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Ontario Regional Blood Coordinating Network

Inspiring and facilitating best transfusion practices in Ontario.

Pediatric Massive Hemorrhage Protocols and Quality Metrics

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CHEO RESEARCH INSTITUTE

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Faculty Disclosure

In compliance with CPD policy, Temerty Faculty of Medicine requires the following disclosures to the session audience

- This program has received no financial external support
- I have no financial interests or conflicts to disclose.
- I will speak about the “off-label use” of tranexamic acid in pediatric trauma

Objectives

At the end of this session audience members will be able to:

List the "*seven key components*" of a pediatric massive hemorrhage protocol (MHP)

Discuss the *"quality equation"* in the context of a pediatric MHP

Apply the *"Donabedian"* approach to measure quality of care

Debate the components of *"value-added health care"*

Why are we talking about QI for pediatric MHPs?

Quintuple Aim of Healthcare Service Delivery

1. Improve **population health**
2. Enhance the **patient care experience**
3. Reduce **costs** (or waste)
4. Address clinician **burnout**
5. Advance **health equity**

Nundy KS. *JAMA*. 2022; 327: 521-22

Adult MHP standardization improves outcomes

MDs are **not good at predicting** need for MHP activation

MHP **non-compliance costs** lives

MHP implementation:

- Lower mortality rate
- Decreased blood component/ product utilization
- Lower complication rates

TABLE 4. Outcomes and Blood Utilization by Compliance

	Compliant (n = 34)	Noncompliant (n = 91)	*p*
24-h survival (%)	88.2 ± 5.5	61.5 ± 5.1	0.004
30-d survival (%)	86.7 ± 5.6	45.0 ± 5.2	<0.001
TEP cycles used	2.07 ± 1.0	2.28 ± 1.1	0.605
24-h RBC units	13.7 ± 1.3	19.5 ± 1.2	0.012
24-h plasma units	9.3 ± 0.7	10.7 ± 0.8	0.301
24-h platelets	4.1 ± 0.7	3.6 ± 0.7	0.372

Values are presented as mean ± SD.

Cotton BA, et al. *J Trauma.* 2009; 67: 1004-12

GUIDELINES Open Access

The European guideline on management of major bleeding and coagulopathy following trauma: sixth edition

Rossaint R, et al. *Crit Care.* 2023

Context of pediatric critical bleeding matters…

Prospective observational multi-center pediatric civilian study (N=449)

Median (IQR) age was 7.3 yr (1.7–14.7 yr)

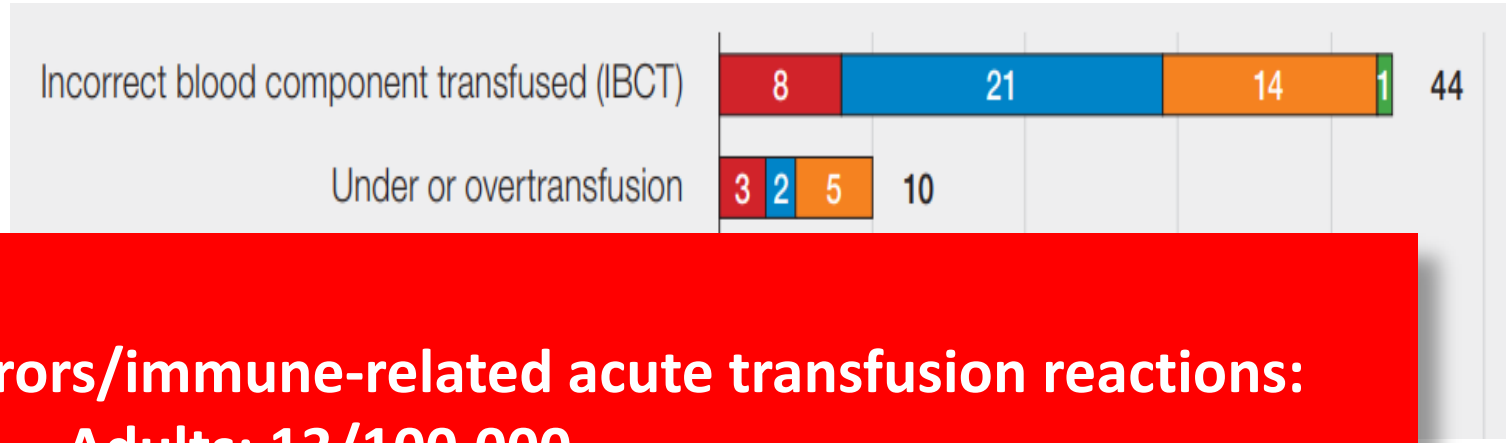
Critical Bleeding Etiology (N=449)	All-cause Mortality at 24 Hrs. (n=99)	All-cause Mortality at 28 days (n=168)
Combined	99 (22%)	168 (37.8%)
Medical (N=89)	32 (36%)	58 (65%)
Trauma (N=207)	50 (24%)	74 (36%)
Operative (N=153)	17 (11%)	36 (24%)

Leonard JC. *Pediatr Crit Care.* 2021

Children are more susceptible to transfusion-related adverse events...

Key Pediatric SHOT Messages:

- **Massive blood loss** in children is **unc** should
- **Comm** regar **dosir**
- **Educ** **resou** for those administering (neonatal) transfusions **to reduce errors**



Adverse events due to errors/immune-related acute transfusion reactions:

Adults: 13/100,000

< 18 yrs: 18/100,000

< 1 yr old: 37/100,000

Stainsby D, et al. *Br J Haematol.* 2008;141:73-9

“So let me get this straight, in children…”

- **Definition** massive hemorrhage (MH) is **evolving**
- Leading cause of death and cardiac ar
- C
- C
  tr
- M
  re
  - Highly variable in content
  - May improve process measures
  - BUT…**don’t save lives** (so far…)

“It should be mentioned that all studies have to be interpreted with caution because of retrospective and observational study designs, varying definitions of massive transfusion, varying age groups included, relatively small sample sizes, nonrandom treatment allocation, and high potential for confounding.”

Steinbicker AU, Wittenmeier E, Goobie SM. Curr Opin Anesthesiol. 2020; 22: 259

Kamyszek RW. *J Trauma Acute Care Surg*. 2019

What are the QI opportunities for adult & pediatric MHPs?
"You can't manage what you can't measure."

Key elements of a pediatric MHP ("7 Ts"):

1. **T**rigger and **T**reat bleeding (apply damage control resuscitation [DCR] principles & STOP bleeding)
2. **T**eam (including telecommunication)
3. **T**ranexamic acid & Cell salvage
4. **T**emperature & **T**raumatic brain injury (TBI)
5. **T**esting
6. **T**ransfusion (MTP) & **T**rouble
7. **T**ermination & **T**RACKING performance

Tan GM, Murto K, Downey LA, Wilder MS, Goobie SM. *Pediatr Anesth.* 2023

The Quality Equation

$$Q = A \times \frac{(O + S)}{W}$$

Quality metrics:
System= A
Process=S
Outcomes= O & W

A=Appropriate

O=Outcomes:

- Efficacious
- Safe

S=Service:

- Efficient,
- Timely,
- Equitable
- Patient-centered

W=Waste (Cost)

Measuring the Quality of Care: Donabedian Approach

Structure or system measures (Flow)**:**

- *"Organization of the system"*
- Measures infrastructure/physical equipment/facilities.

Process measures (Compliance)**:**

- *"Voice of the inner workings of the system"*
- Emphasis on processes directly influencing outcome of interest

Outcome Measures (Performance)

- *"Voice of the consumer"* (Provider or Patient)
- "What are the end results of our QI work" in terms of **mortality, morbidity/safety and waste?**

Process measures associated with survival benefit during MHP activation…

Adults: TXA Survival benefit decreased by 10% for every 15 min of treatment delay until 3 h, after which there was no benefit after trauma

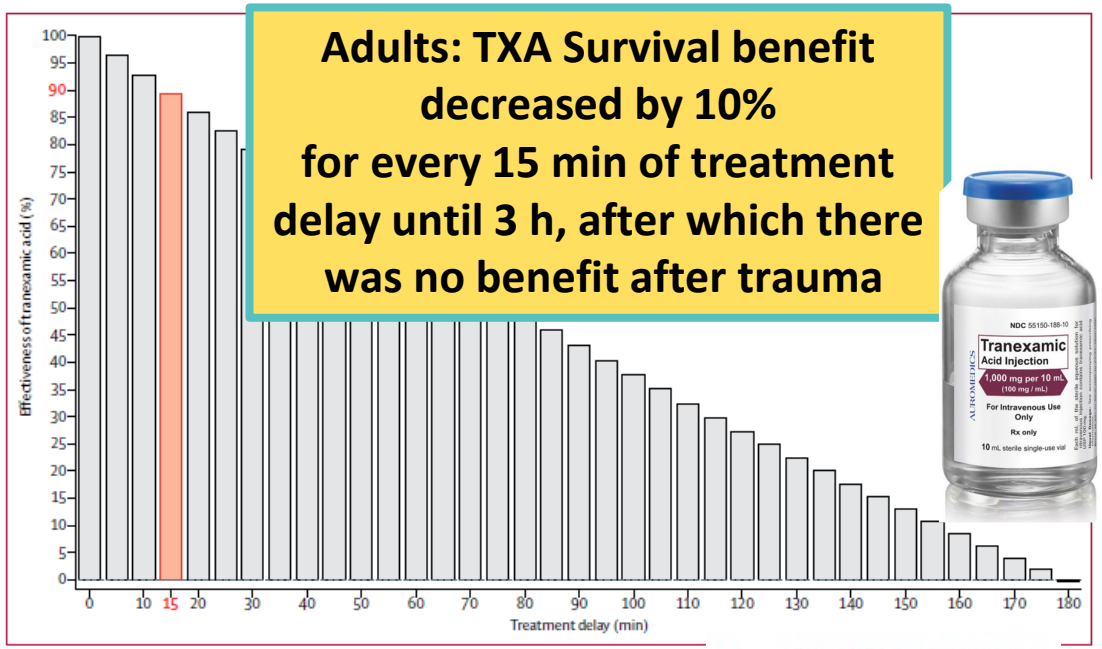
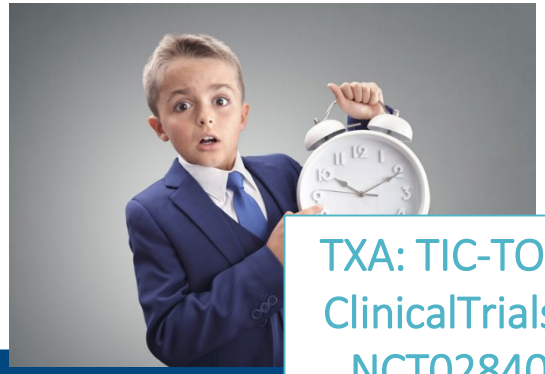


Figure 4: Reduction in effectiveness of tranexamic acid with increasing treatment delay

Lancet 2018; 391: 125–32

Children: Temp <36°C is associated with 3.1-fold ↑ in a bleeding diathesis & 2.4-2.8-fold ↑ in in-hospital mortality after trauma
Okada A, et al. *BMJ Open* 2020

Adults: Each 1-minute delay in the arrival of the first pack of blood components is associated with a 5% increase in the risk of death
Meyer DE. *J Trauma Acute Care Surg* 2017



TXA: TIC-TOC Trial ClinicalTrials.gov : NCT02840097.

Children: Antifibrinolytics associated with 6 and 24-hour all-cause mortality benefit during critical bleeding
Spinella PC. *Crit. Care Med.* 2022

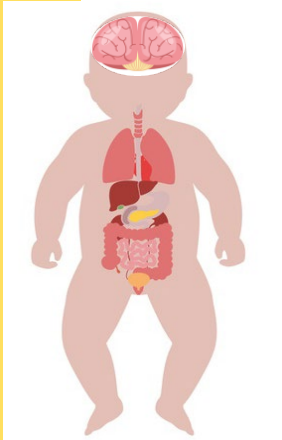
Mortality as an MHP outcome measure …

Adult trauma studies to report:

- **Primary outcome:**
  - 3-6 hr all-cause mortality
- **Secondary outcome**:
  - 24-hr all-cause mortality
  - Time to mortality
  - 28-day mortality (Balance measure)

Pediatric Studies (<12 yrs old)

- Unique size, anatomy, physiology & injury patterns.
- **Primary outcome:**
  - 6 or 24 hr all-cause mortality



Evidence-Based and Clinically Relevant Outcomes for Hemorrhage Control Trauma Trials

John B. Holcomb, MD,✉ *Ernest E. Moore, MD,† Jason L. Sperry, MD, MPH,‡ Jan O. Jansen, MBBS, PhD,§ Martin A. Schreiber, MD,¶ Deborah J. del Junco, PhD,|| Philip C. Spinella, MD,** Angela Sauaia, MD, PhD,†† Karim Brohi, MD,‡‡ Eileen M. Bulger, MD,§§ Andrew P. Cap, MD, PhD,¶¶ John R. Hess, MD, MPH, FACP, FAAAS,|||| Donald Jenkins, MD,*** Roger J. Lewis, MD, PhD,††† Matthew D. Neal, MD,‡‡‡ Craig Newgard, MD, MPH,§§§ Shibani Pati, MD, PhD,¶¶¶ Anthony E. Pusateri, PhD,|||||| Sandro Rizoli, MD, PhD,**** Robert T. Russell, MD, MPH,†††† Stacy A. Shackelford, MD,‡‡‡‡ Deborah M. Stein, MD, MPH,§§§§ Marie E. Steiner, MD, MS,¶¶¶¶ Henry Wang, MD, MS,|||||||| Kevin R. Ward, MD,***** and Pampee Young, MD, PhD†††††*

Ann Surg. 2021

Establishing a Core Outcomes Set for Massive Transfusion: an EAST Modified Delphi Method Consensus Study

Rondi B. Gelbard, MD FACS[1], Jeffry Nahmias, MD MHPE FACS[2], Saskya Byerly, MD[3], Markus Ziesmann, MD FRCSC[4], Deborah Stein, MD FACS[5], Elliott R. Haut, MD PhD FACS[6], Jason W. Smith, MD PhD FACS[7], Melissa Boltz, MD FACS[8], Ben Zarzaur, MD MPH FACS[9], Jeannie Callum, MD BA FRCPC[10], Bryan A Cotton, MD MPH FACS[11], Michael Cripps, MD MSCS FACS[12], Oliver L Gunter, MD MPH[13], John B Holcomb, MD[1], Jeffrey Kerby, MD PhD FACS[1], Lucy Z Kornblith, MD FACS[14], Ernest E. Moore, MD[15], Christina M Riojas, MD FACS[16], Martin Schreiber, MD FACS FCCM[17], Jason L Sperry, MD MPH[18], D. Dante Yeh, MD MHPE FACS

J Trauma Acute Care Surg. 2023

Waste as an MHP outcome measure…

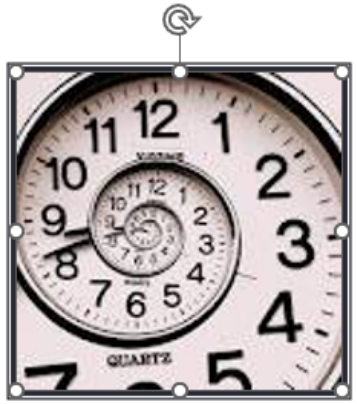
The 8 wastes in healthcare: DOWNTIME

Defects: Any time you need to correct a problem

Overproduction: Preparing more product than is necessary, or preparing it before you need it

Blood Component Wastage & MHP: Delayed deactivation > Over activation
Paganini M. *Int J Environ Res Public Health.* 2021

Extra Processing: Excessive data on forms or stamps that are never used



Waiting: Waiting for equipment to become available, waiting for results, decisions or supplies

Motion: Searching for equipment, supplies, or information

Non-Utilized Resources/Talent: Not engaging to your full scope of professional practice

Inventories: Having more supplies or equipment than is required, expired items

Transportation: Moving equipment & supplies, unnecessary visits

The Japanese word for waste is **MUDA**

“There is no international consensus or benchmark for MHP quality indicators…”

Ideal quality indicator characteristics:

- *Based on **scientific evidence** or expert consensus/previous experience*
- ***Be measurable***
- ***Important** relative to outcome measure of interest*
- Able to **form basis of process review**

Donabedian Component	MHP Quality Indicator	Studies with Indicator N (%)
System	Appropriate Activation	10 (9%)
	Deactivation	4 (4%)
	Time activation to blood arrival	13 (12%)
	PT/INR	**47 (44%)**
Pr		
	Total # components transfused	**40-96 (37-90%)**
	Tranexamic acid	16 (16%)
Outcomes	Mortality in-hospital	**92 (86%)**
	Mortality post-discharge	30 (28%)
	Length of stay	**64 (60%)**
	Morbidity in-hospital	**47 (44%)**
	Morbidity post-discharge	0 (0%)
	Blood component/product wastage	13 (12%)
	Transfusion reaction/complication	5 (5%)

What about temperature as a process measure?

Sanderson B, et al. *Blood Transfus.* 2020

Value proposition in healthcare delivery…

$$\text{Value} = \frac{\text{Quality + Safety + Patient/Family Experience}}{\text{\$ Total Costs (Waste) of Care}}$$

Porter M and Teisberg E *Harvard Business School Press* 2006; Vetter TR *Anesthesiol Clin.* 2015; 33: 771-84; Doyle C, et al. *BMJ Open.* 2013: e001570

Patient outcome measures that matter…?

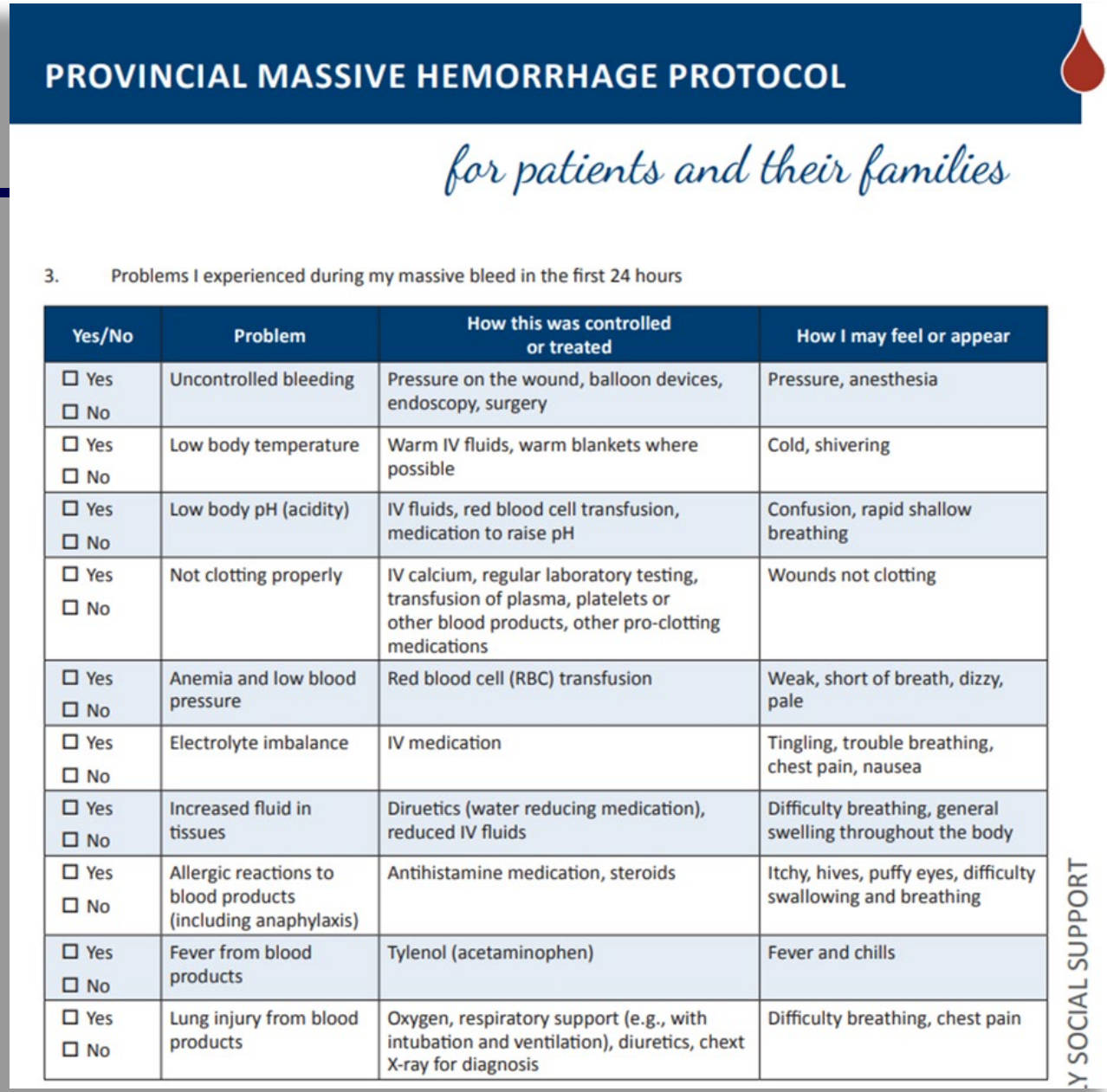
Patient:
Important Outcomes (PIOs),

- Reported Outcome Measures (PROMs)
- Reported Experience Measures (PREMs)

Provider:

- Traditional (e.g., LOS, cancellations, wound infections etc.)
- Reported Experience Measures (PrREMs)

Core Outcomes Measures in Effectiveness Trials (COMET)
https://www.comet-initiative.org/



PROVINCIAL MASSIVE HEMORRHAGE PROTOCOL

for patients and their families

3. Problems I experienced during my massive bleed in the first 24 hours

Yes/No	Problem	How this was controlled or treated	How I may feel or appear
☐ Yes ☐ No	Uncontrolled bleeding	Pressure on the wound, balloon devices, endoscopy, surgery	Pressure, anesthesia
☐ Yes ☐ No	Low body temperature	Warm IV fluids, warm blankets where possible	Cold, shivering
☐ Yes ☐ No	Low body pH (acidity)	IV fluids, red blood cell transfusion, medication to raise pH	Confusion, rapid shallow breathing
☐ Yes ☐ No	Not clotting properly	IV calcium, regular laboratory testing, transfusion of plasma, platelets or other blood products, other pro-clotting medications	Wounds not clotting
☐ Yes ☐ No	Anemia and low blood pressure	Red blood cell (RBC) transfusion	Weak, short of breath, dizzy, pale
☐ Yes ☐ No	Electrolyte imbalance	IV medication	Tingling, trouble breathing, chest pain, nausea
☐ Yes ☐ No	Increased fluid in tissues	Diruetics (water reducing medication), reduced IV fluids	Difficulty breathing, general swelling throughout the body
☐ Yes ☐ No	Allergic reactions to blood products (including anaphylaxis)	Antihistamine medication, steroids	Itchy, hives, puffy eyes, difficulty swallowing and breathing
☐ Yes ☐ No	Fever from blood products	Tylenol (acetaminophen)	Fever and chills
☐ Yes ☐ No	Lung injury from blood products	Oxygen, respiratory support (e.g., with intubation and ventilation), diuretics, chext X-ray for diagnosis	Difficulty breathing, chest pain

Y SOCIAL SUPPORT

Hierarchy of core outcome measures that matter to patients…

Tier 1 Patient health status achieved or retained	• Survival • Degree of health or recovery achieved or retained
Tier 2 Process of recovery	• Time required to achieve recovery (e.g. time to diagnosis, time to treatment plan, duration of treatment) • Disutility of the care process (e.g. missed diagnosis, failed treatment, anxiety, discomfort, errors)
Tier 3 Sustainability of health	• Recurrences of original disease or associated longer-term complications • New health problems created as a consequence of treatment itself

Porter ME. *N Engl J Med* 2010; 363:2477-81

Conclusions:

- ***Key components*** of a pediatric MHP: **"7Ts"**
- ***Quality equation*** and MHP:

$$Q = A \times \frac{(O + S)}{W}$$

- ***Donabedian*** approach to quality care measurement:
  - System measures (Flow)
  - Process measures (Compliance)
  - Outcome measures (Performance)
- *Value added care is associated with* ***patient experience and safety***

Success=
↑Quality,
↓Cost (Waste)
& ↑Provider Morale
Dr. John Toussaint

Thank you!

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Sanderson B, et al. Blood Transfus. 2020.

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Process	Time activation to blood arrival	13 (12%)
	PT/INR	**47 (44%)**
	pH/Base excess/deficit	**46 (43%)**
	Hgb	**38 (36%)**
		68 (64%)
		-96 (37-90%)
		16 (16%)
Outcomes	Mortality in-hospital	**92 (86%)**
	Mortality post-discharge	30 (28%)
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What about temperature as a process measure?

Context of critical bleeding and cause of mortality varies…

Mortality at 28 days, by Case Group N	Mortality during MT N (%)	Mortality at 6 hrs N (%) & Etiology %	Mortality at 24 hrs N (%) & Etiology %	Mortality at 28 Days N (%) & Etiology %
Combined N=168	49 (29%)	69 (41%) Bleed: 78%, CNS inj.: 19%	99 (59%) Bleed72%, CNS inj.: 23%	168 (100%) Bleed: 49% CNS inj.: 35%
Medical N=58	19 (33%)	25 (43%) Bleed: 92%	32 (55%) Bleed: 84% CNS inj.: 3.1%	58 (100%) Bleed: 57% CNS inj.: 12%
Trauma N=74	24 (32%)	35 (47%) Bleed:63% CNS inj.: 37%	50 (68%) Bleed: 56% CNS inj.: 42%	74 (100%) Bleed: 41% CNS inj.: 58%
Operative N=36	6 (17%)	9 (25%) Bleed:100%	17 (47%) Bleed: 94% CNS inj.: 6%	36 (100%) Bleed: 53% CNS inj.: 22%

ARDS more common in critical bleeding in OR and Medical (25%) vs Trauma (15%)

Leonard JC, et al.
Pediatr Crit Care. 2021

Society for Pediatric Anesthesia
education • research • patient safety