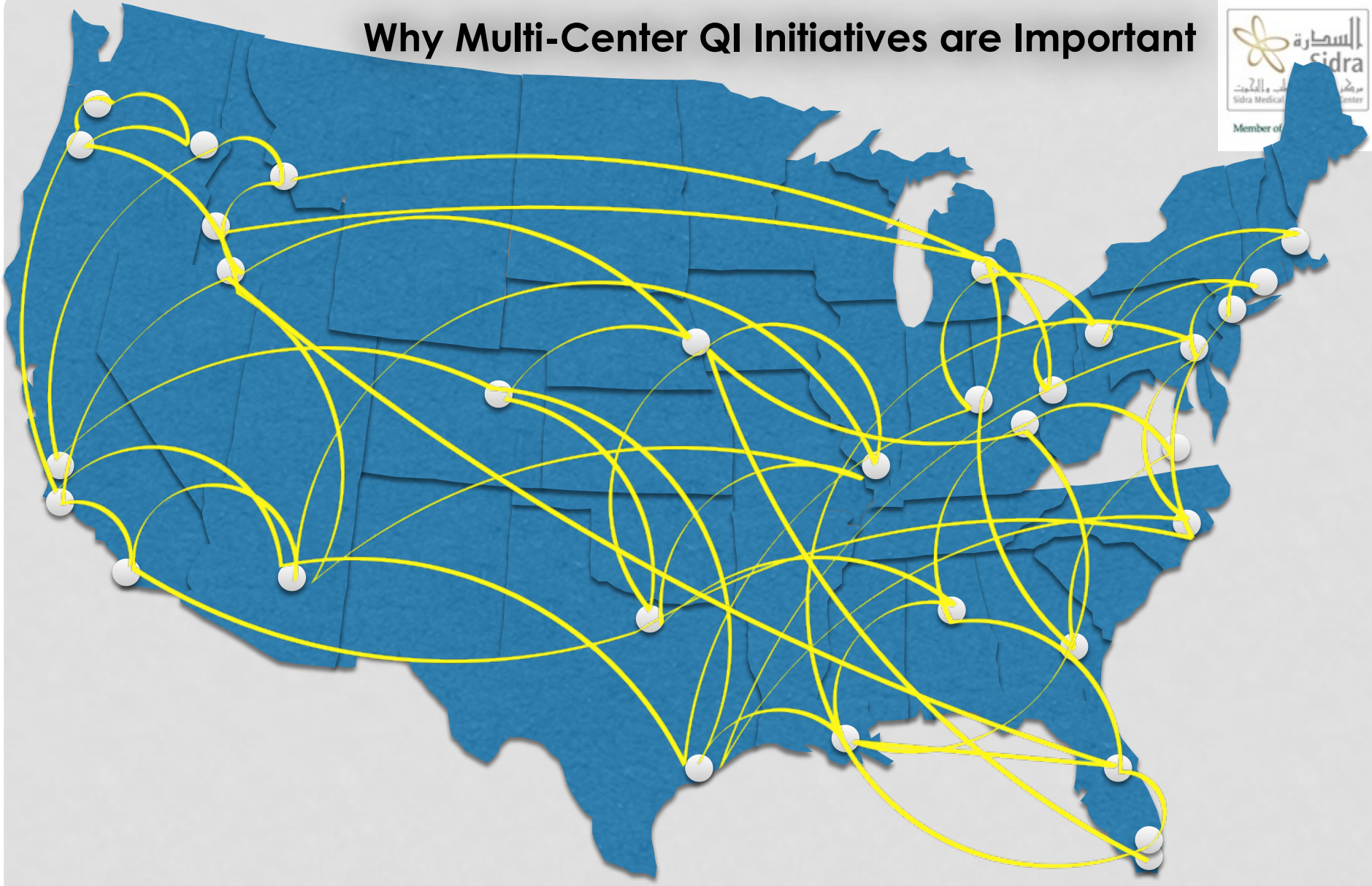
"Science tells us what we can do;
Guidelines what we should do; &
Registries what we are actually doing."

Lucas Kappenberger
Heart Rhythm Society Policy Conference,
Washington, DC, 2005

CATH REGISTRIES: WHY PARTICIPATE?

- Problem of institutional data:
  - Small numbers
  - Variation in complexity / acuity
- Provide benchmark data
- Possibility of risk stratification (CHARM)
- Supplementation of QA
- MOC 4
- Pick and choose: Magic, CCISC, C3PO (QI), IMPACT, CCAD

Why Multi-Center QI Initiatives are Important



Collaboration creates a fluid network promoting comparison, adaptation, and implementation of successful models

C3PO-QI: RADIATION DOSE BENCHMARKS

Sidra Medical and Research Center
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JACC: CARDIOVASCULAR INTERVENTIONS
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RADIATION SAFETY

Radiation Dose Benchmarks During Cardiac Catheterization for Congenital Heart Disease in the United States

Sunil J. Ghelani, MD,* Andrew C. Glatz, MD, MSCE,† Sthuthi David, BS,* Ryan Leahy, MD, MS,‡ Russel Hirsch, MD,§ Laurie B. Armsby, MD,‖ Sara M. Trucco, MD,¶ Ralf J. Holzer, MD, MSc,# Lisa Bergersen, MD, MPH*

ABSTRACT

OBJECTIVES The aim of this study was to define age-stratified, procedure-specific benchmark radiation dose levels during interventional catheterization for congenital heart disease.

BACKGROUND There is a paucity of published literature with regard to radiation dose levels during catheterization for congenital heart disease. Obtaining benchmark radiation data is essential for assessing the impact of quality improvement initiatives for radiation safety.

METHODS Data were obtained retrospectively from 7 laboratories participating in the Congenital Cardiac Catheterization Project on Outcomes collaborative. Total air kerma, dose area product, and total fluoroscopy time were obtained for the following procedures: 1) patent ductus arteriosus closure; 2) atrial septal defect closure; 3) pulmonary valvuloplasty; 4) aortic valvuloplasty; 5) treatment of coarctation of aorta; and 6) transcatheter pulmonary valve placement.

RESULTS Between January 2009 and July 2013, 2,713 cases were identified. Radiation dose benchmarks are presented including median, 75th percentile, and 95th percentile. Radiation doses varied widely between age groups and procedure types. Radiation exposure was lowest in patent ductus arteriosus closure and highest in transcatheter pulmonary valve placement. Total fluoroscopy time was a poor marker of radiation exposure and did not correlate well with total air kerma and dose area product.

CONCLUSIONS This study presents age-stratified radiation dose values for 6 common congenital heart interventional catheterization procedures. Fluoroscopy time alone is not an adequate measure for monitoring radiation exposure. These values will be used as baseline for measuring the effectiveness of future quality improvement activities by the Congenital Cardiac Catheterization Project on Outcomes collaborative. (J Am Coll Cardiol Intv 2014;7:1060–9)

TABLE 2 Total Air Kerma (mGy) Stratified by Procedure Type and Age Group

	Age, yrs				
Procedure	**<1**	**1–4**	**5–9**	**10–15**	**>15**
PDA					
No.	96	181	39	27	19
Median	76 (65–90)	96 (90–111)	160 (114–182)	300 (198–628)	949 (643–1,686)
75th percentile	118 (102–135)	140 (126–153)	195 (168–326)	715 (386–1,547)	1,686 (949–3,170)
95th percentile	230 (192–450)	253 (213–365)	392 (290–448)	1,551 (827–1,557)	3,170 (1,750–3,170)
ASD					
n	6	157	142	98	129
Median	–	120 (101–134)	188 (156–211)	444 (310–550)	630 (550–954)
75th percentile	–	220 (180–266)	300 (247–389)	768 (620–900)	1,470 (1,220–1,949)
95th percentile	–	528 (400–717)	670 (525–991)	1,738 (1,168–3,078)	3,853 (3,243–5,046)
PS					
n	244	44	18	31	25
Median	87 (79–96)	133 (119–153)	244 (100–351)	319 (272–512)	1,781 (778–2,430)
75th percentile	148 (127–174)	208 (147–282)	351 (255–698)	862 (436–1,144)	2,603 (1,789–4,976)
95th percentile	323 (289–417)	365 (282–536)	698 (382–698)	1,456 (1,053–1,710)	4,976 (3,652–9,048)
AS					
n	123	20	18	55	22
Median	122 (107–139)	258 (177–405)	170 (137–296)	780 (464–901)	882 (788–1,420)
75th percentile	204 (170–238)	421 (264–979)	296 (182–664)	1,136 (897–1,570)	1,420 (894–4,531)
95th percentile	361 (294–531)	1,377 (462–1,775)	664 (379–664)	2,111 (1,585–2,842)	4,531 (2,216–5,310)
CoA					
Median	137 (121–156)	233 (191–307)	444 (289–700)	1,043 (834–1,358)	1,716 (1,436–2,420)
75th percentile	228 (182–265)	373 (256–585)	768 (536–1,376)	1,696 (1,317–2,877)	3,024 (2,420–4,375)
95th percentile	600 (411–857)	826 (562–1,089)	1,546 (920–1,771)	3,604 (2,901–4,442)	7,128 (4,948–8,274)
TPV					
n	0	2	8	55	135
Median	–	–	–	1,461 (905–2,151)	2,502 (2,332–3,026)
75th percentile	–	–	–	2,675 (1,837–3,233)	4,050 (3,383–4,656)
95th percentile	–	–	–	4,579 (3,256–6,538)	6,820 (5,367–9,983)

Values in parentheses are 95% confidence interval.
Abbreviations as in Table 1.

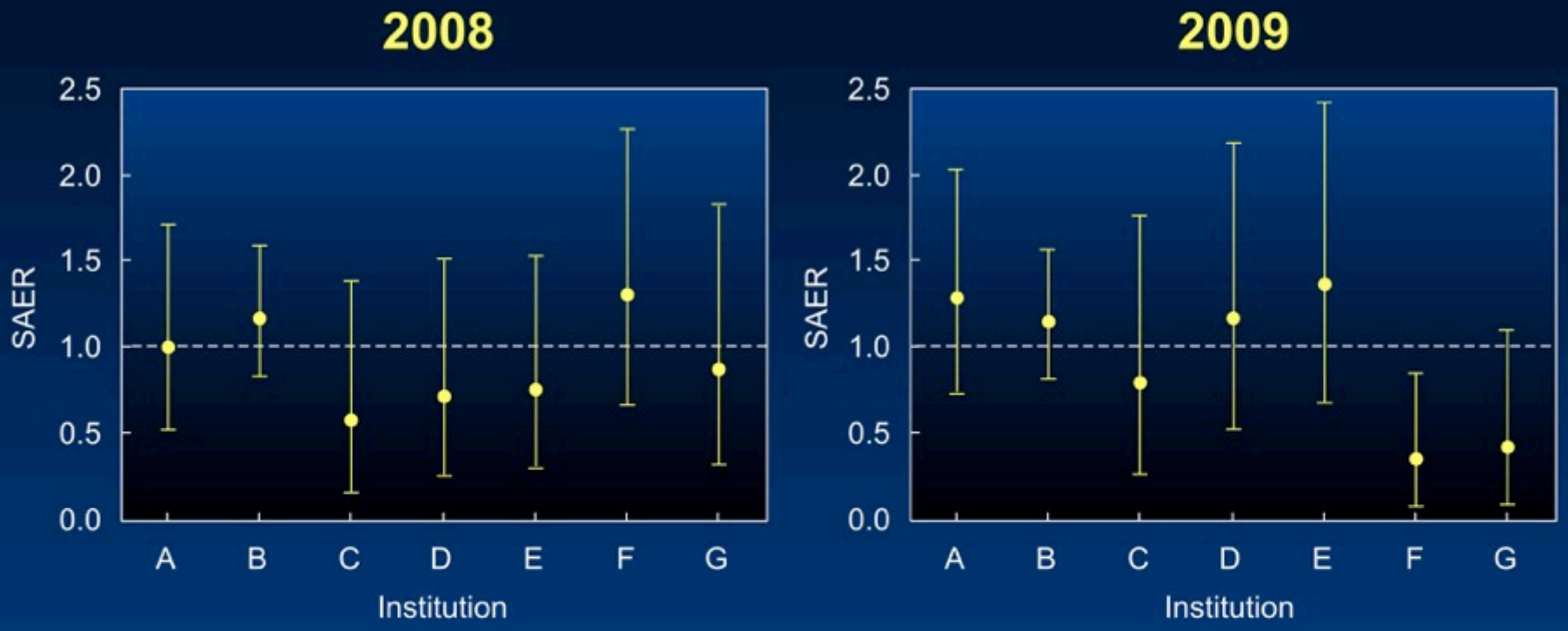
MEDIUM-SIZED RESEARCH REGISTRIES AND QI INITIATIVES

- Examples: Magic, CCISC, C3PO (QI)
- Advantages:
  - Control / access of own data
  - Flexibility to change
  - Supplementing local QI and QA
  - Research
- Disadvantages:
  - Selective participation
  - Smaller number of participating sites

Comparison Report

	All Institutions		Institution A		Institution B		Institution C	
	n	%	*n*	%	*n*	%	*n*	%
Number of Procedures	***12,915***		***1,843***		***4,210***		***1,309***	
Procedure Type								
Interventional	6,124	47%	855	46%	2,340	56%	489	37%
Hemodynamic	3,235	25%	555	30%	950	23%	375	29%
Biopsy	2,817	22%	373	20%	832	20%	257	27%
Other	739	6%	60	3%	88	2%	88	7%
General Anesthesia								
Spontaneously breathing	8,843	30%	1,079	59%	1,618	38%	408	31%
Other	9,069	70%	764	41%	2,589	61%	901	69%
Admission Source								
Elective - Outpatient	4,575	35%	490	27%	1,149	27%	648	50%
Elective - Scheduled	5,582	43%	899	49%	2,041	48%	434	33%
Not elective or scheduled	2,756	21%	454	25%	1,020	24%	227	17%

Outcome: Level 3/4/5 Preventable or Possibly Preventable Adverse Event



C3PO-QI: AD-HOC DATA REPORTS

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ADVERSE EVENTS AND DESCRIPTIONS

NATIONWIDE CHILDREN'S HOSPITAL **07/01/2011 to 06/30/2012**

Date	Initials	Event Name	Seriousness	Preventability	Attributability	Description
7/12/2011						
	M.W	Atrial Arrhythmia	Minor - L2	Not Preventable	Catheterization Related Problem	The patient experienced atrial flutter with rapid ventricular response at the conclusion of the procedure.
7/19/2011						
	B.L	Other access problem	Moderate - L3	Possibly Preventable	Access Related Problem	left iliac artery injury secondary to 4 fr sheath with extravasation.
7/21/2011						
	R.K	Confined vascular tear (perivascular extravasation not greater than in size)	Moderate - L3	Not Preventable	Angioplasty Related Problem	During the initial portion of this injection which was curtailed because the injection machine quickly shutoff because of pressure, there was a stain of the Contegra graft created that appeared self-contained. The catheter was ultimately moved above this into the pulmonary artery and a 2nd angiogram was performed which demonstrated the PA anatomy and the Contegra anatomy, but also revealed that there was some increase in size of this intramural stain of the Contegra graft.
7/28/2011						
	D.O	Vessel trauma	Minor - L2	Not Preventable	Catheterization Related Problem	During a 2nd systolic beat of an angiogram,while injection was being performed and although we placed a 1.0 sec rise time, there appeared to be an area of contrast extravasation that coincides with the aortotomy suture site. It was a very small and narrowed area of extravasation that filtered anterior and into what appeared to be a blind pocket without being washed away. Therefore, it did not appear that there was in fact communication with the aorta.
8/1/2011						
	R.H	Pulse loss (requiring intervention)	Minor - L2	Possibly Preventable	Access Related Problem	Pulse loss post cath - required heparing infusion
	B.N	Heart Block Resolved	Moderate - L3	Not Preventable	Catheterization Related Problem	, there was transient AV block during catheter manipulation across the tricuspid valve and RV outflow tract responding to very brief CPR and 5 mcg of Epinephrine and also bradycardia and similar event during initial expansion of the balloon atrial septostomy catheter in the left atrium that also responded to very brief CPR and 5 mcg of Epinephrine. The patient remained hemodynamically stable throughout the remaining portion of the procedure.
8/4/2011						
	C.C	Confined vascular tear (perivascular extravasation not greater than in size)	Minor - L2	Possibly Preventable	Angioplasty Related Problem	Possibly tiny amount of anterior conduit fracture with contrast extravasation but unable to 100% conbfirm as minisoule.

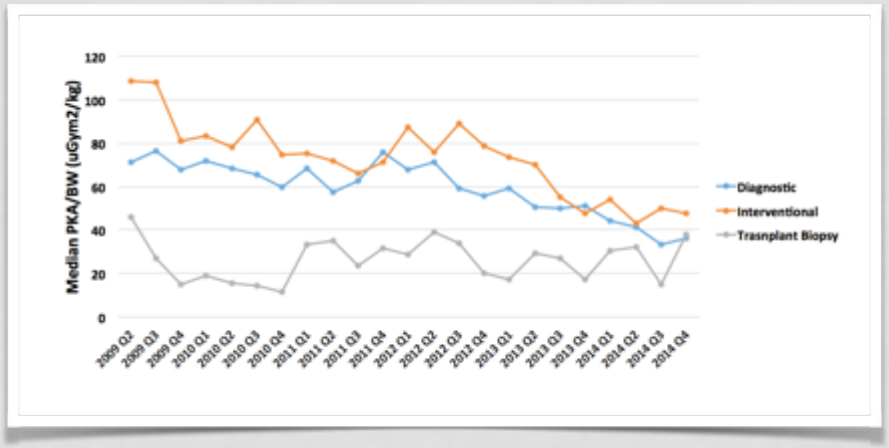
Created on: 06-November-2012 **Page 1 of 13**

C3PO-QI: TABLEAU

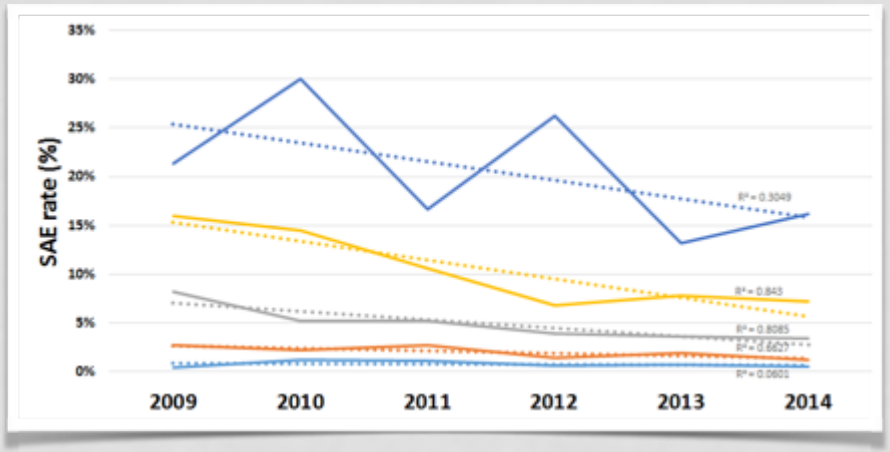
Congenital Cardiovascular Interventional Study Consortium

Catheterization Risk Assessment in Pediatrics (CRISP) launched in 2009

26 participating sites (18 USA, 8 International)



Radiation Exposure



SAER

Time series reports showing institutional comparisons

* provided by CCISC with permission

LARGE SCALE SOCIETAL/GOVERNMENT REGISTRIES AND QI INITIATIVES

- IMPACT, CCAD

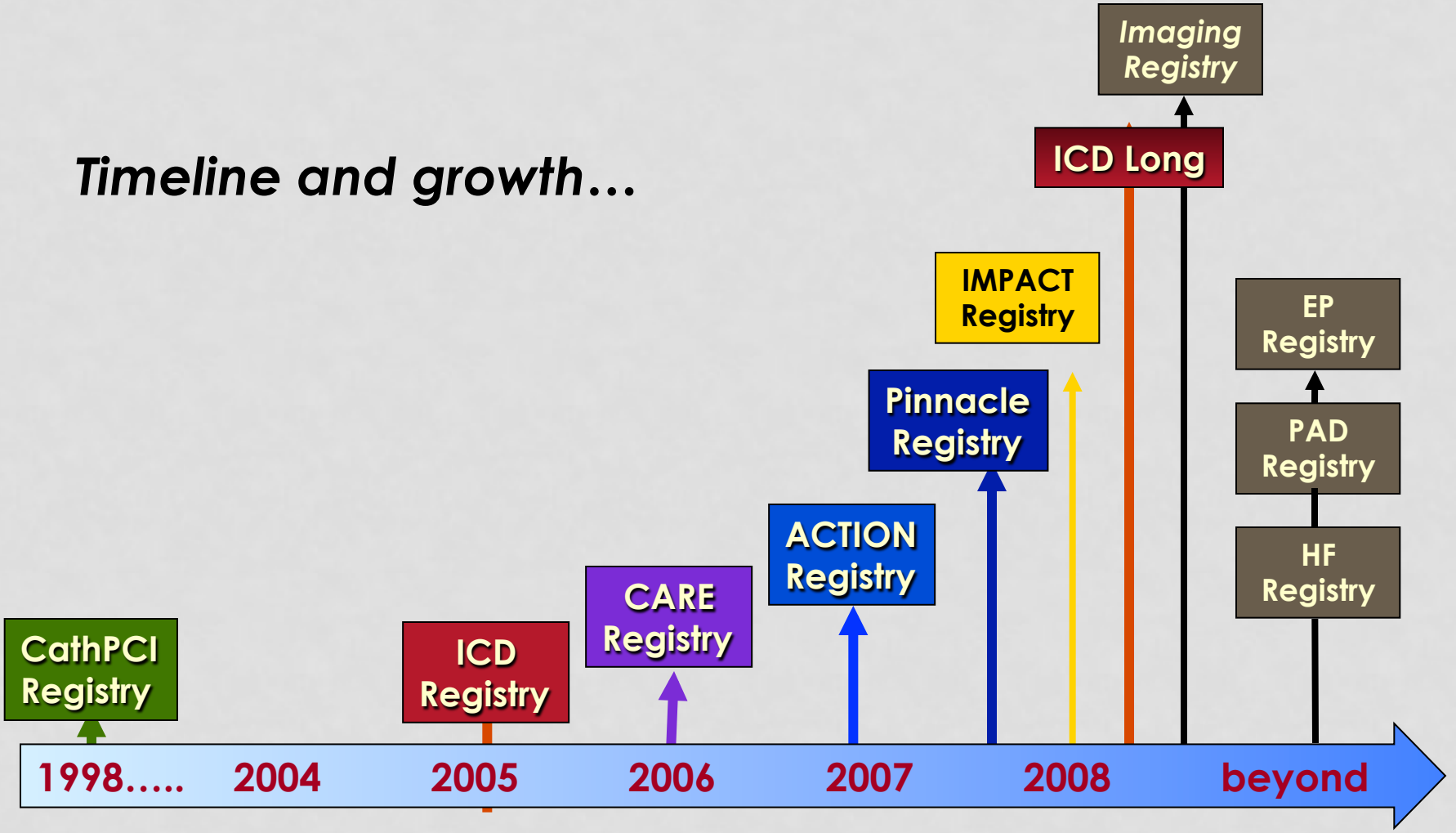
- Advantages of those registries
  - Large number of cases / centers
  - Government/payer support
  - Participation may be/become mandated
  - Well established infrastructure

LARGE SCALE SOCIETAL/GOVERNMENT REGISTRIES AND QI INITIATIVES

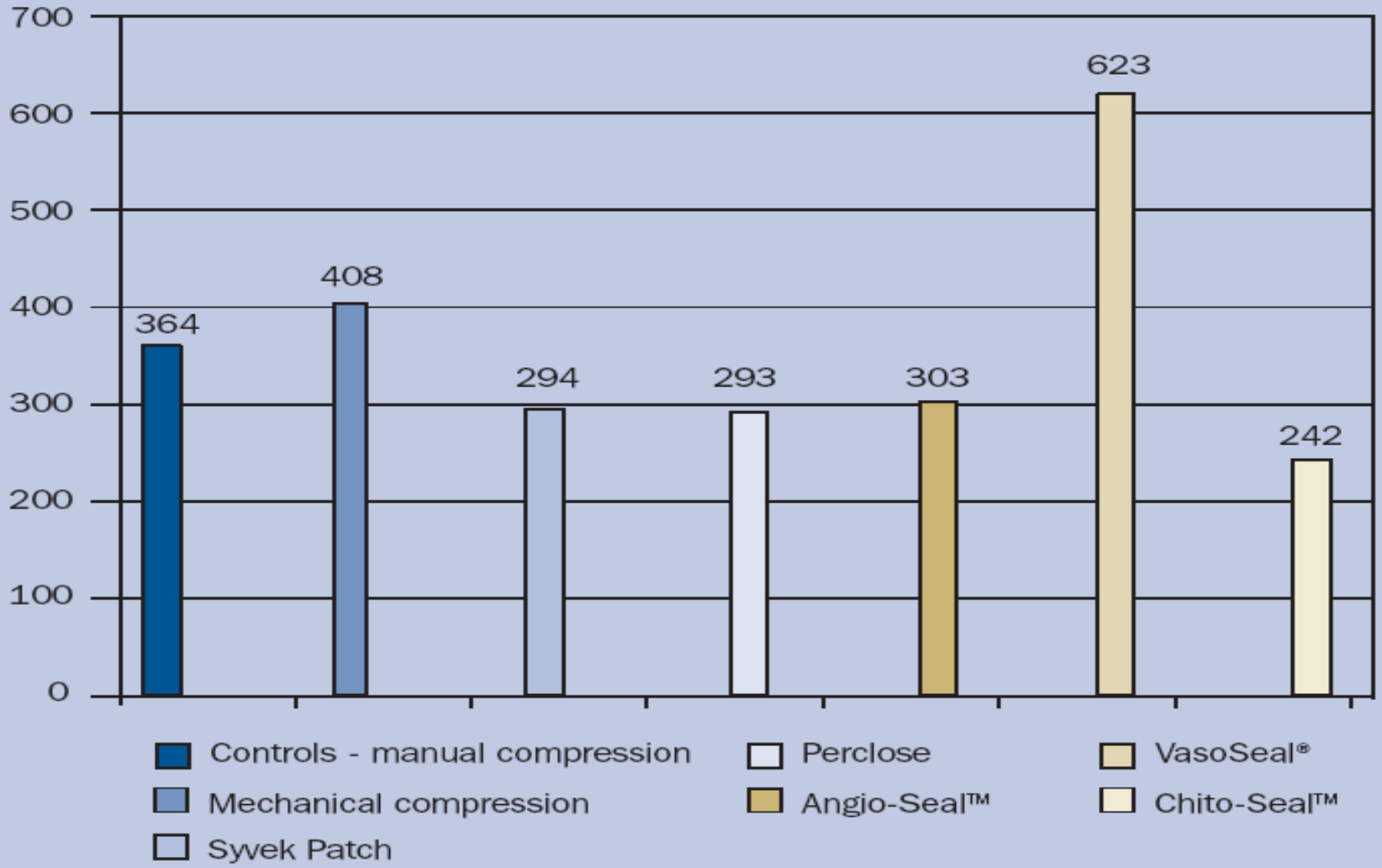
- Disadvantages:
  - Slow to change
  - Customizable ad-hoc data access limited
  - Reports limited to standardized quarterly reports
  - Research process cumbersome

National Cardiovascular Data Registry

Timeline and growth…

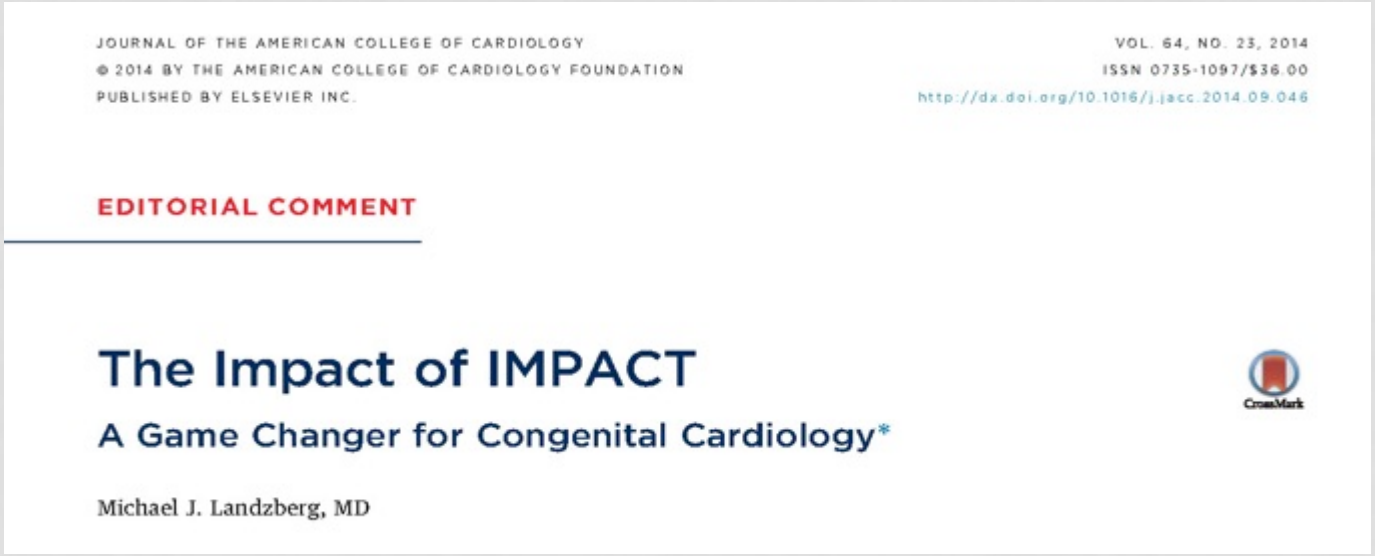


Rate per 10,000 of Local Vascular Complications by Type Hemostasis (Univariate Analysis) - Year 2003 N=13,878



IMPACT Registry

IMproving Pediatric and Adult Congenital Treatments



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EDITORIAL COMMENT

The Impact of IMPACT

A Game Changer for Congenital Cardiology*

Michael J. Landzberg, MD

IMPACT REGISTRY DATA REPORTS

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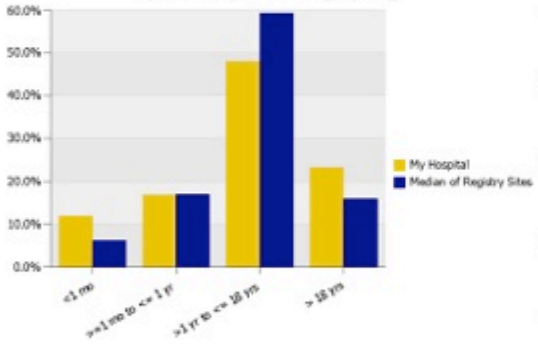
Executive Summary

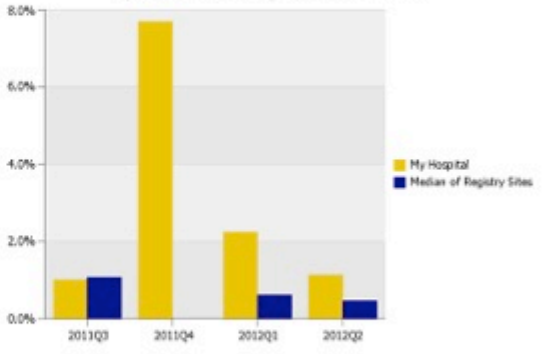
IMPACT Registry™

Nationwide Children's Hospital (989257) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q2

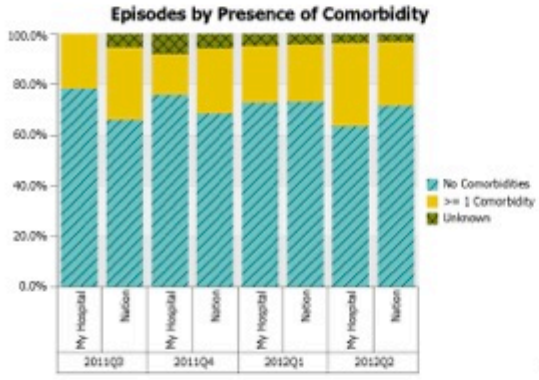
Episodes by Patient Age (R4Q)



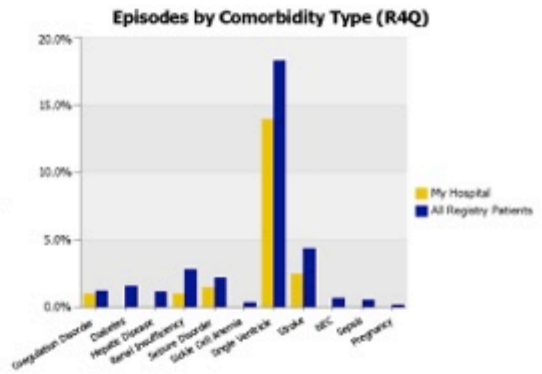
Episodes Resulting in Patient Death



Episodes by Presence of Comorbidity



Episodes by Comorbidity Type (R4Q)



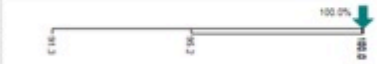
IMPACT REGISTRY DATA REPORTS

Executive Summary

IMPACT Registry™

Nationwide Children's Hospital (989257) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q2

Section IA: Quality Metrics

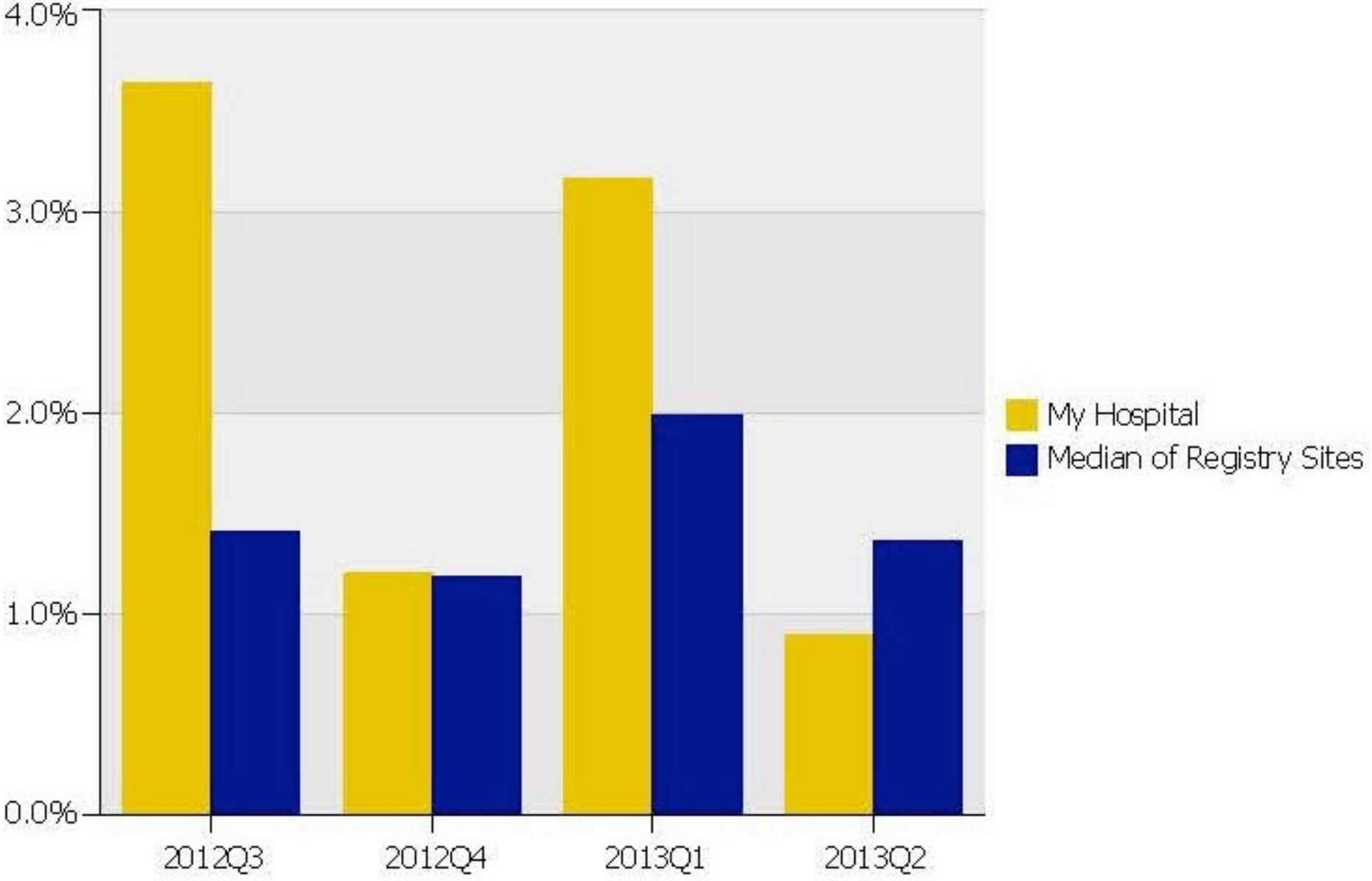
Quality Metrics	Distribution of Hospital Performance (10th percentile … 90th percentile; Better →)
1 **Proportion of patients <1 month of age that have a diagnostic catheterization procedure with a major adverse event or death**	
My Hospital: 40.0% · US Hospitals 50th Ptl: 3.4% · US Hospitals 90th Ptl: 0.0%	
Proportion of patients <1 month of age undergoing a diagnostic catheterization procedure with a major adverse event or death. (May reflect other med/surg Rx during same admission.) [Detail Line:1001]	
2 **Proportion of patients >= 1 month to <= 1 year of age that have a diagnostic catheterization procedure with a major adverse event or death**	
My Hospital: 0.0% · US Hospitals 50th Ptl: 0.0% · US Hospitals 90th Ptl: 0.0%	
Proportion of patients >= 1 month to <= 1 year of age that have a diagnostic catheterization procedure with a major adverse event or death. (May reflect other med/surg Rx during same admission.) [Detail Line:1002]	
3 **Proportion of patients >1 year of age and <=18 that have a diagnostic catheterization procedure with a major adverse event or death**	
My Hospital: 16.7% · US Hospitals: 0.0%	
Proportion of patients > 1 year of age and <= 18 years of age undergoing a diagnostic catheterization procedure with a major adverse event or death. (May reflect other med/surg Rx during same admission.) [Detail Line:1003]	
4 **Proportion of patients >18 years of age that have a diagnostic catheterization procedure with a major adverse event or death**	
My Hospital: 0.0% · US Hospitals: 0.0%	
Proportion of patients > 18 years of age undergoing a diagnostic catheterization procedure with a major adverse event or death. (May reflect other med/surg Rx during same admission.) [Detail Line:1004]	
5 **Proportion of treated ASD closure defects leaving the cath lab with a none to trivial shunt**	
My Hospital: 100.0% · US Hospitals 50th Ptl: 100.0% · US Hospitals 90th Ptl: 100.0%	
Proportion of treated ASD closure defects leaving the cath lab with a none to trivial shunt. [Detail Line:1005]	
6 **Proportion of patients that have a treated isolated ASD closure that have a device embolization (requiring device retrieval)**	
My Hospital: 0.0% · US Hospitals 50th Ptl: 0.0% · US Hospitals 90th Ptl: 0.0%	
Proportion of patients undergoing an isolated atrial septal defect closure procedure that have an intra or post procedure device embolization. [Detail Line:1006]	
7 **Proportion of patients that have an isolated PDA closure procedure leaving the cath lab with a none to trivial shunt**	
My Hospital: 100.0% · US Hospitals 50th Ptl: 100.0% · US Hospitals 90th Ptl: 100.0%	
Proportion of patient undergoing an isolated PDA closure procedure leaving the cath lab with a none to trivial shunt. [Detail Line:1007]	
8 **Proportion of patients that have a treated isolated PDA closure procedure that have a device embolization (requiring device retrieval)**	
My Hospital: 0.0% · US Hospitals 50th Ptl: 0.0% · US Hospitals 90th Ptl: 0.0%	
Proportion of patients undergoing an isolated PDA closure procedure that have an intra or post procedure device embolization. [Detail Line:1008]	

Executive Summary
IMPACT Registry™
Nationwide Children's Hospital (989257) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q2
Section IA: Quality Metrics

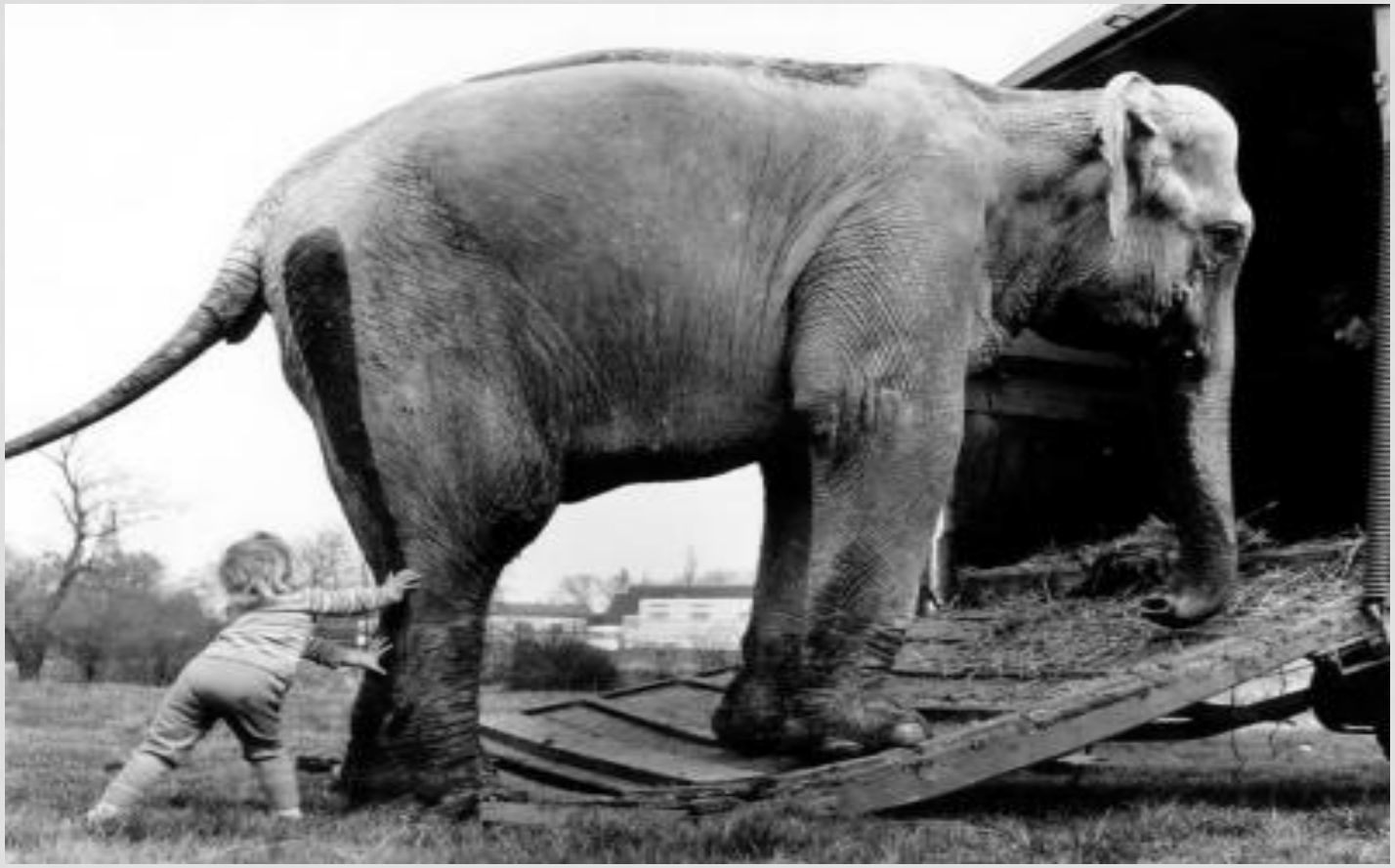
9 **Proportion of patients that had a coarctation repair by balloon angioplasty that have a post procedure coarctation peak systolic gradient of <10 mmHg**	
My Hospital: 62.5% · US Hospitals 50th Ptl: 100.0% · US Hospitals 90th Ptl:	
Proportion of patients undergoing an isolated coarctation procedure by balloon angioplasty reaching a post procedure coarctation peak systolic gradient of <10 mmHg. [Detail Line:1009]	
10 **Proportion of patients that had a coarctation repair with a stent that have a post procedure coarctation peak systolic gradient of <10 mmHg**	
My Hospital: 100.0% · US Hospitals 50th Ptl: 100.0% · US Hospitals 90th Ptl:	
Proportion of patients undergoing an isolated coarctation procedure with a stent reaching a post procedure coarctation peak systolic gradient of <10 mmHg. [Detail Line:1010]	
11 **Proportion of patients that have an aortic valvuloplasty that have a post procedure aortic valve insufficiency increase of two or more grades**	
	

Some elements are so rare that metrics are either 0% or 100%

Episodes of Care Resulting in Patient Death Graph



IMPACT – IMPLEMENTING CHANGE



BCH/CHOP/NCH: DEATH ATTRIBUTABILITY

Catheterization and Cardiovascular Interventions 85:104–110 (2015)

PEDIATRIC AND CONGENITAL HEART DISEASE

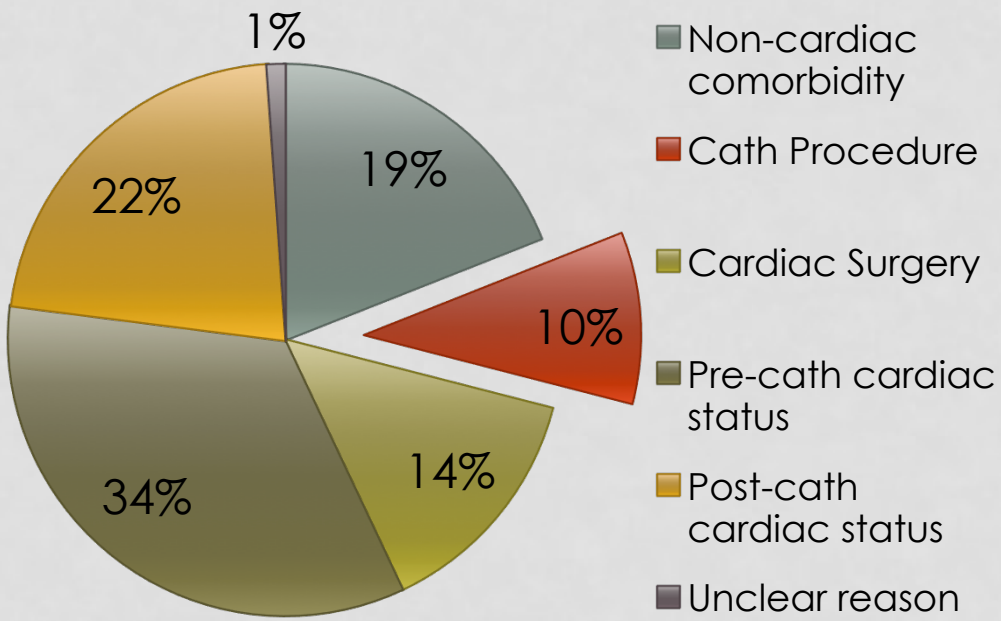
Original Studies

Quality Metrics in Cardiac Catheterization for Congenital Heart Disease: Utility of 30-Day Mortality

Carl H. Backes,[1*] MD, Lisa Bergersen,[2] MD, Jonathan J. Rome,[3] MD, Sarosh P. Batlivala,[3] MD, Andrew C. Glatz,[3] MD, Bugsu Ovunc,[2] MD, Sthuthi David,[2] MS, Brian K. Rivera,[1] MS, Urbee Haque,[1] MS, Kevin Kollins,[1] MD, Han Yin,[1] MS, and Ralf J. Holzer,[1] MD

Objectives: To characterize the frequency and attributability of death among patients who died within 30 days of their cardiac catheterization (30-day mortality). Background: 30-day postprocedure mortality is commonly used as a quality outcome metric in national cardiac catheterization registries. It is unclear if this parameter is sufficiently specific to meaningfully capture mortality attributable to cardiac catheterization in patients with congenital heart disease (CHD). Methods: Multicenter cohort study with 3 participating centers. Records were retrospectively reviewed for patients who died within 30 days of catheterization (06/2007-06/2012). Attributability of death was assigned to each case. Results: A total of 14,707 cardiac catheterization procedures were performed during the study period. Death occurred within 30 days in 279/14,707 (1.9%) of cases. Among the patients who died, 53% of cases were emergent or urgent cases. The median age was 4 mos (1 day–45 years). Death was attributable to the catheterization procedure in 29/279 (10%) of cases. Death was attributable to cardiac surgery in 14%, precatheterization clinical status in 34%, postcatheterization clinical status in 22%, and noncardiac comorbidity in 19%. In 1%, death attributability could not be established. Conclusions: While valuable in adult settings, 30-day mortality is inadequate as a quality metric among patients with CHD undergoing cardiac catheterization. To derive the optimal benefit from catheterization registry data, more robust methodologies to capture procedure-related mortality are needed.

Key words: PEDS; CATH; pediatric interventions; complications; quality



Original Article

Adjusting for Risk Associated With Pediatric and Congenital Cardiac Catheterization

A Report From the NCDR IMPACT Registry

Natalie Jayaram, MD, MSB; Robert H. Beekman III, MD; Lee Benson, MD; Ralf Holzer, MD; Kathy Jenkins, MD, MPH; Kevin F. Kennedy, MS; Gerard R. Martin, MD; John W. Moore, MD, MPH; Richard Ringel, MD; Jonathan Rome, MD; John A. Spertus, MD, MPH; Robert Vincent, MD; Lisa Bergersen, MD, MPH

Background—As US health care increasingly focuses on outcomes as a means for quantifying quality, there is a growing demand for risk models that can account for the variability of patients treated at different hospitals so that equitable comparisons between institutions can be made. We sought to apply aspects of prior risk-standardization methodology to begin development of a risk-standardization tool for the National Cardiovascular Data Registry (NCDR) IMPACT (Improving Pediatric and Adult Congenital Treatment) Registry.

Cardiology in the Young 2015; Page 1 of 9
doi:10.1017/S1047951114002637

Original Article

Procedural characteristics and adverse events in diagnostic and interventional catheterisations in paediatric and adult CHD: initial report from the IMPACT Registry

Robert N. Vincent,[1,2] John Moore,[3] Robert H. Beekman III,[4] Lee Benson,[5] Lisa Bergersen,[6] Ralf Holzer,[7] Natalie Jayaram,[8,9] Kathy Jenkins,[6] Richard Ringel,[10] Jonathan Rome,[11] Gerard R. Martin[12]

[1]Department of Pediatrics; [2]Department of Pediatric Cardiology, Children's Healthcare of Atlanta, Emory University School of Medicine, Atlanta; [3]Rady Children's Hospital, University of California San Diego, San Diego; [4]Cincinnati Children's Hospital Medical Center, University of Cincinnati, Cincinnati, United States of America; [5]Toronto Hospital for Sick Children, University of Toronto, Toronto, Canada; [6]Boston Children's Hospital, Harvard University, Boston, United States of America; [7]Sidra Medical Center, Doha, Qatar; [8]Children's Mercy Hospitals and Clinics; [9]Saint Luke's Mid America Heart Institute; [10]Johns Hopkins Children's Center, Johns Hopkins University, Baltimore; [11]Children's Hospital of Philadelphia, University of Pennsylvania, Philadelphia; [12]Children's National Health System, George Washington University, Washington, District of Columbia, United States of America

Abstract *Objectives:* To report procedural characteristics and adverse events on data collected in the registry. *Background:* The IMPACT – IMproving Paediatric and Adult Congenital Treatment – Registry is a catheterisation registry of paediatric and adult patients with CHD undergoing diagnostic and interventional cardiac catheterisation. We are reporting the procedural characteristics and adverse events of patients undergoing diagnostic and interventional catheterisation procedures from January, 2011 to March, 2013. *Methods:* Demographic, clinical, procedural, and institutional data elements were collected at the participating centres and entered via either a web-based platform or software provided by American College of Cardiology-certified vendors, and were collected in a secure, centralised database. Centre participation was voluntary. *Results:* During the time frame of data collection, 19,797 procedures were entered into the IMPACT Registry. Procedures were classified as diagnostic only (35.4%); one of six specific interventions (23.8%); other or multiple interventions (40.7%); and were further broken down into four age groups. Anaesthesia was used in 84.1% of diagnostic procedures and 87.8% of interventional ones. Adverse events occurred in 10.0% of diagnostic and 11.1% of interventional procedures. *Conclusions:* The IMPACT Registry is gathering

Cardiology in the Young 2015; Page 1 of 11
doi:10.1017/S1047951115002218

Original Article

Characteristics and safety of interventions and procedures performed during catheterisation of patients with congenital heart disease: early report from the national cardiovascular data registry

Ralf Holzer,[1] Robert Beekman,[2] Lee Benson,[3] Lisa Bergersen,[4] Natalie Jayaram,[5] Kathy Jenkins,[4] Kevin Kennedy,[6] John Moore,[7] Richard Ringel,[8] Jonathan Rome,[9] Robert Vincent,[10] Gerard R. Martin[11]

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ORIGINAL INVESTIGATIONS

Procedural Results and Safety of Common Interventional Procedures in Congenital Heart Disease

Initial Report From the National Cardiovascular Data Registry

John W. Moore, MD, MPH,* Robert N. Vincent, MD,† Robert H. Beekman III, MD,‡ Lee Benson, MD,§ Lisa Bergersen, MD, MPH,‖ Ralf Holzer, MD,¶ Natalie Jayaram, MD,#** Kathy Jenkins, MD, MPH,‖ Yan Li, PhD,** Richard Ringel, MD,†† Jonathan Rome, MD,‡‡ Gerard R. Martin, MD,§§ on behalf of the NCDR IMPACT Steering Committee

ABSTRACT

BACKGROUND The National Cardiovascular Data Registry (NCDR) launched the IMPACT (Improving Pediatric and Adult Congenital Treatment) Registry in 2010. By 2013, its patient enrollment exceeded that of other current and historical congenital catheterization registries.

OBJECTIVES This study sought to describe procedural results and safety of 6 common congenital interventions performed in patients enrolled during the IMPACT Registry's initial periods.

METHODS With specified exclusions, we compiled registry data from patients enrolled in the IMPACT Registry from January 2011 through March 2013 who underwent 1 of the following isolated procedures: device closure of atrial septal defect (ASD); device closure of patent ductus arteriosus (PDA); pulmonary valvuloplasty; aortic valvuloplasty; coarctation of the aorta angioplasty and stenting; and pulmonary artery stenting. Patient data, procedural data and results, and adverse events (AEs) were reviewed and described.

RESULTS In 4,152 catheterizations, 1 isolated procedure was reported. There were 1,286 single-ASD procedures, 1,375 PDA procedures, 270 "typical" pulmonary valve procedures, 305 aortic valve procedures, 671 aortic procedures, and 245 pulmonary artery procedures. The reported procedure was performed in >95% of catheterizations. Stated outcomes were accomplished in >98% of ASD and PDA procedures, but less commonly in the others, with coarctation angioplasty procedures being the least successful (51%). Reported major AE rates ranged from 0% to 3.3%; total AE rates ranged

REGISTRIES AND QUALITY GO HAND-IN-HAND WITH RESEARCH

RESEARCH OPPORTUNITIES: USE REGISTRY DATA TO ANSWER YOUR OWN QUESTIONS!

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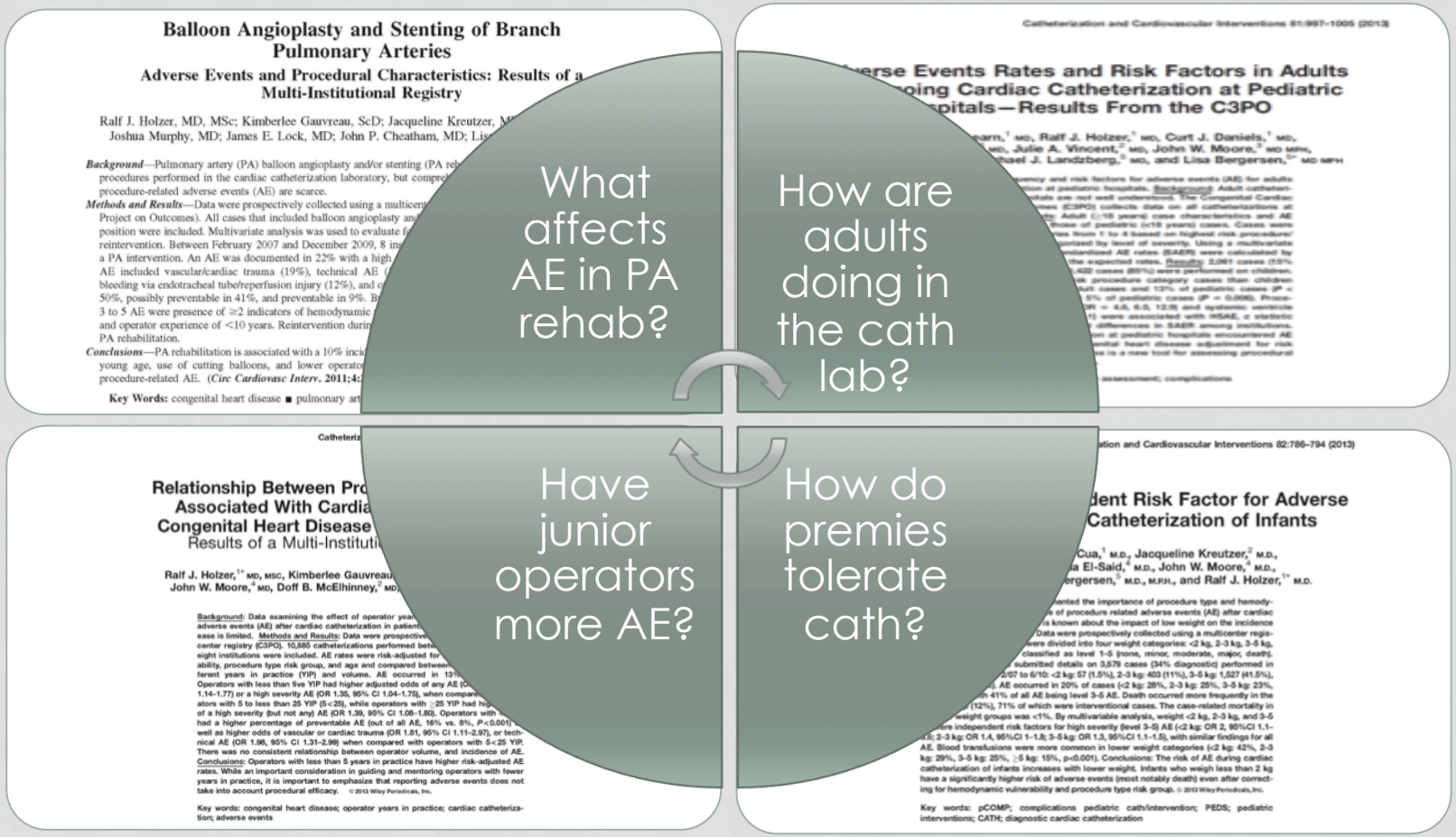

THE PROCESS CREATES OPPORTUNITIES FOR RESEARCH!

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IMPACT Metrics

Disagreement on 30-day mortality

Catheterization and Cardiovascular Interventions 85:104–110 (2015)

PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Quality Metrics in Cardiac Catheterization for Congenital Heart Disease: Utility of 30-Day Mortality

Carl H. Backes,[1]* MD, Lisa Bergersen,[2] MD, Jonathan J. Rome,[3] MD, Sarosh P. Bathivala,[1] MD, Andrew C. Glatz,[1] MD, Bugsu Okuno,[1] MD, Sthuthi David,[1] MD, Brian K. Rivera,[1] MD, Urbee Haque,[1] MS, Kevin Kollins,[1] MD, Han Yin,[1] MS, and Ralf J. Holzer,[1] MD

Objectives: To characterize the frequency and attributability of death among patients who died within 30 days of their cardiac catheterization (30-day mortality). Background: 30-day postprocedure mortality is commonly used as a quality outcome metric in national cardiac catheterization registries. It is unclear if this parameter is sufficiently specific to meaningfully capture mortality attributable to cardiac catheterization in patients with congenital heart disease (CHD). Methods: Multicenter cohort study with 3 participating centers. Records were retrospectively reviewed for patients who died within 30 days of catheterization (06/2007–06/2012). Attributability of death was assigned to each case. Results: A total of 14,707 cardiac catheterization procedures were performed during the study period. Death occurred within 30 days in 279/14,707 (1.9%) of cases. Among the patients who died, 59% of cases were emergent or urgent cases. The median age was 4 mos (1 day–45 years). Death was attributable to the catheterization procedure in 29/279 (10%) of cases. Death was attributable to cardiac surgery in 14%, precatheterization clinical status in 34%, postcatheterization clinical status in 22%, and noncardiac comorbidity in 19%. In 1%, death attributability could not be established. Conclusions: While valuable in adult settings, 30-day mortality is inadequate as a quality metric among patients with CHD undergoing cardiac catheterization. To derive the optimal benefit from catheterization registry data, more robust methodologies to capture procedure-related mortality are needed. © 2014 Wiley Periodicals, Inc.

Key words: PEDIATRIC CATH; pediatric interventions; complications; quality

RESULTS OF INNOVATIVE LOCAL QI CAN BE PUBLISHED!

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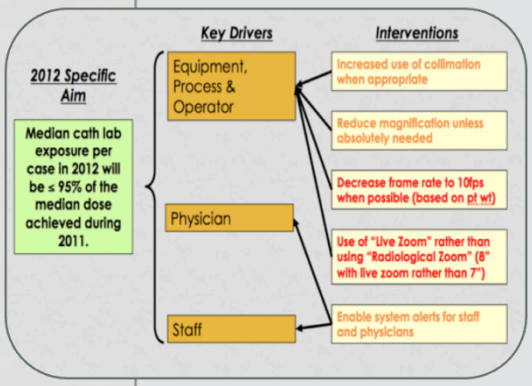

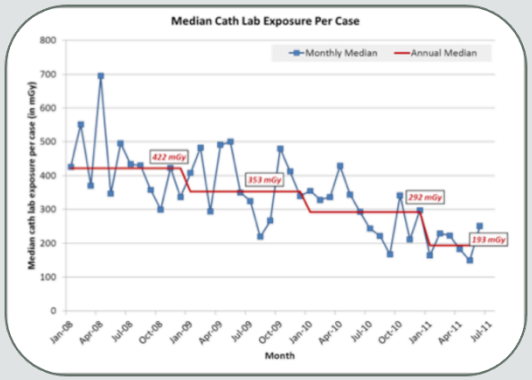

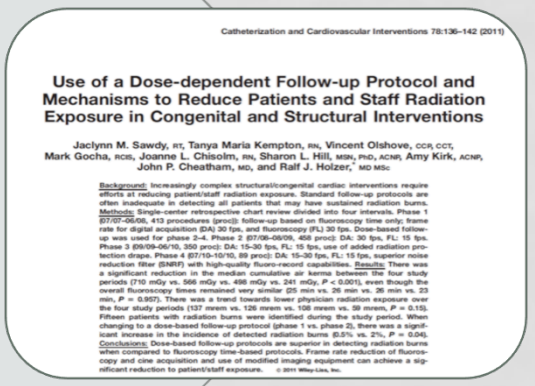

Catheterization and Cardiovascular Interventions 78:136–142 (2011)

Use of a Dose-dependent Follow-up Protocol and Mechanisms to Reduce Patients and Staff Radiation Exposure in Congenital and Structural Interventions

Jaclynn M. Sawdy, RT, Tanya Maria Kempton, RN, Vincent Olshove, CCP, CCT, Mark Gocha, RCIS, Joanne L. Chisolm, RN, Sharon L. Hill, MSN, PhD, ACNP, Amy Kirk, ACNP, John P. Cheatham, MD, and Ralf J. Holzer,* MD MSc

Background: Increasingly complex structural/congenital cardiac interventions require efforts at reducing patient/staff radiation exposure. Standard follow-up protocols are often inadequate in detecting all patients that may have sustained radiation burns. Methods: Single-center retrospective chart review divided into four intervals. Phase 1 (07/07–06/08, 413 procedures (proc)): follow-up based on fluoroscopy time only; frame rate for digital acquisition (DA) 30 fps, and fluoroscopy (FL) 30 fps. Dose-based follow-up was used for phase 2–4. Phase 2 (07/08–09/09, 458 proc): DA: 30 fps, FL: 15 fps. Phase 3 (09/09–06/10, 350 proc): DA: 15–30 fps, FL: 15 fps, use of added radiation protection drape. Phase 4 (07/10–10/10, 89 proc): DA: 15–30 fps, FL: 15 fps, superior noise reduction filter (SNRF) with high-quality fluoro-record capabilities. Results: There was a significant reduction in the median cumulative air kerma between the four study periods (710 mGy vs. 566 mGy vs. 498 mGy vs. 241 mGy, $P < 0.001$), even though the overall fluoroscopy times remained very similar (25 min vs. 26 min vs. 26 min vs. 23 min, $P = 0.957$). There was a trend towards lower physician radiation exposure over the four study periods (137 mrem vs. 126 mrem vs. 108 mrem vs. 59 mrem, $P = 0.15$). Fifteen patients with radiation burns were identified during the study period. When changing to a dose-based follow-up protocol (phase 1 vs. phase 2), there was a significant increase in the incidence of detected radiation burns (0.5% vs. 2%, $P = 0.04$). Conclusions: Dose-based follow-up protocols are superior in detecting radiation burns when compared to fluoroscopy time-based protocols. Frame rate reduction of fluoroscopy and cine acquisition and use of modified imaging equipment can achieve a significant reduction to patient/staff exposure.

GREAT OPPORTUNITIES FOR FELLOWS, STAFF AND RESIDENTS

Catheterization and Ca

PEDIATRIC AND CONGENITAL HEA

Original Studies

Device Therapy for Atrial Sep
Multicenter Cohort: Acute Outcom

Howaida El-Said,[1]* MD, PhD, Sanjeet Hegde,[1] MD,
William Hellenbrand,[3] MD, Jacqueline Kreutzer

Catheterization and Cardiovascular Interventions 75:389–400 (2010)

PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Adverse Event Rates in Congenital Cardiac Catheterization – A Multi-Center Experience

Lisa Bergersen,[1]* MD, Audrey Marshall,[1] MD, Kimberlee Gauvreau,[1] ScD,
Robert Beekman,[2] MD, Russel Hirsch,[2] MD, Susan Foerster,[2] MD, David Balzer,[2] MD,
[illegible]brand,[4] MD, Ralf Holzer,[5] MD, John Cheatham,[3] MD,
[illegible]es Lock,[1] MD, and Kathy Jenkins,[1] MD, MPH

Hybrid Procedures: Adverse Events and Procedural Characteristics—Results of a Multi-Institutional Registry

Ralf Holzer, MD,* Audrey Marshall, MD,† Jackie Kreutzer, MD,‡ Russel Hirsch, MD,§
Joanne Chisolm, RN,* Sharon Hill, ACNP,* Mark Galantowicz, MD,* Alistair Phillips, MD,†
John Cheatham, MD,* and Lisa Bergerson, MD‖

*Department of Cardiology, Nationwide Children's Hospital, Columbus, Ohio, †Department of Cardiology, Cincinnati Children's Hospital, Cincinnati, Ohio, ‡Department of Cardiology, Children's Hospital Boston, Boston, Mass, and §Department of Cardiology, Children's Hospital of Pittsburgh Pittsburgh, Pa, USA

ABSTRACT

Introduction. Procedural cooperation between cardiac surgeon and interventional cardiologist to facilitate interventions such as device delivery or angioplasty (hybrid procedure) has become increasingly common in the management of patients with congenital heart disease.
Design. Data were prospectively collected using a multicenter registry (C3PO). Between February 2007 and December 2008, seven institutions submitted data regarding 7019 cardiac catheterization procedures. Procedural data and adverse events (AEs) of 128 hybrid procedures were evaluated.
Results. There was significant variability in the number of hybrid procedures per center, ranging from one to 89 with a median of eight. A total of 60% of interventional (vs. strictly diagnostic) hybrid procedures were performed by one center. The median weight was 3.7 kg (0.7–86 kg). Single-ventricle circulation was present in 60% of the procedures. Hybrid procedures included: patent ductus arteriosus (PDA) stent placement (n = 55), vascular rehabilitation (n = 25), ventricular septal defect (VSD) device closure (n = 7), valvotomy (n = 3), and diagnostic hybrid procedures (n = 38). Sixteen AEs occurred in 15/128 (12%) procedures. These included minor or trivial AEs (n = 9), moderate AEs (n = 5), major AEs (n = 1), and catastrophic AEs (n = 1). The type of AE documented included arrhythmias (n = 6), hypoxia or hypotension (n = 3), vessel or cardiac trauma (n = 2), and other events (n = 5). Of documented AEs, 9/16 (56%) were classified as not preventable, 6/16 (38%) as possibly preventable, and 1/16 (6%) as preventable. The incidence of AE related to PDA stent placement with surgical exposure (3/50, 10%) was significantly lower when compared with PDA stent placement performed percutaneously (4/5, 80%, $P = .002$).
Conclusion. Hybrid procedures appear to have a low incidence of associated major AEs. PDA stent placement [illegible]ic left heart syndrome (HLHS) or complex single/two ventricle patients may [illegible]rmed using a direct approach with surgical exposure rather than a percutaneous [illegible]se innovative procedures are required to facilitate prospective data collection.

[illegible]diac Catheterization; Adverse Events

[illegible]ort from the Congenital Cardiac
[illegible]omes (C3PO)

Procedure-Type Risk Categories for Pediatric and Congenital Cardiac Catheterization

Lisa Bergersen, MD, MPH; Kimberlee Gauvreau, ScD; Audrey Marshall, MD;
Jacqueline Kreutzer, MD; Robert Beekman, MD; Russel Hirsch, MD; Susan Foerster, MD;
David Balzer, MD; Julie Vincent, MD; William Hellenbrand, MD; Ralf Holzer, MD;
John Cheatham, MD; John Moore, MD; James Lock, MD; Kathy Jenkins, MD, MPH

Background—The Congenital Cardiac Catheterization Project on Outcomes (C3PO) was established to develop outcome assessment methods for pediatric catheterization.
Methods and Results—Six sites have been recording demographic, procedural and immediate outcome data on all cases, using a web-based system since February 2007. A sample of data was independently audited for validity and data completeness. In 2006, participants categorized 84 procedure types into 6 categories by anticipated risk of an adverse event (AE). Consensus and empirical methods were used to determine final procedure risk categories, based on the outcomes: any AE (level 1 to 5); AE level 3, 4, or 5; and death or life-threatening event (level 4 or 5). The final models were then evaluated for validity in a prospectively collected data set between May 2008 and December 31, 2009. Between February 2007 and April 2008, 3756 cases were recorded, 558 (14.9%) with any AE; 226 (6.0%) level 3, 4, or 5; and 73 (1.9%) level 4 or 5. General estimating equations models using 6 consensus-based risk categories were moderately predictive of AE occurrence (c-statistics: 0.644, 0.664, and 0.707). The participant panel made adjustments based on the collected empirical data supported by clinical judgment. These decisions yielded 4 procedure risk categories; the final models had improved discrimination, with c-statistics of 0.699, 0.725, and 0.765. Similar discrimination was observed in the performance data set (n = 7043), with c-statistics of 0.672, 0.708, and 0.721.
Conclusions—Procedure-type risk categories are associated with different complication rates in our data set and could be an important variable in risk adjustment models for pediatric catheterization. (*Circ Cardiovasc Interv.* 2011;4:188-194.)

Key Words: cardiac catheterization ■ cardiovascular interventions ■ complications ■ heart defects congenital ■ outcome

Catheterization for Congenital Heart Disease Adjustment for Risk Method (CHARM)

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Audrey C. Marshall, MD;* Orit B. McElhinney, MD;* Robert H. Beekman III, MD;‡
Russel Hirsch, MD;§ Jacqueline Kreutzer, MD;‖ David Balzer, MD;‖ Julie Vincent, MD;‖
William E. Hellenbrand, MD;‖ Ralf Holzer, MD;¶ John P. Cheatham, MD;¶
John W. Moore, MD;# Grant Burch, MD;** Laurie Armsby, MD;** James E. Lock, MD;*
Kathy J. Jenkins, MD, MPH*

*Boston, Massachusetts; †St. Louis, Missouri; ‡Cincinnati and Columbus, Ohio; §Pittsburgh, Pennsylvania; ‖New York, New York; ¶San Diego, California; and #Portland, Oregon

Objectives This study sought to develop a method to adjust for case mix complexity in catheterization for congenital heart disease to allow equitable comparisons of adverse event (AE) rates.

Background The C3PO (Congenital Cardiac Catheterization Project on Outcomes) has been prospectively collecting data using a Web-based data entry tool on all catheterization cases at 8 pediatric institutions since 2007.

Methods A multivariable logistic regression model with high-severity AE outcome was built using a random sample of 75% of cases in the multicenter cohort; the models were assessed in the remaining 25%. Model discrimination was assessed by the C-statistic and calibration with Hosmer-Lemeshow test. The final models were used to calculate standardized AE ratios.

Results Between August 2007 and December 2009, 9,302 cases were recorded at 8 pediatric institutions of which high-severity events occurred in 454 cases (5%). Assessment of empirical data yielded 4 independent indicators of hemodynamic vulnerability. Final multivariable models included procedure type risk category (odds ratios [OR] for category 2 = 24.3 > 43.4 > 76, all $p < 0.001$), number of hemodynamic indicators (OR for 1 indicator = 1.5, >2 = 1.8, $p < 0.005$ and $p < 0.001$), and age <1 year (OR 1.3, $p = 0.04$). C-statistic 0.737, and Hosmer-Lemeshow test $p = 0.74$. Models performed well in the validation dataset. C-statistic 0.734. Institutional event rates ranged from 1.91% to 7.37% and standardized AE ratios ranged from 0.61 to 1.41.

Conclusions Using CHARM (Catheterization for Congenital Heart Disease Adjustment for Risk Method) to adjust for case mix complexity should allow comparisons of AE among institutions performing catheterization for congenital heart disease.

[illegible]ose Benchmarks During [illegible]heterization for Congenital [illegible]se in the United States

[illegible]C. Glatz, MD, MSCE,† Sthuthi David, BS,* Ryan Leahy, MD, MS,† Russel Hirsch, MD,‡
[illegible]E. Trucco, MD,¶ Ralf J. Holzer, MD, MSc,# Lisa Bergersen, MD, MPH*

[illegible] study was to define age-stratified, procedure-specific benchmark radiation dose levels [illegible]zation for congenital heart disease.

[illegible]acity of published literature with regard to radiation dose levels during catheterization for [illegible]ning benchmark radiation data is essential for assessing the impact of quality improvement

[illegible]d retrospectively from 7 laboratories participating in the Congenital Cardiac Catheteri- [illegible]laboratory. Total air kerma, dose area product, and total fluoroscopy time were obtained [illegible]) patent ductus arteriosus closure; 2) atrial septal defect closure; 3) pulmonary valvulo- [illegible]5) treatment of coarctation of aorta; and 6) transcatheter pulmonary valve placement.

[illegible]009 and July 2013, 2,713 cases were identified. Radiation dose benchmarks are presented [illegible]ile, and 95th percentile. Radiation doses varied widely between age groups and procedure types. Radiation exposure was lowest in patent ductus arteriosus closure and highest in transcatheter pulmonary valve placement. Total fluoroscopy time was a poor marker of radiation exposure and did not correlate well with total air kerma and dose area product.

CONCLUSIONS This study presents age-stratified radiation dose values for 6 common congenital heart interventional catheterization procedures. Fluoroscopy time alone is not an adequate measure for monitoring radiation exposure. These values will be used as baseline for measuring the effectiveness of future quality improvement activities by the Congenital Cardiac Catheterization Project on Outcomes collaborative. (J Am Coll Cardiol Intv 2014;7:1060-9)

severity AEs (levels 1–2) occurred in 9% of patients and higher severity AEs (levels 3–5) occurred in 3% of patient; there were no deaths. Risk factors for any AE (levels 1–5) were age below 1 month (OR 3.5, CI 1.3–9.9), as well as operator experience of less than 10 years (OR 3.8, CI 1.5–9.9). Conclusions: Procedural success is common and AEs, especially higher severity AEs, are rare for BPV in patients with isolated PS. Results have improved considerably when compared to historical data. © 2012 Wiley Periodicals Inc.

Key words: pCOMP; complications pediatric cath/intervention; PEDS, pediatric interventions; pulmonary valvuloplasty

end diastolic pressure ≥ 18 mm Hg (OR 3.1) w
0.751. There were no statistically significant di
Conclusions: Adults undergoing catheterization
less frequently than children did. The congeni
method for adults with congenital heart disease
risk in adult patients. © 2013 Wiley Periodicals, Inc.

Key words: heart defects; congenital; outcome a

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Key Word

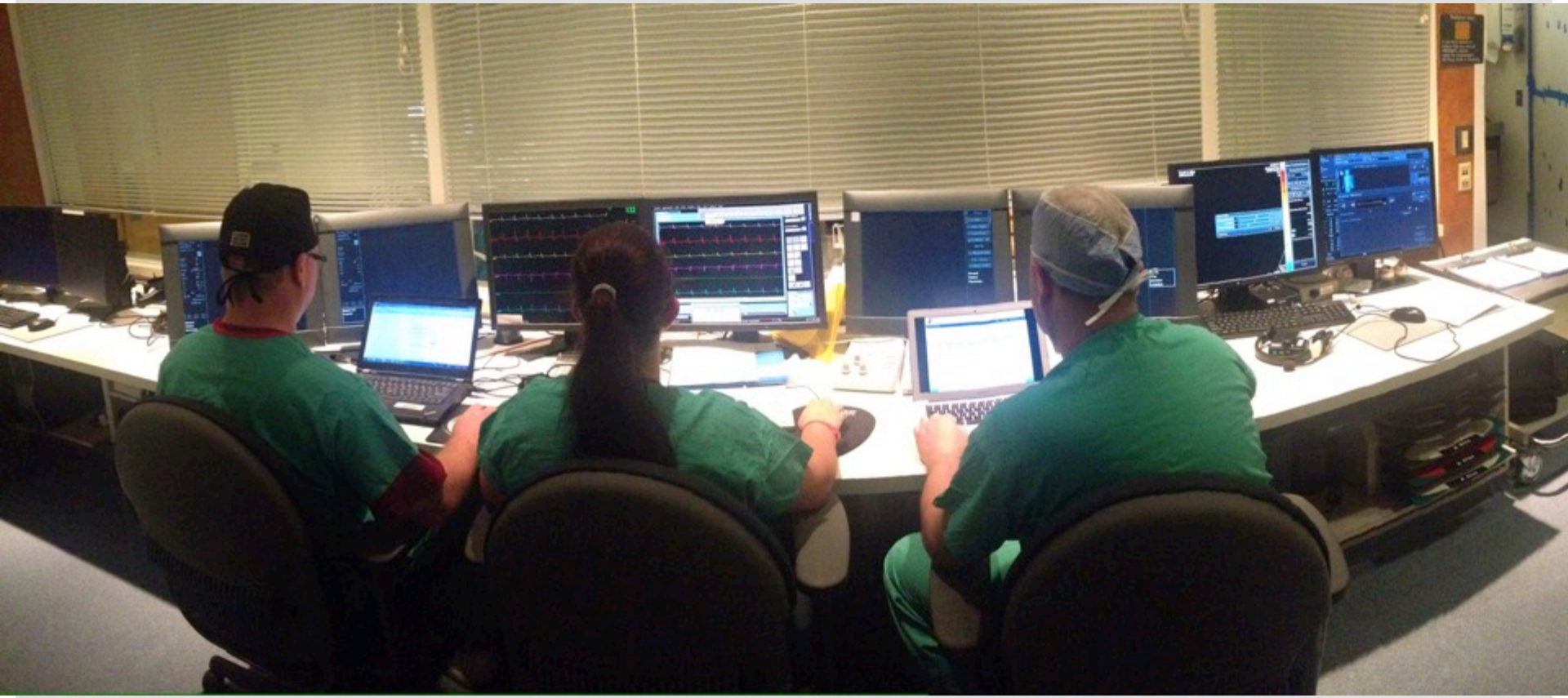
POTENTIAL PROBLEMS OF CATH RELATED DATABASES

- Requirements for participation
- Data audit and data integrity
- Ease of accessing data
- Ownership of data and infrastructure
- Use of data
- Risk adjustment and attributability
- Human resources for data entry

POTENTIAL PROBLEMS OF CATH RELATED DATABASES

- No single DB solution
- Data audit and data integrity
- Ease of accessing / querying data
- Duplication of data entry
- Human resources required
- Registry specific issues
  - Requirements for participation
  - Ownership of data and infrastructure
  - Use of data
  - Risk adjustment and attributability

REGISTRIES = ++ HUMAN RESOURCES



We need more staff just to deal with the problems related to the data entry

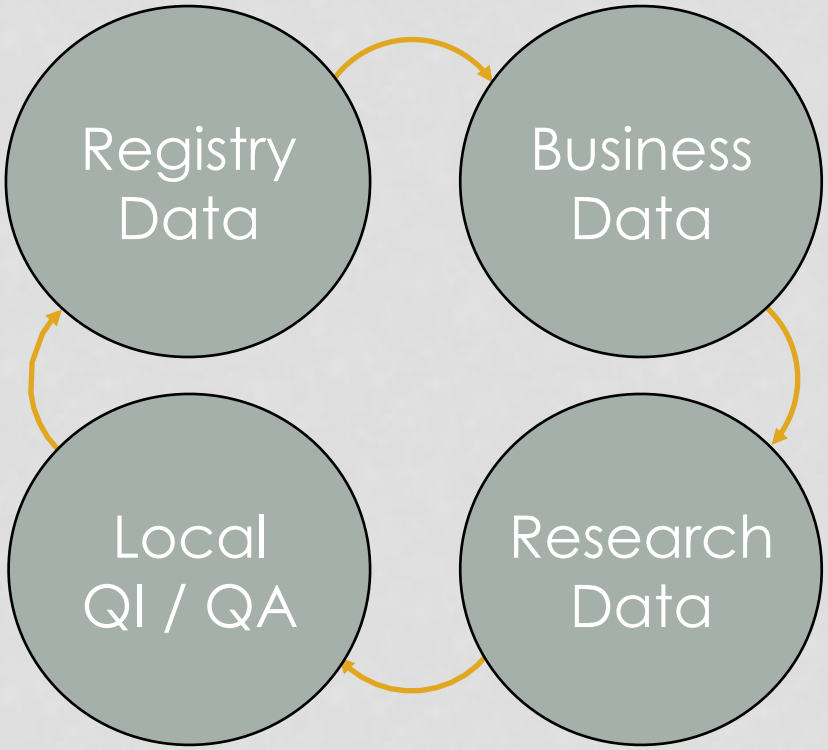
The guys who developed this "(expletive)" should come to our lab and see how functional this is in real life

The world is not made up of only whole integers. Who wrote this junk?

This new software is far from "magical"

HOW DO I PLAN THE DATABASE USAGE IN MY CATH LAB?

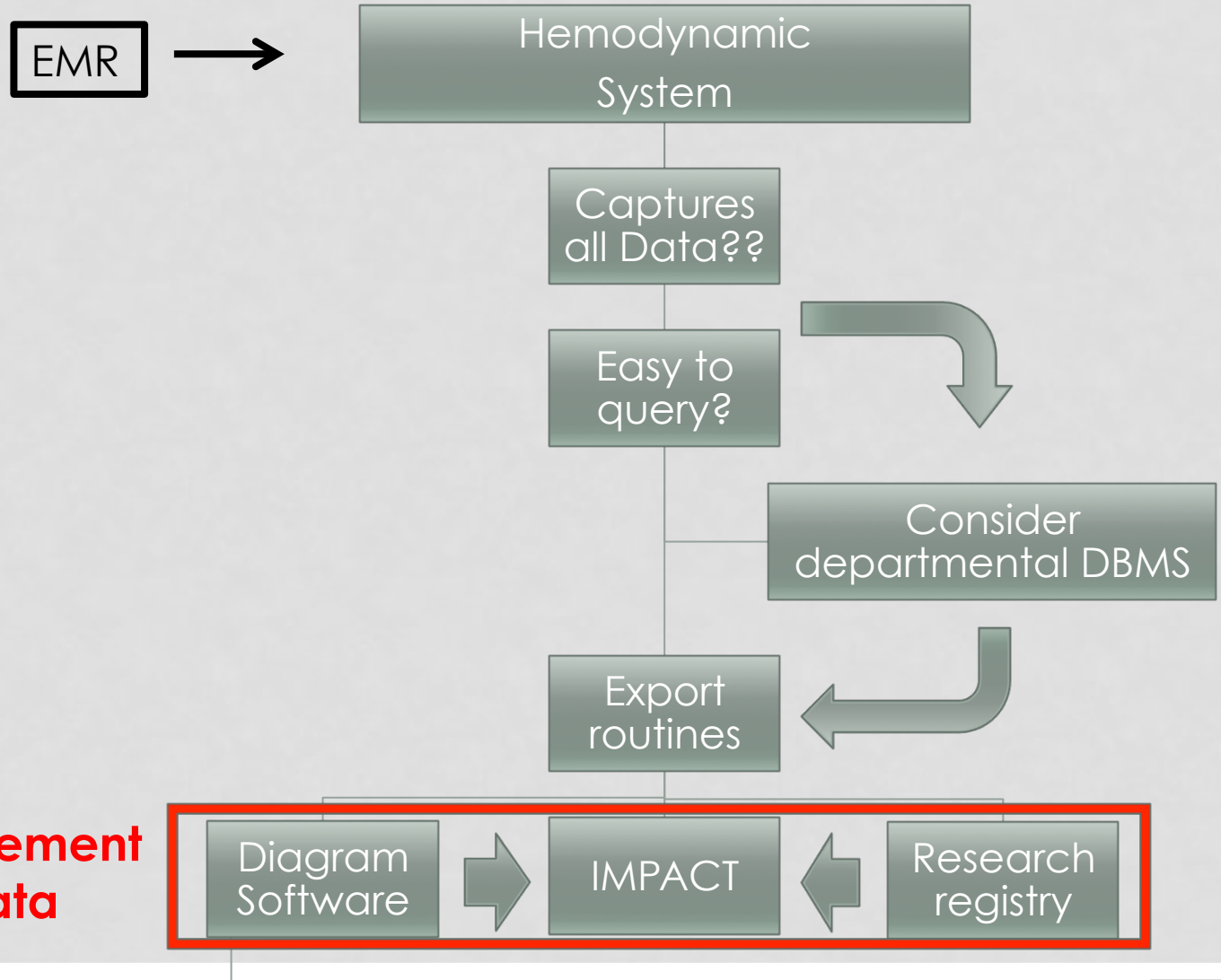
CORE DATA ELEMENTS TO IMPROVE A PROGRAM



STRATEGIES FOR DATA USAGE IN THE CATH LAB

- Goals of data usage
- Systems already in place
- Data entry / validation
- Registry data / participation
- Data extraction / query / analysis
- IS specific issues

EFFICIENT SETUP FOR DATA ENTRY AND DATA CAPTURE



PATH TO QUALITY THROUGH ACCREDITATION?

ACCREDITATION

The act of granting credit or recognition to an institution that maintains suitable standards. Accreditation is necessary to any person or institution that needs to prove that they meet a general standard of quality.

ACCREDITATION FOR CARDIOVASCULAR EXCELLENCE (ACE): HISTORY?

- Originated from the need to accreditate facilities for carotid artery stenting (discussion with CMS)
- Formed July 2009 (start-up funds by SCAI)
- Joint venture agreement with ACCF in 2010
- Congenital Heart Disease (CHD) currently one out of 6 supported accreditation programs

WHY ACCREDITATION?

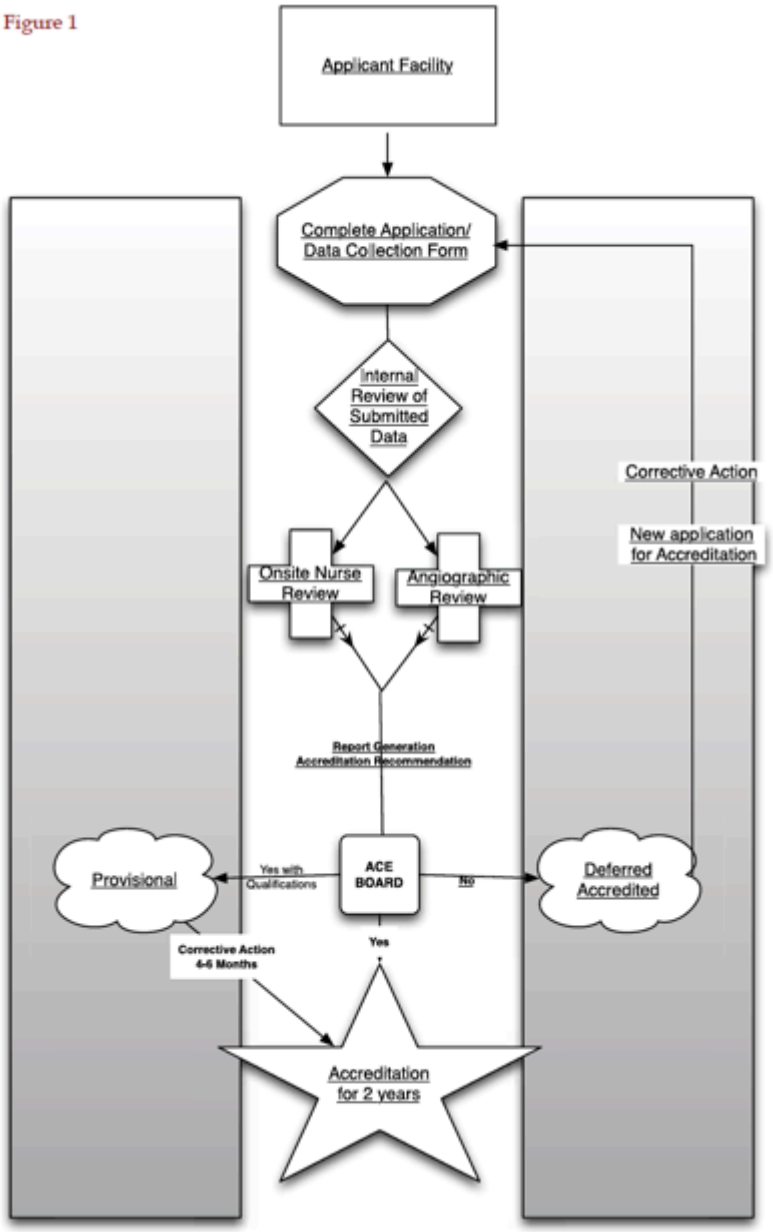
- Documents that an institution is meeting or exceeding standards set by experts in CV care
  - Assurance to patients and insurers
- Minimizing liability
  - Encouraging best practices

Step-by step guideline on how to improve quality in the cath lab

- Minimizing complications
  - Benefits to to payors, patients and society
- Promoting of facility

PATH TO ACE ACCREDITATION

Figure 1



Taken from the ACE website: http://www.cvexcel.org/Assets/3728d6cf-818b-4391-b52d-a16aa3fb187d/635660033036500000/pccl-standards2015-pdf

ACE ACCREDITATION FOR CHD AREAS OF FOCUS (TOC)

- Outcome & performance metrics
- Quality assurance
-

ACE ACCREDITATION FOR CHD AREAS OF FOCUS (TOC)

- Facility
- Equipment
- Leadership structure
- Physician extenders and cardiology fellows
- Nursing personnel
- Technologists and other personnel
- Reporting of results
- Procedure indications and informed consent
- Procedure preparation and conduct
- Outcome & performance metrics
- Quality assurance
- Radiation safety

FACILITY

- On-campus CT surgery, cardiac anesthesia, ICU, and other services
- Mechanical circulatory support and/or ECMO
- Need to define procedures performed and process for introduction of new procedures
- 150 CHD cases with at least 50 involving intervention
- Track and report operator outcome data and compare to national data

LEADERSHIP STRUCTURE

- Medical director
  - 4th year fellowship or training before 2000
  - 5 years experience
  - Broad responsibilities including reviewing criteria for privileging, operator performance, M&M conferences
- Technical director
  - RCIS or RN, 5 years experience
- QA / CQI individual
- Physician privileges
  - PALS if doing peds, 30 hours CME over 2 years
  - Meet facility determined volume requirement
  - Attend at least 50% of M&M, cath conf, and QI meetings

ACE RE-EVALUATION IN ADULT LABS

- Credentialing process started 2011
  - 11/29 in full accreditation >1 year and completed questionnaire
- No changes in leadership
- 5 had new operators, 1 suspended privileges of an operator
- Over 90% felt process improved quality of care
- Over 80% used accreditation status in marketing
- Benefits noted included validation of patient selection, reduced radiation, improved morale, demonstration to leadership that lab was a leader in field, improved confidence in leadership

The value of catheterization laboratory accreditation
Weiner B et. al. CCI;abstract 211:May 1, 2015

CATH LAB ACCREDITATION

- Accreditation is a great tool to guide institutions in a step-by-step process to be transparent, and to document a high standard of quality of care (use of registry data!!)
- Accreditation reduces costs, minimizes complications, and minimizes liability
- Accreditation is particular useful to provide a roadmap for institutions that want to improve on overall outcomes, to put mechanisms into place that are proven in facilitating a high quality of care
- Accreditation may discourage heart caths at facilities unable to meet standards
- Accreditation is a great tool to promote a facility

CONCLUSION

QI initiatives have become a *community* conversation

In the next decade, registries and standardization will continue to allow for the development of more patient-centered care and risk reduction and predicting practices

SUMMARY: QUALITY IN THE CONGENITAL CATH LAB

- Performance of the appropriate procedure
- On the appropriate patient
- In the safest manner possible
- While trying to achieve the best outcome
- Striving to meet patient/family expectations
- In a cost effective manner

SUMMARY: QUALITY IN THE CONGENITAL CATH LAB

- While minimizing complications
- With complete and accurate documentation
- Continuously reassessing for areas of improvement
- And comparing results with registry benchmarks and outcome metrics
- …… with ample opportunity for research

BE PREPARED:
ADVERSE EVENTS DO HAPPEN!