It is broke, how might we fix it?

Systems Engineering and ECMO

Dr. Matthew Paden - CHOA
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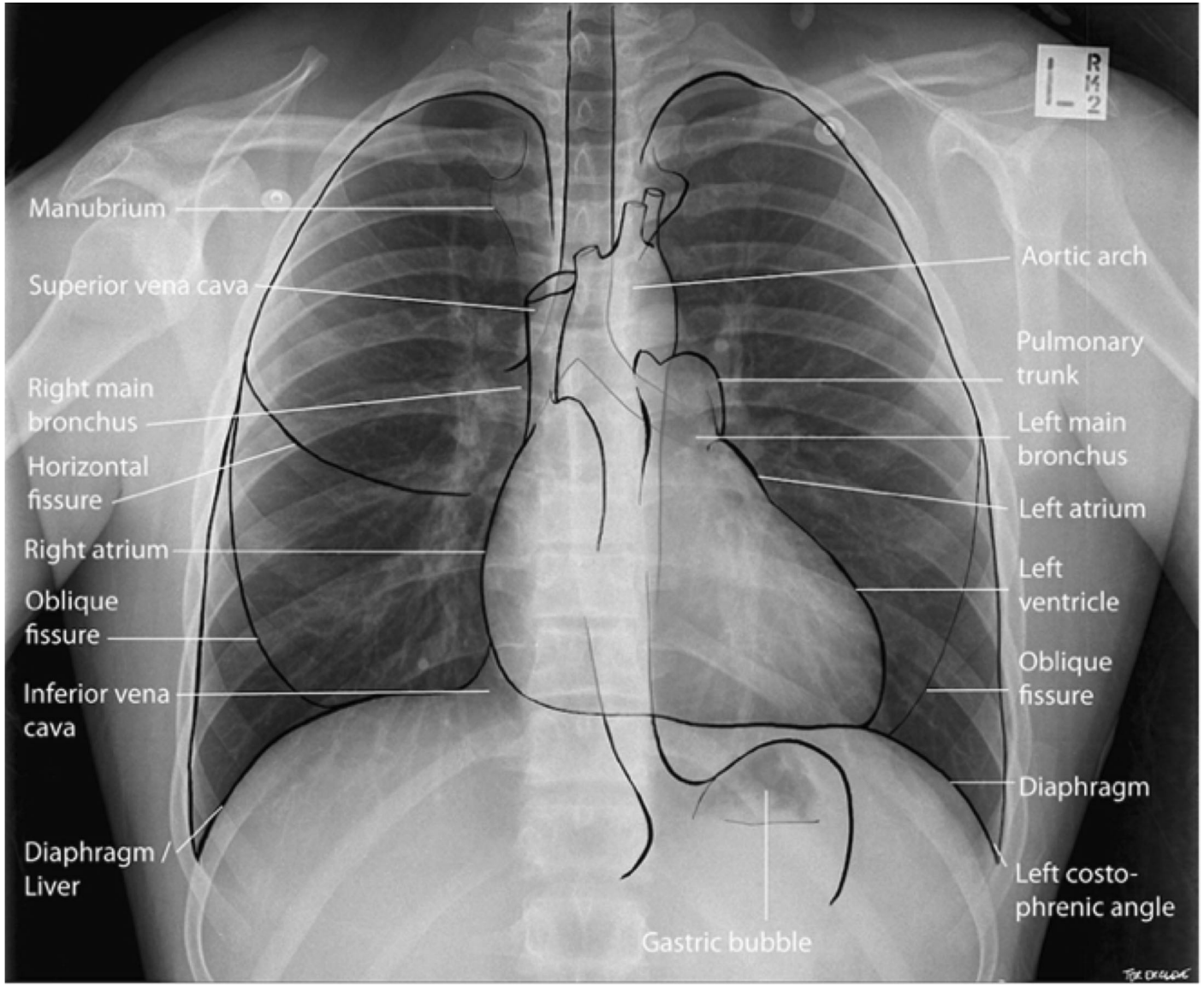
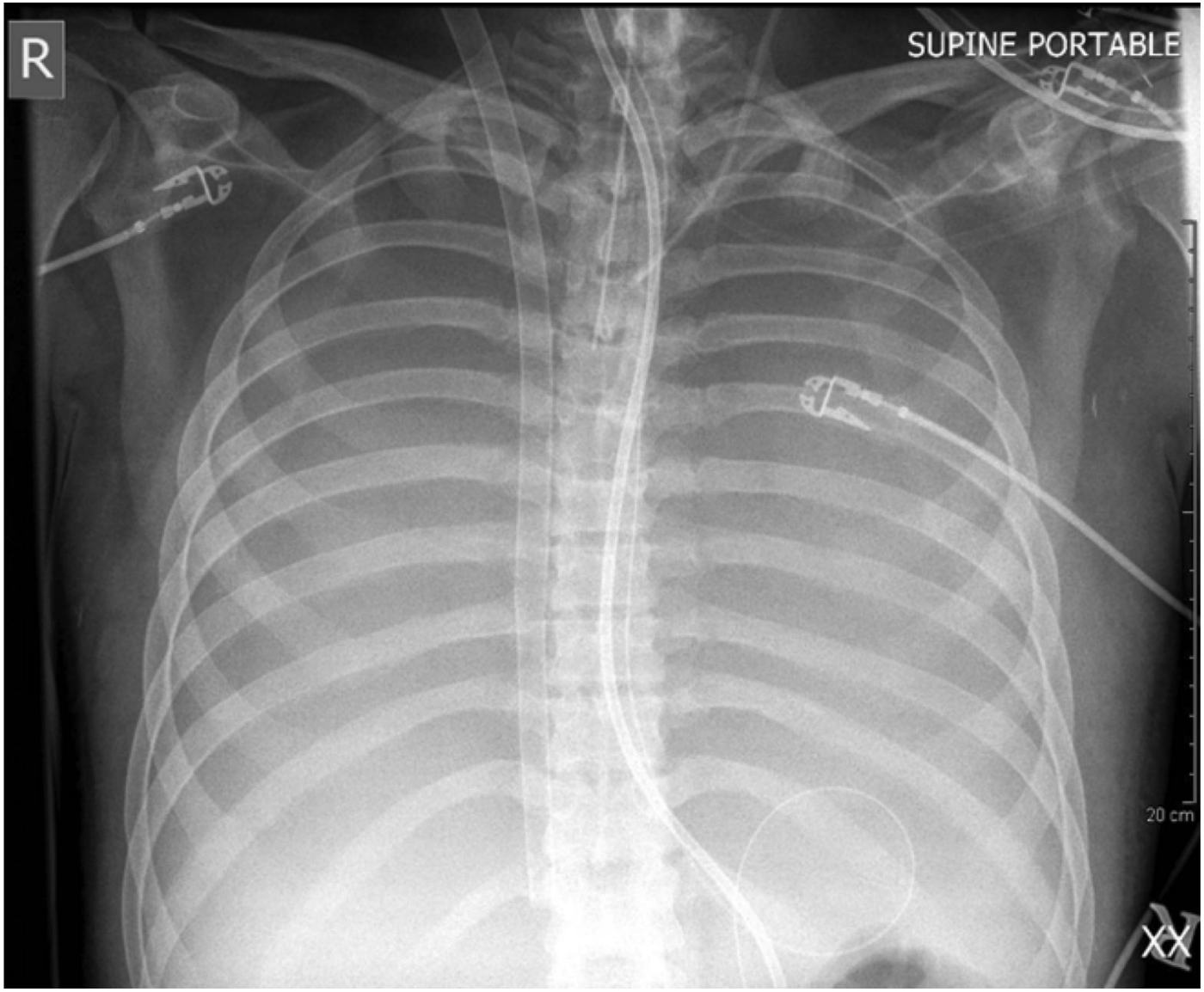

Manubrium
Superior vena cava
Right main bronchus
Horizontal fissure
Right atrium
Oblique fissure
Inferior vena cava
Diaphragm / Liver
Aortic arch
Pulmonary trunk
Left main bronchus
Left atrium
Left ventricle
Oblique fissure
Diaphragm
Left costo-phrenic angle
Gastric bubble


R
SUPINE PORTABLE
20 cm

Extracorporeal Membrane Oxygenation (ECMO):

- Is life-saving therapy
- Provides heart and/or lung support for extended durations
- Is used when conventional methods have failed and the risk of death is high
- Has been used since the 1970's, on over 100,000 patients
- Improves survival from 25% to 75%
- Is conceptually simple, yet very complex to design, implement, and improve

Extracorporeal Membrane Oxygenation (ECMO):

- Membrane oxygenators see a rise in the 1960's
- Dr. Robert Bartlett had been experimenting with the procedure on sheep in the early 1970's
- Dr. J Donald Hill first used ECMO successfully on an adult in 1971
- Esperanza

Extracorporeal Membrane Oxygenation (ECMO):

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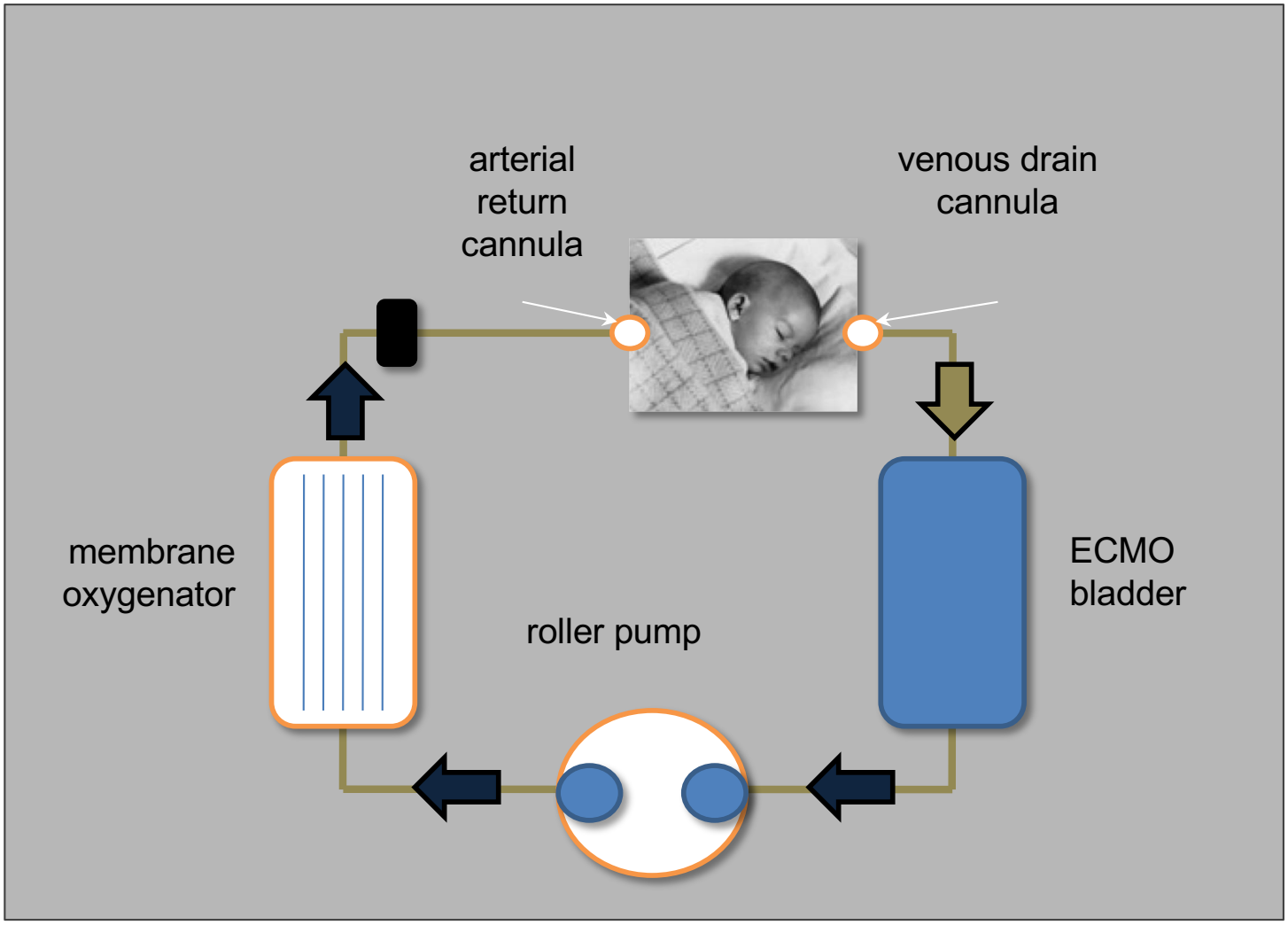
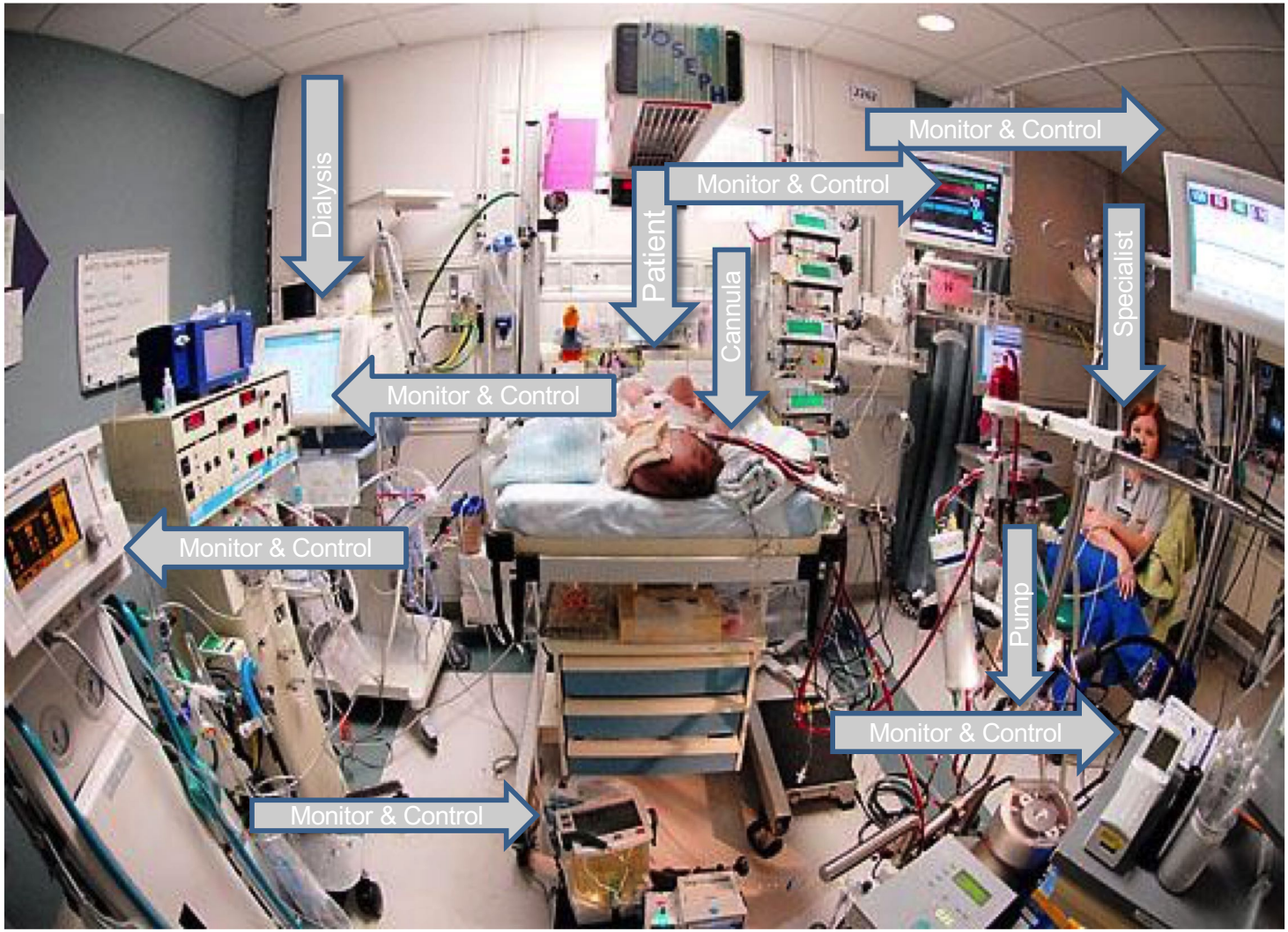

arterial
return
cannula
venous drain
cannula
membrane
oxygenator
roller pump
ECMO
bladder


Dialysis
Patient
Cannula
Specialist
Pump
Monitor & Control
Monitor & Control
Monitor & Control
Monitor & Control
Monitor & Control
Monitor & Control

ECMO is a therapy

- Not FDA approved
- There is no purchasable ECMO device, or in many cases, parts
- Not standardized across circuit design, training, etc
- Implemented at each center in a locally directed manner
- ELSO sets best practice guidelines, but isn't an enforcer

Human-systems Issues

- Many patients suffer complications including procedure-related death
- Not standardized
  - Tribal knowledge
    - May not be useful outside of their facility
    - May be useful but never transferred outside their facility
    - May leave at any time with departing personnel
  - Locally developed implementation/execution methods and experience
  - Inter-center training issues
    - E.g. rollerhead pump goes both ways in manual mode
    - E.g. training for bridge in circuit vs no bridge

Human-systems Issues

- Off-label equipment usage. Lack of real data on usage of equipment for ECMO purposes
- Lack of redundancy in circuit, but failure of any component can be catastrophic
- Iteration and improvement mean trying it out on the next patient
- Maintenance is as needed/identified and different at each center

Human-systems Issues

- No real way to meaningfully compare circuits and outcomes between centers
- Cost
  - Training
  - Components (disposable and not)
  - Research
  - Lawyers
- National data (ELSO registry)
  - Voluntary participation, submitted manually, often well after treatment
  - ELSO report, until recently, been available only twice a year. Requests for additional database queries are made through one person as requested

Can Systems Engineering help ECMO?

- ECMO was not developed using formal systems (or other) engineering, but rather experimentation
- (Mostly) obvious areas ripe for Systems Engineering
  - Data-driven comparison of circuits and outcomes to drive a best of breed circuit
  - Predictive maintenance
  - Common training
  - Formal modelling of circuits and practices
  - Reducing footprint (including portability) and manpower
  - Room layout to better allow for as-needed configurability (e.g. adding dialysis to the mix)
  - Maximizing interoperability
- We uncover more with every project

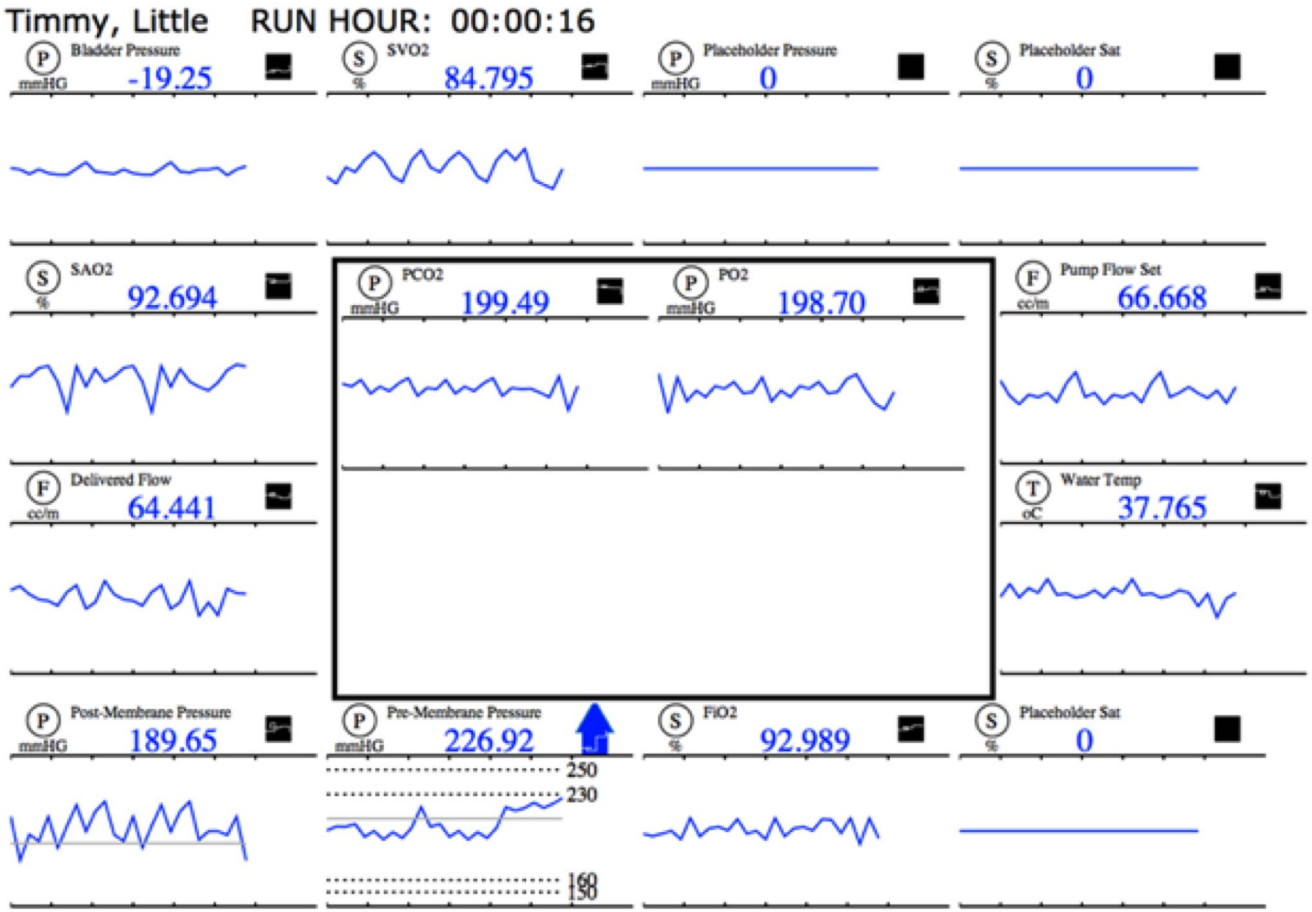
PMASE and CHOA

- Georgia Tech started the Professional Masters of Applied Systems Engineering (PMASE) in 2009
- First capstone projects in 2011, one of which was with CHOA with a goal of “improve ECMO”
- 6 project teams since then, all examining some aspect of ECMO and Systems Engineering
    - Started with CHOA and expanded to 5 total centers
    - Some project built off previous work and some were new
    - There is a required curriculum. All projects do some form of MBSE and have other common requirements, but formulate the rest of the project as required by the sponsors
    - Some projects have affected real change in the community

PMASE ECMO projects to date (2011)

Characterize CHOA's circuit, areas of further study, and propose a roadmap toward portable ECMO

- SysML model of CHOA's circuit and stakeholders
- High-level proposals of areas of future work, ordered with portable ECMO as the end state
- Prototype of fused data display to minimize monitor and control chaos
- Concluded the end goal is a long way off

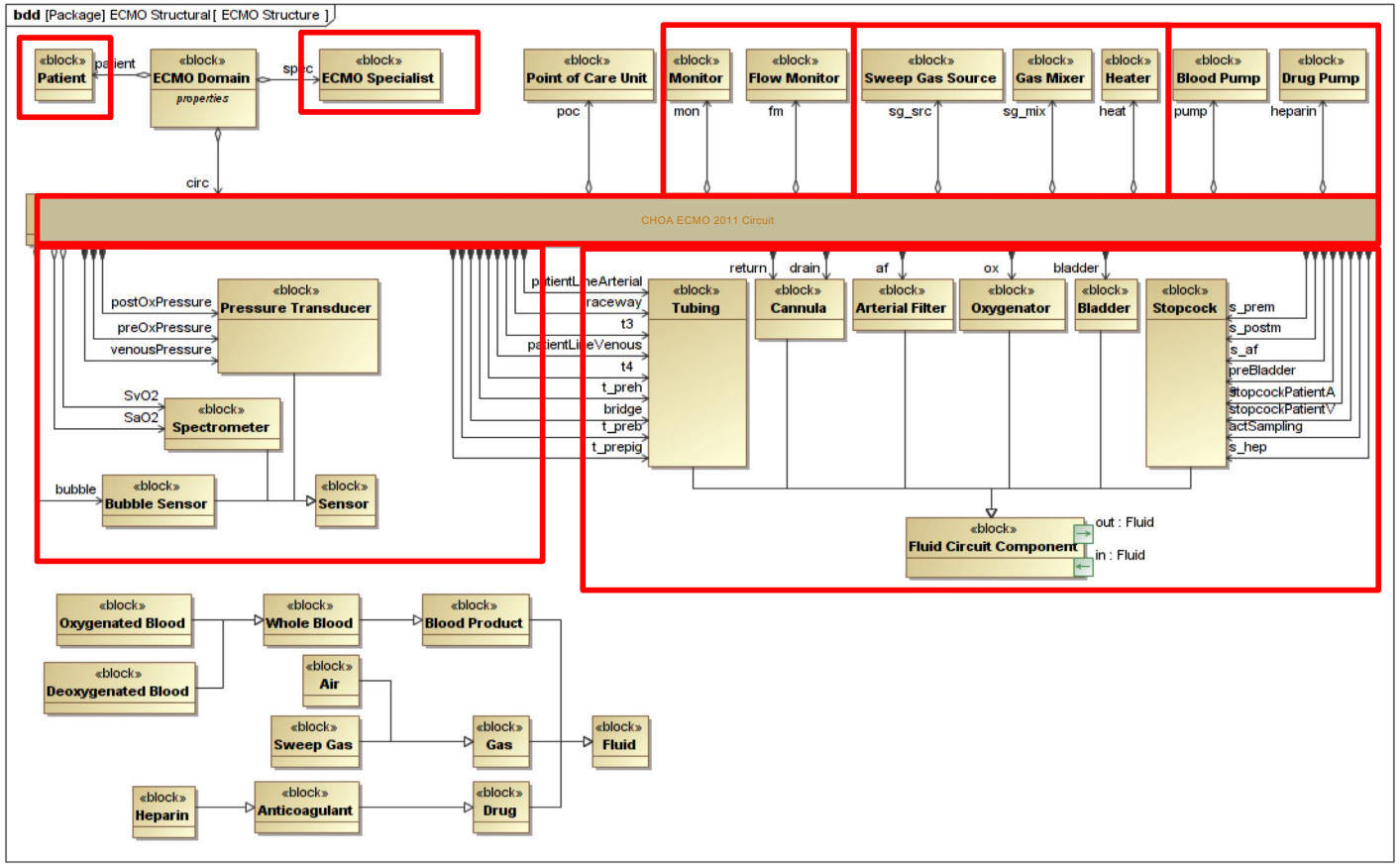


Notional fused data display (2011)

PMASE ECMO projects to date (2012)

Characterize circuits at other centers and develop a framework for trade study for tech insertion

- Similar SysML models, but with other centers' circuits
- Extend existing SysML models with instantiations of generic blocks
- SysML tradespace framework for tech insertion focused comparing heaters for initial analysis

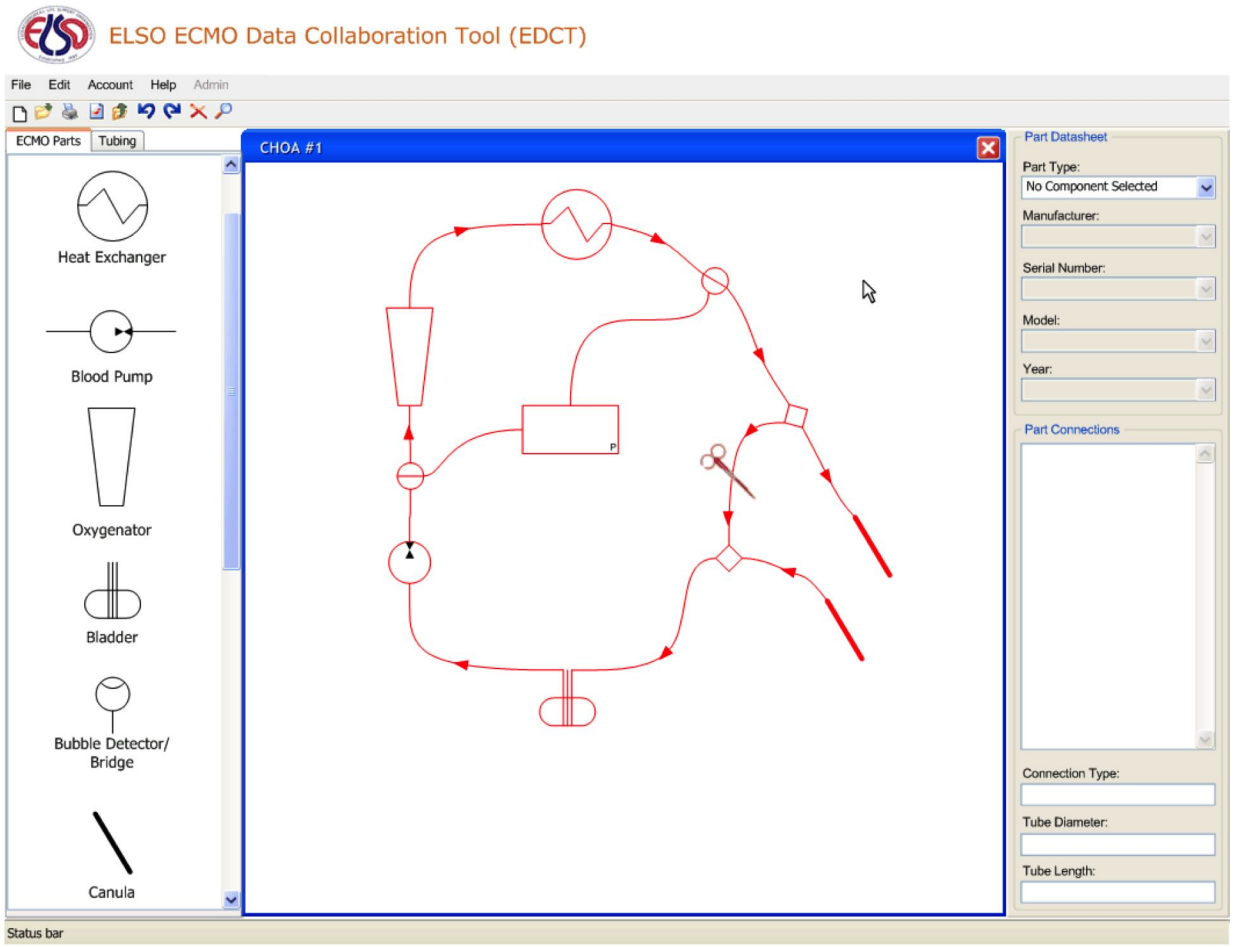


Sample SysML BBD with items for instantiation in trade study (2012)

PMASE ECMO projects to date (2013)

Develop a prototype web application for centers to describe their circuit with the intent of marrying this with outcome data

- ECMO Data Collection Tool (EDCT) provides a palette of available parts for drag-and-drop building of a circuit
- Researched considerations for using this new data with the ELSO registry

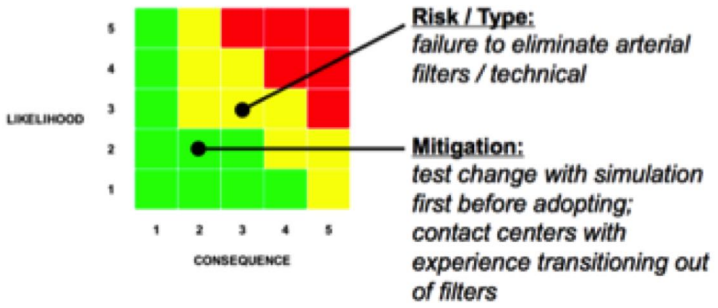


EDCT Circuit builder design mock-up (2013)

PMASE ECMO projects to date (2014)

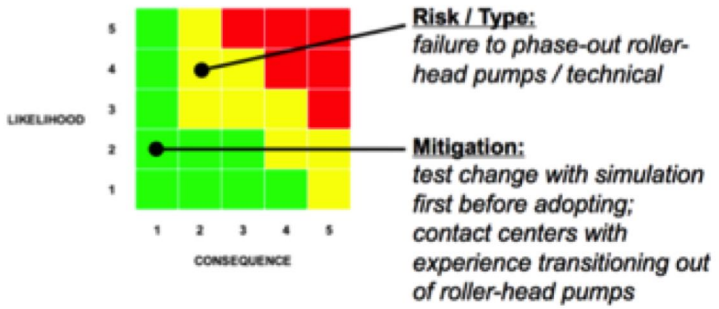
Examine the state of training and equipment selection at centers across the US and propose methods to commonize if possible

- Major focus on interviews with stakeholders at various sites
- Interesting conclusions, including less demand for redundancy



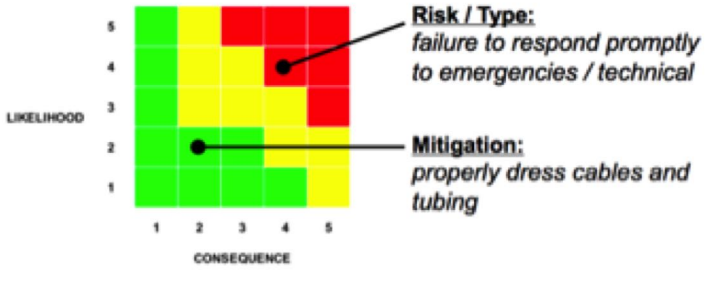
Risk / Type:
failure to eliminate arterial filters / technical

Mitigation:
test change with simulation first before adopting; contact centers with experience transitioning out of filters



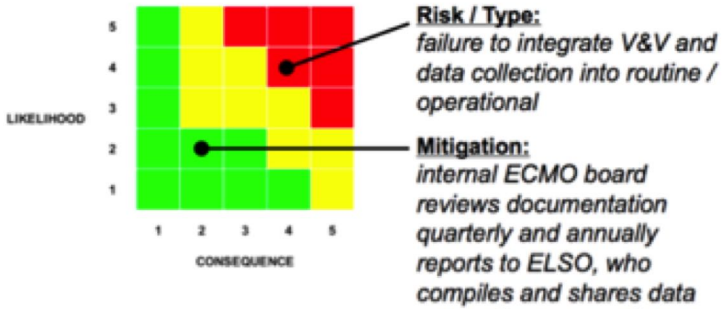
Risk / Type:
failure to phase-out roller-head pumps / technical

Mitigation:
test change with simulation first before adopting; contact centers with experience transitioning out of roller-head pumps



Risk / Type:
failure to respond promptly to emergencies / technical

Mitigation:
properly dress cables and tubing



Risk / Type:
failure to integrate V&V and data collection into routine / operational

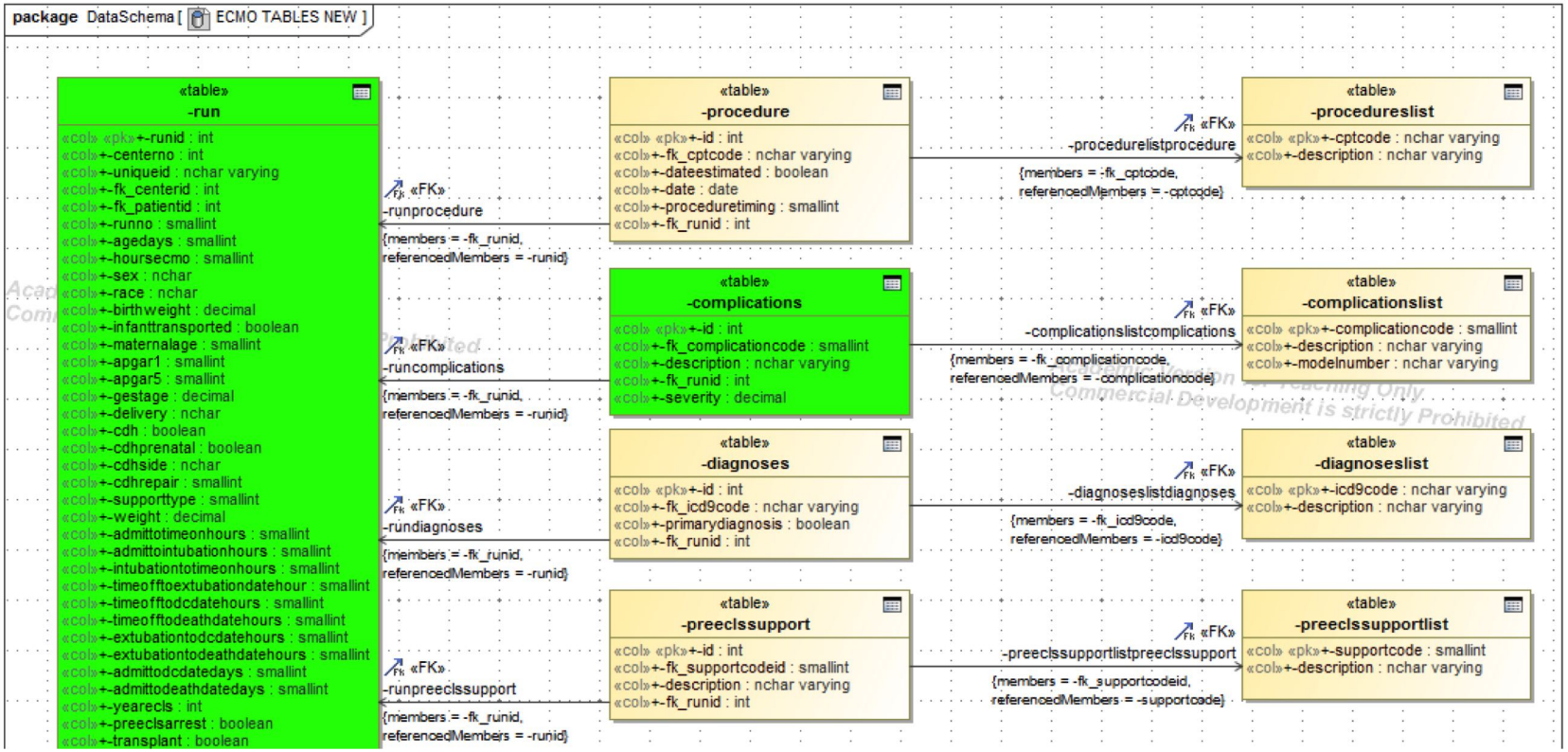
Mitigation:
internal ECMO board reviews documentation quarterly and annually reports to ELSO, who compiles and shares data across the community

Sample risk analysis (2014)

PMASE ECMO projects to date (2016)

Design a system for on-demand publishing of the ELSO registry report and examine database schema/concerns for adding EDCT data and automating centers' data entry

- Compared manual, automated and hybrid methods for data entry
- Risk and requirements analysis for on-demand report publishing
- Some registry data now available on demand

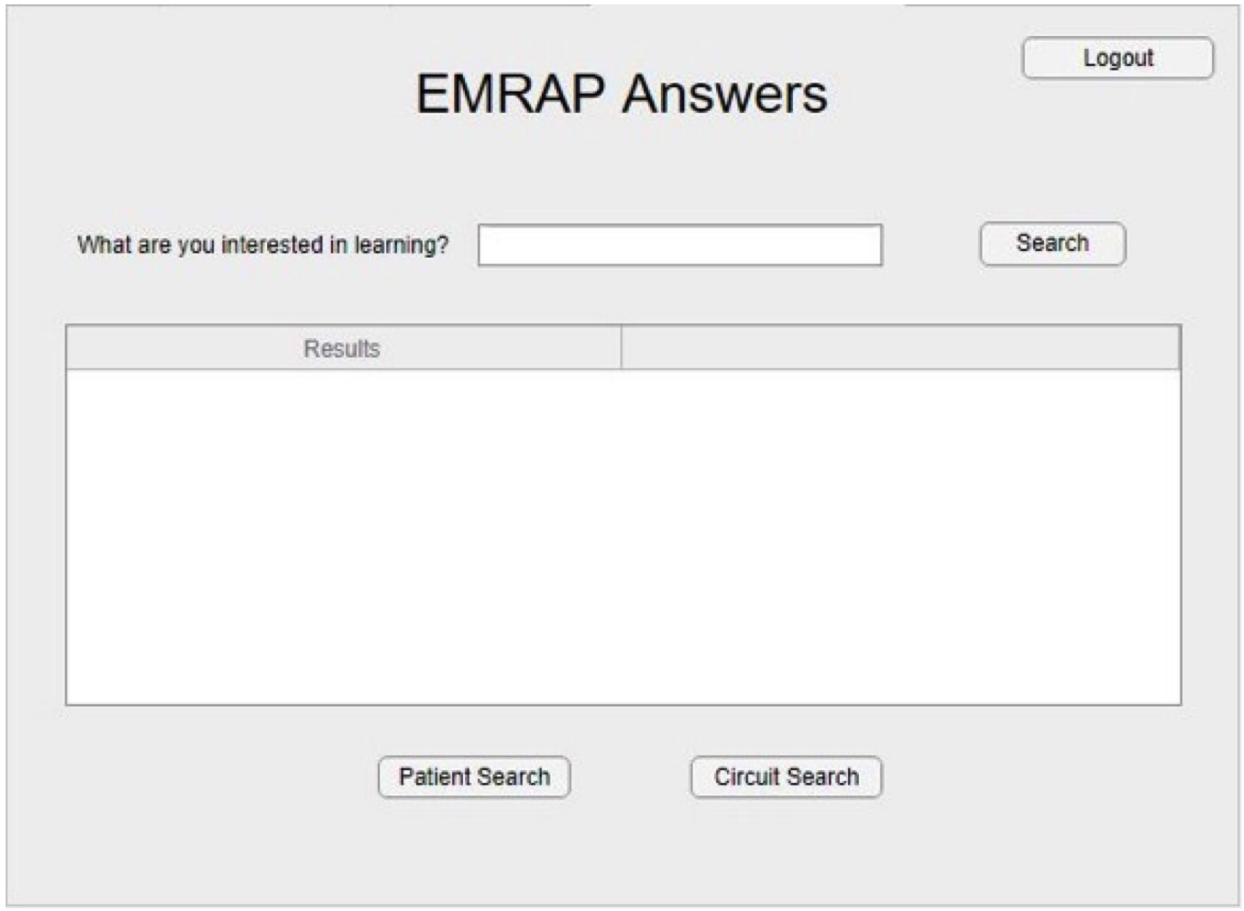


Sample UML package diagram of database schema (2016)

PMASE ECMO projects to date (2018)

Develop a prototype application for automated data entry and machine learning-assisted search of database

- Fast Healthcare Interoperability Resources (FHIR)-based implementation of automation of data entry
- Neural network-based search of registry data (think Google for ECMO community)
- Natural language search focus



Sample UI View of EMRAP Search Tool (2018)

Cost savings realized and to come

Realized

- Optimized international ELSO Registry
- On-demand generation of registry report data
- Basic internet accessible outcome search features
- Novel work by PMASE students, publications and talks

Future

- More expedient access to data to consume
- Automation of data to the registry
- Common training
- Standardization

The future of Systems Engineering and ECMO

- There is no shortage of potential work, comes down to cost and motivation
- Previously identified projects
  - 2011 cohort roadmap
  - Each project has identified new areas of opportunity
- Natural language search for registry database
  - Exciting to sponsors
  - Applicable outside of ECMO
  - Allows new methods of automated data fusion
- Proper automated data entry
- Standardization / FDA approval
- Much more

Selected Publications

1. Pihera, L. Drew, et al. "4.2. 2 Application of Systems Engineering to Improve Extracorporeal Membrane Oxygenation (ECMO) Therapy." *INCOSE International Symposium*. Vol. 22. No. 1. 2012.
2. Pihera, L. Drew, et al. "Applying Systems Engineering to Improve Extracorporeal Membrane Oxygenation Therapy." *INSIGHT* 15.4 (2012): 22-30.
3. Adams, Nathan L., and L. Drew Pihera. "A systems engineering based approach for informing extracorporeal membrane oxygenation (ECMO) therapy improvements." *Procedia Computer Science* 16 (2013): 591-600.
4. Pihera, L. Drew, Tommer R. Ender, and Matthew L. Paden. "Extracorporeal Membrane Oxygenation (ECMO)-A systems of systems engineering characterization." *2013 8th International Conference on System of Systems Engineering*. IEEE, 2013.
5. Blalock, Stephen, et al. "Enabling Extracorporeal Membrane Oxygenation (ECMO) Community Collaboration via Systems Engineering Methodologies." *Procedia Computer Science* 28 (2014): 155-163.
6. Pihera, L. Drew, et al. "Medical Enhancements to Sustain Life during Extreme Trauma Care." *Modeling and Simulation Support for System of Systems Engineering Applications*(2015): 479.
7. Adams, Nathan L., et al. "Model-Based Systems Engineering: Extracorporeal Membrane Oxygenation (ECMO) Therapy." *Modeling and Simulation in the Systems Engineering Life Cycle*. Springer, London, 2015. 349-367.

The future of Systems Engineering and ECMO

QUESTIONS?