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

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Disclosures

• I am a physician

• No engineering background
What is ECMO?

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

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%.
## Overall Outcomes

<table>
<thead>
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<th>Total Patients</th>
<th>Survived ECLS</th>
<th>Survived to DC or Transfer</th>
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<td>Respiratory</td>
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<td>ECPR</td>
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<td>712</td>
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<td>Respiratory</td>
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<td>Respiratory</td>
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<td><strong>Total</strong></td>
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<td>46,490</td>
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</tbody>
</table>

*Source: Extracorporeal Life Support Organization*
• Sounds simple enough, right?
ECMO is not so simple

Image courtesy of CHOA
• 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

• 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 - interview multiple additional ECMO centers
• 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
• Third cohort
  • Requirements/prototype for a web application for characterizing circuits across the US
• Fourth cohort
  • 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
- 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
- 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
• 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
ECMO Data Collaboration Tool
• Many problems – where to start?
• 9 ECMO center
  • Range 1.5 -33 years of experience
  • Differences in equipment / region / personnel / etc.
• 32 questions – procedures / circuits /
  personnel / center history
• Median interview time was ~4 hours
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<th>Criteria Relative Importance</th>
<th>Lack of Consolidated Info</th>
<th>Training</th>
<th>Scaling</th>
<th>Redundancy</th>
<th>Component MTBF / MTTR</th>
<th>Reliability / Availability / Maintainability of SoS</th>
<th>Lack of Standardization</th>
<th>Lack of Simulation</th>
<th>Manpower</th>
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• Standardization / Reliability / MTBF / MTTR
  • None of the 9 centers had the same circuit configuration
  • Failure analyses never formally done in ECMO setting
  • Mixture of pumps
  • “Half of centers have no formal review process for making changes to ECMO circuit”

• Training / Manpower
  • Good consensus on type of training
  • Poor consensus on protocol adherence, dealing with violations
  • Large variation in staffing ratio between centers
  • Reliance on tribal knowledge and individual experience
• **Human systems interface analysis**
  • Mission, functional, and task analyses
  • Define roles, tasks and requirements
  • Extremely valuable for new programs

• **Work domain analysis**

• **Risk analysis of recommendations**
Recommendations

- Train all ECMO specialists at least once per 6 m
- Provide documentation detailing all procedures since reliance on tribal knowledge may lead to mistakes
- Properly label devices to enable clear operations
- Standardize anticoagulation protocol
- Eliminate outlier or redundant components
- Clear egress between patient and ECMO circuit
- Increase use of verification and validation during ECMO to ensure standardized methods are being used
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.
• 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.
Why now?
Subset of Proposed Future Projects

- Information integration
- Therapeutic sensor integration
- Hardware instrumentation
- Redundancy characterization
- Portability analysis
- Training standardization
• MBSE helped bridge the doctor-engineer language barrier
  • Medical practitioners and engineers speak very different languages sometimes.
  • Graphical models help alleviate this
• 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
  • Using this understanding, the engineers were able to prioritize these projects

• This is improving the care of these patients


Questions?