ECMO Preparedness During COVID-19 Pandemic: In Situ Simulation System Based Test

Alyssa C. Stoner, DO, Division of Pediatric Critical Care

Robert D. Schremmer, MD, Division of Pediatric Emergency Medicine

Rachael L. Pedigo, BSN, Center for Pediatric Simulation

Disclosures

- The authors have no conflict of interest of financial relationships relevant to the content of this presentation

Outline

- Introductions
- Overview of Simulation based Clinical System Test (SbCST) Framework
  - Adapted tools utilized for observation, debriefing and reporting
- Children's Mercy Hospital application of SbCST framework to test ECMO cannulation preparedness during COVID-19 pandemic
- Additional examples of SbCST framework application at CMH

Objectives

- Describe a method for testing COVID-19 preparedness during Extracorporeal Membrane Oxygenation (ECMO) cannulation
- Recall the 2 components of the conceptual framework for Simulation based Clinical Systems Testing (SbCST)
- Identify and begin to close the process gaps for ECMO cannulation of a suspected COVID-19 patient

Introductions

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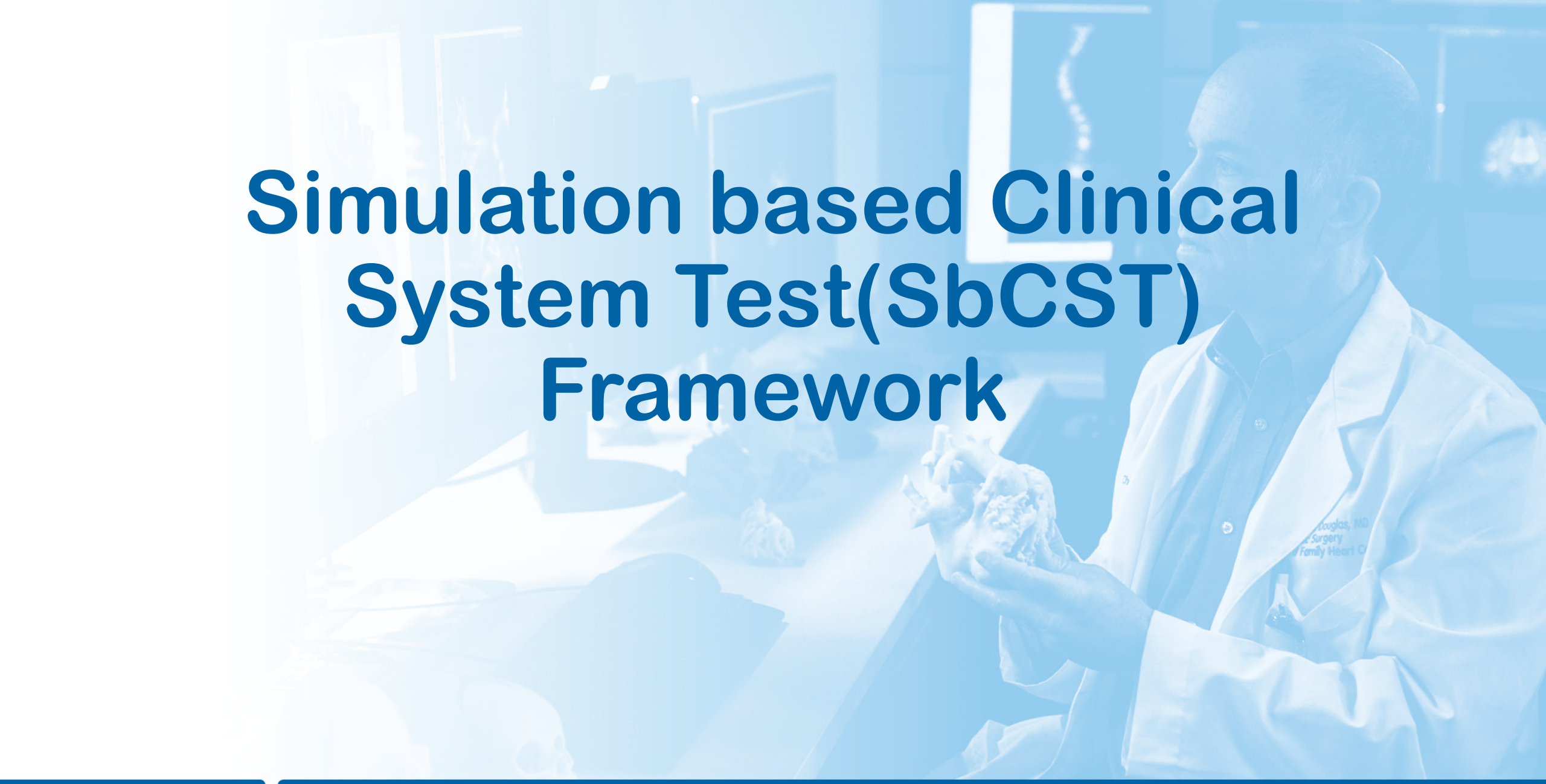
Simulation based Clinical System Test(SbCST) Framework



SbCST Framework

- Coleman et al. described a systematic approach to conduct SbCST in newly built clinical environment
  - Provided documentation and evaluation tools for simulation, with standardized approach
    - Development
    - Implementation
    - Evaluation
  - Described in newly built environment to identify Latent Safety Threats and system inefficiencies prior to patient exposure
  - Suggested additional applications in complex processes ie; ECMO cannulation

SbCST Framework

- Based upon 10 Evidence-based safe design principles
  - Agency for Healthcare Research and Quality
  - Center for Health Design
    - Control and eliminate sources of infection
    - Minimize environmental hazards
    - Optimize adjacencies
    - Support patient/family involvement in care
    - Ensure standardization
    - Reduce communication breakdown
    - Reduce noise
    - Enhance visibility
    - Reduce staff fatigue
    - Automate where possible

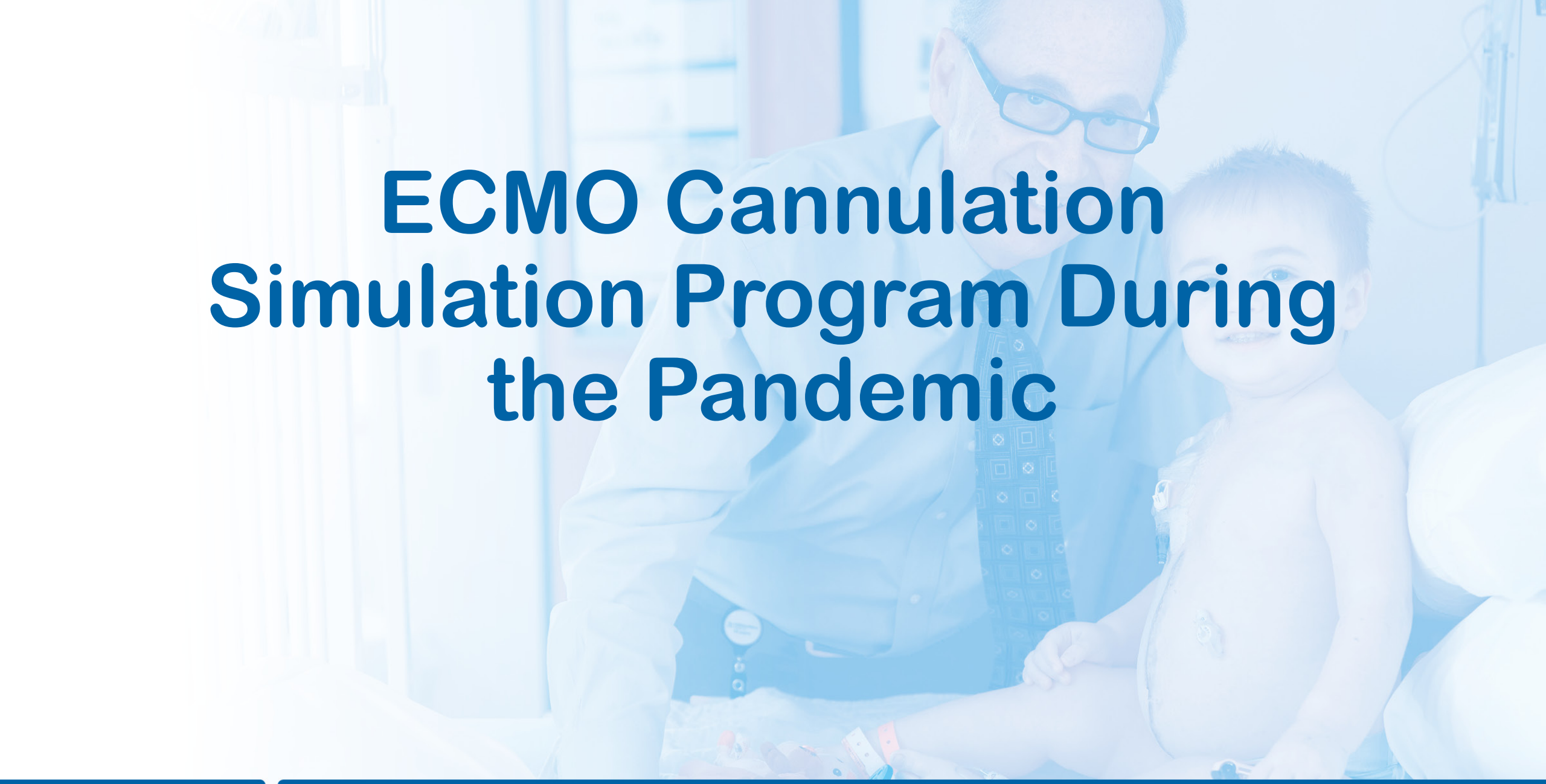
SbCST Framework - Domains

- **Resource Issues**
  - Personnel, medication, and equipment—whether missing, malfunctioning, or unable to use due to lack of provider familiarity with the device
- **Process/Systems Issues**
  - Process, policies, or procedures that do not work as well as anticipated in the clinical setting
- **Overall Design/Facility Issues**
  - Facility or space set up concerns that are not conducive to effective, efficient, and safe patient care
- **Clinical Performance Issues**
  - Cognitive skills, technical skills, or institutional process knowledge of clinical personnel that can be a focus for future simulation-based training
- **Infection Control**
  - Infection control and prevention, ability to limit cross contamination
- ***Communication***

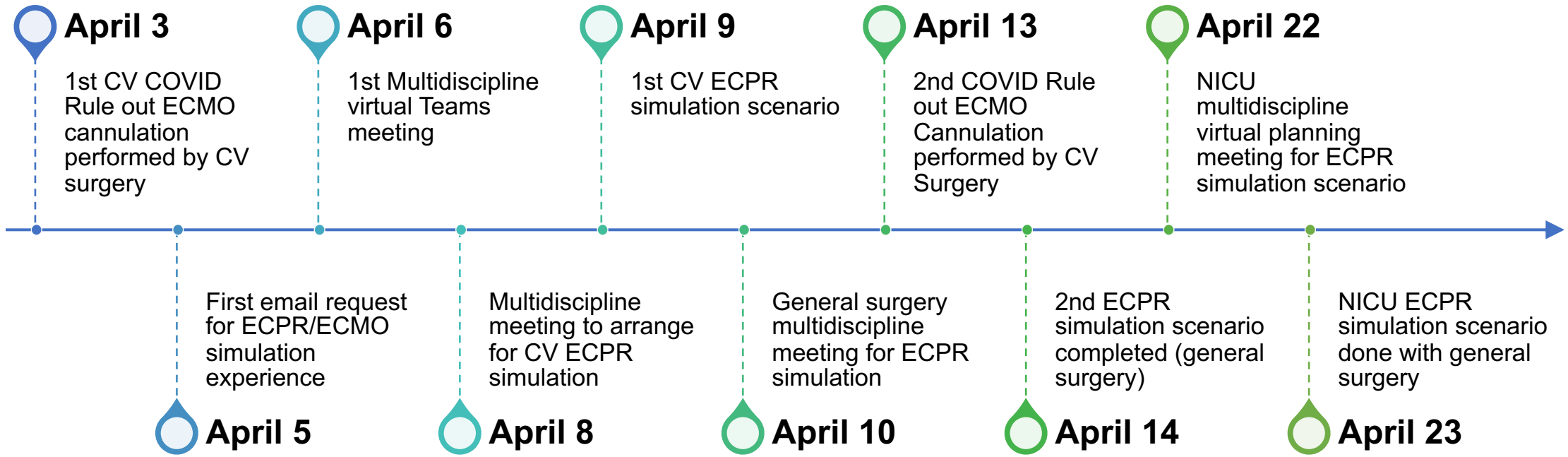
Suggested Timeline

Phase	Timeline
Developmental Phase - Stakeholder engagement - Needs assessment - Scenario Development - Simulation Preparation	 6-8 months 3-4 months 2-3 months 3 months
Implementation Phase - Testing day preparation - SbCST testing day	1 Week
Evaluation Phase - SbCST testing day - Reporting and follow up	1 day - 1month

ECMO Cannulation Simulation Program During the Pandemic



Compressed Timeline



The "How and Why"

- Rapidly changing guidelines and recommendations
- Patient requiring Extracorporeal Cardiopulmonary Resuscitation (ECPR)
- Goals: minimize staff exposure, optimize equipment and supplies inside the room, and determine a better mode of communication to reduce door opening/closing
- In situ simulation deemed the most effective form of process testing
- Utilized washable gowns, re-usable face shields, and staff-assigned N95 masks

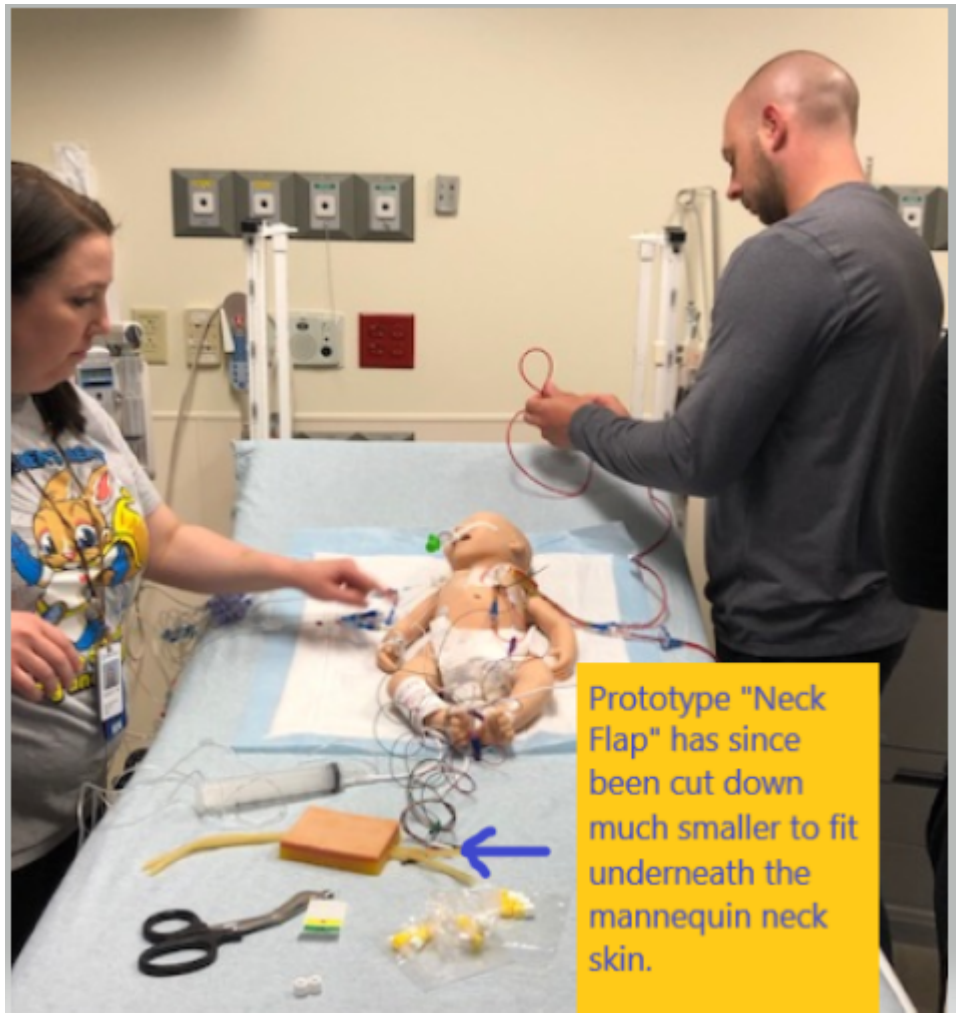
Off to the Races…Well Almost

Simulation team identified key stakeholders to begin planning the simulations.

- PICU nursing staff
- PICU intensivist
- PICU fellow
- PICU Respiratory Therapist
- PICU Pharmacist
- Operating Room : RNs (scrub and circulator)
- Surgeon and Surgeon Assistant
- ECMO specialist(s)
- Observers both inside and outside door
- Infection Control & Prevention Representative
- Simulation staff

Children's Mercy

Scenario Details and Design



- Use of existing simulation program that includes ECPR and neck cannulation
  - Many details were previously outlined
- A silicone neck "flap" allowed for cannulation
  - Muscle, fascial, skin layers and within it, two rubber vessels that can be cut down for cannula insertion
- Scenario: The existing scenario used in the past was tweaked to include a rule- out COVID-19 patient requiring contact and airborne precautions.

Scenario Details and Design

- A low fidelity infant mannequin was utilized for the procedure
  - During the scenario a simulation educator operated and performed CPR on a high-fidelity infant mannequin to simulate artifact on the bedside patient monitor
- All supplies and equipment that would be included in this were opened, utilized, and included to capture the highest level of fidelity possible

- **Ready, Set, GO!!**

COVID CONSIDERATIONS FOR ECPR & ECMO CANNULATIONS IN THE PICU

ADAPTED from: Jenna Miller, MD and Alyssa Stoner, DO

Modified by: Marita Thompson, Md and Kari Davidson, RN

Pre-Procedure

Team Plan	Procedural Items	Don PPE
Inside Room: Cannulating surgeon (& Fellow), OR support staff, Intensivist & Fellow, Bedside nurse (medication administration), Code recorder & communicator, ECMO primer(s), ECMO specialist, 2x Sterile compressors (fellow or nurse), RT, CV Anesthesia (as applicable) **Outside Room:** ECMO 2 (gopher), Resource Nurse/RT, CA, PPE & Door monitors, Pharmacist, Order Entry provider	**Equipment:** - Reference COVID equipment check list - PPE cart for emergency use only **Medication Plan:** - Fentanyl: 10mcg/kg - Vecuronium: 0.1mg/kg - Cannulation Heparin 75 Units/kg - Volume PRN	**PPE-Enhanced Contact Droplet Precautions** - Use PPE Buddy system - PPE guides posted throughout unit - Remove all jewelry - Gown - Gloves - Eye Protection - N95/PAPR

Cannulation

Pre-Procedure	Cannulation Tips	Procedure
- Time out performed - Leave pump outside room until 100% certain moving forward with cannulation per surgeon - Discuss cannula sizes - Hand up to sterile field once ready	**Patient Positioning** -Beds 1-4 only have a head board with necessary O2 and air ports 	**Minimize Environmental Noise** 1. Close doors off to rest of unit if in PICU rooms 1 – 4 2. Keep cannulation and OR carts away from door opening or ante room for AGP protection – avoid opening doors 3. Speak loudly if PAPRs in use 4. Only bring minimal cannula supplies in room; have gopher grab additional supplies PRN

Post Procedure

Doff PPE	Additional Considerations	
- High Risk for self-contamination - Refer to PPE conservation/reuse guidelines - Buddy system - Don gown to wipe down large machines (ECHO, CXR machine, OR carts)	- Consider alternating ECMO specialists Q4-6 hours to achieve breaks from PPE - Obtain imaging for cannula placement per provider discretion, noting risk of radiographic exposure without donning lead & limited space for machines	- Difficult to hear verbal instructions and orders in full PPE: speak clearly and use closed loop communication - N95 seals should be checked prior to entering the room and adjust as necessary

INTRODUCTION

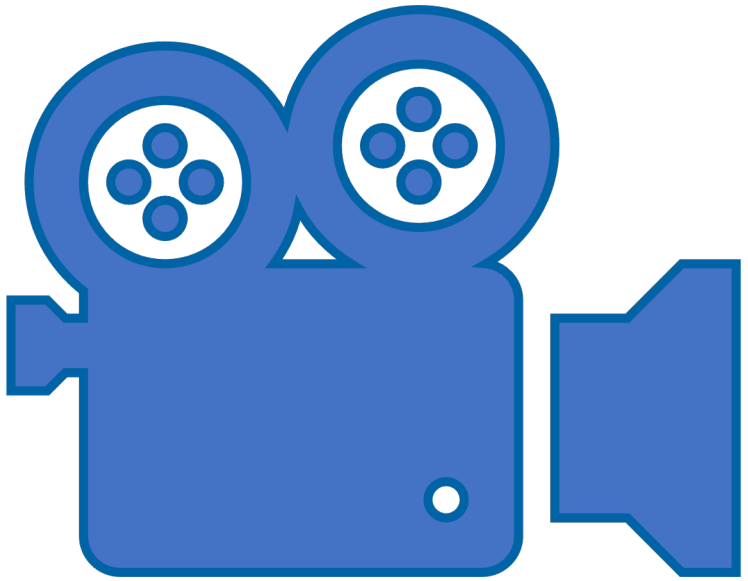
- The following is a *guideline* for cannulation of suspected COVID or COVID-confirmed patients in the PICU
- Each patient is unique, and some components of the guideline may not be applicable or achievable
- There are some components that can be achieved in all settings such as appropriate use of PPE with an observer or use of a buddy system when donning and doffing PPE

Work Products and Application to Pre-Briefs

Footage of NICU Scenario

"1-day old infant transferred to the NICU in respiratory failure requiring escalation of care. He develops Pulmonary Hypertension and deteroriates requiring resuscitation and ultimately ECMO support. The infant has possible COVID 19 exposure from Mom."

Now…The fun part!



Video Recap

- Despite a highly trained team
  - COVID added additional level of complexity
  - Multiple LSTs observed during simulation
    - Multiple barriers to communication in and outside of room
    - Various issues with donning and doffing PPE
    - Able to minimize contamination to surgical supplies and equipment
    - Lack of ability to social distance due to clinical setting

Tools Utilized for Simulation, Debriefing, and Reporting.

OVERVIEW:

Date:

Phase/Specialty:

Scenario:

SIMULATION CENTER STAFF

Facilitator:

Simulation Technician:

SCHEDULE	Approximate Start Time	Timeframe
Scenario Pre-Brief		
Scenario Time		
Move to Classroom		
Debrief		

PARTICIPANT ROLES :

EMBEDDED PARTICIPANTS

OBSERVERS

SCENARIO OUTLINE

PATIENT BACKGROUND:

VITAL SIGNS & PATIENT STATUS: See scenario template

EQUIPMENT/SUPPLIES:

OPTIONAL SYSTEM REPS

Adapted from Colman et al. *Simulation-based clinical systems testing for healthcare spaces: from intake through implementation.* Advances in Simulation. (2019) 4:19.

Intro to Debrief

We are going to spend the next 45 mins discussing issues with the equipment, with the process, with facilities, and with personnel. We have scribes taking notes so that everyone's observations and ideas are captured. It is very important for our scribes that we have one person talking at a time and no side conversations. Everyone's input is important. At the end, we will open the discussion to cover any observations we missed.

SIMULATION PROCESS TESTING GOALS & NOTES

Overall Design/Facility Issues: *Facility or space set up concerns that are not conducive to effective, efficient, and safe patient care*	**Resource accessibility/workflow efficiency:** *Issues related to personnel, medication, and equipment—whether missing, malfunctioning, or unable to use due to lack of provider familiarity with the device*
Process/System Issues: *Issues related to process, policies, or procedures that do not work as well as anticipated in the clinical setting*	**Clinical Performance Issues:** *related to cognitive skills, technical skills, or institutional process knowledge of clinical personnel that can be a focus for future simulation-based training*
Infection Control: *issues related to infection control and ability to limit cross contamination*	

SCENARIO

STEP-BY-STEP PROCESS	PROCESS BEING TESTED	OBSERVATION NOTES

Adapted from Colman et al. *Simulation-based clinical systems testing for healthcare spaces: from intake through implementation.* Advances in Simulation. (2019) 4:19.

Children's Mercy *** Simulation-based Clinical Systems Test (SbCST)

Project:

PRELIMINARY Report of Findings with Failure Modes and Effects Analysis (FMEA)

Background/Definitions	Use of Clinical Simulation to Promote High-Reliability in Healthcare
High-reliability science is the study of organizations in industries like commercial aviation and nuclear power that operate under hazardous conditions while maintaining safety levels that are far better than those of health care. These organizations have become known as **High Reliability Organizations (HROs)**. Five key principles of organizational safety culture have emerged as drivers of high reliability (Weick & Sutcliffe, 2007): • **Preoccupation with failure** • **Reluctance to simplify observations** • **Sensitivity to front-line operations** • **Commitment to resilience** • **Deference to expertise** Hospital quality and patient safety departments are increasingly examining the potential of adapting and applying the lessons of HRO science to health care in order to reach levels of quality and safety that are comparable to those of the best high-reliability organizations. ***In situ* simulation**, simulation that is physically integrated into the clinical environment, provides a method to improve teamwork, communication, and patient safety in high-risk patient care areas. It is likely that the most valuable benefits of *in situ* simulation are related to the identification of latent hazards, knowledge gaps, and opportunities for clinical teams to rehearse infrequent and/or high-risk clinical scenarios.	**Simulation-based Clinical System Testing (SbCST)** is a robust process improvement tool that can be used to proactively test the complex systems (people + physical environment + processes) involved in new patient care settings. By involving front-line personnel in clinical simulations aimed at stressing systems to find potential threats to patient/provider safety (LST – latent safety threats), it applies at least 3 HRO principles: Preoccupation with failure, Reluctance to simplify observations, and Sensitivity to front-line operations. **Failure Modes and Effects Analysis** (FMEA) is an established and widely used means of proactively seeking out both latent and active weaknesses and failures in healthcare systems in order to analyze causes, assess risk, and address resolutions (The Joint Commission, 2005). Incorporation of FMEA into patient strategies is required by Joint Commission for hospital accreditation. By adding the optional tool of FMEA Risk Prioritization to the SbCST findings, new hospitals can both prioritize how to address SbCST findings AND meet the Joint Commission requirement before their first accreditation survey. **Overview of this SbCST** After meeting with the Children's Mercy ECMO Transport group, the Simulation Center developed a scenario to test the ECMO Transport processes, workflows, resources and space. This is followed by scripted debriefing with leaders and key stakeholders. A total of *** LSTs were identified. There are ** staff (RN, MD/DO, RT, Perfusion and ECMO Team) who participated in the simulation. Specific outcomes and results are outlined in the following section.

Failure Mode and Effects Analysis Worksheet

Project Leader(s):
Simulation Lead:
Project Aim/Goal:
Targeted Units/Departments:
Resources, facilities, processes, and/or personnel to be examined:

FMEA Scoring Tool:

Risk Priority Number (RPN) *is calculated by multiplying* ***Severity*** *score by* ***Probability*** *score. Issues are considered significant priorities if* ***RPN*** *is between 8-16 on scale of 1-16.*

	4 - Catastrophic	3 - Major	2 - Moderate	1 - Minor
Severity Categories	***Failure could cause death, injury*** *Patient Outcome:* • *Death or major permanent loss of function (sensory, motor, physiologic, or intellectual)* *Visitor Outcome:* • *A death; or hospitalization of ≥3* *Staff Outcome:* • *A death; or hospitalization of ≥3* *Equipment/Facility damage: Firer beyond incipient stage; or damages ≥$250,000*	***Failure could cause high degree customer dissatisfaction*** *Patient Outcome:* • *Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual); or* • *Increased length of stay or increased level of care for ≥3 patients* *Visitor Outcome:* • *Hospitalization of 1-2 visitors* *Staff Outcome:* • *Hospitalization of 1-2 staff; or* • *≥3 staff experiencing lost time, or restricted duty* *Equipment/Facility damage:* • *Damages $100,000-$250,000*	***Failure can be overcome, but there is minor performance loss*** *Patient Outcome:* • *Increased length of stay or increased level of care for 1-2 patients* *Visitor Outcome:* • *Evaluation, treatment of 1-2 visitors* *Staff Outcome:* • *Medical expenses, lost time, or restricted duty for 1-2 staff* *Equipment/Facility damage:* • *Damages $10,000-$100,000; or* • *Fire, at/smaller than incipient stage*	***Failure not noticeable to customer, no effect on delivery of service*** *Patient Outcome:* • *No injury, nor increased length of stay, nor increased level of care* *Visitor Outcome:* • *Evaluated, but no treatment* *Staff Outcome:* • *First aid only, no lost time, or restricted duty* *Equipment/Facility damage:* • *Damages <$10,000; or* • *Loss of utility without adverse patient outcome*
Probability Ratings	**Frequent** *Likely to occur immediately or within a short period (may happen several times in 1 year)*	**Occasional** *Probably will occur (may happen several times in 1 to 2 years)*	**Uncommon** *Possible to occur (may happen sometime in 2 to 5 years)*	**Remote** *Unlikely to occur (may happen sometime in 5 to 30 years)*

2/3/2020 Stoner, adapted from Coleman, et al.

Outcomes and Results

I. Table 1: Potential Latent Safety Threats Identified with FMEA Hazard Scores (RED=Very High Priority 12-16; YELLOW=High Priority 8-11)

Item #	Potential LSTs Identified During Debriefings By Participants and Observers	Severity	Probability	Risk Priority Number	Potential Solutions Identified During Debriefings By Participants and Observers	Steering Team Recommendations (findings discussed 1 day after simulation)	Comments
	Resource Issues *(Issues related to personnel, medication, and equipment—whether missing, malfunctioning, or unable to use due to lack of provider familiarity with the device)*						
1					-		
2					-		
3					-		
4					-		
5					-		
	Process/Systems Issues (Issues related to process, policies, or procedures that do not work as well as anticipated in the clinical setting)						
6					-		
7					-		
8					-		
9					-		
					-		
11					-		

2/3/2020 Stoner, adapted from Coleman, et al.

Item #	Potential LSTs Identified During Debriefings By Participants and Observers	Severity	Probability	Risk Priority Number	Potential Solutions Identified During Debriefings By Participants and Observers	Steering Team Recommendations (findings discussed 1 day after simulation)	Comments
12					-		
13					-		
	Overall Design/Facility Issues (Facility or space set up concerns that are not conducive to effective, efficient, and safe patient care)						
17					-		
							-
	Clinical Performance Issues *(related to cognitive skills, technical skills, or institutional process knowledge of clinical personnel that can be a focus for future simulation-based training)*						
20					-		
	Infection Control: *Issues related to infection control and ability to limit cross contamination*						
21					-		

2/3/2020 Stoner, adapted from Coleman, et al.

Examples of Application of the SbCST Framework

- Airway Management in the ED COVID Simulation
- Airway Management in the OR COVID Simulation
- ECMO Transport Scenario

References

- Colman, N., Doughty, C., Arnold, J. *et al.* Simulation-based clinical systems testing for healthcare spaces: from intake through implementation. *Adv Simul* **4,** 19 (2019). https://doi.org/10.1186/s41077-019-0108-7

Contact Information

- Alyssa Stoner, DO: acstoner@cmh.edu
- Robert Schremmer, MD: rschremmer@cmh.edu
- Rachael Pedigo, BSN: rlpedigo@cmh.edu