Pediatric ECMO Cannulation Trainer
Proof-of-Concept
Design and Implementation

IMSH Hot Topic Presentation

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Hot Topic Learning objective

1. Identify strategic steps in the proof-of-concept (POC) development process.

2. Discuss the significance of interdisciplinary collaboration and end user engagement in POC development.

3. Describe how to incorporate simulation, cost-effective tools and equipment for POC development.
Pediatric ECMO Cannulation Trainer Project

- **Proof-of-Concept** (POC): Hands-on visual demonstration of an idea
  - **Prototyping** helps develop and validate POC

**Proof-of-concept development process (5 phases)**

- **Phase 1**: Discover and validate the “need”
- **Phase 2**: Investigate currently available/utilized products.
  - Explore all the possible ways a need can be solved without creating a new product
- **Phase 3**: New product development
  - Prototype design and fabrication with end user feedback
- **Phase 4**: New product pilot and survey
- **Phase 5**: Implement and share
ECMO Cannulation Trainer Project Phase 1-2

• **Phase 1:** Discover and validate the “need”
  • Identified a need for a pediatric surgical ECMO cannulation trainer
  • Surgery, sim center, and perfusion validated ”need “
  • Identified quality indicators potentially impacted

• **Phase 2:** Investigate currently available/utilized products.
  • External search – YouTube, Google, lit search, and manufacturers
  • Internal search – Surgery, sim center, respiratory therapy and perfusion
  • Document search in Microsoft OneNote
ECMO Cannulation Trainer Project Goals

1. Develop a realistic and inexpensive Pediatric ECMO Cannulation Trainer

2. Identify potential measurable outcomes by implementing the project:
   1. Improve surgical competency and efficiency in ECMO cannulation
   2. Increase surgical/perfusion competency, safety and efficiency in connecting to the ECMO circuit
   3. Develop new concepts to incorporate the design into simulation scenarios
   4. Develop and standardize simulation tools

3. Pilot/survey the proof-of-concept obtaining objective feedback on the design and skills video

4. Evaluate survey data from pilot, modify educational tools and finalize Pediatric ECMO Cannulation Trainer for dissemination.
Phase 3: Prototype fabrication with end user feedback

Project summary:

- Prototype iterations: (3) hearts, (10) neck tissues, (3) vessels set-ups, (2) base holders for neck/heart
- 8 simulations testing ECMO Cannulation Trainer POC
- 3 Videos demonstrating POC, 5 design recommendation videos
- Produced 1 skills video for pilot
Phase 3 continued:
Collaboration with simulation manufacturer

Neck Prototype #3

#4 (Neck and 1st heart)
Phase 3 continued

#5 (2nd heart and vessel connections)

#7 (3rd heart and base holder design)
ECMO Cannulation Trainer Design Outcomes

Anatomically accurate model simulates all steps for Pediatric ECMO neck cannulation (cut down) in an 18-25kg patient.

**Neck simulator: (single use)**
- Right side of neck with anatomically accurate landmarks (mandible, clavicle, SCM)
- Realistic tissue layers (skin, fat, platysma, SCM) for cutting and spreading to expose the vessels
- Correct vessel (IJV/Carotid) positioning, color, and feel for cutting, suturing and cannula insertion

**Heart: (reusable design)**
Clear 3D printed heart provides visualization during insertion of the wire/cannula
Phase 4 and 5

- **Phase 4:** New product pilot and survey
  - Survey evaluates ECMO Cannulation Trainer final design, skills video, and surgeon pre/post confidence
  - Evaluate Pilot outcomes:
    - Survey data
    - Modify educational tools
    - Finalize Pediatric ECMO Cannulation Trainer Program

- **Phase 5:** Implement and share
Prototype development lessons learned

• Avoid analysis paralysis

• Start with basic materials to determine the size, shape and concept prior to developing refined prototypes.
  • Expect multiple iterations during prototype development

• Utilize simulation/end user feedback to evaluate each prototype
  • Test, document findings, adjust design and repeat

• Start with small focus group, increase size as project develops momentum

• Ensure to budget the appropriate number of prototypes for end user feedback/pilot
Low-cost video lessons learned

- **Video tools utilized:**
  - Google Pixel, solid state drive (SSD)
  - Gimbal, tripod/boom, shoulder harness, head strap

- **Filming tips:**
  - Prepare script before filming
  - Film horizontally (helps with editing)
  - Be aware of back drop, wear gloves and turn phones on silence
  - Best to have narrator, person performing task and videographer
Thank you!