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Problem. Solved.

Applying Model Based Systems Engineering (MBSE) to Extracorporeal Membrane Oxygenation (ECMO)

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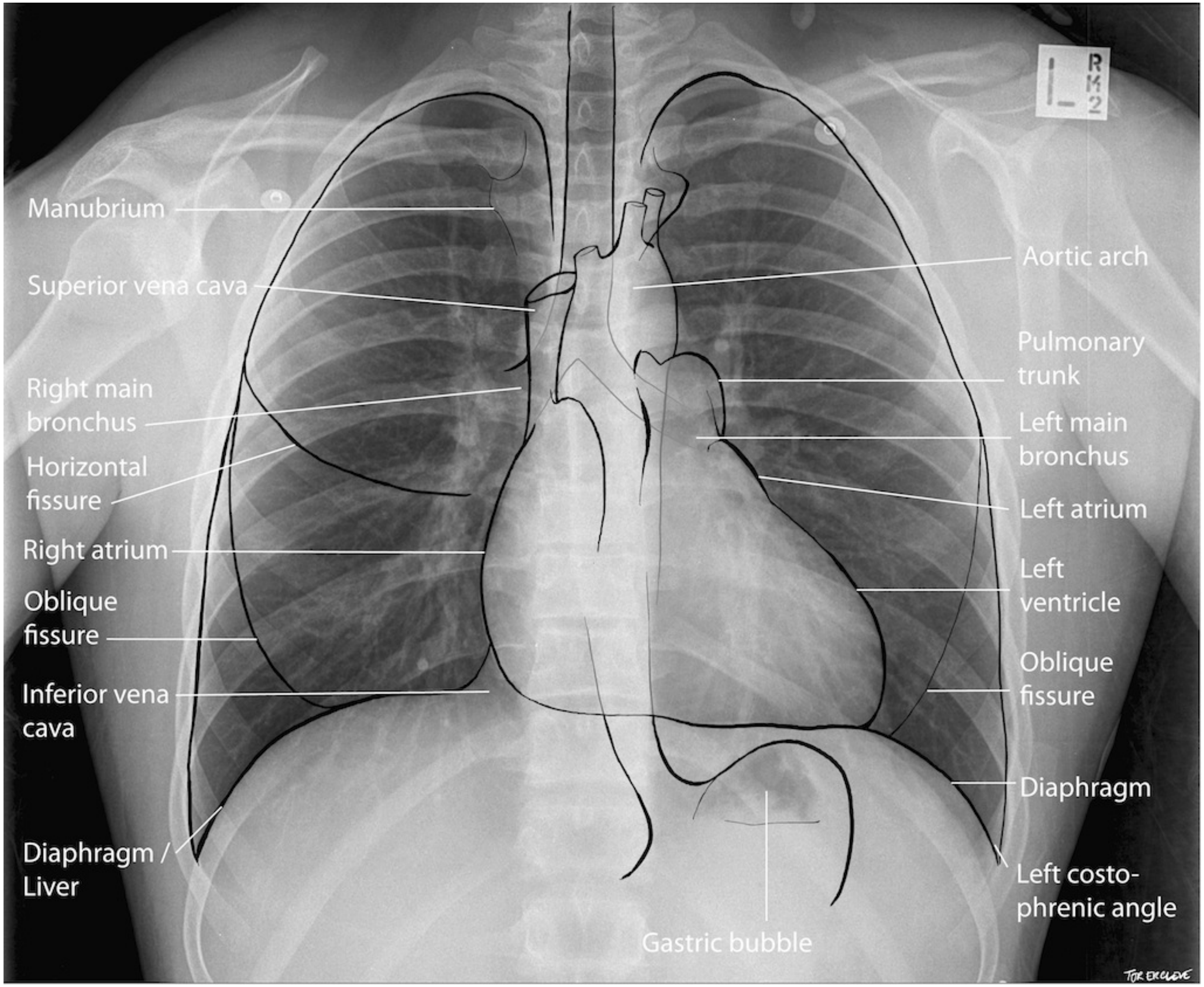
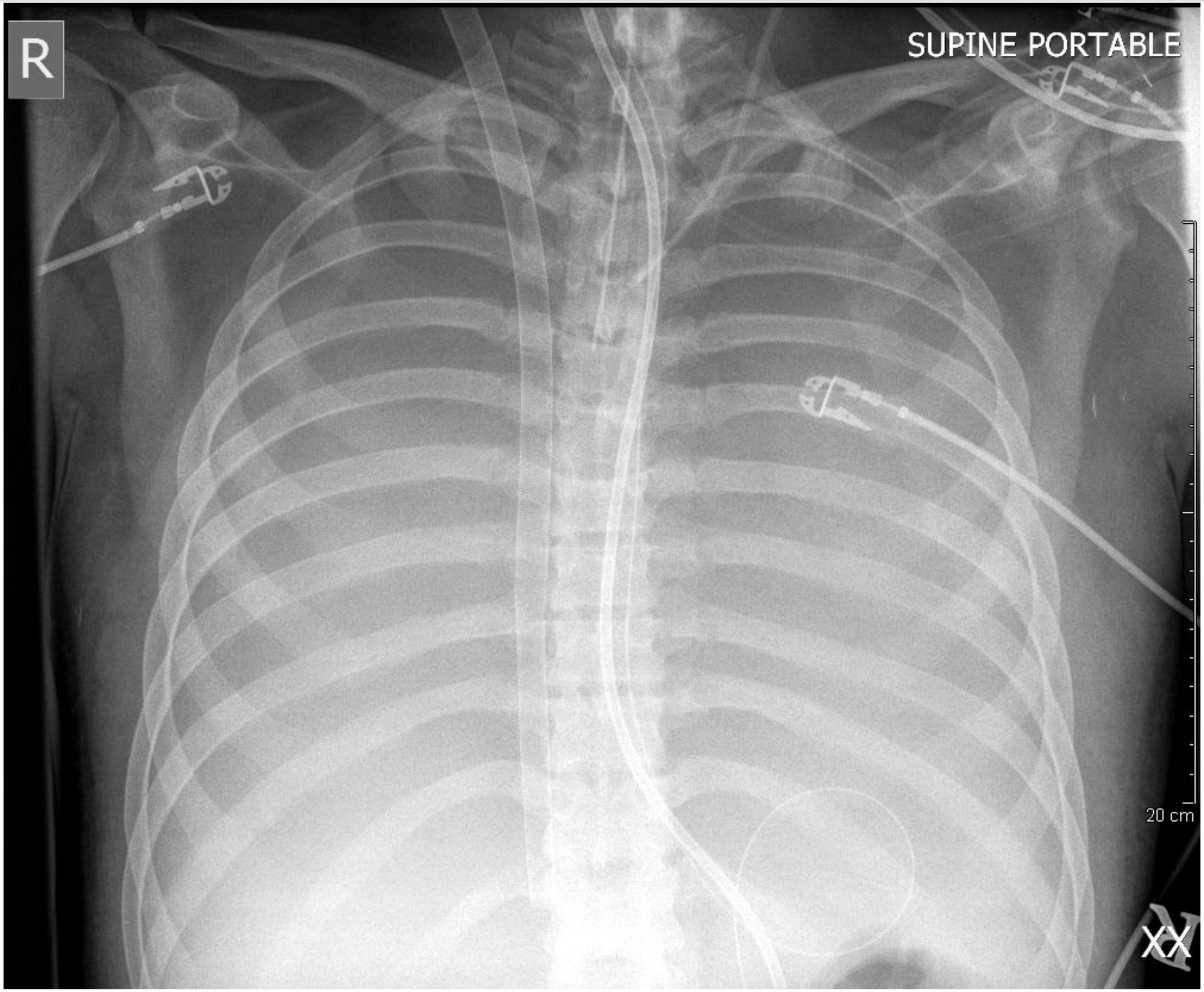
Summit on Model Based Systems Engineering in Healthcare, Boston, MA

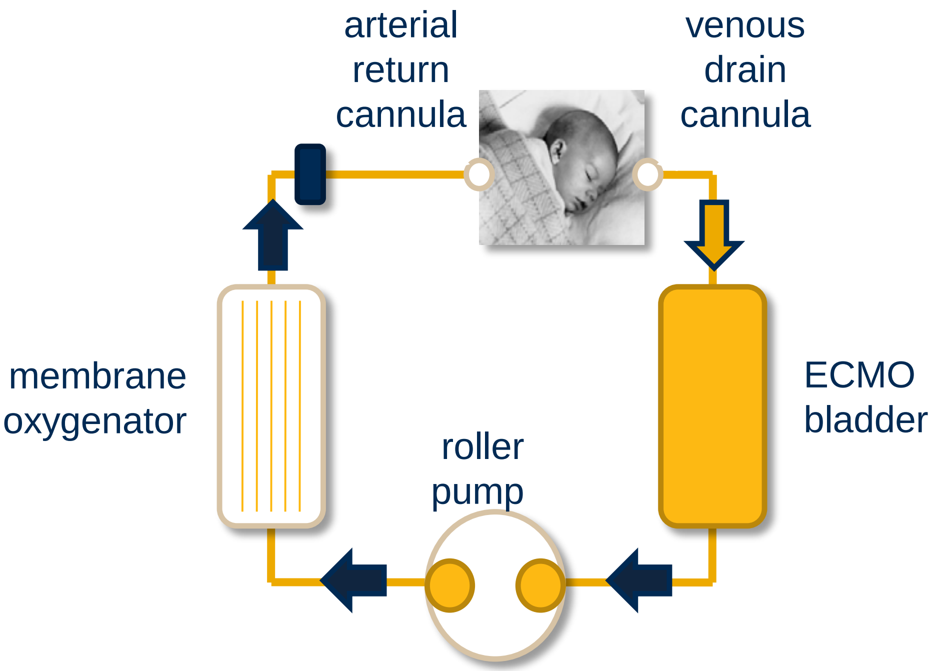

Manubrium
Superior vena cava
Right main bronchus
Horizontal fissure
Right atrium
Oblique fissure
Inferior vena cava
Diaphragm / Liver
Aortic arch
Pulmonary trunk
Left main bronchus
Left atrium
Left ventricle
Oblique fissure
Diaphragm
Left costo-phrenic angle
Gastric bubble


R
SUPINE PORTABLE
20 cm
XX

What is ECMO?

- **Extracorporeal Membrane Oxygenation**
- **Provides patient with heart and/or lung bypass (rest)**

Typical ECMO circuit



Source: "Extracorporeal Membrane Oxygenation: a broken system"

Further ECMO Info

- Developed by Dr. Robert Bartlett, first used on an infant in 1975.
- Remove blood from the body, oxygenate, and return (similar in function to a heart-lung bypass machine).
- Used in cases where traditional means fail, and survival expectancy is less than 20-25%.
- Can improve survival to nearly 75%.

Further ECMO Info (cont'd)

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ECLS Registry Report

International Summary

January, 2014

Extracorporeal Life Support Organization
2800 Plymouth Road
Building 300, Room 303
Ann Arbor, MI 48109

Overall Outcomes

	Total Patients	Survived ECLS		Survived to DC or Transfer	
Neonatal					
Respiratory	27,007	22,782	84%	20,093	74%
Cardiac	5,425	3,339	62%	2,206	41%
ECPR	980	626	64%	388	40%
Pediatric					
Respiratory	6,149	4,034	66%	3,496	57%
Cardiac	6,784	4,443	65%	3,388	50%
ECPR	2,071	1,123	54%	840	41%
Adult					
Respiratory	5,146	3,317	64%	2,905	56%
Cardiac	4,042	2,255	56%	1,636	40%
ECPR	1,238	476	38%	355	29%
Total	58,842	42,395	72%	35,307	60%

Further ECMO Info (cont'd)

- **Sounds simple enough, right?**

ECMO is not so simple

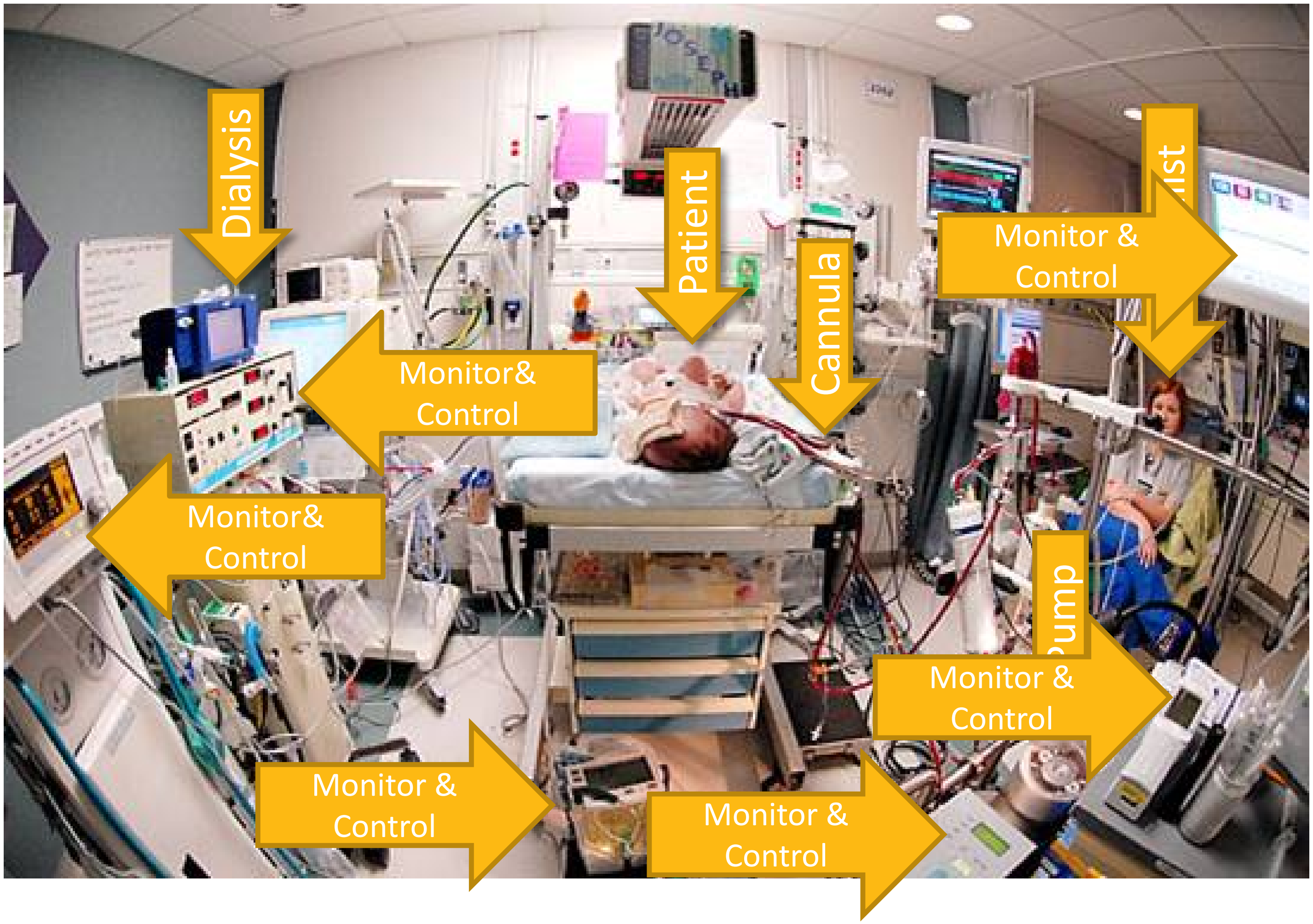

Image courtesy of CHOA

Problems with current implementation

- No standardization between sites
- Need for highly trained staff
- Incredibly complex, disparate systems all requiring second to second monitoring 24 hours a day

- VERY high complication rate = death.

ECMO and MBSE Background

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- Initial partnership between Georgia Tech Professional Master's of Applied Systems Engineering (PMASE) and Children's Healthcare of Atlanta (CHOA)
  - Stated long-term goal of "improving" ECMO. Part of the work was figuring out what "improve" could mean
  - Work would include a mix of traditional and model-based systems engineering
  - Long term partnership with many PMASE capstone teams (12 week projects).

ECMO and MBSE Background (cont'd)

- GT PMASE teams with CHOA in 2011 (CHOA would sponsor all PMASE teams)
- Collaboration expanded in 2012
  - Kapi'olani Medical Center (Hawaii)
  - Miller's Children's Hospital (California)
  - Rady Children's Hospital (California)
  - University of Arizona Medical Center
- 2014 Cohort is trying to interview multiple additional ECMO centers

ECMO and MBSE Background (cont’d)

- First cohort:
  - Characterize the system (stated requirement)
  - Propose future work and direction (stated requirement)
    - Reduce complexity?
    - Work toward a portable ECMO circuit?
    - Work toward eventual FDA approval?
    - Other improvements?
  - Figure out how to foster communication (derived requirement)
- Second cohort
  - Refine the models of the first cohort
  - Expand to begin requirements elicitation
  - Develop a framework for starting activities like trade space analyses

ECMO and MBSE Background (cont'd)

- Third cohort
  - Requirements/prototype for a web application for characterizing circuits across the US (to be detailed in a paper/presentation at CSER 2014)
- Fourth cohort started project in May 2014
  - Work is focused on gathering data on existing ECMO protocols at various centers and suggesting a path toward standardization of protocols

How can MBSE begin to help the problems

- No standardization between sites
  - Model an "improved" state of a standardized circuit (with respect to data automation and visualization)
  - Model the structure and behavior of existing circuits around the US, use this as well as patient outcomes to fuel best of breed trade studies
  - Model the stakeholders and their responsibilities at different locations, find common areas and major differences
- Need for highly trained staff
  - Use models to find possible areas for automatic data capture to reduce burden on staff
- Incredibly complex, disparate systems all requiring second to second monitoring 24 hours a day
  - Model a possible new display for fusing data in one location

Partial Systems Engineering Approach

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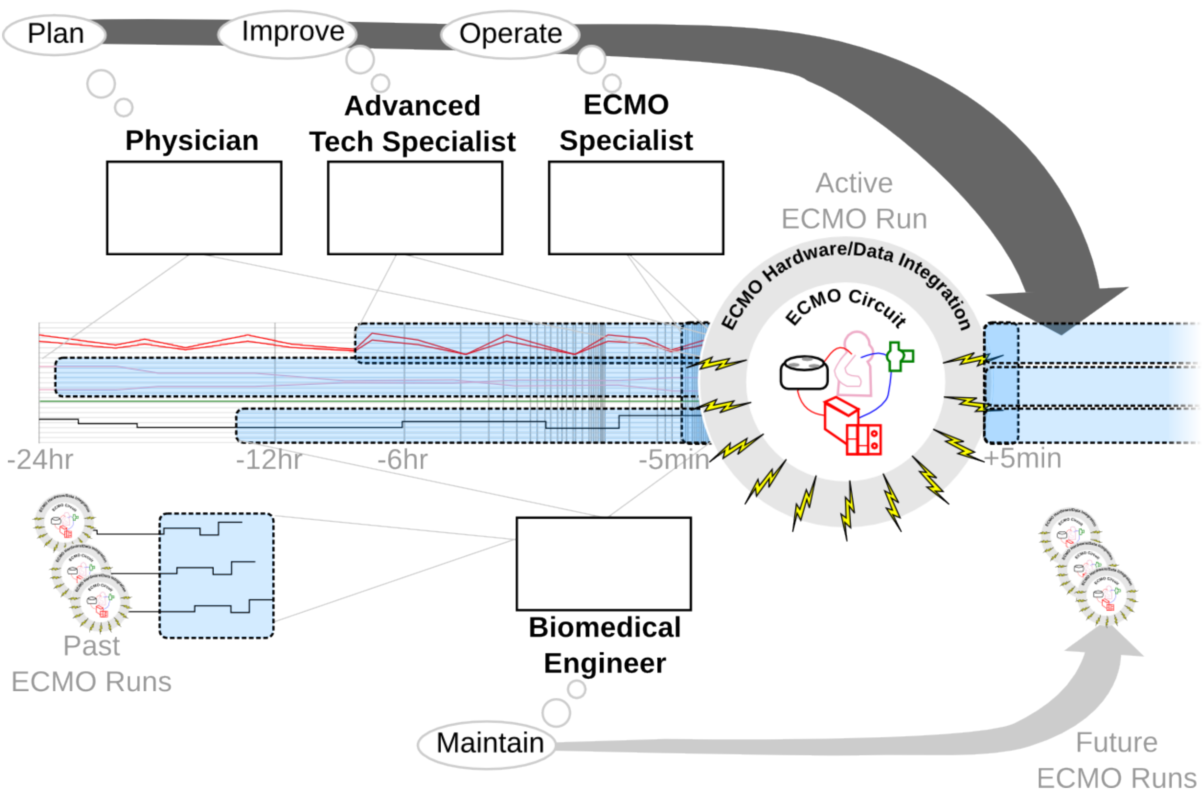
- Stakeholder interviews
  - Not specifically MBSE, but did help to inform our models of stakeholders, ECMO structure and behavior, areas for automation and more
- MBSE Techniques (first 2 cohorts)
  - DoDAF OV-1 (model an “improved” state)
  - SysML Model (model existing structure, behavior, requirements, stakeholders)
  - N-squared diagram (model data flow in the SoS and areas for improvement)
  - Prototype visualizations (model a fused data display)

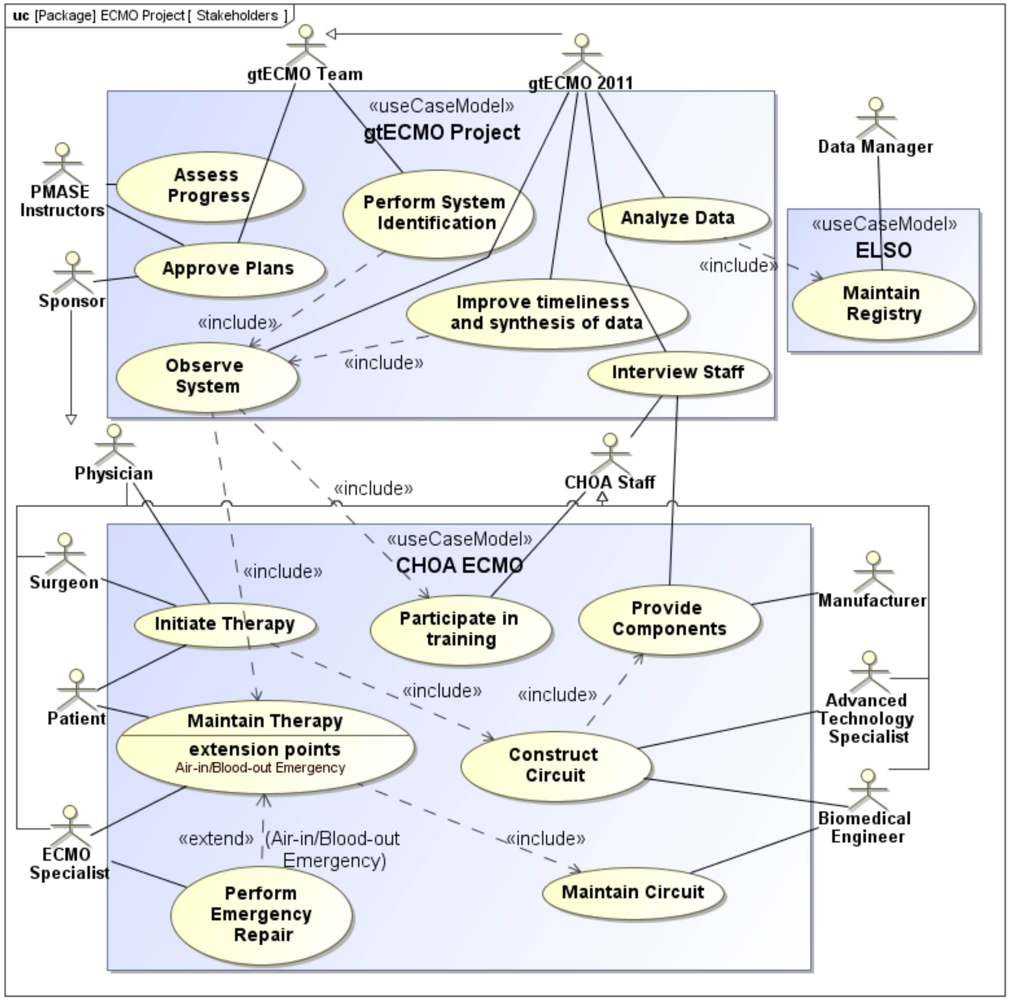
DoDAF OV-1 – Capture the need

Improving ECMO Therapy through Data Synthesis and Visualization



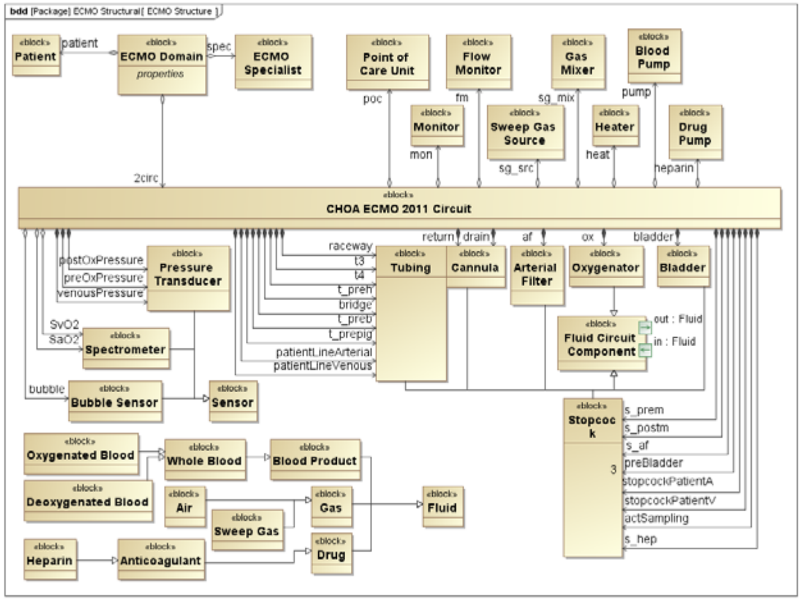
- **Shows the Operational View of ECMO in the future "improved" state**
  - **Lightning bolts represent data automation**
  - **Role-based data visualization (denoted by graphs)**
  - **Maintaining historical data**
- **Shows what different stakeholders care about**
  - **Data**
  - **Time intervals**
  - **General operations**
- **Communicate what data synthesis and visualization is meant to accomplish**

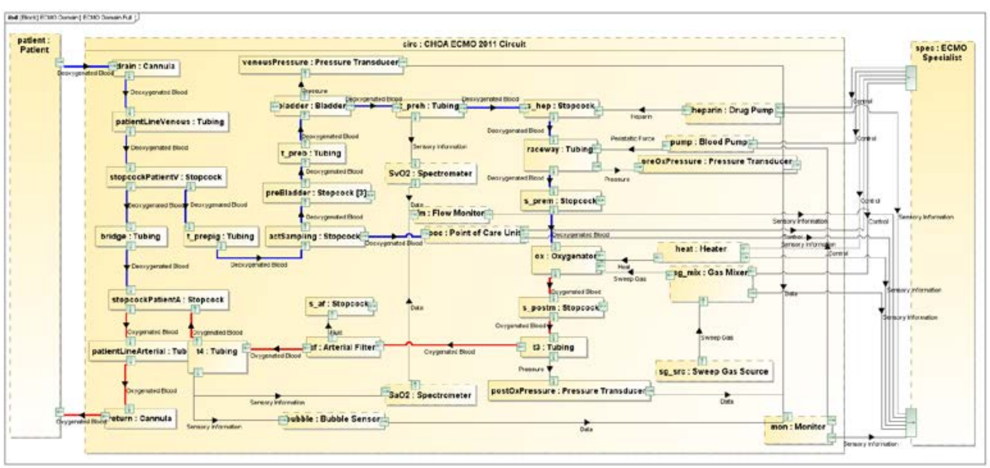
SysML Use Case Diagram



- Capture the stakeholders
  - Requires iteration with a SME
  - Find "is a" relationships (e.g. the Sponsor is a Physician)
- Capture stakeholder actions
  - Some actions include others
  - Some actions extend others
- In order to reduce burden on staff, need to know who all is burdened
- If looking toward standardizing, need to know how things are done now
- This is specific to CHOA

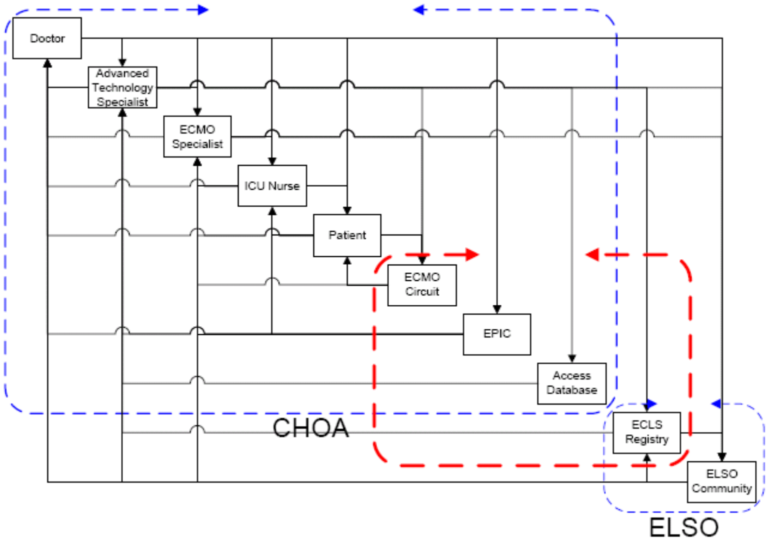
SysML Structural Diagrams

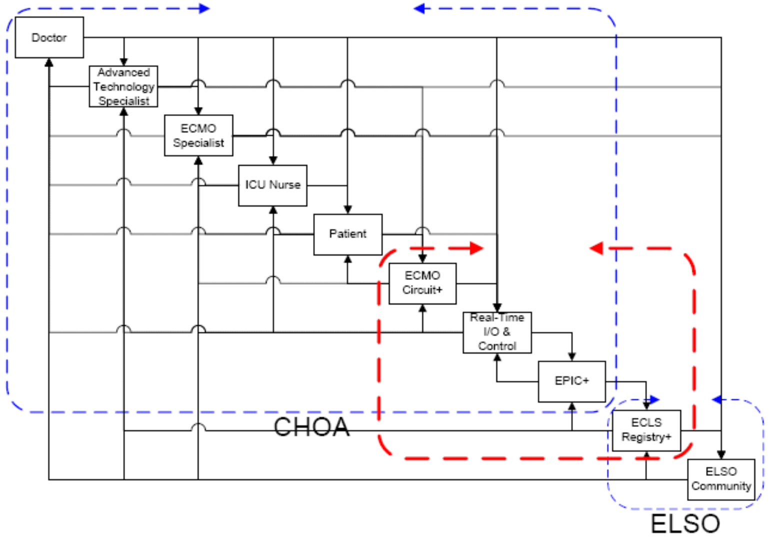




- Capture the structure at a System and System of Systems Level
- Capture the internal structure of the circuit (including flows)
- For standardization, need to know how the system is structured and how it behaves at various locations
- Capture all the disparate systems
- This is specific to CHOA

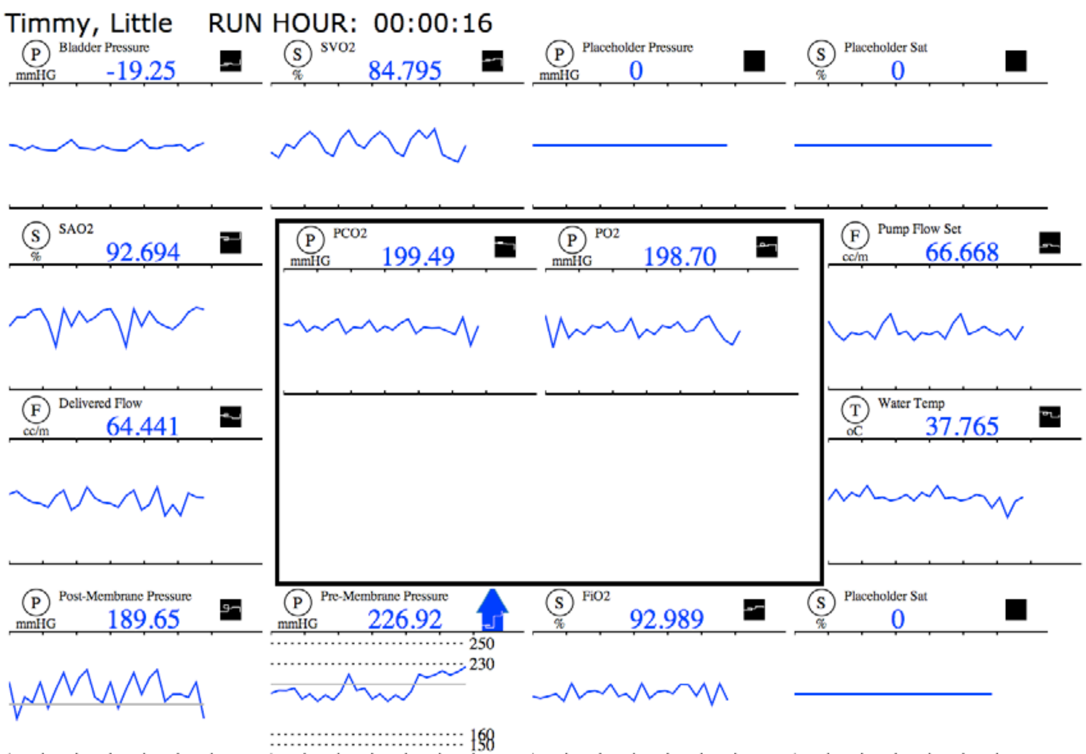
N-Squared Diagram





- Shows feed-forward and feed-back loops
  - In this case, showing the flow of information in a deployed setting
  - Shows both present state and desired future state
- Almost all lines in the current state (top) are performed manually by humans
  - Minimize the number of loops that humans perform (e.g by automated data entry)
  - Allows more time to be spent focusing on patient
- This is specific to CHOA

Prototype Visualization



- Possible fused data display (rather than the chaos shown in the bedside image)
  - Attempt to show relevant ECMO data and patient data together
  - Layout in a similar format to actual circuit
  - Show trends over a timeframe symbols
  - Historical graph available when needed
  - Timeframe did not allow for much iteration
- Ideally allow the current user of the display to tailor what's visible to what they care about

So What

- Developed a common language that can be used across sites internationally
  - Document different circuit configurations and look for best of breed
  - Standardization will allow potential reductions in complications and improved patient survival.

So What

- **Changes to the international registry of ECMO patients that will allow capture of important engineering variables associated with complications**
- **Has served as a impetus for recognition and conversation in the ECMO community to address these problems.**

Subset of Proposed Future Projects

- Information integration
- Therapeutic sensor integration
- Hardware instrumentation
- Redundancy characterization
- Portability analysis
- Training standardization

Conclusions

- MBSE helped bridge the doctor-engineer language barrier
  - Medical practitioners and engineers speak very different languages sometimes.
  - Graphical models help alleviate this
  - With very little instruction, the sponsor was able to read the models and understand their intent
- Approach is likely to be beneficial in other non-engineering domains
  - We feel that if we are able to foster communication using models between engineers and medical staff, the approach is would carry over into other areas
- Helped lead to a logical prioritization of future efforts (though priorities change in the other 40 weeks of the year)
  - The first cohort proposed a series of projects at the beginning of the partnership
  - The modeling done by the first cohort specifically lead to a greater understanding (by the engineers) of the system and where the sponsor wished to move toward (eventual FDA certification and portable ECMO)
  - Using this understanding, the engineers were able to prioritize these projects with the goal of FDA certification and portable ECMO
  - Detailed further in the 2011 INCOSE paper

Related Papers

Georgia Tech Research Institute

- Pihera, LD, et al. (2011). Application of Systems Engineering to Improve Extracoporeal Membrane Oxygenation (ECMO) Therapy. In Proceedings of INCOSE.
- Adams N and Pihera LD (2012). A Systems Engineering Approach for Informing Extracorporeal Membrane Oxygenation (ECMO) Therapy Improvements. In Proceedings of CSER.
- Pihera, LD, Ender TR, Paden ML (2013). Extracorporeal Membrane Oxygenation (ECMO) - A Systems of Systems Engineering Characterization. In Proceedings of IEEE SoSE.

Questions?