Enhancing the Quality of Care in the Intensive Care Unit
A Systems Engineering Approach

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KEYWORDS
- Systems engineering
- Intensive care units
- Health care quality
- Health care systems
- Patient harms

KEY POINTS
- Health care systems must embrace a more formal process to deal with rising costs, complexity, and patient harms.
- Systems engineering methodologies have been applied successfully to solve other major industrial problems.
- The systems engineering process reproducibly formalizes defining system problems and goals and prioritizes development of a system to meet those goals.
- The Patient Care Program Acute Care Initiative project will use a holistic patient-centered systems engineering approach to reengineer the intensive care unit.
- Application of systems engineering principles to the Patient Care Program Acute Care Initiative project will help enhance the quality of care and reduce patient harms.

Funding sources: This work has been funded by The Gordon and Betty Moore Foundation and The Systems Institute of Johns Hopkins University. Additional support includes: Mr Ravitz: Agency for Healthcare Research and Quality Grant 1R18HS020460; Dr Romig: Department of Anesthesiology & Critical Care Medicine; Dr Pronovost: none; Dr Sapirstein: Department of Anesthesiology & Critical Care Medicine. Conflict of interest: Dr Tropello, Mr Ravitz, Dr Romig, and Dr Sapirstein have no conflicts to report. Dr Pronovost has received funding from the Agency for Healthcare Research and Quality, the National Institutes of Health, RAND, and the Commonwealth Fund for research related to measuring and improving patient safety; honoraria from various hospitals and health care systems and the Leigh Bureau to speak on quality and safety; consultancy with the Association for Professionals in Infection Control and Epidemiology, and book royalties for Safe Patients, Smart Hospitals: How One Doctor’s Checklist Can Help Us Change Health Care From the Inside Out.

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http://dx.doi.org/10.1016/j.ccc.2012.10.009
criticalcare.theclinics.com
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INTRODUCTION

Health care technologies in the United States have been growing rapidly over the last half century, leading to ever-increasing treatment options, costs, and complexity. When compared with other industries, such as aerospace, defense, and information technology, the health care industry has underused systems engineering (SE) to help facilitate the design and reengineering of its complex network of systems.\(^1\)\(^,\)\(^2\) In SE, the designers and users of a system describe the desired goals and priorities, and then create a system to meet those goals. This is not the case in health care. Technology companies, rather than clinicians and patients, usually design technologies. It is often unclear what goal or problem the technology solves or if it improves care. Technologies are often not well integrated into the overall care system. Technologies fail to talk to each other and may consume valuable clinician time and add to health care costs. Without proven benefit, many health care technologies have the potential to make care less safe and increase the risks for patient harm.\(^3\) We hypothesize that the application of SE can significantly improve patient safety.

Recently, the Centers for Medicare and Medicaid Services launched a national effort to reduce 9 types of patient harm. These harms include adverse drug events, catheter-associated urinary tract infections, central line-associated bloodstream infections, fall injuries, pressure ulcers, surgical site infections, venous thromboembolisms, ventilator-associated pneumonias, and obstetric adverse events.\(^4\) This is only a limited list, because health care experts have identified several other patient harms. The health care industry is addressing these harms as if each one occurs in isolation or independently, when they are interdependent. For example, patients who do not receive early and frequent mobilization are at risk for both pressure ulcers and venous thromboembolism, and it is no surprise that patient harms cluster, because 1 harm leads to another. Yet nobody wants these harms to occur: not patients, not clinicians, not insurers, not technology companies. Still, the approach of health care to reduce harm relies on ever-increasing heroism of clinicians rather than designing safe systems. Current approaches at harm reduction often rely on brute force efforts and clinicians work on preventing 1 or 2 harms, although patients are at risk for many more harms. Without a systems approach to prevent these harms, improvement efforts are typically independent initiatives by providers and patients.\(^5\)\(^,\)\(^6\)

The Armstrong Institute of Johns Hopkins University School of Medicine in conjunction with the Gordon and Betty Moore Foundation and the University of California San Francisco is beginning a 2-year initiative, called the Patient Care Program Acute Care Initiative (PCPACI). The goal of the PCPACI is to enhance the quality of care and reduce patient harms in the intensive care unit (ICU) by using a holistic transdisciplinary patient-centered SE approach to reengineer the ICU. The PCPACI plans to significantly improve measures of clinical processes and outcomes for ICU-acquired deep venous thrombosis-pulmonary embolism, delirium and weakness, ventilator-associated injuries, and central line-associated blood stream infections (CLABSI) by integrating clinical information systems, integrating clinical equipment, designing or reengineering interprofessional care team workflows, and incorporating patient-family goals.

The first part of this article provides a brief overview of SE methodology, focusing on the overarching SE core principles used within all SE methodologies and domains. In sharp contrast to health care, SE methods begin by defining goals and desired outcomes and develop forward. The second part of the article proposes the application of SE methodologies to the PCPACI, highlighting a few examples within the ICU-acquired weakness and early mobilization subsystems.
OVERVIEW OF SE METHODOLOGY

The origins of SE are not clear, but its core principles, or systems methodology, emerged to help manage the rapid growth of many complex systems. The International Council of Systems Engineering (INCOSE) describes the history of the field and offers this comprehensive definition of a system as

…a construct or collections of different elements that together produce results not obtainable by the elements alone. The elements, or parts, can include people, hardware, software, facilities, policies, and documents; that is, all things required to produce systems-level results. The results include system level qualities, properties, characteristics, functions, behavior and performance. The value added by the system as a whole, beyond that contributed independently by the parts, is primarily created by the relationship among the parts; that is, how they are interconnected.7,8

At some level, SE principles have been used since antiquity to build complex systems such as the Egyptian pyramids and Roman cities and aqueducts. During World War II, various military systems became increasingly complex and difficult to manage without a formal methodology to evaluate the performance of the whole system, its subsystems, and the relationships among these components.9 In this period, formal definitions and principles of SE were codified in textbooks and successfully applied to military and other systems.

The modern world is even more complex and the application of SE methodologies has grown and broadened into many domains such as computer information systems, spacecraft systems, financial systems, transportation systems, and many others.9,10 We face a series of multidisciplinary challenges in designing an integrated system for the ICU. SE principles and best practices are focused on managing complex development efforts involving a diverse set of domains. For the PCPACI ICU project, the development team includes stakeholders from different domains, including clinical care, patients and families, human factors, computer engineering, information technology, health care economics, and epidemiology. The holistic approach to system development used by SEs ensures that expertise of each of these disciplines is factored into system design, capabilities, and life-cycle sustainment. Although each domain has developed a set of unique tools and methodologies, all use common core principles when developing a systems-based solution. All SE approaches to improving complex systems include the following phases9,10:

1. System concept development
2. Requirements analysis
3. Functional definition
4. Implementation
5. Verification and validation
6. Iteration

System Concept Development

The first phase in developing a new system is defining the problem(s), stakeholder(s), and goal(s). Although it may seem trivial, this first step is important, because it helps set scope and boundaries. A problem that is not clearly defined and concise can squander resources and lead to an ineffective and inefficient system solution. Conversely, if a problem is too narrowly defined, it can result in a system that lacks essential functions. Stakeholders are individuals or groups who may be directly or indirectly involved in any part of a system, and it is essential to identify all stakeholders early
in the process so they can participate in defining system scope and other phases of system development. The completed system must achieve its desired goals. The goals must be clear, concise, and prioritized; the goals help define necessary and unnecessary system functions. Commonly, the goals also inform the metrics needed to validate an implemented system. For example, when developing a new ventilator system, a goal might be reduction of ventilator-associated injuries. Metrics used to validate such a ventilator system should include use of evidence-based therapies and rates of acute respiratory distress syndrome and ventilator-associated pneumonia.

Requirements Analysis

Requirements analysis is a phase in which stakeholders, informed by the problem statement and goals, state their requirements for a system: how the system will be used, where it will be used, who the users are, what is needed to support and maintain the system. Systems engineers distinguish necessary from desired features and begin to identify resource constraints. Engineers resolve conflicts between the requirements of different stakeholders. To achieve this goal, systems engineers engage stakeholders using a variety of methods, including individual interviews, focus groups, workshops, and surveys. Mandatory system requirements emerge from the problem statement and goals. Acceptable and appropriately functioning systems typically satisfy all the mandatory requirements. Furthering the example of a new ventilator system, an intensivist’s requirement could be stated as “no patients should receive harmful tidal volumes.” A resource constraint within this example would be that respiratory therapists are not available every minute of the day to identify patients receiving harmful tidal volumes. Commonly, stakeholder requirements conflict with resource constraints. These discrepancies are addressed in the functional definition phase of system development.

Functional Definition

The functional definition phase of system development defines what the system should do. During this phase, subsystems of the whole system are mapped out along with their individual and interdependent inputs, ideal functions, and expected outputs. Common tools used are block diagrams, flow diagrams, object-oriented models, computer simulations, and prototype designs of graphical user interfaces (GUIs) (ie, computer application displays). During this phase, systems engineers automate, standardize, and install redundancy within critical, complex, or time-consuming system functions. In the example of a new ventilator system, one of the functions might be for the processor subsystem to receive an input of patient height and automatically calculate ideal (ie. safe) tidal volume ranges, which would then be displayed on the user interface subsystem to inform the providers.

Implementation

In the implementation phase, the system is developed and built. Subsystems such as computer programs, processes to support human performance, and physical materials are built and tested. This subsystem testing is followed by integration into the overall system, which is then tested as a whole. At the end of this phase, the system should function and produce the expected outputs. Systems engineers begin collecting and monitoring predefined metrics in order to validate the overall function of the system.

Verification and Validation

One of the most important phases of system development is verification and validation throughout the life cycle of the system. Systems engineers use predefined metrics to
verify that the completed system is fulfilling stated goal(s) and functioning in an optimal fashion. After verification, the validation process is conducted when users operate the system in a simulated or real environment and perform evaluations. Data often expose unanticipated system weaknesses or opportunities for improvement. Feedback from this process and any operational use is available for an iterative process in which systems engineers can evolve the system.

**Iteration**

Iteration ideally takes place in a parallel fashion throughout all phases of systems development and should not be limited to implemented systems. For example, stakeholders may change their requirements during the implementation phase of system development and engineers would iterate back through the functional definition phase with new requirements as they continue to work in parallel on system implementation. Changing or adding new requirements often requires compromises between stakeholders, because they can increase costs and development times of a project.

**APPLICATION OF SE METHODOLOGY**

The PCPACI set out to enhance the quality of care and reduce patient harms in the ICU by using SE methodology. The following sections provide examples of how the PCPACI has used and will continue to use SE methodology. For brevity and consistency, examples focus on ICU-acquired weakness and early mobilization subsystems.

**System Concept Development**

A simple problem statement is that ICUs often deliver poor quality of care, which causes harm to and disrespects patients and negatively affects their family members. The PCPACI has initially limited the problem scope and set goals to focus clinical improvements in ICU-acquired deep venous thrombosis-pulmonary embolism, ICU-acquired delirium, ICU-acquired weakness, ventilator-associated injuries, CLABSI, and disrespectful and undignified care. Fig. 1 shows the system scope and highlights how, in the long-term, the PCPACI will work to iteratively scale the system to prevent other ICU-related harms and implement the system across ICUs in many health care systems. The initial system developed in the PCPACI will be validated in the surgical ICU (SICU) at The Johns Hopkins Hospital over a 2-year period ending in 2014. The project includes long-term goals to implement and validate the system in other ICU subspecialty environments such as cardiac, medical, and neurologic ICUs. The project has a goal to implement the system within other academic and community hospital systems.

The PCPACI has placed stakeholder involvement at the core of its system, with an emphasis on the goals of patients and their families. Fig. 2 shows some of the stakeholders involved in the PCPACI and shows how the patient and their family members are the most important stakeholders when considering system development.

The PCPACI has several goals for the system. Most of the goals are specific to particular harms, such as ICU-acquired weakness and early mobilization subsystems. Three examples of specific goals are:

1. The system will permit patients and family members to participate in patient care to the degree at which it would not interfere or negatively affect care
2. The system will provide early and appropriate physical rehabilitation activities to at least 70% of all patients in the ICU
3. The system will improve physical function, compared with best prehospital or inpatient physical performance, in at least 20% of all patients in the ICU
The first goal is pertinent to the entire system, whereas the second and third goals are specific to the ICU-acquired weakness and early mobilization subsystems. The second and third goals exemplify how clear goal definition during this phase of system development helps to create performance metrics, such as percentage of patients able to participate in physical rehabilitation, which systems engineers use during the system validation phase.

Fig. 1. Initial scope and future scalability of the PCPACI system. The diagram shows the 5 clinical patient care elements as well as loss of dignity that are initially targeted in the surgical ICU. In future phases, additional care elements will be added incrementally as shown by the \((n + 1)\) quality initiative and the system will be implemented in other ICU environments on campus. The system will be implemented in other academic health systems (University of San Francisco) and community health systems.

Fig. 2. PCPACI stakeholders. The figure places the patient and family in the center of a group of stakeholders in the PCPACI system. Other major stakeholders in the system are shown around the patient and family.
Requirements Analysis

The requirements analysis phase of the PCPACI system is an ongoing process as stakeholders individually, or in groups, continue to further refine system requirements or conceive of additional requirements. Systems engineers do not include every requirement in the functional definitions, because, although it may be important to a specific stakeholder, a requirement may not help to achieve any stated system goal(s). For example, a PCPACI stakeholder required real-time calorimetry on all ventilated patients. Although real-time calorimetry likely has some usefulness, it would not help fulfill any system goal(s).

The PCPACI development group has provided 1 mandatory and complex system requirement in which patients and their family members must be able to express their desired level of patient care participation in real time and the system should adapt to their desired level of participation. For example, a patient’s partner may want to participate in passive range-of-motion physical therapy for a given day. Three examples of related requirements are:

1. Family members who would like to participate in physical therapy must first complete an appropriately designed training course
2. Patients and family members may participate in patient care activities, but their participation must not interfere with patient care as determined by care providers
3. Nurses may initiate physical therapy using activity plans prescribed by consulting physical therapists if they meet inclusion criteria and are not excluded by their physical condition (Box 1).

System requirements for clinical interventions are provided by many stakeholders, including physicians, nurses, physical therapists, and administrators, and are guided by patient safety and regulatory considerations. For example, all stakeholders believed that the most responsible path for involving family members in physical therapy activities was to require a minimum level of basic physical therapy training via frequent courses or online training modules.

<table>
<thead>
<tr>
<th>Box 1</th>
<th>Example of exclusion criteria for early physical rehabilitation protocol</th>
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<tbody>
<tr>
<td>1.</td>
<td>Richmond Agitation and Sedation Scale = -4, -5, or 3 or greater</td>
</tr>
<tr>
<td>2.</td>
<td>Poor oxygenation: pulse oximetry less than 88%, FiO₂ (fraction of inspired oxygen) greater than 60%, positive end-expiratory pressure greater than 10 cm H₂O or high frequency oscillation ventilation</td>
</tr>
<tr>
<td>3.</td>
<td>Tachypnea: respiratory rate greater than 45 breaths per minute</td>
</tr>
<tr>
<td>4.</td>
<td>Acidosis: recent arterial pH less than 7.25</td>
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<tr>
<td>5.</td>
<td>Hypotension: mean arterial pressure (MAP) less than 55 mm Hg, increase in vasopressor dose within the past 2 hours, norepinephrine greater than 0.15 μg/kg/min, dopamine greater than 15 μg/kg/min, phenylephrine greater than 1 μg/kg/min, vasopressin greater than 0.02 units/min</td>
</tr>
<tr>
<td>6.</td>
<td>Hypertension: MAP greater than 140 mm Hg, any dose of a continuous intravenous infusion of nitroglycerin, nitroprusside, nicardipine, diltiazem, esmolol, or labetolol</td>
</tr>
<tr>
<td>7.</td>
<td>New deep vein thrombosis: duration of anticoagulation less than 36 hours (only applicable for rehabilitation to affected limb and for ambulation)</td>
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Fig. 3. Early mobilization subsystem functional block. The figure presents sequential steps in the systems approach to performing early mobilization of patients in the ICU. Patients must meet criteria for the therapy and the system considers patient and family preferences and participation. Information regarding scheduling and performance of mobilization is displayed on the ICDS, and metrics are collected for ongoing reassessment of the therapy. If the status of the patient changes, this is considered in the therapeutic evaluation. The process can be expanded to other (n + 1) quality initiatives.
The functional definition phase of the PCPACI system is planned to continue through 2012. Stakeholders and systems engineers are applying stakeholder requirements to formulate a detailed model of a functional system. Engineering resources and expertise come from the Johns Hopkins University Applied Physics Laboratory (APL) and Whiting School of Engineering, and performance measurement expertise comes from the Bloomberg School of Public Health. APL has collaborated with Johns Hopkins Medicine (JHM) for several decades and APL engineers and JHM researchers and clinicians have successfully built a wide range of successful devices and systems. Engineers and computer scientists are working to clearly define the integration of necessary clinical information systems with clinical equipment and configure clinical processes and work flow. Fig. 3 shows a functional block diagram of the work flow and scheduling for the early mobilization subsystem.

The integrated clinical dashboard system (ICDS) included in Fig. 3 facilitates patients’ and family members’ ability to coordinate with nurses on desired times for participation in physical therapy. For example, a patient’s partner may prefer physical therapy to take place during the afternoon because they would be able to leave work during their lunch break. Within reason, the nurse can facilitate scheduling this request for participation in physical therapy using the ICDS.

Patients in the ICU are at risk for many harms, but clinicians have not clearly defined all of them or the strategies to prevent them. However, some harms and prevention strategies have been described. The ICDS will provide visual alignment of specific tasks needed to prevent defined patient harms with the relevant data regarding those harms. For example, early rehabilitation may affect venous thromboembolism, ventilator-related injuries, and acquired weakness. A significant investment is planned to build the ICDS, which will serve as an interface to display, analyze, and inform stakeholders of all PCPACI subsystems. Patients and family members will receive an e-tablet device that will provide access to the family-specific portion of the ICDS and facilitate data input and display daily therapies and interventions. Fig. 4 shows an early prototype design of the ICDS GUI.

The ICDS GUI includes several clockfaces to visually enhance time-sensitive functions within different subsystems. It is the goal of the ICDS to efficiently display functions that will improve performance in subsystems in which evidence-based practices can prevent harm to patients. In addition, the ICDS will integrate data and communications generated by the patient and family members, such as facilitating scheduling physical therapy with nurses. The right side of Fig. 4 shows the period available for future exercise during which nurses would be available for physical therapy and

![Fig. 4. Integrated clinical dashboard GUI prototype. An idealized prototype of the GUI for ICU confusion awareness and management is shown. The ICDS analyzes patient data and presents information in a 24-hour-clock format. The format uses a series of concentric circles for each domain, with vital signs at the core and radiating outward to drug administration. The display features a current time line (red line), which sweeps in a clockwise fashion. The GUI shows information related to each domain over the previous 12 hours and uses color coding to indicate expected performance or results (green) or issues of concern (red) such as excessive patient activity. Pending tasks or events that will occur over the next 12 hours are displayed in advance of the current time indicator. More detailed information about events can be obtained by selecting a field. The icon in the bottom right corner allows users to select other displays that specifically address information related to prevention of other patient harms.](image)
patients or family members could schedule times to have physical therapy. This facility would allow better coordination of family participation with patient care.

**Implementation**

The implementation phase of the PCPACI system is planned to continue until April, 2013. Engineers at the APL have started programming some parts of the ICDS and are working to integrate the ICDS with current clinical information systems at the Johns Hopkins University Health System. The PCPACI plans to implement an early prototype system by May, 2013 and to begin collecting metrics after that time for system validation.

**Verification and Validation**

The PCPACI will begin collecting standardized data in the SICU at Johns Hopkins Hospital in November, 2012. These data will establish a performance and incidence baseline that will enable comparison to determine if the new PCPACI system is improving the quality of patient care. Examples of benchmark metrics related to ICU-acquired weakness and early mobilization include incidence rates of ICU-acquired weakness, percentage of patients receiving early physical rehabilitation activities, and percentage of patients with improved physical mobility compared with their best prehospital and inpatient physical performances. Teams of researchers will collect these data throughout the project period. This process will allow comparison of data quality from automated electronic sources with manually abstracted data. As time passes, the PCPACI will strive to improve metric performance data relative to the new system and not the previous SICU system. This push for further performance improvement will take place through incremental system evolution as data highlight system weaknesses or strengths. Systems engineers will work in an iterative stepwise fashion, using all phases of SE methodology, to enhance the system and maximize performance throughout the life cycle of the system.

**SUMMARY**

Our rapidly expanding and fragmented health care systems are unsustainable. Our health care system too often harms patients, is too costly, and too often relies on the heroism of clinicians rather than good system design. Recent analyses from the Institute of Medicine suggest that about one-third of health care spending, or $750 billion, is wasted on inefficiencies and does nothing to make patients better. New financial pressures and government policies will force changes in the health care industry to improve on inefficiencies, poor quality, and negative patient outcomes. If we (the stakeholders and advocates for patient care quality) do not actively collaborate to design improvements in performance and delivery of health care, then changes will be driven not by careful design and testing but rather by financial constraints.

We believe that the reengineering of our health care systems requires an SE approach using SE methodologies that have been developed and have proved successful in a myriad of other industries over the last half century. We have highlighted the core principles of all SE methodologies and how these principles facilitate a more holistic and comprehensive system design and life-cycle development. We have further shown our current application of these principles to the PCPACI system, with the goal of enhancing the quality of care and reducing patient harms in the ICU. By using a holistic and comprehensive systems approach to improving quality and reducing patient harms in the ICU, the PCPACI will develop a system that does not address harms via fragmented solutions but a system that is capable of addressing
all harms and adapting functions to address future patient and family goals. We hope that stakeholders of other health care systems can use this systems approach to take action and reengineer their own systems.

REFERENCES