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Editorial

How systems engineering can improve care in the ICU

Per CDC reports, between 5 and 12% of patients with COVID-19 in the US have required admission to an ICU. Many of these patients have received invasive ventilation and have reported mortality rates from 17% to over 80% [1,2]. Despite some debate on the use of ventilators, guidelines continue to recommend early intubation in patients with COVID-19 pneumonia and worsening respiratory function. As a result, US hospitals have seen a dramatic increase in the need for both ICU beds and ventilators. Hospitals addressed a shortage in ICU beds through surge planning, where patients were housed in locations outside traditional ICUs. Concurrently, a private-public partnership that included increased manufacturing and a Dynamic Ventilator Reserve plan formed to mitigate a potential ventilator shortage. What was not and remains un-addressed is how a hospital would scale the specialized workforce and know-how in parallel with an increase in ventilator supply, to ensure that each ventilator is managed according to best practice.

Over the last two decades, several interventions that can reduce mortality and avoidable harms in ICU patients have been identified. These include ventilation with low tidal volumes [3], prone positioning [4] and Initiatives to reduce hospital acquired infections, blood clots and ulcers. However, even under normal conditions, intensivists do not always fully comply with best practice guidelines. For example, the LUNG-SAFE [5] study showed that 35.1% of patients with ARDS received a tidal volume above 8 ml/kg predicted body weight. The same study described that only 40.1% of patients had a plateau pressure measurement irrespective of ARDS severity, and that 82.6% of patients received a positive end expiratory pressure less than 12 cmH2O. Prone positioning was only utilized in 16.3% of patients with severe ARDS. Data have also indicated that DVT prophylaxis in some ICU's are administered only about one-half the time.

This type of compliance data is unfortunately common in healthcare and is a result of two major problems. The first is the absence of decision support that confirms a patient is receiving a recommended therapy in real-time, along with alerting when a patient is not. The second is a lack of interoperability of devices and data, especially in complex settings like an ICU. For example, a patient's height and gender, the two variables used to size an appropriate set tidal volume, reside in an Electronic Health Record (EHR) and do not get communicated to a ventilator. As such, a ventilator is not able to determine whether a tidal volume being delivered is appropriate. Clinicians are also not alerted when a patient receives a breath that may violate their protective ventilation protocol. While such "disconnects" can be somewhat mitigated through the hard work and dedication of ICU clinicians under normal conditions, they can become amplified and unmanageable during a surge. This can unnecessarily expose patients to avoidable harm. One may even speculate that ventilator associated injury may be one of the causes of the large variation in mortality that has been reported in patients with COVID-19 pneumonia.

Adopting a systems engineering approach to ICU management provides a solution to this problem. Systems engineering is used by all major industries in the US outside of healthcare to attain robust, safe, and resilient operations. When utilizing this strategy, one first defines a specific problem. Next, they describe the requirements necessary to solve this problem, and then design solutions that satisfy the requirements. Finally, they validate that the correct solution was built, and then iteratively improve the solution based on real world operational feedback. Without such an approach, complex industries, such as defense or aerospace, would not be able to deliver products or services with high reliability at scale.

Such a system engineered approach is needed to consistently deploy best practices in an ICU. For example, in a systems engineered model, a ventilator best practice ("process control") would be defined using a goal ("lung protection") and specific requirements, such as inclusion criteria ("ventilated") and limits (e.g. tidal volume/predicted body weight, driving pressure and PEEP). An underlying technology platform would then automatically integrate all sources of data, compute whether delivered volumes and pressures complied with the process control and deliver decision support accordingly. Finally, integrated reporting would allow rapid feedback and drive improved compliance. A similar process could be applied to each best practice in an ICU. Once implemented, such a systems engineered model would allow intensivists to seamlessly deploy process controls across an extended population of patients and magnify their impact consistently across physical spaces in wide distributions. For example, Intensivists would be able to ensure that patients with ARDS or COVID-19 pneumonia were being consistently ventilated in compliance with an institution's best practice protocol regardless of whether they were housed in an ICU or a surge location. This would allow a health system or hospital to maximally leverage ICU clinicians in a way that minimizes variability in care both during normal conditions and crises such as the COVID-19 pandemic.

Our experience during COVID-19 has made it clear that it is time for healthcare to be governed by the design of a safe and consistent system. Our Health system is too complex and dynamic for compliance with best practices to depend on the heroism and sacrifice of healthcare workers alone. This is especially true during times of crises. With this in mind, multiple hospitals across the US have deployed a technology platform based on systems engineering in response to the pandemic. This platform connects patient data in the hospital EHR with data from medical devices and uses decision support to drive compliance with best practices, including protective lung ventilation, in real-time. Mobile tools are used to support scaling ICU services as needed, and to improve coordination between the entire care team including unit directors, specialty services such as palliative care and hospital administration. Ultimately, these hospitals intend to use this systems based

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platform to ensure that each ICU patient receives care consistent with evidence based best practice at all times. Results from this novel approach are expected to be available for review in the near future.

COVID-19 has forced us to contemplate decisions we thought unimaginable a few short weeks ago. It is time to rethink how we administer care across our large and complex healthcare delivery system. We believe that it is essential that US hospitals adopt a systems engineering approach to meet the challenge of this pandemic and whatever lies ahead.

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Declaration of competing interest

Dr. Lecamwasam is the Chief Innovation Officer of Talis Clinical. Dr. Pronovost is a Strategic Advisor to Talis Clinical.

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