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 costophrenic angle
Gastric bubble
What is ECMO?

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

Source: “Extracorporeal Membrane Oxygenation: a broken system”
• 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>
<tr>
<th></th>
<th>Total Patients</th>
<th>Survived ECLS</th>
<th>Survived to DC or Transfer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Neonatal</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td>27,007</td>
<td>22,782</td>
<td>20,093</td>
</tr>
<tr>
<td>Cardiac</td>
<td>5,425</td>
<td>3,339</td>
<td>2,206</td>
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<tr>
<td>ECPR</td>
<td>980</td>
<td>626</td>
<td>388</td>
</tr>
<tr>
<td><strong>Pediatric</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td>6,149</td>
<td>4,034</td>
<td>3,496</td>
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<tr>
<td>Cardiac</td>
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<td>4,443</td>
<td>3,388</td>
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<tr>
<td>ECPR</td>
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<td>1,123</td>
<td>840</td>
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<tr>
<td><strong>Adult</strong></td>
<td></td>
<td></td>
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<tr>
<td>Respiratory</td>
<td>5,146</td>
<td>3,317</td>
<td>2,905</td>
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<tr>
<td>Cardiac</td>
<td>4,042</td>
<td>2,255</td>
<td>1,636</td>
</tr>
<tr>
<td>ECPR</td>
<td>1,238</td>
<td>476</td>
<td>355</td>
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<tr>
<td><strong>Total</strong></td>
<td>58,842</td>
<td>42,395</td>
<td>35,307</td>
</tr>
</tbody>
</table>

Survived ECLS: %84, %62, %64, %66, %65, %54, %64, %56, %38, %72, %60
Survived to DC or Transfer: %74, %41, %40, %57, %50, %41, %56, %40, %29, %60
• Sounds simple enough, right?
ECMO is not so simple
• 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.
• 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).
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
• 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 (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
• 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
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
• 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
• 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.
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


Questions?