

Systems Approach and Systems Engineering Applied to Health Care: Improving Patient Safety and Health Care Delivery

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espite the introduction of technology in medicine, challenges related to patient safety and quality health care delivery still abound. The economic and personal costs associated with these challenges are enormous. To address these challenges, APL, Johns Hopkins Medicine, and the Whiting School of Engineering's Systems Institute have teamed to couple systems engineering principles and best practices with clinical expertise to develop innovative approaches to the socio-technical dynamics involved in health care. This work focuses on understanding the interactions among people (clinicians, patients, families, and other stakeholders), processes (institutional, regulatory, professional ethics, etc.), and technology (medical devices and instrumentation) in the health care domain to formulate a systems approach to innovations that lead to improved patient outcomes. APL and Johns Hopkins Medicine are collaborating on improvements at the device level, specifically medication infusion pumps that represent significant patient safety challenges, as well as at the unit level in the intensive care unit.

INTRODUCTION

The delivery of safe and high-quality health care has reached a crisis in the United States in terms of personal loss due to preventable errors, as well as economic loss. Estimates of the economic costs in the intensive care unit (ICU), which represents just a portion of the health care system at large, approach nearly 1% of the gross domestic product.¹ A natural impulse to address these challenges is to introduce technology to mitigate risks due to human error and communication. Although

the introduction of technology to health care may have contributed to improvements in mortality and morbidity, its application has not proven a panacea. In fact in some cases, it has spawned new challenges for safety and quality.

In 2005, the National Academy of Engineering (NAE) and the Institute of Medicine (IOM)² highlighted the need for a systems approach to the health care system and the application of systems engineering tools to

improve health care. Yet despite the NAE/IOM's recommendations, only narrowly focused efforts to implement these recommendations have occurred, and no substantive systems approach has gained traction or success. As a result, we contend that the health care system has not been addressed from a systems perspective at all.

Through a series of projects, APL and Johns Hopkins Medicine (JHM) have focused on applying a systems approach using engineering principles and best practices to hospital-based care, specifically, care in the ICU. The ICU is a good starting point to establish a systems approach because of the high costs and complexity of technology and care processes. The eventual objective of these APL and JHM projects is to achieve the ability to scale this systems approach to the broader health care system. In part because of its highly complex nature, the ICU domain has been perceived as a locus where systems improvement can have dramatic benefit on care and costs. A combination of high burdens of illness, personal stress, and technology create a triad involving the integration of people, technology, and the environment, and this triad is fundamental to the systems approach APL and JHM adhere to when addressing health care challenges.

A SYSTEMS APPROACH TO HEALTH CARE

A systems approach maintains a perspective in which the overall effectiveness and efficiency in achieving objectives depends on identification, understanding, and management of interrelated processes as a collective system. This description of a systems approach raises the question: what is a system? The International Council of Systems Engineering (INCOSE)³ offers this sound definition of a system:

A system is a construct or collection 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.

Armed with this definition of a system, we can expand on the systems approach concept by requiring the following:

- Definition of the objectives or goals of the system
- Elaboration of the interdependencies between the processes of the system
- Clarification of the roles of the constituent system elements necessary to achieve objectives (thereby reducing cross-functional barriers)

- Definition of the system's capabilities
- Establishment of performance expectations prior to operational employment
- Measurement and evaluation of performance to continually improve the system through measurement and evaluation

Using a systems approach as a lens to look at today's health care "system" makes it readily apparent that health care as it exists today is neither a system nor a system of systems. Health care as a whole is not managed as a set of interrelated processes. The interdependencies among the constituent elements (everything from devices to electronic medical records, from in-patient care to home care, etc.) are loosely defined at best. Cross-functional boundaries abound in health care settings—the boundaries exist between patients and the clinical team, within the clinical team itself, between the patient and the patient's family, and between the operators of medical devices and the devices themselves. The current model of medical delivery generates an abundance of data, but the system often fails to generate actionable information. This failure to produce information results in an inability to establish meaningful performance expectations or to permit measurement and evaluation. For example, many health care entities struggle to produce meaningful and accurate performance measures of something as simple as hand-washing compliance. As a result, service delivery in health care continues to rely on a model that is highly dependent on the expertise of an individual provider. This results in inconsistencies in capabilities, common objectives, and expectations. It is not surprising that in such a poorly integrated system the capacity for continuous improvement is limited.

COLLABORATION WITH JOHNS HOPKINS ARMSTRONG INSTITUTE FOR PATIENT SAFETY AND QUALITY

Collaborations in health care across the JHU enterprise, including APL, Johns Hopkins Medicine, and the Johns Hopkins School of Engineering, are long-standing. For several decades engineers, medical researchers and clinicians have collaborated on a wide range of studies and device developments. This partnership continues today, most recently with the addition of patient safety to the areas of collaboration. Motivated by the absence of a systems approach to health care,⁴ Dr. Peter J. Pronovost at Johns Hopkins Medicine recognized APL's experience with systems engineering and connected with APL to form a team to take on the challenges noted by the NAE and IOM in their 2005 report.² A practicing anesthesiologist and vocal advocate for patient safety, Dr. Pronovost founded the Quality and Safety Research

Group at Hopkins and, in 2011, formed the Johns Hopkins Armstrong Institute (AI) for Patient Safety and Quality to “. . . continuously reduce preventable harm, improve patient outcomes, and enhance the value and equity of care around the world by advancing the science of patient safety and quality through discovery, implementation, education, evaluation and collaborative learning.”⁵ The AI’s perspective includes evaluating technology, identifying cultural barriers, defining best care practices, and implementing simple processes to improve safety and quality of patient care. Dr. Pronovost took this approach to address central line infections in critical care settings—a preventable harm that, prior to intervention via these simple procedures, annually killed more people than breast cancer. His team’s research and methodology established and implemented a simple set of process rules that have produced measurable reductions in central line-acquired blood stream infection around the world.^{4, 6}

This holistic view of technology, people, and procedures and policies is the foundation for the systems approach that APL and AI have teamed to pursue. Since 2010, APL and AI have collaborated on the following projects:

- 2010—An internally funded study of usability and safety issues related to medication infusion pumps
- 2011—A 3-year effort funded by the Agency for Healthcare Research and Quality (AHRQ) to further investigate usability and safety issues related to medication infusion pumps. The project evolves over three phases spanning requirements elicitation, prototype development, and in the third year, test and evaluation of the prototype in a simulated health care setting.

- 2011–2012—An effort funded by the Johns Hopkins University Whiting School of Engineering Systems Institute (WSE-SI) to study integration and interoperability opportunities and challenges in the ICU, emphasizing the role of the patient and family in their own care within the ICU

What follows is a description of the early activities and current progress associated with these three projects.

2010—Usability and Safety Issues Related to Medication Infusion Pumps

System Engineering and Health Care

The 2005 NAE and IOM² report called for the application of systems engineering tools to health care. A 2012 Special Report from the *New England Journal of Medicine* included “systems-based practice” among its recommendations for the next generation of the Graduate Medical Education (GME) process.⁷ In alignment with these recommendations, the activities APL and AI have undertaken exhibit a systems approach to health care and follow systems engineering principles and best practices. For each collaborative project, APL and AI follow the well-established sequence of system development, test and evaluation, and fielding illustrated in Fig. 1. The process illustrated in Fig. 1, commonly referred to as the “V-model,” and sometimes represented as a spiral,⁸ establishes a framework for disciplined development and management of a system from concept to fielding. Implementation of, and adherence to, such a framework is not pervasive in health care: device and system development efforts, development of new clinical protocols, and the integration of devices, protocols, and health care operations do not utilize a documented,

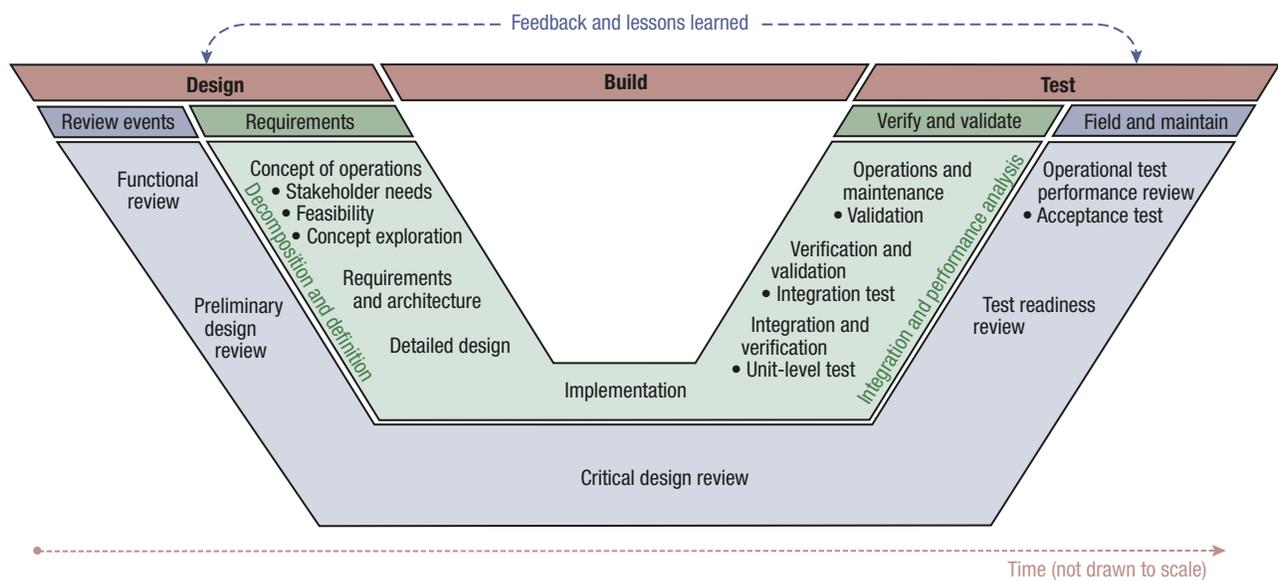


Figure 1. System development life cycle.

repeatable, and robust framework. Our collaboration places stakeholder involvement at the core of the process throughout the system's life cycle. On numerous occasions, we heard comments such as, "We normally do not get asked what we want our systems to do, how they should function, what they shouldn't do." Such questions and requirements elicitation are essential initial steps of the systems engineering process illustrated in Fig. 1. Asking such questions to determine stakeholder needs is, in fact, the first step in the process, and continual stakeholder involvement throughout is essential.

Coupled with the sequence of steps depicted in Fig. 1, APL and AI also adhere to systems engineering's best practice of maintaining a comprehensive set of artifacts and documents and execution of reviews and analyses. Accordingly, at the appropriate times in the project's life cycle, the team produces and maintains requirements documents, system design documents, test and evaluation plans, analysis documents, and other important items. This enables all system requirements to be traced through the design and evaluation phases, ensuring delivery of a system that meets stated objectives.

An important aspect of systems development in the health care area is the nature of test and evaluation on the vertical right side of the V-model in Fig. 1. These test and evaluation activities are shaped significantly by institutional and federal rules, regulations, and policies governing the use of animal models and human subject research for certain health care-related research activities. Depending on the nature of the development focus, these test and evaluation considerations must be addressed early in the project's life cycle to minimize or prevent rework or, ultimately, project failure. Only through the conduct of a disciplined systems approach can system goals of effectiveness, efficiency, and safety be achieved throughout the product life cycle.

Requirements Elicitation Methods and Findings

In applying systems engineering to several projects, the APL and AI team performed requirements elicitation using several methods. These included small focus group discussions (two to three subject matter experts), workshops ranging from approximately one dozen subject matter experts to as many as 50 participants, and an on-line survey provided to the 50 invited participants in a specific workshop regarding medication infusion pumps. The team also visited two ICUs at Johns Hopkins Hospital, the Weinberg ICU (WICU), and the Surgical ICU (SICU) for approximately 40 hours of observation of ICU rounding and non-rounding operations.

The focus group discussions were generally informal roundtable conversations lasting no more than 90 minutes, where the project team was composed of systems engineers, human factors engineers, and nurses. The objective was to learn the nature of operations within the ICU, with emphasis on understanding and charac-

terizing the technology systems that interface with and within the ICU, the people who interface and interact with and within the ICU, and the processes, policies, and guidelines that occur within and shape ICU operations. We also sought to understand which "work-arounds" ICU staff employ to effectively execute their roles. Our line of questioning and our perspective during these elicitation activities was to understand the following:

- What entities (e.g., people, technology, other items such as paper forms, etc.) interact within the ICU?
- What entities (e.g., pharmacy, hospital administration, food service, etc.) does the ICU interact with outside the ICU?
- How often do entities interact in the ICU?
- How long does the interaction exist?
- Is information exchanged via these interfaces and interactions? Is the exchange performed orally, via paper, electronically, or via another means?
- Is information (digital, oral, paper, etc.) within the ICU readily available for, initially, baseline performance assessment and, eventually, continuous assessment of performance? In other words, is the information stored and is it accessible?
- Are materials exchanged via these interfaces and interactions? What is the nature of this material (e.g., hazardous, private, etc.)?

ICU Interoperability Workshop

The workshop events held for requirements elicitation afforded the opportunity to explore topics that came up during observation visits and focus group discussions in the presence of a large cross-sections of stakeholders interested in improving safety in the ICU. APL and JHM held two workshops related to ICUs. One of these workshops, held 23 June 2011, centered on the larger issues in the ICU. The second workshop, held on 10 January 2012, was directly in support of the AHRQ Simulation grant and focused on usability and system-related issues associated with large-volume medication infusion pumps (LVMIPs), ubiquitous medical devices used in the ICU as well as in other care settings.

The ICU Interoperability Workshop took place on 23 June 2011, at the East Baltimore campus of the Johns Hopkins University Hospital for a concentrated 2-hour discussion. Participants included approximately a dozen ICU stakeholders, primarily nurses and doctors, from various ICUs across the hospital. Attendees included the chief medical information officer and the director of clinical informatics at the Children's Center at Johns Hopkins Hospital, an associate professor of anesthesiology and critical care, several assistant professors of

anesthesiology and critical care, an assistant professor of surgery, an assistant director of the central nursing program, an ICU nurse manager, and an ICU nurse clinician. The goal of the workshop was to elicit information and ideas from all participants regarding opportunities to improve patient safety and quality of health care delivery through integration and interoperability.

APL provided the infrastructure necessary to collect inputs from the participants. Specifically, APL provided each participant with a laptop to type comments while the discussion took place. The comments typed by participants were visible to the other participants via their respective APL laptops (in parallel, the typed comments were combined into a single database for the data to be reviewed by all team members). Real-time comments typed into the laptops served as another communication path among the participants to complement the ongoing oral discussion.

The 2-hour session began with a brief introduction by the two project leads, Dr. A. Sapirstein (JHM) and Alan Ravitz (APL), with Dr. Sapirstein serving as the workshop facilitator. In this facilitator capacity, Dr. Sapirstein initiated and guided the discussion, keying off the oral discussion and/or the computer-entered “chatter” to probe and lead the discussion toward achieving the event’s objectives.

The workshop was cast within a set of thought-provoking topics to stir discussion and assess which interactions within the ICU the assembled subject matter experts considered most important. The topics were split into segments, where each segment was intended to provoke discussion and produce information about interactions among technology, patients, people, and other entities. Two large screen displays in front of the room displayed the current topic and set of questions, as shown in Table 1.

Table 1. ICU workshop discussion topics

Interaction Type and Definition	Questions for Discussion
<i>Clinician-to-Nonpatient Interactions</i>	
You are stranded on an island with 20 injured survivors and can call for 5 personnel with various types of expertise to help. Who would they be (i.e., what role) and why?	<ul style="list-style-type: none"> • Who do you interact with? • Why do you interact with that person? • What information does that person give you, or do you give him/her? • How do you interact with that person? • When and how frequently do you interact with this person? • If this interaction did not occur, what would be the consequence on quality of care and patient safety?
<i>Clinician-to-Patient Interactions</i>	
The survivors have suffered different types of injuries and conditions, and your team is checking on them. What are the main things the team must look for in (newly) admitted patients?	<ul style="list-style-type: none"> • Why does this interaction take place? What do you learn from it? • What tools and resources do you need during this interaction? • If this interaction did not occur, what would be the consequence on quality of care and patient safety?
<i>People-to-Equipment Interactions</i>	
If a limited amount of resources* can be brought onto the island, or be built from airplane scraps, what would you need?	<ul style="list-style-type: none"> • What equipment or devices do you use for your job? • Why do you use this device? • What information does this device give you or help you to acquire? • How do you use this device? • When and how frequently do you interact with this device? • If you could no longer use this device or equipment, what would be the consequence on quality of care and patient safety?
<i>ICU-to-Resource Interactions</i>	
The ICU island has connections to other resources.* Which resources would you select for connection to your ICU island and why?	<ul style="list-style-type: none"> • Who do you interact with? • Why do you interact with that resource? • What information does that resource give you or do you give the resource? • How do you interact with that resource? • When and how frequently do you interact with this resource? • If this interaction did not occur, what would be the consequence on quality of care and patient safety?

* For example, pharmacy, blood bank, medical references, etc.

After the workshop, the project team compiled the electronic notes and the notes from the oral discussion. An analysis phase followed, which led to a set of UML (Unified Modeling Language)-based engineering artifacts that describe the As-Is nature of interaction among people, processes, and technology in the ICU. Results from this analysis formed the basis for the next phase of the project where the project team began formulating concepts for an ICU designed with interoperability at the heart.

2011—A 3-Year Effort to Further Investigate Usability and Safety Issues Related to Medication Infusion Pumps

Medication Infusion Pump Workshop

Many different devices are used in the ICU, but the LVMIP is a good candidate for study because of its prevalent use and the very visible safety issues associated with this specific device. This combination of characteristics makes the possibility that device design improvements and increased interoperability of LVMIPs have a good potential to improve patient safety.

A specific aim of the 3-year APL and AI LVMIP project funded by AHRQ centers on eliciting stakeholder input regarding patient safety and quality health care delivery challenges associated with LVMIPs. Our focus is on LVMIPs used for fluid delivery to patients in hospital settings, particularly the ICU. Our method of elicitation featured a workshop, held at APL on 10 January 2012, in APL's Warfare Analysis Laboratory (WAL). The workshop was titled "Infusion Pump Workshop 2012: A Systems Engineering Approach for Human Factors Solutions." The WAL facility is regularly used for war-gaming, as well as in-depth system development discussions, the latter function being most analogous to this project. The WAL makes for an ideal setting for a facilitated discussion among numerous stakeholders and features an electronic messaging system through which attendees can insert comments, questions, and notes, which provides another source of information flow and communication in addition to the oral discourse that transpires during the facilitated discussion. The WAL proved to be an excellent venue, enabling us to achieve our objectives.

Workshop Preparation

In keeping with systems engineering best practices and principles, before leaping to the prototyping process, our first step was to elicit user needs and requirements from infusion pump stakeholders. Our targeted stakeholder population included clinicians who use these devices daily in critical care settings, pharmacists who fill the prescriptions that the pumps deliver, pump manufacturers, regulators from the Food and Drug Administration, and medical device industry engineers.

The project team included subject matter experts from JHM: emergency department and critical care physician Julius Pham, M.D., Ph.D.; human factors engineer Pete Doyle, Ph.D.; and project analyst Mayowa Ijagbemi. From APL, the team included systems engineers Alan Ravitz, John Benson, and Ruth Vogel and project analyst and administrator Namrata Shrestha. The project team prepared for the January 2012 event over the 4 months preceding the event.

Leading into the workshop, the project team accumulated a large list of user needs from several sources including the outcomes of a 2010 joint APL and AI task analysis pilot study, which was a small-scale investigation of LVMIP issues. The project team also relied on the 2010 Association for the Advancement of Medical Instrumentation (AAMI) infusion pump summit, which provided a collection of "Clarion Themes"⁹ that emerged at the summit. These resources provided several dozen user-needs topics that the project team could use at the January workshop. Since our workshop was planned for approximately one 7-hour session, the project team had to prioritize the user needs available to us from these sources—the higher-priority items would form the basis for the agenda and discussion at the workshop.

To determine topic priorities for discussion at the workshop, the project team turned to the approximately 50 workshop invitees by posting an online survey accessible to the invitees approximately 10 days before the event. The survey presented 25 usability-focused user needs in the form of the problem statements summarized in Table 2 and asked the respondents to rank each item according to the following criteria:

- How frequently does each problem occur?
- When the problem does occur, how severe is the outcome to patient safety?
- How likely is it that the problem described in each problem statement will generate an interesting discussion during the workshop?

The responses to these Problem Statements (in the form *unsure*, *low*, *medium*, and *high*) were assigned numerical values and rank-ordered using a final score measure. The respondents were also presented with a series of other problem statements that the team considered pump design "best practices." In other words, these are design features that the project team believed all pumps should possess. The project team asked the respondents to agree or disagree and to provide comments.

The project team received responses from more than 30 of the 50 invited attendees. Their responses to the usability user-needs items gave the team the sequence of the 25 usability user-needs topics shown in Table 2, which are listed in the order resulting from the survey results. Furthermore, the respondents' answers to the

Table 2. Infusion pump problem statements

- Frequent alarms fatigue users [Sum]
- Ability to easily override safety features [Sum]
- Difficult to manage multiple infusion lines [CT4]
- Same alarm cues for critical and noncritical events [TA]
- Misinterpretation of a physician's order [TA]; 7.1-1 Most pumps are not interoperable with a host of data systems, including medication orders, drug library, electronic medical administration (eMAR) records, bar code medication administration (BCMA), and reporting. [CT2]
- Bypassing and forgetting to reset programming after a bolus [Sum]
- Errors in calculating conversions [Sum]
- Drug concentration options are not prominently displayed (e.g., need to scroll down for some). User reverts to non-DERS (Drug Error Reduction System) administration by bypassing safety functions [CT3]
- No maximum rate feature for bolus dosing for specific drugs
- Pump workflow doesn't match the user workflow. The sequence for programming the pump differs from the user's sequence of tasks for medication delivery. [Sum]
- Inadequate/nonstandard visual cues for different classes of drugs [Sum]
- Can hang two bags of the same drug on pumps with more than one pump channel. [TA] Inability to know total dose of medication being infused if two or more pumps are infusing the same medication
- Inadequate notification of approaching out-of-tolerance conditions
- Inadequate display field sizes, line break position, and use of bolding to differentiate selection options [Sum]
- Prompts to enter rate or volume to be infused (VTBI) come before prompts on dose [CT3]
- Takes too much time to read pump status during use (e.g., indication of med being infused) [CT3]; rate information is displayed rather than more important dose information. [CT3]
- Insufficient alerts when input errors have been made [Sum]
- Pump interface features associated with high risk control functions are not standardized across pumps (e.g. control/label placement, color coding or order of data entry) [Sum]
- Use of weight data that varies from the primary source (medical records vs. bed scales vs. memory)
- Pump does not provide adequate indication of need for additional medication product in time for pharmacy to provide it. [TA]; 8.1.2. Sometimes notifications from the pump indicating infusions are nearing completion do not occur until after infusion is complete, interrupting continuous medication delivery. [TA]
- Lack of forcing function to confirm/check important data entries [CT3]
- Some pumps allow users to edit the rate even if pulled from the library [Sum]
- Program too much VTBI
- Display content and format make it difficult to read in different settings (e.g. lighting, distance, angles) [TA]
- Pump fails and a replacement is not available [Sum]

CT3, Clarion Themes;⁷ TA, Task Analysis; Sum, AAMI Summit.⁷

best practices items allowed the team to sense the thoughts of the responding stakeholders; the project team drew a threshold of 75% to define “consensus”; in other words, if the 75% or more respondents agreed with the project team's assessment, the project team declared that these items were indeed best practices for pump design. Table 3 summarizes the results of the best practices portion of the survey.

Workshop Execution

Workshops such as ours benefit significantly from professional facilitation. The project team selected John

Deadwyler of Bernard Consulting Group, St. Louis, Missouri, because of his familiarity with the topics of infusion pumps and patient safety plus the recognition and respect he commands from the infusion pump community as an effective facilitator.

The 50 workshop attendees self-identified as members of predefined categories of expertise, which allowed a measure of anonymity for the attendees but also allowed analysis of the outputs in terms of areas of expertise.

Box 1 is a sample slide showing one of the 25 problem statements with a succinct statement of a root cause

Table 3. Results of best practices portion of survey

Best Practice	% Agreement
Items above 75 agreement threshold	
• Adequate control size and separation per human factors criteria	94.3
• Conventional and consistent use of data entry cursor	88.6
• Means to easily determine control labels in dark environments	86.1
• Reliable indication of battery status that allows enough time for users to change pump or plug into a power source	86.1
• Medication identification cues per pharmacy best practices, e.g., Tall Man lettering	85.7
• Standardized keypad control layout to include decimal point placement	83.3
• Functional grouping of controls and display, e.g. through use of color and spatial proximity	82.9
• Indication if audio alarm is disabled	80.6
• Access to standardized training, embedded training, or opportunities to practice use with feedback	80.6
• Ready indication of the drug library version presently loaded	77.1
• Consistent use of alarm characteristics	75.0
Items below 75 agreement threshold	
• Standardized concentrations and dosing units for drugs	52.8
• Alarm test feature	61.1
• Cues to indicate intravenous occlusion	63.9
• A forcing function to prevent the previous patient's profile from being used on a new patient	65.7
• Consistency in labeling across media	72.2

usability problem along with a reference to the source of the statement. Next, a clinical example provided context for the problem statement. For this context, two JHM nurses with extensive experience using medication infusion pumps in hospital settings led a short (2–3 minutes) discussion of how this particular problem statement

manifests in the real world. Next, the discussion moved into the user-need area, which generated the richest section of the facilitated discussion in terms of inputs from the attendees.

Requirements Elicitation Findings

The collective outcome of the requirements elicitation activities described above proved formative for engineers and clinicians alike in terms of highlighting the challenges and opportunities to improve patient safety in the ICU. Several themes emerged from these requirements, including:

- Systems integration—clinicians strongly expressed a desire to see devices and systems more tightly integrated into the larger health IT enterprise. Opportunities for integration exist at all levels of operation from the bedside to and across the ICU and hospital-level enterprise. Integration at the bedside does not just mean connecting computer devices to exchange information but also taking a broader view of integration, creating, for example, LVMIPs that are more tightly integrated with medication bags, tubes, and poles to ensure that the right drug is delivered to the right patient, particularly in multiple line infusions where confusion tends to per-

BOX 1. SAMPLE PROBLEM STATEMENT SLIDE FROM WORKSHOP

Problem Statement (2.1.1)

Takes too much time to read pump status during use (e.g. indication of med being infused). [CT3]; rate information is displayed rather than more important dose information. [CT3]

Clinical Example

Clinicians can't immediately see which channel is running epinephrine versus vasopressin because of banner. They end up taping the name of medication on top of channel.

Failure Mode

Delay in monitoring infusion status; interpret rate as dose

Result

Matter of convenience; over or under infusion; affects rate

User Need (Preliminary)

Quick access to identifying medication being infused; display both rate and dose information

sist regarding matching the right drug to the right patient. At the enterprise level, opportunities for integration abound and include, for example, using a bed scale or the patient's electronic medical record as the source for the patient's weight in drug delivery calculations. This system would replace the reliance on the bedside caregiver's assessment of patient's correct weight and computation of appropriate drug delivery settings.

- Information presentation, prioritization, and communication—nurses, doctors, and patients and families all expressed frustration over the nature of how information is presented and communicated.
- Today's clinical information systems force clinicians to access numerous disparate systems located physically in the patient's room, as well as extended ICU and hospital enterprise systems. Further, today's clinical information systems present data-heavy and dense display formats including spreadsheets, black-on-white text, and multiple windows, forcing the clinicians to mentally assimilate the data into information, a process and environment difficult to contend with, particularly in the high-stress ICU where patients require intense clinical attention. Imagine an airline pilot having to leave the cockpit to lower the landing gear or to change the flap settings on the wing. That is in effect what nurses and doctors must do in the patient's ICU room, where controls and displays for the medical devices are spatially separated.
- ICU doctors care for multiple patients concurrently, sometimes in different locations, and they need to have access to macro-level information regarding the patients' statuses and health trends. They also require detailed information regarding specific test results, physiological parameters, and other key information to safely care for each patient. Today, these doctors must contend with the same data-heavy, dense displays which challenge the ability to obtain a comprehensive, timely, and accurate awareness of the clinical situation of their patients.
- Patients and families have limited or no access to information systems within the ICU. During our requirements elicitation sessions, we learned the importance of communication—communication between the patient and the clinical team, between the clinical team and the family, and between the patient and family present in the hospital as well as family not present in the hospital. This “communication triad”—patient–family (in room and remote)—clinical team—must support multilingual situations, situations where the patient may be intubated, and it must inform the clinical team,

patient, and family and also accept inputs from all three. Communication throughout the triad should incorporate the best attributes of common social media tools such as FaceTime, Facebook, Twitter, and Skype but with the appropriate context-aware controls to protect privacy.

- Clinicians cannot provide the necessary care when they do not understand a patient's needs and when they are unable to communicate with the family, who may possess valuable information. Further, these tools, coupled with advancements in graphical user interfaces tailored to the patient and family, can mitigate potentially anxiety-ridden events such as transfer from the ICU to another part of the hospital or discharge from the hospital. In our conversations with patients and family representatives, we learned that while they generally wanted to leave the ICU, they desired a comprehensive pre-briefing before transfer. When faced with transitioning to another part of the hospital, patients and families desire information: answers to such questions as how long it will take to transfer to the new location? Will we be traveling on elevators? Who will be coming with me? Who will move my belongings? How will my family know where to find me? Who will be taking care of me in the new location, and what are their roles? What kind of care will I receive in the new location? All of these questions are knowable before a patient transfer: the route (or routes) of the journey is known, the approximate duration of the journey is known, the process for moving belongings and notifying family members can be arranged, and the staff schedule can provide information regarding who the patient will see in the new location.
- Device control standardization and programming navigation—nurses find that some pumps use confusing or nonintuitive placement and representation of functions such as “run,” “stop,” etc.
- Clinicians expressed frustration with the menus, option choices, and user interface designs of infusion pumps, especially during stressful situations. They desire more streamlined menu layouts and better navigation and control sequences that are more effectively aligned with workflow.

These requirements elicitation activities produced invaluable insights to the ICU's inner workings from many different perspectives, validating the essential role that this step of the system development life cycle plays at the outset of the development effort. The findings described here formed the foundation for the early concept exploration products describing a new ICU design.

2011–2012—Integration and Interoperability Opportunities and Challenges in the ICU Emphasizing the Role of the Patient and Family in Their Own Care Within the ICU

Early Concept Exploration—Integration and Interoperability in the ICU

Our requirements elicitation findings are consistent with a widely held assertion among champions of patient safety that improving integration within the ICU will lead to the desired goal of safe and effective health care delivery. This assertion derives from the realization that other fields and industries have realized performance improvements by capitalizing on improved information awareness, timeliness, completeness, and accuracy—attributes that are notably lacking in health care. To this end, APL and AI have examined activities with the ICU with a focus on identifying where and how integration and interoperability could improve clinical situational awareness and command and control. Accordingly, APL and AI determined that a new paradigm is needed for the design and integration of technology within the ICU to achieve the advantages of interoperability. This new paradigm is needed because today's medical systems are effectively closed proprietary systems that severely curtail the ability to extract data and information. Without such information, efforts to improve situational awareness, clinical analytics, and automated clinical decision support are handicapped even before they begin.

The new paradigm, illustrated in Fig. 2, inserts an “open middleware” layer that does not currently exist in today's operational health care settings. The use of open middleware effectively lowers the barrier to accessing information within existing and future technologies in the ICU, thus making possible information integration in support of clinical situational awareness, automated

clinical decision support, and analytics. Further, the open middleware supports rapid development of data-driven innovations in areas such as technology, clinical protocol, and patient and family involvement in their own health care.

Figure 3 envisions an ICU with improved information awareness, analytics, and automated clinical support and highlights the participation of the patient and family in this new ICU. The clinical team shares a common view of the clinical situation of each patient—they can survey the clinical status at a macro-level via a bird's-eye view with the ability to zero in on a specific room, a patient within a room, and the activities, devices, and systems within that room to view patient status, alarms, trends, and discrete parameter values.

In contrast to today's ICU design, this proposed ICU system possesses an information display system based on a common Integrated Clinical Picture (ICP) user interface that is graphical rather than exclusively text based. The ICP is designed for rapid, intuitive information integration, assimilation, and sense-making. This ICP supports monitoring of the clinical system, much like many commercially available clinical information systems do today. Additionally, this new ICU system also provides the ability to control the state of clinical systems (infusion pumps, ventilators, and other medical devices involved in the care of the ICU patient) and nonclinical systems (lighting, heating, ventilation, television controls, etc.). This ICU system is context and location aware, in the sense that each person's access to the system is governed by their role (patient, family, clinician, administrator, etc.) and the location of that person (e.g., a remotely located clinician may or may not have the same system access as one at the bedside).

The patient and family also have access to the ICU system, and this access is intended to contribute meaningfully to their respective and collective ICU experi-

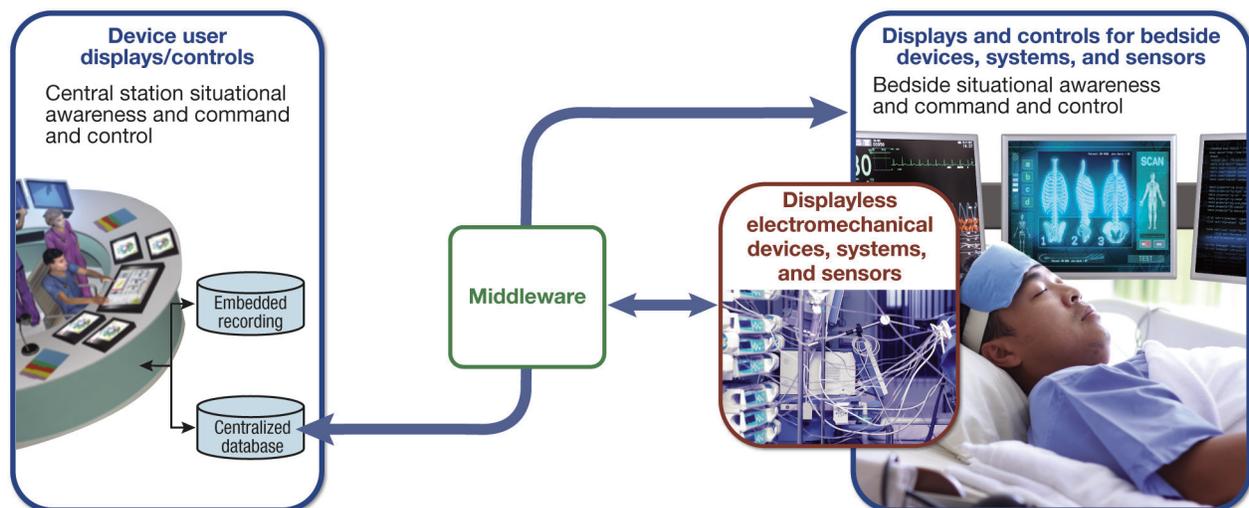


Figure 2. Notional architecture concept for an Integrated ICU.



Figure 3. A notional integrated ICU concept of operations.

ences. This ICU design leverages information residing in existing information systems to pull and push the necessary information and provides a means to effectively convey the information tailored to the patient's specific needs, challenges, and situation. There are no technical barriers to enabling such a capability, and the payoff in terms of patient and family experience may be substantial.

Topics such as fresh air and lighting indeed may not exclusively involve the use of technology (computers, devices, etc.), and during our requirements elicitation sessions, we regularly reminded our discussion participants that, just because they were talking to a collection of engineers, they should not exclusively focus on topics they considered computer related. We encouraged them to simply express what they wanted in the new ICU. If we are to take a true systems approach to the ICU, then a broad, open-minded perspective is necessary and all factors are important to consider.

As a result, we learned that the needs of the patient and family are not limited to improved communication but also extend beyond what people commonly consider technology-related topics. Throughout our discussions, patients and family members expressed the need for improvements in the ICU environment. They called for quieter settings, stating, for example, "Instead of placing

a patient room across the hall from the nurse's station, can you position the patient's room so that it has less background noise? I was in the room across the hall from the nurse's station. Beyond the round-the-clock talking, I heard conversations I would prefer having not heard—conversations about the nurse's private lives, discussions about patients, etc." Patients and families also expressed a desire for access to fresh air ("long ago, hospital rooms had balconies") and natural light.

The proposed new ICU design has these environmental factors in mind. Rooms are strategically located to minimize collateral noise, and flooring, walls, and ceiling materials mitigate the effects of distracting sounds. Windows and advanced lighting systems including the use of light tubes are present in this new ICU design to promote the benefits of natural lighting.

FUTURE PLANS

Health care in the United States is a complex enterprise that involves much personal and emotional cost, as well as financial cost. Even if you are indifferent to the number of lives adversely affected by preventable errors, one illness, injury, or loss is too many if that affected life is yours or the life of someone close to you. The work Johns Hopkins has undertaken since 2010 has taken

a systems approach to health care by focusing on the ICU—an area of health care delivery characterized by a high degree of technology reliance, grave clinical situations, intense anxiety, and significant costs. Beyond the initial requirements elicitation and conceptual development APL and AI have completed, much more work is needed in terms of characterizing needs and requirements of the patient, family, and the hospital team. Greater progress and results could be achieved with additional workshops with broad cross-sections of participants including those from the social sciences, hospitality, and other disciplines traditionally not involved in health care idea-storming discussions.

Without completely leaving behind the requirements elicitation and documentation stage of the system development life cycle, the Johns Hopkins project team will begin progressing toward design and implementation of the new ICU model discussed above. The designing and prototyping will range from the device level (LVMIP), in terms of improved information presentation designs, prioritization displays, and system controls, to the integration of devices and systems across the ICU to support tactical bedside clinical care. Eventually the system should permit strategic clinical care planning and execution for individual patients and service prioritization across all patients in an ICU. We envision that new analytical tools will sequence care processes not solely on the basis of perceived acuity but also on the basis of innovative information associations available through a system of automated information aggregation and analysis.

Coupled with these prototype design and implementation activities, Johns Hopkins will develop measures of effectiveness and measures of performance that quantitatively and qualitatively provide guideposts. This will ensure that the efforts to capitalize on the advantages of a systems approach to an interoperable ICU indeed lead to improved safety and quality in health care delivery.

Finally, we must continue to keep the patient and family at the center of this systems approach. These are the lives we endeavor to save and improve. It is our col-

lective responsibility to build a new ICU, and indeed, a new health care system to achieve the goal of saving and improving lives. Doing so will require intense and coordinated collaboration from all of society.

ACKNOWLEDGMENTS: The authors thank J. Benson, J. Burck, S. Griffiths, K. Roncal, N. Shrestha, W. Sternberger, G. Tran, and R. Vogel of APL and M. Ijagbemi, M. Romig, and R. Wyskiel of JHM for their contributions to the projects discussed here. The authors also thank WSE-SI for funding the efforts related to re-engineering the intensive care unit. This project was supported by Grant R18HS020460 from AHRQ. The authors thank AHRQ for providing funding to support the medication infusion pump work described in this article. The content is solely the responsibility of the authors and does not necessarily represent the official views of AHRQ.

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